Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
1.01	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, General, Q1	We recommend that the manufacturers/distributors should be required to verify the license prior to distributing a Category 3 source in accordance with 37.71. We also recommend that the licensed users not be required to verify the license of the manufacturers/distributors when returning the Category 3 sources. By requiring HDR source users to verify the license of Varian/Nucletron each quarter would be of no security benefit and would only increase the workload on licensee staff.	LVS	Letter	02/23/2017	ML17068A160
1.02	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, General, Q2	No, this addition would not increase the physical security of the source which is already covered under 10 CFR 20.1801 and 1802. However, this addition would prevent a licensee from illegally manipulating a license and providing that to a manufacturer/distributor. We recommend that Category 3 licenses be included in the LVS.	SA	Letter	02/23/2017	ML17068A160
1.03	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, General, Q3	Yes, we recommend that Category 3 source user licensees be exempted from any requirement to verify the manufacturer/distributor license when returning Category 3 sources.	LVS	Letter	02/23/2017	ML17068A160
1.04	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, General, Q4	If NRC decides not to exempt all Category 3 licensees, then we recommend that medical users of Category 3 sources should be exempted as they are required to be properly vetted and approved by Health Departments and other state agencies before they can begin to treat patients with Category 3 sources.	LVS	Letter	02/23/2017	ML17068A160
1.05	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, NSTS, Q1	No. A majority of Category 3 sources utilized are for the HDR which are exchanged at quarterly frequencies. A requirement to track Category 3 sources in NSTS would not increase the security of these sources and would only add unnecessary burden to licensees who would be required to enter source exchanges into NSTS every 3 months. This would add a great amount of burden to the manufacturer/distributors.	NSTS	Letter	02/23/2017	ML17068A160
1.06	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, NSTS, Q2	No.	NSTS	Letter	02/23/2017	ML17068A160
1.07	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, NSTS, Q3	No. The sources are still in possession of the licensee until received after shipment to requiring the NSTS reporting to be completed prior to the receipt after shipping would not be correct. 10 CFR 37.75, 77, and 79 have requirements for the shipping coordination including estimated receipt time of the sources. Therefore this change would not add any security value to the process.	NSTS	Letter	02/23/2017	ML17068A160
1.08	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, NSTS, Q4	No. NSTS only indicates that the sources are in possession of a licensee, not their physical security status. NSTS indication would only change by an individual entering this information after the discovery of a change in status.	NSTS	Letter	02/23/2017	ML17068A160
1.09	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, NSTS, Q5	The NRC needs to include results of a cost benefits analysis regarding how much time would be required by licensees, manufacturers and distributors for maintaining Category 3 sources in NSTS. By requiring Category 3 sources, this would also increase the workload on Category 2 licensees such as radiography licensees due to the fact that their sources would not fall below the NSTS reporting requirements until they are below the Category 3 thresholds. It is assumed that most radiography licensees return their sources above this limit. Due to this requirement the workload to these licensees and their manufacturer/distributors would greatly increase with no benefit.	NSTS	Letter	02/23/2017	ML17068A160
1.10	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, LVS, Q1	We have the availability to access LVS online and will maintain this access.	LVS	Letter	02/23/2017	ML17068A160
1.11	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, LVS, Q2	We transfer one Category 3 source quarterly. The source is transferred directly to the manufacturer.	LVS	Letter	02/23/2017	ML17068A160
1.12	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, LVS, Q3	No.	LVS	Letter	02/23/2017	ML17068A160

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1.13	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, LVS, Q4	Yes. We have had one experience using LVS to verify a license. Our Gamma Knife center tried to use LVS to verify the manufacturer/distributor's license but there was an error and he was told to contact the licensing agency. The LVS licenses should be periodically verified to be accurate and accessible by the NRC to prevent licensees having to contact the licensing agencies.	LVS	Letter	02/23/2017	ML17068A160
1.14	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, NSTS licensees, Q1	We currently utilize online access for reporting to NSTS and will maintain this access.	NSTS	Letter	02/23/2017	ML17068A160
1.15	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, NSTS licensees, Q2	Yes. We have noticed that the half-life utilized by NSTS does not match what is used by our treatment planning system. NSTS uses a 5.27 year half-life for Co-60 while the treatment planning system uses a 5.26 half-life. This will lead to a difference in activity levels as the number of years increases. A second issue is that the significant digits for activity are not same in NSTS as what is provided to us by the manufacturer/distributor. A third issue was the reliability of issued tokens. Several did not work due to a dead battery.	NSTS	Letter	02/23/2017	ML17068A160
1.16	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, Security, Q1	No. The typical Category 3 source is used in a hospital cancer setting for patient care. IAEA states that Category 3 sources could cause injury if a person handles them for some hours. It also states that a fatal exposure would take days or weeks to occur. Enhancing these sources would not be beneficial for the cost involved. The HDR source utilized is Ir-192 which has a half-life of 73.831 days and a maximum activity level of 13 curies when installed. These sources would not cause a wide-scale radiological exposure if used for nefarious purposes.	SA	Letter	02/23/2017	ML17068A160
1.17	Deborah P. Steva, RSO	University of Virginia	Medical	FRN, Security, Q2	Yes, any Category 3 generally licensed device should be changed to a specific licensed source.	GLDs	Letter	02/23/2017	ML17068A160
2.01	Jerry Sullivan, President	Dyna-Log, Inc.	Industrial	General	After analyzing the reports, it appears there is an issue with the license vetting and not security of the category 3 business sites. That is the issue that should be addressed. Personally, I am in full support of increasing the application requirements for category 3 sources. The KDHE is very diligent in their vetting process and works closely with the licensees to assure safety and adequate security for these minimal source user/owners.	SA	Email	02/28/2017	ML17153A171
2.02	Jerry Sullivan, President	Dyna-Log, Inc.	Industrial	General	By eliminating category 3 and forcing those businesses to be issued a category 2 license, you will only eliminate small businesses who cannot afford the additional financial burden of extra security. The category 2 license appears to only have the additional security requirements and still does not address the issue of the application requirements.	SA	Email	02/28/2017	ML17153A171
3.01	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	General	Colorado agrees with NRC Commissioner Burns and NRC Chairman Svinicki in the following response to NRC Commissioner Baran's Proposed Staff Re-Evaluation of Category 3 Source Accountability (ADAMS ML16292A817): "The current NRC regulations for transfers of radioactive sources are adequate to protect public health and safety, commensurate with the associated risks." Further, Colorado maintains that the Agreement States have effectively adopted and implemented the NRC regulations for source security and accountability.	SA	Letter	03/01/2017	ML17068A155

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3.02	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	General	In 2009, when evaluating the rationale for expansion of the National Source Tracking System (NSTS) to Category 3 sources, NRC staff did not conduct or provide a threat basis for Category 3 quantities of radioactive materials. Further, in its 2014 report, the Radiation Source Protection and Security Task Force stated "In preparation for the 2014 Task Force report, the Task Force reviewed information from the intelligence community regarding the current threat of terrorist organizations using radioactive sources or other radioactive materials against the U.S., along with isotope production and usage information, in order to determine whether changes to the radioactive sources list or threshold levels were needed. Although the U.S. still faces a general, credible, threat of terrorism utilizing radioactive materials, the Task Force is not aware of any specific threat leveled against a specific target. In addition, the global use of radioactive sources has remained stable both in species and quantity such that the addition of novel radionuclides or changes in thresholds for the existing list is not justified at this time."	SA	Letter	03/01/2017	ML17068A155
3.03	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	General	The 2015 operation by the U.S. Government Accounting Office did not identify a regulatory gap. Instead, the operation revealed a single, isolated failure on the part of one individual in one Agreement State program. One isolated, individual failure does not constitute reason to expand security or accountability requirements for Category 3 quantities of radioactive materials.	SA	Letter	03/01/2017	ML17068A155
3.04	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	General	Colorado agrees with Chairman Svinicky in her following response to Commissioner Baran's Proposed Staff Re-Evaluation of Category 3 Source Accountability (ADAMS ML16292A817): "Arguments that sources at the high end of Category 3 can be aggregated to Category 2-levels are similarly unavailing. Such arguments are inherent to any scheme that manages hazard through the application of a set of graded requirements, escalating in stringency as one progresses through the categories. Such categorization approaches are replete in the NRC regulatory framework for managing hazard and the logic of aggregation, lacking more, does not invalidate them."	SA	Letter	03/01/2017	ML17068A155
3.05	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	General	In light of the above comments, Colorado does not support expansion of license verification requirements to Category 3 quantities of radioactive materials or the inclusion of Category 3 quantities of radioactive materials in the National Source Tracking System.	SA	Letter	03/01/2017	ML17068A155
3.06	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, Q3	In response to question #3: If the NRC changed the regulations to limit license verification only through the LVS or the transferee's license issuing authority for transfers of Category 3 quantities of radioactive material, transfers from licensees to manufacturers and distributors should be exempted from the limitations. The NRC should consider such an exemption for transfers of Category 1 and 2 quantities as well.	LVS	Letter	03/01/2017	ML17068A155
3.07	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, NSTS, Q3	In response to question #3: The NRC should not consider changes to the current NSTS reporting requirements because, as stated in the general comments listed above, there has been no demonstration that the current requirements are not adequate to ensure safety and security of radioactive materials.	NSTS	Letter	03/01/2017	ML17068A155

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3.08	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, AS Q1	In response to question #1: Colorado has 17 licensees authorized to possess Category 1 quantities, 15 licensees authorized to possess Category 2 quantities and 48 licensees authorized to possess Category 3 quantities. These numbers are based on the total possession limits authorized on the licenses and do not reflect actual inventories of sources. Colorado does not maintain and cannot easily access inventory information for sources of below Category 1 and 2 quantities.	WBL	Letter	03/01/2017	ML17068A155
3.09	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, AS Q2	In response to question #2: Colorado uses the NRC's Web Based Licensing (WBL) System and maintains all active licenses in WBL. Therefore, there should be no need for the manual verification process to be used for verification of a Colorado license.	WBL	Letter	03/01/2017	ML17068A155
3.10	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, AS Q3	In response to question #3: Colorado uses WBL for all radioactive materials licensees.	WBL	Letter	03/01/2017	ML17068A155
3.11	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, AS Q4	In response to question #4: Because Colorado uses WBL for all radioactive materials licensees, the only additional regulatory oversight required would be for inspectors to verify that licensees transferring Category 3 quantities performed the proper license verification. While the impact of these additional inspection items is not precisely known, it is expected to be minimal.	WBL	Letter	03/01/2017	ML17068A155
3.12	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, NSTS, AS Q1	In response to question #1: The NRC does not have authority to require the Agreement States to administer the annual inventory reconciliation process in the manner that NRC has administered the process. Therefore, if the NRC chose to discontinue administration of the annual inventory reconciliation process for Agreement State licensees, Agreement States would get to choose how to administer the process. This could simply be ensuring at inspection that the licensee has conducted the required annual inventory reconciliation. Verifying compliance with this requirement during inspection would require minimal additional regulatory burden. However, continuing the NRC's process for annual inventory reconciliation would demand an additional regulatory burden estimated at 65 hours annually for Colorado Category 1 and 2 licensees and 100 hours annually for Colorado Category 3 licensees.	NSTS	Letter	03/01/2017	ML17068A155
3.13	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, Security, Q1	In response to question #1: The NRC should not consider expanding physical security requirements to include Category 3 quantities because, as stated in the general comments listed above, there has been no demonstration that the current requirements are not adequate to ensure safety and security of radioactive materials. Additionally, the regulatory burden on the Colorado Agreement State program of such expanded provisions is estimated at one additional full-time technical staff member.	SA	Letter	03/01/2017	ML17068A155

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3.14	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, Security, Q2	In response to question #2: If the NRC determines that expansion of source security and accountability requirements are needed for Category 3 quantities, NRC should prohibit such quantities from being possessed under a general license. Additionally, Colorado believes that the general licensing program does not provide for adequate accountability of sources. Colorado would support revision of the program to require sources that pose a higher safety risk to be possessed under a specific license and allow sources that pose a lower safety risk to be exempt from regulation.	GLDs	Letter	03/01/2017	ML17068A155
4.01	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, NSTS, AS Q1	Regarding adding Category 3 sources to NSTS: In their current form, NSTS and WBL do not share basic licensee information such as addresses. If any basic licensee information changes, we are required to make the change in both WBL and NSTS. Not only is this inefficient, it has the potential to cause data discrepancies. Because we have approximately 1.5 times the Category 3 licensees as Category 1 and 2 licensees, this problem would more than double.	Cred&SysArc	Email	03/01/2017	ML17068A157
5.01	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	General	I believe we are asking the wrong questions. The result of the GAO audit and investigation was that the GAO was able to obtain a license under false pretenses and purchase a source that was authorized by that license.	SA	Letter	03/02/2017	ML17068A156
5.02	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	General	In the latest investigation, the fact that they were able to obtain the license at all indicated a breakdown in the existing policies and procedures by one individual working for the issuing authority. But, even with that breakdown, the material that could be acquired as authorized on the license would not have been a "quantity of concern." Only after the licensee illegally altered the official license were they able to request enough radioactive material to be considered a "quantity of concern." This is the exact same thing that occurred during an earlier GAO investigation, in that even though they were able to acquire a radioactive material license under false pretenses, in order to be able to attempt to acquire radioactive material in "quantities of concern" they had to alter the license, or create a falsified document. So what is the root cause of these incidents? It certainly is not that the current regulatory requirements are inadequate.	SA	Letter	03/02/2017	ML17068A156
5.03	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	General	It seems to me that the problem lies in the ability of a licensee with nefarious intent being able to perform illegal alterations of the document so that they could attempt to acquire radioactive material for which they are not authorized. Therefore, would not a more prudent question be "How do we make our licenses less susceptible to alteration or falsification?"	SA	Letter	03/02/2017	ML17068A156
5.04	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	General	If a licensee of ours were to alter a current document in an attempt to acquire radioactive materials for which they are not authorized, our Agency would most certainly suspend the license and level harsh civil penalties against them. If we did not, then we are not upholding our responsibility to properly regulate the possession and use of radioactive material.	SA	Letter	03/02/2017	ML17068A156
5.05	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	General	Many other documents have implemented anti-forging techniques, so examples are readily available. I recommend that the working group first address the root cause of the problem by considering recommendations that will make licenses more difficult to alter or forge. I also urge the working group to make clear determinations of what level of protection is appropriate for each category of byproduct material activity.	SA	Letter	03/02/2017	ML17068A156

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5.06	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	General	The next question should be "What is actually broken that requires regulatory change to address it?" What data do we have that indicates that current policy and regulation, when used as intended, is inadequate? I agree with Chairman Svinicky that current regulations for transfers of radioactive sources are adequate, and there is no need to include Category 3 sources in the same requirements as that required for Category 1 and 2 sources.	SA	Letter	03/02/2017	ML17068A156
5.07	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	General	We need to use common sense in our regulation of radioactive material. For decades radiophobia has driven public and congressional opinion, and we have allowed it to do so. The proper amount of respect for radiation is certainly appropriate; being more afraid of any radioactive material than to a toxic chemical that can be bought at your local hardware store is unacceptable.	SA	Letter	03/02/2017	ML17068A156
5.08	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	General	The NRC and Agreement States should take more proactive measures to allay unnecessary radiophobia. NRC and Agreement States have the expertise in determining what constitutes an appropriate level of protection and should take measures to assure that protection is in place, but we should not have to take inordinate and unnecessary measures beyond that.	SA	Letter	03/02/2017	ML17068A156
5.09	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, General, Q1	No. The issue is that a licensee illegally altered a legal document which limits total licensed activity to Category 3 quantities of radioactive material in a manner that might have allowed the acquisition of Category 2 quantities of radioactive material. That does not mean that Category 3 quantities of radioactive material should be subject to the same physical protection as Category 2 quantities of radioactive material.	SA	Letter	03/02/2017	ML17068A156
5.10	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, General, Q2	Even if an incremental increase in public safety were to be realized if the regulations were changed as stated in the question, how could we measure it? I question whether there would be a measurable increase in the security of these materials if such requirements were implemented. In my opinion, current regulations provide a reasonable assurance of public health and safety. There is no amount of regulation that will provide an absolute assurance of public health and safety. If regulators follow the current guides and requirements in issuing licenses, the current verification system appears quite adequate.	SA	Letter	03/02/2017	ML17068A156
5.11	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, General, Q3	I am not convinced that such a move will result in a measurable increase in public safety.	SA	Letter	03/02/2017	ML17068A156
5.12	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, NSTS, Q1	I agree with Chairman Svinicky that current regulations for transfers of radioactive sources are adequate, and there is no need to include Category 3 sources in the same requirements as that required for Category 1 and 2 sources. There is no data that indicates that the current system is inadequate.	NSTS	Letter	03/02/2017	ML17068A156
5.13	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, NSTS, Q2	First, I do not believe there is any evidence to support including Category 3 sources in the NSTS. However, if the NRC is able to provide data that supports such a move, I would expect a lesser level of reporting requirements than for Category 1 and 2 sources.	SA	Letter	03/02/2017	ML17068A156

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5.14	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, NSTS, Q3	No. There is no indication that the current requirements are inadequate.	SA	Letter	03/02/2017	ML17068A156
5.15	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, NSTS, Q4	I do not believe there would be a measurable increase in safety or security.	SA	Letter	03/02/2017	ML17068A156
5.16	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, LVS, AS Q1	60	WBL	Letter	03/02/2017	ML17068A156
5.17	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, LVS, AS Q2	We would encourage licensees to use the LVS.	LVS	Letter	03/02/2017	ML17068A156
5.18	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, LVS, AS Q3	No, we are producing our own on line database system that meets our total needs better than the WBL.	WBL	Letter	03/02/2017	ML17068A156
5.19	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, LVS, AS Q4	Unknown.	LVS	Letter	03/02/2017	ML17068A156
5.20	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, NSTS, AS Q1	It is my opinion that the above statement is not entirely correct, in that I do not perceive that the NRC administers the annual inventory reconciliation process on behalf of the Agreement States. Rather, it is my opinion that the Agreement States have adopted compatible rules that facilitate the NRC's annual inventory reconciliation process. The annual inventory reconciliation is a requirement for licensees, not the Agreement State. Were the NRC to abandon the current process, it is most likely that we would enforce that requirement during regular inspections, resulting in minimal additional regulatory burden.	NSTS	Letter	03/02/2017	ML17068A156
5.21	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, Security, Q1	No, there is no documented evidence that supports such a move.	SA	Letter	03/02/2017	ML17068A156
5.22	Karl D. Walter, Director, Office of Radiation Control	State of Alabama Department of Public Health	Agreement State	FRN, Security, Q2	I continue to believe the GL program should be abolished and sources should be either specifically licensed or exempt. However, if the NRC continues the GL program, it would seem prudent that any Category 3 source should be specifically licensed.	GLDs	Letter	03/02/2017	ML17068A156

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6.01	Don Popielarczyk	Metal Forms, Ltd.	Industrial	General	Q#1- is Online reporting of the receipt of source Category 2 or 3 from the Original Manufacturer the same as filling out the 748C Form?	NSTS	Email	03/02/2017	ML17068A159
6.02	Don Popielarczyk	Metal Forms, Ltd.	Industrial	General	Q#2- Is the Source Manufacturer License verification when shipping a Category 2 or 3 back to the original manufacturer as listed on Online reporting website in printable form for License verification records (Currently I have only been able to view their Name in list form on Credentialed website)) Would it not simplify things if the verification of the Original Manufacturer license not be required for transfer back to the Original Manufacturer?	LVS	Email	03/02/2017	ML17068A159
6.03	Don Popielarczyk	Metal Forms, Ltd.	Industrial	General	Q#4- Would it simplify things if on the Inventory form there was a tab for transferring (each checked individual source) back to the original Manufacturer for disposal OR to populate portions the 748B Form for single or group shipments. Due to the Complexity of the rules will there be any Credentialed Radiation Security Consultants allowed to assist in guidance, implementation & for maintaining or Instructional Course for compliance and record keeping of rules?	NSTS	Email	03/02/2017	ML17068A159
7.01	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	General	Generally, the Agency does not support the full inclusion of Category 3 sources into the 10 CFR 37 rulemaking. Better accountability and licensing practices can be implemented without overly burdensome methods and costs for licensees and regulators alike.	NSTS	Letter	03/06/2017	ML17068A162
7.02	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, General, Q1	The Agency believes it is time to make the verification system as paperless as possible. The verification methods can be similar to those for Category 2 material. The Agency would like new regulatory language that requires pending transfers of radioactive material to new licenses to be vetted directly with the licensing authority rather than through third party certifications.	LVS	Letter	03/06/2017	ML17068A162
7.03	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, General, Q2	Based on the history of known events, there is no evidence that safety or security would be favorably impacted by this change. We would point to the 2014 Radiation Source Protection and Security Task Force Report that indicated they were not aware of any specific threats that would justify a change in security measures. However, current intelligence regarding evolving threats must always be considered when making these decisions. The Agency is not opposed to better tracking of new licenses issued to ensure the proper radioactive material and quantities are ordered if the current threat environment warrants it.	SA	Letter	03/06/2017	ML17068A162
7.04	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, General, Q3	The Agency is in favor of excepting returns to a well-established manufacturer/distributor for that specific source.	LVS	Letter	03/06/2017	ML17068A162
7.05	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, General, Q4	First, NRC may want to consider only including 'portable' Category 3 sources in this effort. Most of the noteworthy devices are somewhat portable.	SA	Letter	03/06/2017	ML17068A162

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
7.06	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, General, Q4	Secondly, if bundling of Category 3 sources into a Category 2 configuration is the primary concern, NRC may again want to consider focusing on the prelicensing and licensing procedures for all licenses that potentially could aggregate Category 3 sources before millions of dollars in administrative and physical protective measures are spent by both industry for implementation and regulatory agencies for enforcement of such a rule. It appears that it will be more efficient to catch these problems during the initial licensing process rather than burying industry with more regulations.	SA	Letter	03/06/2017	ML17068A162
7.07	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, NSTS, Q1	Based on the history of known events, there is no evidence that safety or security would be favorably impacted by this change. We would point to the 2014 Radiation Source Protection and Security Task Force Report that indicated they were not aware of any specific threats that would justify a change in security measures. However, current intelligence regarding evolving threats must always be considered when making these decisions.	SA	Letter	03/06/2017	ML17068A162
7.08	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, NSTS, Q2	NRC should consider less restrictive reporting based on risk.	SA	Letter	03/06/2017	ML17068A162
7.09	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, NSTS, Q3	We would recommend that Category 1 be reported on the same day and Category 2 stays the same. NRC also should require all licensees including distributors involved with Category 1 and 2 transfers to report receipt of sources in the NSTS including distributors, nationally and internationally.	NSTS	Letter	03/06/2017	ML17068A162
7.10	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, NSTS, Q4	Based on the history of known events, there is no evidence that safety or security would be favorably impacted by this change. We would point to the 2014 Radiation Source Protection and Security Task Force Report that indicated they were not aware of any specific threats that would justify a change in security measures. However, current intelligence regarding evolving threats must always be considered when making these decisions.	SA	Letter	03/06/2017	ML17068A162
7.11	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, NSTS, Q5	None.	NSTS	Letter	03/06/2017	ML17068A162
7.12	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, LVS, AS Q1	139	WBL	Letter	03/06/2017	ML17068A162
7.13	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, LVS, AS Q2	The Agency will encourage the use of LVS but is prepared to handle whatever manual verifications are required.	LVS	Letter	03/06/2017	ML17068A162

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7.14	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, LVS, AS Q3	IEMA prefers not to adopt the WBL at this time because of local administrative and professional preferences. The speed of entering and extracting information is of paramount importance to us. Use of a third party system including support for the system is a major concern.	WBL	Letter	03/06/2017	ML17068A162
7.15	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, LVS, AS Q4	For the verification of Category 3 licenses only, the impact would be minimal. The impact of licensing and inspecting Category 3 licensees to the level mandated by 10 CFR 37 would be immense, requiring an additional 1-2 FTEs.	LVS	Letter	03/06/2017	ML17068A162
7.16	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, NSTS, AS Q1	First of all, NRC does not solely administer the process. Most Agreement States are in constant contact with the licensees and assist with their efforts to meet the reconciliation throughout the process.	NSTS	Letter	03/06/2017	ML17068A162
7.17	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, NSTS, AS Q1	The Agency also believes that many of the licensees involved have operations in every jurisdiction and likely prefer dealing with one NRC portal directly on this rather than 38 different parties.	Cred&SysArc	Letter	03/06/2017	ML17068A162
7.18	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, NSTS, AS Q1	Additional concerns about data security would also have to be addressed if the number of players involved in this effort is expanded.	Cred&SysArc	Letter	03/06/2017	ML17068A162
7.19	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, NSTS, AS Q1	Finally, regarding resources, most states are in a far less desirable position than NRC to support such an operation either with staffing or funds.	NSTS	Letter	03/06/2017	ML17068A162
7.20	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, NSTS, AS Q1	This should remain an NRC mandate.	NSTS	Letter	03/06/2017	ML17068A162
7.21	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, Security, Q1	Based on the history of known events, there is no evidence that safety or security would be favorably impacted by this change. We would point to the 2014 Radiation Source Protection and Security Task Force Report that indicated they were not aware of any specific threats that would justify a change in security measures. However, current intelligence regarding evolving threats must always be considered when making these decisions.	SA	Letter	03/06/2017	ML17068A162
7.22	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, Security, Q1	Again, you may want to consider only including 'portable' Category 3 sources in this effort. Most of the noteworthy devices in this group are somewhat portable. NRC should also require a 2-lock rule for all portable devices. Many licensees implement this procedurally, but it is not required. Non-portable Category 3 sources are usually fixed to a structure and unlikely to be stolen from a licensee without personnel noticing the theft.	SA	Letter	03/06/2017	ML17068A162

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7.23	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, Security, Q1	Secondly, if bundling of Category 3 sources into a Category 2 configuration is the primary concern, NRC may again want to consider focusing on the prelicensing and licensing procedures for all licenses that potentially could aggregate Category 3 sources before millions of dollars in administrative and physical protective measures are spent by both industry for implementation and regulatory agencies for enforcement of such a rule. It appears that it will be more efficient to catch these problems during the initial licensing process rather than burying industry with more regulations.	SA	Letter	03/06/2017	ML17068A162
7.24	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, Security, Q2	If this measure moves forward, the Agency believes that Category 3 sources will have to be specifically licensed especially to address situations involving collocation. The upside is many of the general licensees involved also have specific licenses which will ease the transition.	GLDs	Letter	03/06/2017	ML17068A162
7.25	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	FRN, Security, Q2	At a national level, NRC will have to consider the impact this will have on manufacturers for distributing product as well as the administrative burden for States/NRC to amend regulations and multiple sealed source and device evaluations. Devices currently in use will have to be reissued under specific licenses and all labels on existing devices will have to be changed. Additional training for these licensees may also be warranted.	GLDs	Letter	03/06/2017	ML17068A162
7.26	Charles G. Vinson, Head, Radioactive Materials Section	Illinois Emergency Management Agency	Agreement State	General	As a final comment, Agreement States are very interested in the mechanism that will be used to implement oversight of Category 3 sources if it is deemed necessary. Rulemaking is obviously the preferred method over orders or legally binding amendments.	GLDs	Letter	03/06/2017	ML17068A162
8.01	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	General	North Carolina opposes the expansion of the National Source Tracking System (NSTS) to include Category 3 quantities of radioactive material. North Carolina believes that such a move will only marginally increase the safety and security of these quantities of radioactive material, if any at all, while adding a significant regulatory burden and cost to the Nuclear Regulatory Commission (NRC), Agreement States, and licensed entities.	NSTS	Letter	03/06/2017	ML17068A161
8.02	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	General	The 2015 undercover operation conducted by the U.S. Government Accounting Office (GAO) did not reveal a systemic failure in the current regulatory environment. Rather, it pointed out the importance of following current licensing practices for the issuance of new radioactive materials licenses.	SA	Letter	03/06/2017	ML17068A161
8.03	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	General	The addition of Category 3 quantities of radioactive materials to the NSTS would not have prevented the GAO from acquiring that radioactive materials license under the circumstances that occurred in that Agreement State.	NSTS	Letter	03/06/2017	ML17068A161

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8.04	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	General	The argument that the GAO did procure that license, modified it, placed orders for radioactive material and could have aggregated that material into a Category 2 or more quantity of material is an unconvincing argument for including Category 3 quantities of radioactive material in NSTS. By that reasoning, someone with malevolent intent and strong financial backing could procure the number of exempt sources to achieve the same end-result while remaining completely undetected. Although this example is extreme, it appears to apply the same reasoning leading to the recommendation to include Category 3 quantities of radioactive materials into NSTS.	NSTS	Letter	03/06/2017	ML17068A161
8.05	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	General	In addition, given that there are devices containing Category 3 quantities of radioactive materials that can be possessed under a general license, North Carolina fails to see how expanding NSTS would improve overall safety and security without a corresponding fundamental change in the regulatory environment. It seems more imperative that we dissolve the general license program and only allow the possession of radioactive material under the specific license program or exempt it from regulation.	GLDs	Letter	03/06/2017	ML17068A161
8.06	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	General	While North Carolina can add additional checks and administrative measures for tracking Category 3 sources, it is unclear if this additional effort will provide any real added security benefit, though it would clearly add immediate burdens to licensees and regulators.	NSTS	Letter	03/06/2017	ML17068A161
8.07	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	General	North Carolina feels strongly that a security risk benefit analysis be conducted based upon operational experience with existing practices for the control of Category 1 and Category 2 quantities of radioactive materials prior to moving forward with new regulations or regulatory expectations regarding Category 3 quantities of radioactive materials and NSTS. This analysis should cite specific events that show how NSTS and other tracking tools prevented the wrong individuals from accessing materials.	NSTS	Letter	03/06/2017	ML17068A161
8.08	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	General	In addition, a study to show how this regulation would have directly benefited the Country's Cat 3 licensed community in past real world (not GAO) scenarios. A well-funded and organized terrorist group could easily meet all the licensing criteria and still receive materials legally, even with imposed additional constraints, and chances are they would apply directly for the Category 1 or 2 sources instead of ordering suspiciously large amounts of Category 3 sources.	SA	Letter	03/06/2017	ML17068A161
8.09	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, General, Q1	No. There is no evidence that in the current terrorist threat environment that the distribution of these sources is not already well controlled. The current regulations have been, and in North Carolina's experience, are, adequate to assure that these transfers occur safely. Eventually, if the technology and resources can accommodate this without any extra burden, then it might be worthwhile, but at this time, it seems like very little gain for a lot of extra effort.	SA	Letter	03/06/2017	ML17068A161
8.10	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, General, Q2	North Carolina is not aware of a security or safety problem with current Category 3 quantity radioactive source transfer practices and we do not believe that requiring license verification through LVS or the Agreement States' regulatory authorities would result in any improvement in safety or security. The increased costs to the Agreement States to administer this program does not appear to be cost justified.	LVS	Letter	03/06/2017	ML17068A161

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8.11	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, General, Q3	Yes.	LVS	Letter	03/06/2017	ML17068A161
8.12	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, General, Q4	The NRC should perform an analysis of the cost benefit of any new rules and the security benefit based on the present threat environment and allow for public discussion of this analysis before creating any additional requirements.	SA	Letter	03/06/2017	ML17068A161
8.13	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, NSTS, Q1	North Carolina does not believe that Category 3 quantity sources should be included in the NSTS. This will be a burden on licensees and the State, and adds nothing augmenting source safety or security. Inspectors regularly check that inventories are within the limitations as issued on a license and rarely is anything in disagreement.	NSTS	Letter	03/06/2017	ML17068A161
8.14	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, NSTS, Q2	No.	NSTS	Letter	03/06/2017	ML17068A161
8.15	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, NSTS, Q3	No. The existing reporting requirements for the transfer and accounting of Category 1 and 2 quantities of radioactive materials currently in 10 CFR Part 37 are sufficient, and adding additional reporting requirements for NSTS will not increase the level of safety or security for these sources while adding significantly to the regulatory burden on licensees and the State.	NSTS	Letter	03/06/2017	ML17068A161
8.16	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, NSTS, Q4	No.	NSTS	Letter	03/06/2017	ML17068A161
8.17	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, NSTS, Q5	A realistic assessment of the value-added, or lack thereof, for this action in relation to the costs of administering this additional program element needs to be performed and made available to all relevant stakeholders for discussion. Also, the issue is less of inventories, limits and accountability of sources, but rather the validation of the licenses. North Carolina feels the emphasis for any future security risk benefit studies should prioritize LVS efforts over NSTS at this time.	NSTS	Letter	03/06/2017	ML17068A161

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8.18	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, NSTS, AS Q1	The entire purpose of NSTS is that it is a national database. It is more efficient and cost-effective to have the NRC continue in its current role as the single point of contact maintaining this database. Deferring this responsibility to the Agreement States will result in significant costs to the Agreement States with a corresponding decrease in data reliability, data security, and availability. Also, North Carolina respectfully reminds the NRC that this initiative is the NRCs initiative, not that of the Agreement States. The costs, therefore, are the NRC's to bear.	NSTS	Letter	03/06/2017	ML17068A161
8.19	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, Security, Q1	No.	SA	Letter	03/06/2017	ML17068A161

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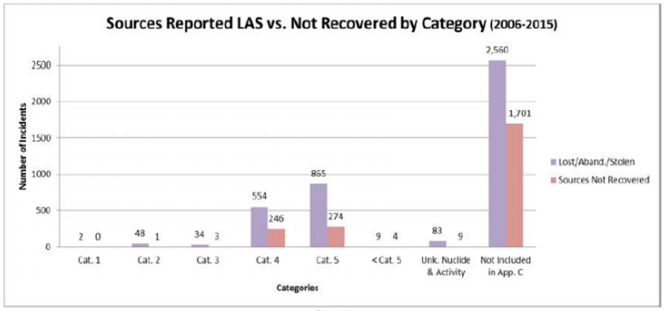
8.20	David Crowley, Manager, Radioactive Materials Branch	North Carolina Department of Health and Human Services	Agreement State	FRN, Security, Q2	Yes – with the additional opinion that North Carolina feels that the possession and use of radioactive material should be regulated under either the specific licensing program or exempt from regulation. The general licensing program, as currently administered, is costly and yields few net benefits.	GLDs	Letter	03/06/2017	ML17068A161
9.01	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	General	The GAO final report, entitled "Nuclear Security: NRC Has Enhanced the Controls of Dangerous Radioactive Materials, but Vulnerabilities Remain" offers three recommendations. Only one of the three recommendations is directly related to the actual findings of both the 2007 and 2015 GAO investigations, in which, the common denominator of risk was due to federal and state agencies failing to properly review license applicants.	SA	Letter	03/06/2017	ML17153A198
9.02	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	General	Before addressing the questions pertaining to the solicitation of comments listed in 7590-01-P, it is important to highlight the 2015 Nuclear Material Events Database (NMED) Annual Report published by Idaho National Laboratory (INL/LTD-16-37644). The report provides valuable data over the past decade regarding the number of reported events with respect to each security category.	SA	Letter	03/06/2017	ML17153A198
9.03	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	General	The following chart represents data that was extrapolated from Page 6, Table 2, entitled, "Number of Sources Lost/Abandoned/Stolen (LAS) and Sources Not Recovered (NR) – Excluding Irretrievable Well Logging Sources":  Chart-A	SA	Letter	03/06/2017	ML17153A198

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9.04	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	General	There were at least 4,155 reported lost, abandoned or stolen (LAS) sources between 2006 and 2015. The following spreadsheet illustrates the percentage of data categorically: Category # of LAS Percentage 1 2 0.05% 2 48 1.16% 3 34 0.82% 4 554 13.33% 5 865 20.82% <5 9 0.22% Unknown nuclide & activity 83 2.0% Not included in App. C 2,560 61.61% Total reported 4,155	SA	Letter	03/06/2017	ML17153A198
9.05	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	General	There were 4,072 sources of known nuclide and activity, which accounted for 98% of the total LAS of 4,155 over the ten consecutive years reported. There was 41% more category 2 sources reported LAS compared to category 3 sources over the same decade. Grouping categories 1, 2 and 3 together only accounted for 2% of the total number of reported LAS sources. Ironically, category 3 represented only 1.3%, but categories 4, 5 and <5 accounted for 35%. The remaining 63% were nuclides that are not listed in Appendix C.	SA	Letter	03/06/2017	ML17153A198
9.06	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	General	It is highly probable that there would not be a distinguishable reduction in the number of reported LAS sources as a result of increasing security of category 3 to that of category 1 and 2.	SA	Letter	03/06/2017	ML17153A198
9.07	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	General	The following comments are offered from the perspective of a manufacturer who distributes fixed nuclear gauging devices within the United States, consultation and instruction to licensees thereof. Applicable comments correspond with the order that the questions were presented by the Working Group:	SA	Letter	03/06/2017	ML17153A198
9.08	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, General, Q2	Comment: VEGA has not detected any attempt by a purchaser to misrepresent, alter or fictitiously submit a specific license for purchase or distribution of a nuclear device. Implementing the online features of the LVS system for all devices, regardless of nuclide or quantity would most likely increase the integrity of the license validation process and confirm regulatory endorsements in real-time.	LVS	Letter	03/06/2017	ML17153A198
9.09	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, General, Q3	Comment: Offering exemptions based on the transfer purpose or the activity of any given shipment will be subject to interpretation and execution that may not coincide with the receiving party's reporting criteria if based on aggregate quantities and/or type of re-distribution.	LVS	Letter	03/06/2017	ML17153A198

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9.10	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, General, Q4	Comment: To be effective and consistent, this would need to address the loss of security controls associated with nuclear gauging devices distributed under a general license for domestic or international distribution.	LVS	Letter	03/06/2017	ML17153A198
9.11	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, NSTS, Q4	Comment: NMED data over the last decade suggest that category 2 sources are currently at the same risk as category 3 sources for being reported lost, abandoned or stolen. This would suggest that security and safety measures would not be increased by virtue of merging category 3 sources under NSTS.	SA	Letter	03/06/2017	ML17153A198
9.12	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, NSTS, Q5	Comment: To be effective and consistent, this would need to address the loss of security controls associated with nuclear gauging devices distributed under a general license for domestic and international distribution.	SA	Letter	03/06/2017	ML17153A198
9.13	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, LVS, Q1	Comment: We would have to sign-up multiple employees to have online access to accommodate the volume of potential orders.	LVS	Letter	03/06/2017	ML17153A198
9.14	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, LVS, Q2	Comment: Potentially one-hundred sources transferred to or from our facility each month.	LVS	Letter	03/06/2017	ML17153A198
9.15	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, LVS, Q3	Comment: No. The data may not offer any additional value as manufacturers and distributors already keep and provide detailed records internally and to the appropriate agency having jurisdiction.	LVS	Letter	03/06/2017	ML17153A198
9.16	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, Security, Q1	Comment: No. The attempt to implement the additional security requirements for existing category 3 sources used in fixed gauges has proven to be excessive and oftentimes misinterpreted by agencies and inspectors. Adding the same security requirements for category 3 (both generally licensed and specifically licensed gauges), would have an enormous impact that could never be fully implemented or enforced based on the applications and industries that would be affected. It is more likely that the attempt to conform to the additional requirements will actually increase the security risk because it will expand awareness by ancillary observers and social exchanges. Trying to create physical and electronic controls, plus additional vetting and training for employees, contractors and local emergency responders will influence product cost and taxpayers. Also, the inherent cost with compliance will affect the overall marketability of devices that are critical to many process operations.	SA	Letter	03/06/2017	ML17153A198

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9.17	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, Security, Q2	Comment: Yes. The limiting of quantities associated with generally licensed items is arguably a much greater need and has been a significant security and safety risk that supersedes entertaining increased controls for category 3.	GLDs	Letter	03/06/2017	ML17153A198
10.01	Carmine M. Plott, Chair, NC Radiation Protection Commission Wayne R. Thomann, Vice-Chair	North Carolina Department of Health and Human Services	Agreement State	General	The Radiation Protection Commission has been monitoring and assessing the proposal and agrees with the North Carolina Agreement State and the Nuclear Energy Institute with regard to this issue.	NSTS	Letter	03/08/2017	ML17074A220
10.02	Carmine M. Plott, Chair, NC Radiation Protection Commission Wayne R. Thomann, Vice-Chair	North Carolina Department of Health and Human Services	Agreement State	General	We oppose the expanded regulation of these sources as such changes would add significant burden to our regulated community with no significant benefit to the public we serve.	NSTS	Letter	03/08/2017	ML17074A220
11.01	Greg Schrad, Plant Engineer	Gilberton Power Company	Industrial	FRN, Security, Q2	I attended the 03/02/2017 webinar on this subject and brought up a concern when possible security changes were talked about. We use our Cat 3 sources in permanently mounted level indicators and we have not changed them in 20 years and do not plan on moving them for another 20 years. The level is continuously monitored remotely. We meet all the requirements for a general license with Cat 3 sources.	SA	Email	03/09/2017	ML17074A283
11.02	Greg Schrad, Plant Engineer	Gilberton Power Company	Industrial	FRN, Security, Q1	I have read 10CFR37, specifically on physical security of Cat 2 sources. If the security requirements for Cat 3 sources change and we have to meet Cat 2 security requirements, the changes we would have to make would be substantial and cause a burden financially and physically. I would assume that most companies in similar source use situations would have the same problems.	SA	Email	03/09/2017	ML17074A283
11.03	Greg Schrad, Plant Engineer	Gilberton Power Company	Industrial	FRN, NSTS, Q1	I do not see an issue with the change in reporting, it might bind the system up for a while, but it can happen.	NSTS	Email	03/09/2017	ML17074A283
11.04	Greg Schrad, Plant Engineer	Gilberton Power Company	Industrial	FRN, Security, Q1	The security plans, initial training, continuing training, alarmed access, and new security zones (as I read with category 2) will add a lot. We also don't currently have a good replacement for our detectors if we had to change them to a non-nuclear detector.	SA	Email	03/09/2017	ML17074A283

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
12.01	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, General, Q1	No Comment.	SA	Letter	03/09/2017	ML17074A285
12.02	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, General, Q2	No Comment.	SA	Letter	03/09/2017	ML17074A285
12.03	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, General, Q3	No Comment.	LVS	Letter	03/09/2017	ML17074A285
12.04	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, General, Q4	No Comment.	LVS	Letter	03/09/2017	ML17074A285
12.05	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q1	Several stakeholders have considered the issue and recommended the strengthening of regulations for higher activity devices and/or tracking of Category 3 sources including the OAS* and NRC staff**. *OAS Petition for Rulemaking Regarding 10 CFR 31.5 and 31.6; Comment on Draft Proposed Rule 10 CFR Parts 30, 31, 32 and 150. The purpose of this petition is to strengthen the regulation of radioactive materials by requiring an SL for higher-activity devices that are currently available under the GL in 10 CFR 31.5. **In 2008, NRC staff proposed to amend NRC regulations to expand the NSTS to include Category 3 sources including fixed industrial gauges (e.g., level gauges, conveyor gauges, thickness gauges, blast furnace gauges, dredger gauges, and pipe gauges); well-logging devices; medium and low-dose-range brachytherapy devices; and certain radiography devices. Staff also recommended inclusion in the NSTS of "sources below the Category 3 threshold, but greater than or equal to a 10th of the Category 3 threshold," base on "…the nature of the sources at 1/10 of Category 3, their potential to aggregate to Category 2, and the costs to the licensed industry and the NRC." 71 Federal Register 19,749 (April 11, 2008). On June 30, 2009, by a 2-2 vote, NRC announced that the Commission "was unable to reach a decision on the staff's recommendation to issue a final rule expanding the number and type of radioactive sources" covered under the NSTS. Press Release 09-121 titled, "NRC Commission Split 2-2 on Expansion of National Radioactive Source Tracking System," NRC, June 30, 2009.	NSTS	Letter	03/09/2017	ML17074A285

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12.06	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q1	In 2015, the DSWG and CRCPD's E-34 Committee asked state radiation control program directors to complete a survey on the management and disposition of disused sources. The survey included a question as to whether or not all Category 3 sources should in principle be tracked by NRC. 63% of the respondents ranked this item as a high- or medium-priority.* In response to a specific question as to whether NRC should expand the NSTS to track Category 3 sources, 58% of respondents marked this item as a high- or medium-priority.** *Responses to Question 45, DSWG and CRCPD E-34 Committee Joint Survey of Radiation Control Program Directors, May 2015. Forty-two state radiation control program directors responded representing 38 individual states. **Responses to Question 48, DSWG and CRCPD E-34 Committee Joint Survey of Radiation Control Program Directors, May 2015.	NSTS	Letter	03/09/2017	ML17074A285
12.07	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q1	Over the past decade, the U.S. Government Accountability Office (GAO) has undertaken two covert vulnerability-testing efforts that revealed weaknesses in NRC and Agreement State licensing programs.* Out of five attempts, GAO was twice able to obtain licenses and then alter them to obtain agreements to purchase devices containing, in aggregate, dangerous quantities of radioactive materials. These may be isolated instances and the DSWG recognizes that NRC and Agreement States have taken significant steps to help ensure that radioactive materials licenses are granted only to legitimate organizations and that licensees can only obtain such materials in quantities allowed by their licenses. *GAO has completed audits of the security aspects of NRC and Agreement State licensing processes that raised concerns about the relative ease with which lower activity sources can be purchased and potentially aggregated to higher activity levels. See Testimony Before the Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, U.S. Senate, "Nuclear Security: Actions Taken by NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources Are Not Effective," GAO Report 07-1038T, July 12, 2007; Report to the Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, U.S. Senate, "Nuclear Security: NRC and DHS Need to Take Additional Steps to Better Track and Detect Radioactive Materials," GAO Report 08-598, June 2008; and, Report to the Committee on Homeland Security, U.S. House of Representatives, "Nuclear Security: NRC Has Enhanced the Controls of Dangerous Radioactive Materials, but Vulnerabilities Remain," GAO Report 16-330, July 2016.	NSTS	Letter	03/09/2017	ML17074A285
12.08	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q1	Nonetheless, the DSWG believes that the overall fail rate experienced in the GAO vulnerability-testing efforts is cause for the collective attention by all stakeholders and encourages NRC and the Agreement States to continue their joint effort to address the issues identified in the GAO reports and work to achieve improvements in the system, where appropriate.	NSTS	Letter	03/09/2017	ML17074A285
12.09	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q1	Since Category 3 sources are not currently tracked, regulators face challenges when performing oversight. These challenges, as well as the mobility of some of these sources, may provide an opportunity for loss or theft as determined by a prior NRC Agreement State Working Group.	NSTS	Letter	03/09/2017	ML17074A285

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12.10	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q1	The DSWG agrees with the above-identified stakeholder recommendations and generally supports the inclusion of Category 3 sources in the NSTS, but encourages NRC to work with OAS and CRCPD to first address the states' concerns about existing problems and needed improvements to the database. (See below response to Question 5.)	NSTS	Letter	03/09/2017	ML17074A285
12.11	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q2	The DSWG encourages the NRC to work with the states via CRCPD and OAS to determine the number of existing Category 3 sources.	NSTS	Letter	03/09/2017	ML17074A285
12.12	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q2	The DSWG further recommends that NRC work with CRCPD, OAS and HPS to gather information about the potential burdens and costs of imposing the same reporting requirements for Category 3 sources that are currently required for Category 1 and 2 sources.	NSTS	Letter	03/09/2017	ML17074A285
12.13	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q2	Although the DSWG does not believe that added workload and costs should be used as the primary basis for excluding Category 3 sources in the NSTS, the DSWG encourages the NRC to take these factors into consideration and to work with affected stakeholders to develop a manageable and efficient reporting system to address critical improvements.	NSTS	Letter	03/09/2017	ML17074A285
12.14	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q3	The DSWG supports the consideration of requiring source transfers to be reported prior to, or on the same day as, the source shipment date. Since NRC requires the information to be reported anyway, requiring reporting prior to, or on the same day, as the shipment should not create a significant burden and should improve efficiency and help to eliminate existing vulnerabilities associated with post-transfer tracking.	NSTS	Letter	03/09/2017	ML17074A285
12.15	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q3	In this regard, the DSWG notes that it is standard industry practice to complete waste manifest, export and import authorization and other paperwork before radioactive materials and waste are shipped.	NSTS	Letter	03/09/2017	ML17074A285
12.16	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q4	The DSWG believes that the inclusion of Category 3 sources in the NSTS would provide a corresponding increase in safety and/or security. Although it may be difficult to quantify the amount or degree of increased safety and security, existing vulnerabilities have been identified via the GAO vulnerability-testing efforts and specific instances of excessive aggregation and non-compliance.	NSTS	Letter	03/09/2017	ML17074A285
12.17	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q4	For instance, according to presentations at industry meetings, over 10,000 disused sources were collected and indefinitely stored at a waste broker's facility in Texas. Recent inspections by state regulators reportedly determined that over 10% of the stored sources were leaking.	SA	Letter	03/09/2017	ML17074A285
12.18	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q4	In January 2012, the Illinois Emergency Management Agency (IEMA) denied a radioactive waste broker application to renew its license due to continued noncompliance. The company failed to make sufficient progress in decommissioning their facility. In April 2013, IEMA seized their financial assurance instrument, thereafter completing decommissioning activities in the summer of 2014.	NSTS	Letter	03/09/2017	ML17074A285

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12.19	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q4	In another instance, a waste processor in the State of Washington accumulated legacy radioactive waste, without being required to fund the total cost for end-of-life management of the unsealed and sealed sources. Over time, the volume of legacy waste grew and the company could not adequately fund proper financial assurance for packaging, shipping and disposal. The company continued to request authorization to store more waste in order to generate sufficient funds to cover normal day-to-day expenses. Eventually, the state stopped authorizing acceptance of additional radiative material unless the company started addressing the disposition of the waste material being stored on site. In the end, the company declared bankruptcy and another waste processing company purchased the bankrupt facility, posted adequate financial assurance, and worked with the state to establish a timetable for removal of all legacy waste.	NSTS	Letter	03/09/2017	ML17074A285
12.20	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q4	These instances provide support for the increases in safety and security that may be achieved by including Category 3 sources in the NSTS. The DSWG cautions, however, that tracking of Category 3 sources in the NSTS is only one component. In order to meaningfully reduce existing vulnerabilities, NRC and the Agreement States need to impose systems to regularly review the information and use it to address potential concerns – i.e., the continued storage of disused sources that have no potential benefit, the aggregation of risk-significant quantities of radioactive materials and the importance of regulatory compliance by licensees.	NSTS	Letter	03/09/2017	ML17074A285
12.21	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q5	Some states have expressed concern that the National Source Tracking System (NSTS) and Web-Based Licensing (WBL) do not communicate with one another and therefore require duplicative efforts to enter and/or search for the same information in each system.	Cred&SysArc	Letter	03/09/2017	ML17074A285
12.22	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q5	State databases may have fields that are different than those in the federal databases and are not interconnected, which again requires duplicative efforts and can therefore be costly and time-consuming to complete.	Cred&SysArc	Letter	03/09/2017	ML17074A285
12.23	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q5	Only a handful of states use WBL and there is a significant backlog of states waiting to get authorization to use the system.	WBL	Letter	03/09/2017	ML17074A285
12.24	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, Q5	NRC should make it a priority to work with states to address the above issues and should evaluate potential opportunities to expand the use of WBL in an effort to increase regulatory efficiency and consistency.	WBL	Letter	03/09/2017	ML17074A285
12.25	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, LVS, Q1	No Comment.	LVS	Letter	03/09/2017	ML17074A285
12.26	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, LVS, Q2	No Comment.	LVS	Letter	03/09/2017	ML17074A285

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12.27	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, LVS, Q3	No Comment.	LVS	Letter	03/09/2017	ML17074A285
12.28	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, LVS, Q4	No Comment.	LVS	Letter	03/09/2017	ML17074A285
12.29	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS licensees, Q1	No Comment.	NSTS	Letter	03/09/2017	ML17074A285
12.30	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS licensees, Q2	No Comment.	NSTS	Letter	03/09/2017	ML17074A285
12.31	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, LVS, AS Q1	The DSWG has been working with various stakeholders in an effort to get an accurate and current accounting of Category 3 quantities of radioactive material. The responses indicate that there are significant obstacles to compiling this information including • a need for clarity as to what information is being requested—i.e., an accounting of the number of sources, devices or licensees; • a lack of availability of data, since Category 3 sources are not currently included in the NSTS and are not tracked by many, if not most, states; and, • associated costs and time to gather the information, which often requires physical review of license files manually.	LVS	Letter	03/09/2017	ML17074A285
12.32	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, LVS, AS Q1	The four states of Connecticut, Illinois, Pennsylvania and Washington recently provided information to the DSWG regarding the number of Category 3 licenses issued in their individual states. (See Appendix 1.) The information indicates that the data varies significantly from state-to-state.	LVS	Letter	03/09/2017	ML17074A285
12.33	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, LVS, AS Q1	The DSWG is concerned about the lack of an accurate and current accounting of Category 3 quantities of radioactive material, as well as the difficulties and challenges associated with gathering this information due to the lack of state and/or federal tracking databases. Accordingly, the DSWG encourages NRC to work with the states via the OAS and CRCPD to identify issues associated with collection of the information and to work toward implementing a tracking system that that does not impose undue burdens or have unintended consequences.	LVS	Letter	03/09/2017	ML17074A285
12.34	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, LVS, AS Q2	No Comment.	LVS	Letter	03/09/2017	ML17074A285
12.35	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, LVS, AS Q3	No Comment.	LVS	Letter	03/09/2017	ML17074A285

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12.36	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, LVS, AS Q4	No Comment.	LVS	Letter	03/09/2017	ML17074A285
12.37	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, NSTS, AS Q1	No Comment.	NSTS	Letter	03/09/2017	ML17074A285
12.38	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q1	Certain higher activity Category 3 sources present significant risks and challenges, as recognized by the American Federation of Scientists* and the GAO.** Under the current system, some sources that are considered to be dangerous by the IAEA are not tracked or licensed in a manner to address existing vulnerabilities.*** *Ensuring the Security of Radioactive Sources: National and Global Responsibilities, Charles Ferguson, President of the Federation of American Scientists, 2012. **See Appendix I (Potential Effects of a Radiological Dispersal Device with Category 1, 2 and 3 Quantities of Radioactive Material), Report to the Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, U.S. Senate, "Nuclear Security: NRC and DHS Need to Take Additional Steps to Better Track and Detect Radioactive Materials," GAO Report 08-598, June 2008. ***IAEA Code of Conduct and IAEA Safety Guide #RS-G-1.9 (Categorization of Radioactive Sources) includes a system for categorizing radioactive sources based on their potential to cause harm to people. The system categorizes sources into five categories, Categories 1 through 5, with Category 1 being the greatest risk and Category 5 being the lowest risk. Categories 1, 2, and 3 are all classified as "dangerous" sources.	SA	Letter	03/09/2017	ML17074A285
12.39	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q1	Additionally, the DSWG is concerned that some licensees are purchasing and using devices just below the Category 2 threshold so as to avoid the increased reporting and security requirements for Category 1 and 2 sources. Due to a lack of financial planning, these sources often end up in long-term storage once they become disused, as noted by the Radiation Source Protection and Security Task Force (RSPSTF).* *"The NRC should evaluate requiring licensees to review and document the reasons for storage of risk significant sources longer than 24 months and the feasibility of establishing a maximum time limit on the long-term storage of risk-significant sources not in use." As recommended in Action 7-1, 2006 Task Force, 2006 Task Force Report. "The NRC incorporated this action into its evaluation for 2006 Recommendation 9-2 in consultation with Federal and State partners. The evaluations will factor into the NRC's decision whether to pursue rulemaking and the public consultation process." 2010 Task Force, 2010 Task Force Report, p. 37, at http://www.nrc.gov/security/byproduct/2010-task-force-report.pdf.	SA	Letter	03/09/2017	ML17074A285

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12.40	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q1	Some of these sources, such as those used in the well logging industry, are mobile and therefore subject to loss or theft. Additionally, the potential for aggregation of these sources into risk significant quantities is a valid concern, as noted by the RSPSTF* and National Academies of Sciences (NAS).** *The 2010 Radiation Source Protection and Security Task Force Report recognizes that Category 3 sources can be aggregated into a "risk significant quantity." 2010 Task Force, 2010 Task Force Report, p.9, http://www.nrc.gov/security/byproduct/2010-task-force-report.pdf. **"Sources that fall into Category 3 and lower can be assembled into Category 2 or 1 quantities of radioactive material. Further, it may be the case that some radiation sources near the upper threshold for Category 3 pose more serious risks than other sources that fall near the lower threshold of Category 2 in scenarios other than those used to create the source categorization system." Radiation Source Use and Replacement, National Research Council, National Academies of Sciences (NAS), page 43, note 1, 2008.	SA	Letter	03/09/2017	ML17074A285
12.41	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q1	The 2015 survey by the DSWG and CRCPD's E-34 Committee asked respondents whether individual Category 3 sources, such as Am/Be sources used in well logging, should be subject to greater security requirements. 74% of the respondents ranked this item as a high- or medium-priority.* In response to a survey question at to whether licensees who may possess several Category 3 sources exceeding the Category 2 level should be subject to greater security requirements, 74% of respondents also ranked their responses to this item as a high- or medium-priority.** *Responses to Question 39, DSWG and CRCPD E-34 Committee Joint Survey of Radiation Control Program Directors, May 2015. **Responses to Question 40, DSWG and CRCPD E-34 Committee Joint Survey of Radiation Control Program Directors, May 2015.	SA	Letter	03/09/2017	ML17074A285
12.42	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q1	Based on the inherent risks, mobility and potential for aggregation of certain higher activity Category 3 sources, the DSWG generally supports the expansion of physical security requirements for Category 1 and 2 quantities of radioactive material to include Category 3 quantities. Before implementing new regulatory requirements, however, the DSWG encourages NRC to work with affected stakeholders—including regulators (via OAS and CRCPD), manufacturers, brokers and processors, and licensees (via HPS)—to ensure a smooth transition and minimize any unintended consequences.	SA	Letter	03/09/2017	ML17074A285
12.43	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	In order to possess a General License (GL) source, the user has only to file limited registration information with the NRC or Agreement State after obtaining the source. In many instances, there is no significant evaluation by a regulatory agency prior to or during the possession of a GL source.	GLDs	Letter	03/09/2017	ML17074A285
12.44	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	In contrast, possession of a Specific License (SL) source requires the user to submit a license application and undergo a facility inspection in advance of obtaining the source. Additional requirements for SL sources include adherence to license conditions, periodic renewals, state approved radiation safety training and procedures, and periodic inspections by the NRC or Agreement State.	GLDs	Letter	03/09/2017	ML17074A285

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12.45	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	In 2008, HPS considered the issue and submitted comments to NRC supporting their position that all Category 3 sources and greater should be subject to an SL.* Likewise, in 2010, the OAS petitioned NRC to increase the regulatory control over certain GL sources.** When the OAS petition came before the Commission, the additional controls failed upon a tie vote, resulting in a non-decision. However, the NRC did authorize Agreement States to increase controls on GL sources at their own discretion. As a result of this, few states enacted increased controls. *Health Physics Society (HPS) comments on Docket NRC-2008-0272, "Limiting the Quantity of Byproduct Material in a General Licensed Device." Their comments established the HPS position that all Category 3 sources and greater should be subject to a SL. **OAS Petition for Rulemaking (PRM) 31-5 as found at http://www.regulations.gov/#!documentDetail;D=NRC- 2008-0272-0059 and http://www.regulations.gov/#!documentDetail;D=NRC-2008-0272-0001; SECY 10-10-0105, Limiting the Quantity of Byproduct Material in a Generally Licensed Device; Commission Voting Record Decision Item: SECY-10-0105, Final Rule: Limiting the Quantity of Byproduct Material in a Generally Licensed Device (RIN 3150-AI 33), December 2, 2010. In addition to OAS, nine Agreement States also supported this position.	GLDs	Letter	03/09/2017	ML17074A285
12.46	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	A previous NRC-Agreement State Working Group determined that there is a lack of oversight of GL licensees by the regulators.* That working group also found that regulators have not taken an active role in ensuring that GL licensees maintain control over and accountability for GL sources and in ensuring that licensees possess, use, and transfer GL devices in accordance with the regulations. This has led to a loss of control and sometimes to improper disposal or even to orphaned or abandoned sources.** Subsequently, NRC and Agreement States implemented registration and annual reporting requirements for GL sources. *Final Report of the NRC-AS Working Group to evaluate Control and Accountability of Licensed Devices (NUREG- 1551). **In response to an inquiry regarding information about missing nuclear materials over a five year period, the NRC documented 18 instances of Reportable Licensed Lost, Abandoned or Stolen Material (LAS) Events from 1997 to July 7, 2002. Response to Freedom of Information Act (FOIA)/Privacy Act (PA) Request, NRC Form 464 Part I, FOI/PA 2003-0082, December 18, 2002.	GLDs	Letter	03/09/2017	ML17074A285

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12.47	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	The 2015 survey by the DSWG and CRCPD's E-34 Committee asked respondents whether all Category 3 sources should be specifically licensed. Although 76 percent of respondents ranked their responses to this item as a high- or medium-priority,* only 16% of the respondents answered in the affirmative as to whether or not their individual state requires that all Category 3 sources be specifically licensed** and 24% responded in the affirmative as to whether or not their individual state requires that some or all generally licensed devices be specifically licensed.*** Of significant note, 57% responded in the affirmative when asked whether NRC will need to adopt rules requiring the specific licensure of Category 3 sources before their individual state can act to do so.**** *Responses to Question 41, DSWG and CRCPD E-34 Committee Joint Survey of Radiation Control Program Directors, May 2015. **Responses to Question 42, DSWG and CRCPD E-34 Committee Joint Survey of Radiation Control Program Directors, May 2015. ***Responses to Question 43, DSWG and CRCPD E-34 Committee Joint Survey of Radiation Control Program Directors, May 2015. ****Responses to Question 44, DSWG and CRCPD E-34 Committee Joint Survey of Radiation Control Program Directors, May 2015.	GLDs	Letter	03/09/2017	ML17074A285
12.48	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	The limited requirements and oversight for a GL source provide a window of opportunity for aggregation or misuse of higher activity Category 3 sources prior to the required reporting to regulatory agencies. Accordingly, the DSWG believes that an SL should be required for Category 3 sources.	GLDs	Letter	03/09/2017	ML17074A285
12.49	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	The DSWG recognizes that additional regulation may be labor-intensive, costly and pose additional burdens on the NRC and Agreement States. However, due to the estimated small number of Category 3 GL sources in the United States, the DSWG believes that reduction in current vulnerabilities from increased regulation outweighs the anticipated costs. The DSWG encourages NRC to work with the states through OAS and CRCPD to make the transition efficient and reduce unanticipated costs, where appropriate.	GLDs	Letter	03/09/2017	ML17074A285
12.50	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	In preparation for the DSWG's response to the NRC's Federal Register notice on Category 3 source protection and accountability, the LLW Forum asked five states to provide the following information: • total number of specific licenses; • total number of Category 3 specific licenses; • total number of Category 3 general licenses; • total number of Category 3 specifically licensed sources; • total number of Category 3 generally licensed sources; and, • total time to collect this data.	SA	Letter	03/09/2017	ML17074A285
12.51	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	The states initially responded that this assignment would very tedious because most states do not electronically track Category 3 sources and it would require reviewing individually (i.e., manually) all specific licensees and all general licensees to determine if they authorize Category 3 radioactive sealed sources.	SA	Letter	03/09/2017	ML17074A285

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

<table>
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<tr><td>12.52</td><td>Disused Sources Working Group</td><td>Low-Level Radioactive Waste Forum, Inc.</td><td>NGO</td><td>FRN, Security, Q2</td><td>Additionally, it would require states to contact each broad scope licensee because they are authorized to possess “Any byproduct material with atomic numbers 3 through 83” or “Any byproduct material with atomic numbers 1 through 83, and 88, with half-lives of less than or equal to 120 days,” and the radioactive sealed sources are not specifically accounted for by the radioactive materials license.</td><td>SA</td><td>Letter</td><td>03/09/2017</td><td>ML17074A285</td></tr>
<tr><td>12.53</td><td>Disused Sources Working Group</td><td>Low-Level Radioactive Waste Forum, Inc.</td><td>NGO</td><td>FRN, Security, Q2</td><td>One of the five states declined to respond because they did not have a tracking system and could not afford to commit the staff time to do the manual review of each specific and general license.</td><td>NSTS</td><td>Letter</td><td>03/09/2017</td><td>ML17074A285</td></tr>
<tr><td>12.54</td><td>Disused Sources Working Group</td><td>Low-Level Radioactive Waste Forum, Inc.</td><td>NGO</td><td>FRN, Security, Q2</td><td><table>
<tr><th>State</th><th>Total number of SL's</th><th>Number of Category 3 SL's</th><th>Number of Category 3 GL's</th><th>Number of Category 3 SL's sources</th><th>Number of Category 3 GL's sources</th><th>Hours to Collect Data</th></tr>
<tr><td>CT</td><td>155</td><td>19</td><td>1</td><td>3</td><td></td><td>6</td></tr>
<tr><td>IL</td><td>624</td><td>102</td><td>14</td><td>135</td><td>50</td><td>40</td></tr>
<tr><td>PA</td><td>630</td><td>91</td><td>16</td><td>63</td><td>11</td><td>30</td></tr>
<tr><td>WA</td><td>330</td><td>22</td><td>0</td><td>42</td><td>0</td><td>8</td></tr>
</table>
The above chart summarizes the states’ responses.</td><td>NSTS</td><td>Letter</td><td>03/09/2017</td><td>ML17074A285</td></tr>
<tr><td>12.55</td><td>Disused Sources Working Group</td><td>Low-Level Radioactive Waste Forum, Inc.</td><td>NGO</td><td>FRN, Security, Q2</td><td>Connecticut has a total number of 2 Category 1 SLs, 2 sources that are Category 1 SLs, 16 Category 2 specific licenses and 225 Category 2 specifically licensed sources.</td><td>NSTS</td><td>Letter</td><td>03/09/2017</td><td>ML17074A285</td></tr>
<tr><td>12.56</td><td>Disused Sources Working Group</td><td>Low-Level Radioactive Waste Forum, Inc.</td><td>NGO</td><td>FRN, Security, Q2</td><td>Illinois numbers will vary once we start sending out inquiries on true possession vs. authorization and also factor in co-location.</td><td>NSTS</td><td>Letter</td><td>03/09/2017</td><td>ML17074A285</td></tr>
<tr><td>12.57</td><td>Disused Sources Working Group</td><td>Low-Level Radioactive Waste Forum, Inc.</td><td>NGO</td><td>FRN, Security, Q2</td><td>Pennsylvania stated the reasoning our total number of Cat 3 specifically licensed sources are listed as indeterminate is based on two major factors. The first factor would be 10 CFR 35.65 (Authorization for calibration, transmission, and reference sources) which states:

1. Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use.

a. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations. Meaning that these licensees would not be required to register all of their check sources with the state of Pennsylvania, therefore none would be listed on the license, and no record is kept of these sources within the Department.</td><td>NSTS</td><td>Letter</td><td>03/09/2017</td><td>ML17074A285</td></tr>
</table>

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

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12.58	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	Secondly, we have other Universities and other facilities that fall under a Broad Scope. These licensee in many cases are currently allowed to possess “Any byproduct material with atomic numbers 3 through 83” or “Any byproduct material with atomic numbers 1 through 83, and 88, with half-lives of less than or equal to 120 days,” in which these materials are not specifically account for by source. All tolled, the state currently licenses 17 broad scope licenses within the state that could fall under one, two, or both of these classes. Based on these 2 factors, we cannot currently determine an accurate total number of sources within the state.	NSTS	Letter	03/09/2017	ML17074A285
12.59	Disused Sources Working Group	Low-Level Radioactive Waste Forum, Inc.	NGO	FRN, Security, Q2	Washington stated that the total number of specifically licensed Category 3 sources was estimated by reviewing the licensees' inventory records in the latest inspection reports, and by assuming that each high dose-rate remote afterloader has one Category 3 source.	NSTS	Letter	03/09/2017	ML17074A285
13.01	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	General	Tennessee does not believe a realistic vulnerability assessment of potential risks of Category 3 sources has been performed and documented in support of a future rulemaking considering inclusion of Category 3 sources for increased source security and accountability requirements. There seems to be a lack of historical information to conclude these quantities are a significant risk.	SA	Letter	03/09/2017	ML17074A288
13.02	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	General	We believe that adoption of Category 3 quantities of radioactive material into the LVS/NSTS systems will only marginally increase the safety and security of these quantities of radioactive material, while adding a significant regulatory and economic burden to the various State Radiation Control Programs, our licensed entities, and the Nuclear Regulatory Commission. Also, to realistically include these quantities would require changes in the regulations which would be a significant regulatory burden.	SA	Letter	03/09/2017	ML17074A288
13.03	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	General	In addition, Tennessee concurs that there are devices containing Category 3 quantities of radioactive materials that can be possessed under a general license, and to increase the overall safety and security would require changes in the regulations and licensing culture.	GLDs	Letter	03/09/2017	ML17074A288
13.04	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, General, Q1	No. There is no evidence in Tennessee that the current regulations have not been adequate to assure that these transfers occur safely and this would cause an extra burden, which would not accommodate the safety and security risk.	SA	Letter	03/09/2017	ML17074A288
13.05	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, General, Q2	Tennessee is not aware of a security and/or safety problem with current Category 3 quantity radioactive source transfer practices and we do not believe that requiring license verification through LVS or the Agreement States’ regulatory authorities would result in any improvement in safety or security.	LVS	Letter	03/09/2017	ML17074A288
13.06	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, General, Q3	Yes, we believe this would cause undue burden.	LVS	Letter	03/09/2017	ML17074A288

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13.07	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, General, Q4	Tennessee concurs that the NRC should perform an analysis of the cost benefit of any new rules and the security benefit based on the present threat environment and allow for public discussion of this analysis before creating any additional requirements.	SA	Letter	03/09/2017	ML17074A288
13.08	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, NSTS, Q1	Tennessee does not believe that Category 3 quantity sources should be included in the NSTS. As with the statements concerning LVS, this will be an unnecessary burden on licensees and the State because of the limited increase in source safety or security.	NSTS	Letter	03/09/2017	ML17074A288
13.09	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, NSTS, Q2	No. Rationally Category 1 and 2 sources should have a greater value imposed on their source safety and security.	NSTS	Letter	03/09/2017	ML17074A288
13.10	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, NSTS, Q3	No. NRC has reviewed their program and the adequacy of 10 CFR Part 37 and concluded the existing reporting requirements seem to be adequate for the transfer and accounting of Category 1 and 2 quantities of radioactive materials. If future reviews show otherwise, then it can be addressed at that time.	SA	Letter	03/09/2017	ML17074A288
13.11	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, NSTS, Q4	No. See answer in Question 1.	NSTS	Letter	03/09/2017	ML17074A288
13.12	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, NSTS, Q5	As stated with regards to the LVS question, Tennessee concurs that the NRC should perform an analysis of the cost benefit of any new rules and the security benefit based on the present threat environment and allow for public discussion of this analysis before creating any additional requirements.	NSTS	Letter	03/09/2017	ML17074A288
13.13	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, NSTS, AS Q1	This would create a significant burden and cost for the licensing staff in Tennessee. Since this is a National System, unless all aspects of the ISMP system becomes a required standard and all states are allowed to have access to all aspects of the system, then having the states input data would not be efficient.	NSTS	Letter	03/09/2017	ML17074A288
13.14	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, Security, Q1	No, there is no historical data to conclude this is a rational decision.	SA	Letter	03/09/2017	ML17074A288

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13.15	Debra G. Shults, Director, Division of Radiological Health	State of Tennessee Department of Environment and Conservation	Agreement State	FRN, Security, Q2	Yes, but also the requirements for general license devices are not conducive for a regulatory authority to monitor security of these devices. If security requirements are forthcoming then Category 3 GL devices should be required to be specifically licensed.	GLDs	Letter	03/09/2017	ML17074A288
14.01	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, General, Q1	Yes, Category 3 sources should utilize the same verification requirements as Category 2 sources prescribed in 10 CFR 37.71.	LVS	Letter	03/09/2017	ML17074A284
14.02	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, General, Q2	Yes, safety and security would increase for Category 3 sealed sources. Using the NRC's License Verification System (LVS) would address many of the safety and security concerns raised by the United States Government Accountability Office (GAO) report. Specifically, the LVS would provide a means to ensure that the license used is current and unaltered. Using the LVS, which also communicates with the National Source Tracking System (NSTS) inventory system, would also verify that a licensee could not accumulate multiple Category 3 sources from various other licensees that would allow them to exceed their license limits and exceed the Category 2 limits.	LVS	Letter	03/09/2017	ML17074A284
14.03	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, General, Q2	The safety increase for requiring LVS usage for adding a Category 3 source would be about the same as requiring LVS usage for Category 2 source activities because two Category 3 sources could easily exceed a Category 2 quantity. Currently, many licensees are subject to the increased controls and the current 10 CFR 37 security requirements for the aggregation of Category 3 sources.	LVS	Letter	03/09/2017	ML17074A284
14.04	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, General, Q3	No. The LVS/NSTS is fundamentally a "cradle-to-grave" accounting system for these sources from the time of manufacture until disposal. However, it would be beneficial to exempt from the NSTS transfer and annual reconciliation requirements any sources whose activities have decayed below the Category 3 threshold.	NSTS	Letter	03/09/2017	ML17074A284
14.05	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, General, Q4	Yes. Any license verifications should be limited to Category 3 sealed sources.	LVS	Letter	03/09/2017	ML17074A284
14.06	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, NSTS, Q1	Yes. Entering the sources into the NSTS works with the LVS. Using the LVS would address the GAO concerns about ensuring that the license used is current and unaltered. The NSTS inventory system would also verify that the licensee could not accumulate multiple sources from various other licensees that would allow them to exceed their license limits and exceed the Category 2 limits.	NSTS	Letter	03/09/2017	ML17074A284
14.07	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, NSTS, Q2	Yes. The timely NSTS reporting would ensure that the licensee inventories are accurate.	NSTS	Letter	03/09/2017	ML17074A284

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14.08	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, NSTS, Q3	Currently, 10 CFR 20.2207(f) requires the report to be submitted by the close of the next business day after the transaction. This should be adequate. Having different reporting times may cause confusion and be difficult to monitor.	NSTS	Letter	03/09/2017	ML17074A284
14.09	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, NSTS, Q4	The increase in safety for using the NSTS for a Category 3 source would be about the same as requiring NSTS usage for Category 2 source activities because two Category 3 sources could easily exceed a Category 2 quantity. Currently, many licensees are subject to the increased controls, and the current 10 CFR 37 security requirements for the aggregation of Category 3 sources.	NSTS	Letter	03/09/2017	ML17074A284
14.10	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, NSTS, Q5	Nothing at this time.	NSTS	Letter	03/09/2017	ML17074A284
14.11	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, LVS, AS Q1	The Texas Department of State Health Services (DSHS) currently has approximately 248 Risk Significant Radioactive Material (RSRM) licensees, and 97 licensees with Category 3 sources who are not already under RSRM requirements. The Texas Commission on Environmental Quality (TCEQ) currently has two licensees that are authorized to possess Category 1, 2, and 3 quantities of material. One is a storage and processing facility and the other is both a storage and processing facility and Low-Level Radioactive Waste (LLRW) disposal site.	WBL	Letter	03/09/2017	ML17074A284
14.12	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, LVS, AS Q2	The state would encourage the use of LVS among licensees but would also plan for the additional burden imposed by the manual license verification process, as needed.	LVS	Letter	03/09/2017	ML17074A284
14.13	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, LVS, AS Q3	The State of Texas would consider it, but adoption of WBL is unknown at this time. Although Texas does not use WBL, we do provide a copy of amended licenses to the LVS for Category 1 and 2 quantities and we would consider adding Category 3 sources to this process.	WBL	Letter	03/09/2017	ML17074A284
14.14	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, LVS, AS Q4	The impact on the time and resources for TCEQ would be minimal. The DSHS, however, is unable to determine the impact at this time. The extent of the impact is a function of the number of source transfers and shipments that will occur and DSHS cannot know that number in advance. Most of the Category three sources would be used in well logging, fixed gauges, or medical high-dose radiation (HDR) units. The well logging and fixed gauge sources have relatively long half-lives and are not frequently replaced. Shorter half-life Ir-192 sources used in medical HDR units are typically replaced every three to six months. Currently DSHS spends approximately one hour per week following up on overdue licensee transfer documentation for Category 1 and 2 sources.	LVS	Letter	03/09/2017	ML17074A284
14.15	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, NSTS, AS Q1	At this time, there would be a minimal burden to the TCEQ and the impact to the DSHS is unknown. Presently, DSHS' involvement is to follow up on those that have not submitted their inventory reconciliations. The DSHS would likely provide hard copy documents only when specifically requested. Furthermore, the DSHS would likely send reminder correspondence with an option for the licensee to request a hard copy if they do not have access to NSTS.	NSTS	Letter	03/09/2017	ML17074A284

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14.16	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, Security, Q1	No. There is no need to expand the entire physical protection security requirements to Category 3 quantities or sources. Imposing these requirements could be burdensome for licensees only possessing Category 3 quantities whose facilities do not currently meet the physical security requirements for Category 1 and 2 quantities.	SA	Letter	03/09/2017	ML17074A284
14.17	Charlotte Sullivan, Regulatory Licensing Unit Manager	Texas Department of State Health Services	Agreement State	FRN, Security, Q2	Yes, a specific license should be required for the possession and use of Category 3 activity in a device and above. Category 3 sources are those radionuclide source activities that equal or exceed up to ten times the IAEA "D" values as those that could result in harm. Page 17 of the International Atomic Energy Agency (IAEA) Publication 1387, IAEA Nuclear Security Series No. 11, "Security of Radioactive Sources" defines "D values" as follows: "In recognition of the fact that human health is of paramount importance, the categorization system is based primarily on the potential for radioactive sources to cause deterministic health effects. The D value is the radionuclide specific activity of a source which, if not under control, could cause severe deterministic effects for a range of scenarios that include both external exposure from an unshielded source and inadvertent internal exposure following dispersal (e.g. by fire or explosion) of the source."	SA	Letter	03/09/2017	ML17074A284
15.01	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, General, Q1	Yes.	SA	Letter	03/10/2017	ML17074A289
15.02	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, General, Q2	California believes there may possibly be an incremental increase in security by using the 10 CFR 37. 71 process; however, we do not have sufficient information to quantify the increase.	SA	Letter	03/10/2017	ML17074A289
15.03	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, General, Q3	Yes, California believes that exempting transfers to manufacturers and distributors would be acceptable since these are entities known to the transferring licensee. However, such exemption should be limited to only situations in which the transferring licensee had procured the licensed material from the manufacturer/distributor to whom it is being transferred.	LVS	Letter	03/10/2017	ML17074A289
15.04	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, General, Q4	No Comment.	LVS	Letter	03/10/2017	ML17074A289
15.05	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, NSTS, Q1	No. California believes including Category 3 into the NSTS is unnecessary since unauthorized interdiction of a category 3 shipment would not in of itself result in procurement of a category 2 (or greater) quantity.	NSTS	Letter	03/10/2017	ML17074A289
15.06	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, NSTS, Q2	Category 3 should not be included into the NST System. (See 1. above)	NSTS	Letter	03/10/2017	ML17074A289

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15.07	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, NSTS, Q3	While California is not aware of any incidents that would argue for a shorter transaction reporting time than current requirements, we would support a change to require reporting to NSTS within 24 hours of the shipment/receipt, regardless of intervening holidays/weekends. We do not believe this would cause significant hardships on licensees, although it would involve more preplanning in some cases.	NSTS	Letter	03/10/2017	ML17074A289
15.08	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, NSTS, Q4	Such action may increase security however, the issue is whether the safety/security increase would warrant such inclusion. California does not have sufficient information to quantify the increase in security, but does not believe it would be sufficient to warrant inclusion in NSTS.	SA	Letter	03/10/2017	ML17074A289
15.09	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, NSTS, Q5	No.	NSTS	Letter	03/10/2017	ML17074A289
15.10	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, LVS, AS Q1	California has 149 Category 1 and 2 licensees with another approximately 150 Category 3 level licensees.	WBL	Letter	03/10/2017	ML17074A289
15.11	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, LVS, AS Q2	California would encourage our licensees to use the LVS system, but would expect that there would be an increased burden imposed due to the need for manual license verification.	LVS	Letter	03/10/2017	ML17074A289
15.12	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, LVS, AS Q3	California would continue to voluntarily provide license information to the LVS. This process has worked well for the Category 1 and 2 licenses.	LVS	Letter	03/10/2017	ML17074A289
15.13	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, LVS, AS Q4	California estimates approximately 450 additional person hours per year. This is a significant impact and deflects work on arguably more important security and safety matters.	LVS	Letter	03/10/2017	ML17074A289
15.14	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, NSTS, AS Q1	California cannot not take on this additional burden based on current funding levels, and if asked to do so may implement an alternate process for annual inventory reconciliation.	NSTS	Letter	03/10/2017	ML17074A289
15.15	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, Security, Q1	No. Current licensing and inspection techniques appropriately secure Category 3 level sources.	SA	Letter	03/10/2017	ML17074A289
15.16	Gonzalo L. Perez, Chief, Radiologic Health Branch	California Department of Public Health	Agreement State	FRN, Security, Q2	Yes.	SA	Letter	03/10/2017	ML17074A289
16.01	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	General	The Board agrees with NRC Chairman Kristine Svinicki that the current regulatory requirements for transfers of radioactive sources are adequate for safety and security, and there is no need to include Category 3 sources in the same requirements as required for Category 1 and 2 sources.	LVS	Letter	03/10/2017	ML17101A569

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
16.02	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q1	Therefore, the CRCPD Board does not support the expansion of the National Source Tracking System (NSTS) with Category 3 quantities of radioactive materials.	NSTS	Letter	03/10/2017	ML17101A569
16.03	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, General, Q1	CRCPD considers the current verification of licenses prior to transfer for Category 3 sources to be adequate for safety and security. These transfers are between licensees, the manufacturers or internally within the same company. States have successfully handled license verification as required under health and safety for many years. The current regulations are adequate to assure these transfers are properly handled. No changes should be made.	LVS	Letter	03/10/2017	ML17101A569
16.04	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, General, Q2	CRCPD does not see a benefit in safety and security if licensing verification is required through the NRC's License Verification Systems. As mentioned in Question 1 above, the States have handled license verification under health and safety for many years. There have been few, if any instances, of problems or events associated with license verification. Additional requirements may result in delaying or impeding the completion of a transfer.	LVS	Letter	03/10/2017	ML17101A569
16.05	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, General, Q3	CRCPD believes that license verification is important for entities transferring radioactive sources. License verification ensures accountability of ALL licensed sources.	LVS	Letter	03/10/2017	ML17101A569
16.06	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, General, Q4	NRC should continue to evaluate the impact on Category 3 source licensees and the States. NRC and the States already have the ability to monitor the location and movement of Category 3 sources through rigorous licensing and inspection programs.	SA	Letter	03/10/2017	ML17101A569
16.07	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q1	CRCPD does not support the inclusion of Category 3 sources in the NSTS.	NSTS	Letter	03/10/2017	ML17101A569
16.08	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q1	It has been estimated that there are 30,000-40,000 Category 3 sources in use or storage. It would be most challenging to ensure and verify that all Category 3 sources have been correctly added to NSTS. Considering how the sources may be used or how many may be transferred, it is possible that the integrity of NSTS could be compromised.	Cred&SysArc	Letter	03/10/2017	ML17101A569
16.09	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q1	Many State Programs license Category 3 sources with a maximum possession limit and do not have a readily available inventory of sources in use or storage. Collection and verification of inventory of Category 3 sources will impact licensee and State personnel resources.	NSTS	Letter	03/10/2017	ML17101A569
16.10	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q1	It is recognized that this evaluation of Category 3 sources is a comment from the 2015 General Accounting Office (GAO) report. The identified event was the failure to follow written policy and procedures. There is no correlation between this failure and the suggested inclusion of Category 3 sources in NSTS.	NSTS	Letter	03/10/2017	ML17101A569

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

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16.11	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q1	The NRC has not provided supporting evidence or data that the existing regulatory approach to Category 3 source security through use of NSTS is inadequate or unsafe to protect public health and safety.	NSTS	Letter	03/10/2017	ML17101A569
16.12	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q2	CRCPD supports the reporting requirements in 10CFR Part 37, including if Category 3 sources are included in NSTS.	SA	Letter	03/10/2017	ML17101A569
16.13	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q3	Alternatives to the current NSTS reporting requirements for Category 1 and 2 sources should not be changed. There appears to be no rationale for suggesting any changes.	NSTS	Letter	03/10/2017	ML17101A569
16.14	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q4	CRCPD does not believe that there will be any increase in safety or security if Category 3 sources are included in NSTS. Mishandling or errors during shipments will continue to occur. NSTS does not limit or control these types of errors.	NSTS	Letter	03/10/2017	ML17101A569
16.15	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q5	As mentioned in Question 1 of this section, resource impact for the licensees and States must be further evaluated.	NSTS	Letter	03/10/2017	ML17101A569
16.16	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, Q5	Also, there is concern about the integrity of the information contained in the NSTS database with the inclusion of a large number of Category 3 sources.	Cred&SysArc	Letter	03/10/2017	ML17101A569
16.17	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, AS Q1	Currently only NRC personnel have access to the NSTS for any type of change and the annual reconciliation.	NSTS	Letter	03/10/2017	ML17101A569
16.18	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, AS Q1	If the Agreement States were required to manage the annual inventory reconciliation process and if Category 3 sources were included in the NSTS, what would the additional regulatory burden be on the Agreement States to perform the annual inventory reconciliation for Category 1, 2, and 3 sources? Especially considering Agreement State staffs do not have access to the database.	NSTS	Letter	03/10/2017	ML17101A569
16.19	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, AS Q1	With the significant activity increase to NSTS, it appears that NRC is passing off some of its duties to the Agreement States. The reconciliation process could involve an increase amount of staff time and resources from November to February.	NSTS	Letter	03/10/2017	ML17101A569

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

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16.20	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, NSTS, AS Q1	This appears to be an unfunded mandate, at the time that NRC is experiencing some budget issues in the future.	NSTS	Letter	03/10/2017	ML17101A569
16.21	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, Security, Q1	NRC should not implement all of 10 CFR Part 37 requirements to further strengthen and secure Category 3 sealed sources. The Part 37 requirements would be an over burdensome regulatory requirement, given how these sources are used. Some licensees will have difficulty in meeting these requirements. There is no evidence or data that implies that the current requirements are not adequate to ensure public health, safety and security of these sources.	SA	Letter	03/10/2017	ML17101A569
16.22	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, Security, Q2	If an expansion of source security is implemented by NRC for Category 3 sealed sources, Generally Licensed Devices containing a Category 3 activity MUST be specifically licensed.	GLDs	Letter	03/10/2017	ML17101A569
16.23	Jared W. Thompson, Chairperson	Conference of Radiation Control Program Directors, Inc.	NGO	FRN, Security, Q2	CRCPD supports the re-evaluation of the NRC's General License Program to ensure that all potentially high risk sources have appropriate and relevant security to avoid possible malicious uses.	GLDs	Letter	03/10/2017	ML17101A569
17.01	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, General, Q1	We believe that the current methods are sufficient for transferring radioactive materials. From the background information the failure that GAO discovered was one individual failing to follow procedures and not a systemic wide failure.	LVS	Letter	03/10/2017	ML17101A553
17.02	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, General, Q2	We do not believe that there would be an increase in safety or security requiring licensees to use LVS for transferring quantities of Category 3 materials. Especially quantities aggregated up to category 3 quantities. This requirement would easily be defeated by performing multiple transfers of quantities under category 3 quantities.	LVS	Letter	03/10/2017	ML17101A553
17.03	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, General, Q3	We believe that transfers to known licensed manufacturers, distributors, waste processors, and commercial disposal sites should be exempted. These entities are well known and highly regulated.	LVS	Letter	03/10/2017	ML17101A553
17.04	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, General, Q4	If NRC is to track transfers of quantities of category 3 radioactive materials, it should be limited only to individual sources that are at the high end of category 3. This would only include individual sources that larger than 50% of category 2 activity (including any generally licensed sources). It would not include any aggregation of radioactive materials.	LVS	Letter	03/10/2017	ML17101A553

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17.05	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, NSTS, Q1	We do not support the inclusion of category 3 source in the NSTS. The current system of accountability of category 3 sources is adequate to protect public health and safety. There is no systemic failure of the current process only a localized failure of an individual not following procedures. Localized failures will occur regardless of the system in place. Inclusion of these sources in NSTS would be a tremendous cost burden to licensees and Agreement States. NRC has not demonstrated that inclusions of category 3 sources would improve health and safety.	NSTS	Letter	03/10/2017	ML17101A553
17.06	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, NSTS, Q2	No.	NSTS	Letter	03/10/2017	ML17101A553
17.07	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, NSTS, Q3	No.	NSTS	Letter	03/10/2017	ML17101A553
17.08	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, NSTS, Q4	No.	NSTS	Letter	03/10/2017	ML17101A553
17.09	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, NSTS, AS Q1	It would be a tremendous burden on the Agreement States.	NSTS	Letter	03/10/2017	ML17101A553
17.10	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, NSTS, AS Q1	The regulations require licensees to report the annual reconciliation to NSTS. This is a "National" tracking system and the Agreements States do not have access to all the data nor should they. It would require a rule change to require licensees to submit the reconciliation report to both NSTS and their agreement state for the state to have the authority to reconcile something not required to be reported to them. Even with this rule change each Agreement State would be allowed to complete this reconciliation anyway they choose. The decision would be based on resources available and would vary between the 37 Agreement states. This would be a regulatory and cost burden to the Agreement State and licensees, especially licensees who have licenses in multiple Agreement States and NRC.	NSTS	Letter	03/10/2017	ML17101A553
17.11	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, LVS, AS Q1	NRC has the number of category 1 and 2 licenses in NSTS.	WBL	Letter	03/10/2017	ML17101A553

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17.12	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, LVS, AS Q1	We estimate that we have 330 licenses that are authorized to possess category 1, 2, and 3 quantities of radioactive materials. Of this group it includes ~90 HDR licenses, ~15 fixed gauge licensees. This number also includes ~130 medical use licensees and 26 nuclear pharmacies authorized to possess 1 curie of radioactive materials authorized for 10 CFR 35.400 uses. These medical licenses are included since FDA authorizes the use of Co-60 for interstitial and intracavitary treatment of cancer and the category 3 quantity for Co-60 is 810 millicuries.	WBL	Letter	03/10/2017	ML17101A553
17.13	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, LVS, AS Q2	We would encourage the use of LVS.	LVS	Letter	03/10/2017	ML17101A553
17.14	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, LVS, AS Q3	See below.	LVS	Letter	03/10/2017	ML17101A553
17.15	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, LVS, AS Q4	We would provide NRC copies of the license. We would not adopt WBL because it does not fit our business processes in licensing, inspection, billing, etc.	WBL	Letter	03/10/2017	ML17101A553
17.16	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, LVS, AS Q4	This would increase the number of licenses to determine whether to send them to NRC five-fold and would be large resource burden. We would look at the most cost efficient method to assure we don't miss one. (For example, last year we completed 1,998 licensing actions.) We may decide to send NRC all of our completed licensing actions and NRC can determine if they meet the criteria to be entered into WBL.	WBL	Letter	03/10/2017	ML17101A553
17.17	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, Security, Q1	No.	SA	Letter	03/10/2017	ML17101A553
17.18	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, Security, Q1	From the background information the failure that GAO discovered was one individual failing to follow procedures and not a systemic wide failure.	SA	Letter	03/10/2017	ML17101A553

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17.19	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, Security, Q2	If NRC is to limit the quantities possess under a general license then it should be limited only to individual sources that are at the high end of category 3. This would only include individual sources that larger than 50% of category 2 activity. It would not include any aggregation of radioactive materials.	GLDs	Letter	03/10/2017	ML17101A553
17.20	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, Security, Q2	NRC should consider reevaluating the concept of a “General License” and determine if it is needed.	GLDs	Letter	03/10/2017	ML17101A553
17.21	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, Security, Q2	NRC should consider either requiring a specific license for radioactive materials or have the radioactive material exempt. The concept of a general license that allows untrained, unmonitored personnel to use and possess radioactive material based on the potential radiation dose received in a year has several flaws.	GLDs	Letter	03/10/2017	ML17101A553
18.01	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	This letter and attachment document the basis for our conclusion that the expansion of LVS, NSTS, and additional security measures for Category 3 sources adds little to no value, is not supported by historical analysis of the threat, and cannot be cost justified. Simply put, this effort is a solution looking for a problem.	SA	Letter	03/10/2017	ML17074A291
18.02	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	At a time of shrinking resources, additional tracking and verification would result in a large administrative burden for licensees, NRC, and the Agreement States to address a problem that does not exist.	SA	Letter	03/10/2017	ML17074A291
18.03	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	Based on the information provided in the federal register notice and public meetings, NRC has provided no evidence that a fundamental problem exists—other than the GAO findings—to demonstrate that legitimate licenses have been altered by licensees to obtain material they are not authorized to possess, that licensees are maliciously obtaining material in excess of their licensed possession limits, that licensees are not accounting for Category 3 sources, or that there is a threat or adversary interest in Category 3 quantities of material.	SA	Letter	03/10/2017	ML17074A291
18.04	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	Overall, no evidence has been provided to indicate that the existing requirements and the current regulatory framework are not adequate to oversee licensed activities and ensure public health and safety.	SA	Letter	03/10/2017	ML17074A291
18.05	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	In 2006, NRC implemented pre-licensing guidance to ensure that applicants were legitimate and that radioactive materials would be used as intended. This guidance has been updated as needed.	SA	Letter	03/10/2017	ML17074A291

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18.06	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	The most recent GAO investigation was successful because of the failure of one State employee to follow the existing pre-licensing guidance and was not the result of a regulatory gap. No amount of additional regulation would have prevented the GAO from obtaining material if the licensing entities do not follow the pre-licensing guidance..	SA	Letter	03/10/2017	ML17074A291
18.07	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	Instead of pursuing rulemaking, NRC and Agreement States should review and enhance, if needed, the pre-licensing guidance and utilize it.	SA	Letter	03/10/2017	ML17074A291
18.08	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	The staff was directed to conduct a vulnerability analysis to inform the decision on source security and accountability actions. We applaud such direction.	SA	Letter	03/10/2017	ML17074A291
18.09	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	The details of this assessment, such as the scope, timing, and role of stakeholders in providing input, were not provided during the public meeting.	SA	Letter	03/10/2017	ML17074A291
18.10	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	Any vulnerability assessment must provide a specific rationale for the tracking and inventory requirements for these sources and discuss the public health and safety effects due to malicious use of Category 3 sources.	SA	Letter	03/10/2017	ML17074A291
18.11	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	Previous analysis of potential health effects from the use of sources identified radionuclide “quantities of concern” to be in the range of Category 1 and 2 values.	SA	Letter	03/10/2017	ML17074A291
18.12	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	If this current effort proceeds, a comprehensive draft vulnerability assessment should be made available to stakeholders for review and comment prior to any final decision on whether to proceed with any regulatory enhancements.	SA	Letter	03/10/2017	ML17074A291
18.13	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	Further, 10 CFR 30.41 describes the requirements for license verification prior to the transfer of material. There is no evidence to suggest that this process is broken.	LVS	Letter	03/10/2017	ML17074A291
18.14	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	The overwhelming majority of licensees possessing Category 3 sources have decades of regulatory history and virtually all transfers of material that occur between licensees are with known entities and based on long term commercial relationships. We are not aware of any evidence to suggest that these licensees are altering their license or maliciously attempting to obtain material in excess of their possession limits.	LVS	Letter	03/10/2017	ML17074A291
18.15	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	There simply is zero to negligible risk with the transfer of Category 3 material between these licensees. Adding requirements for tracking sources in NSTS and utilizing LVS only adds an administrative burden with no increase to security.	SA	Letter	03/10/2017	ML17074A291

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18.16	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	General	As stated above, based on all available information, we conclude that the expansion of LVS, NSTS or additional security measures for Category 3 sources adds little to no value, is not supported by historical analysis of the threat or any new compelling threat indicators that demonstrate that the current regulatory mechanisms are not effective in protecting Category 3 radioactive materials, and cannot be cost justified. We respectfully suggest that the staff recommend that no additional resources be expended for such activities.	SA	Letter	03/10/2017	ML17074A291
18.17	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, General, Q1	No, changes should not be made to 10 CFR 30.41, 40.51, or 70.42 to prescribe license verification as described in 37.71. This would significantly impact radioactive material and radioactive waste transfers, transportation, and shipping without any evidence to suggest the current regulations and process is broken.	LVS	Letter	03/10/2017	ML17074A291
18.18	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, General, Q2	There would be significant cost with no increase in safety or security for Part 50 licensees, Part 40 and 70 fuel cycle facilities, and other established Part 30 licensees (e.g. manufacturers/distributors, medical institutions, waste brokers, and universities) if they are required to use LVS for Category 3 transfers. These licensees have decades of regulatory history, transfer material with known entities based on long term commercial relationships, and are not at risk for altering licenses to maliciously obtain material. New licensees go through rigorous pre-application screening to verify that they are legitimate applicants that will use radioactive material as licensed. There is a lack of evidence to demonstrate the requiring LVS for Category 3 transfers would improve safety or security greater than a negligible amount.	LVS	Letter	03/10/2017	ML17074A291
18.19	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, General, Q3	If the NRC changes the regulations to require LVS, which we do not support, it should clearly exempt Part 50 licensees, Part 40 and 70 fuel cycle facility licensees, manufacturers and distributors, and medical institutions. These licensees are well known and do not pose a risk to altering their license or maliciously obtaining material in excess of their possession limits.	LVS	Letter	03/10/2017	ML17074A291
18.20	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, General, Q4	The existing regulations and procedures are adequate to address Category 3 transfers and any modifications to the regulations are unnecessary.	LVS	Letter	03/10/2017	ML17074A291
18.21	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS, Q1	No, NSTS should not be expanded to include Category 3 sources. NSTS was implemented to track high-risk nuclear materials from the time they are manufactured or imported through the time of their disposal, export, or decay. Category 3 sources have rightly been excluded from tracking because, based on NRC analysis, potential health effects from the use of material in a radiological dispersal or exposure device are in the range of Category 1 and 2 values. Expanding the scope of material tracked in NSTS to Category 3 sources would increase the number of licensees using LVS by approximately a factor of 3, while increasing the number of sources tracked to an estimate of well over an additional 100,000 sources. Absent any new data that shows there is serious health effects from malicious use of Category 3 sources and a legitimate vulnerability, increasing the level of tracking is excessive, unnecessary, and unjustifiable.	NSTS	Letter	03/10/2017	ML17074A291
18.22	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS, Q2	If NRC promulgates a rule requiring Category 3 source tracking in NSTS, the rule should use a graded approach that recognizes the lower level of risk and not impose the same stringent reporting requirements for Category 1 and 2 sources.	NSTS	Letter	03/10/2017	ML17074A291

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18.23	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS, Q3	The current reporting requirements for Category 1 and 2 sources are adequate.	NSTS	Letter	03/10/2017	ML17074A291
18.24	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS, Q4	There would be no more than a negligible increase to safety or security if the regulations required Category 3 source tracking in NSTS. NSTS is intended to increase accountability of sources and plays no part in securing material to prevent theft. There are no examples of licensees attempting to maliciously obtain material that were prevented from doing so with the use of NSTS. Furthermore, in real time, NSTS would not be able to detect the occurrence of licensee exceeding their possession limit.	NSTS	Letter	03/10/2017	ML17074A291
18.25	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS, Q5	NRC should consider first time users, Agreement States, and the financial burden on NRC for requiring Category 3 source tracking in NSTS. Furthermore, NRC developed the concept of the Integrated Source Management Portfolio (ISMP) to integrate information technology tools to form a comprehensive program to ensure the security and control of high risk Category 1 and 2 quantities. ISMP currently works by integrating NRC and Agreement State Category 1 and 2 licensee data from NSTS, the Web–Based Licensing (WBL) System, and LVS. Requiring the use of NSTS without having all Agreement State licenses in WBL would lead to a process with significant gaps. Without the automated process through LVS, NRC and Agreement State staff would have to manually review NSTS and the license to verify transfers are valid and that possession limits are not exceeded.	NSTS	Letter	03/10/2017	ML17074A291
18.26	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, Q1	No Comments.	LVS	Letter	03/10/2017	ML17074A291
18.27	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, Q2	A typical nuclear power plant may process less than 10 transfers annually of Category 1 and 2 quantities of material. Expanding this requirement to include Category 3 materials would represent a large increase in regulatory burden and could impact the ability of the licensee to make radioactive material shipment in a timely fashion. Nuclear power plants may have 80-100 Category 3 quantity transfers per year, with a majority made during refueling outages. Less than 1% of these transfers are directly to/from a manufacturer, but are shipments to well-known entities.	LVS	Letter	03/10/2017	ML17074A291
18.28	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, Q3	License verification (LVS) should not be required for established, well known, and credible licensees. There is no risk that these licensees would alter their license. In addition to established manufacturers, any rule should at a minimum exempt Part 50 licensees, Part 40 and 70 fuel cycle facility licensees, distributors, and medical institutions. NRC should provide the criteria for what they consider “established”.	LVS	Letter	03/10/2017	ML17074A291
18.29	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, Q4	Licensees with LVS access using the system typically receive error messages to contact the license-issuing regulatory authority directly. There appear to be delays in updating LVS with current licenses issued by Agreement States. This creates added burden to the licensee to obtain a current license outside the online LVS process. This problem will be magnified if all Category 3 Agreement State licenses are not in WBL.	Cred&SysArc	Letter	03/10/2017	ML17074A291
18.30	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS licensees, Q1	No Comment.	NSTS	Letter	03/10/2017	ML17074A291

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
18.31	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS licensees, Q2	NRC should revise the definition of a "nationally tracked source" in 10 CFR 20.1003 to clarify the scope of "radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control". NRC is using a literal interpretation of the definition to include bulk material in storage capsules, which are not intended for distribution. This interpretation has implications for source manufacturers and other licensees (such as those with material targets, bulk special form capsules that are imported, or research reactors), which have been cited for failing to report such "sources" per 10 CFR 20.2207(a). This bulk material is stored until needed to manufacture sources. These storage capsules are cut open, the required material removed and the remaining material would be welded into a new capsule. The sources produced from this material for distribution would be recorded in NSTS. The intent of NSTS was not to track bulk material that was not intended for distribution, but rather was intended to track a distributed sealed source through its life cycle. The NRC should consider rulemaking, generic communications, or other regulatory guidance to clarify this non-safety related issue.	NSTS	Letter	03/10/2017	ML17074A291
18.32	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, AS Q1	No Comment.	LVS	Letter	03/10/2017	ML17074A291
18.33	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, AS Q2	No Comment.	LVS	Letter	03/10/2017	ML17074A291
18.34	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, AS Q3	No Comment.	LVS	Letter	03/10/2017	ML17074A291
18.35	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, AS Q4	No Comment.	LVS	Letter	03/10/2017	ML17074A291
18.36	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS, AS Q1	NRC should reexamine the need to continue the annual inventory reconciliation process and question the safety and security value that it provides. NRC states that this effort currently takes a significant amount of time and resources for the Category 1 and 2 sources. This is a significant administrative burden for NRC and licensees to largely resolve administrative issues, not safety or security concerns. While 10 CFR 20.2207(g) requires the annual reconciliation, that section of the rule also requires licensee to correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. That provision should be sufficient to adequately ensure licensees maintain an accurate inventory, without the need for the burdensome annual reconciliation.	NSTS	Letter	03/10/2017	ML17074A291
18.37	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS, AS Q1	If NRC expanded NSTS to include Category 3 sources, the time and effort needed to complete this task would increase by a factor of 3 and is not justifiable from a resource perspective to address an issue that does not increase safety or security. If NRC adopts Category 3 tracking in NSTS, it should not apply the annual reconciliation and NRC should consider a rulemaking to eliminate the annual inventory reconciliation.	NSTS	Letter	03/10/2017	ML17074A291

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18.38	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, Security, Q1	No. Based on the risk profile, threat, and vulnerability there is not a demonstrable need to enhance the security requirements of Category 3 quantities to levels similar to Category 1 and 2 quantities.	SA	Letter	03/10/2017	ML17074A291
18.39	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, Security, Q2	No Comment.	GLDs	Letter	03/10/2017	ML17074A291
19.01	Paul Gray, Chairman	International Source Suppliers and Producers Association	NGO	General	We appreciate the opportunity to comment and the ISSPA both concurs and supports the positions made and comments provided by the aforementioned organizations [NEI and Source Security Working Group].	SA	Letter	03/08/2017	ML17074A221
19.02	Paul Gray, Chairman	International Source Suppliers and Producers Association	NGO	General	We conclude that based on all available information, and discussions with many licensees and industry associations, that expansion of the WBL, NSTS, and LVS, and adding further security controls for Category 3 sources, is unwarranted.	SA	Letter	03/08/2017	ML17074A221
19.03	Paul Gray, Chairman	International Source Suppliers and Producers Association	NGO	FRN, NSTS, Q1	We strongly discourage the expansion of NSTS to include Category 3 sources.	NSTS	Letter	03/08/2017	ML17074A221
20.01	--	JL Shepherd & Associates	Industrial	General	The security and accountability of high level Category 1 and 2 sources are well established, per 10 CFR 37. Category 1 and 2 sources are used for specifically licensed and highly specialized applications. Category 3 sources are used in much wider areas of beneficial uses to the public, such as diagnostic and therapeutic medicine, non-destructive testing, and quality assurance for manufacturing processes and first responders' instrumentation for radiological emergencies. As there is wide-ranging use of these sources, correspondingly, there are many more of these sources in daily use.	SA	Letter	03/09/2017	ML17081A013
20.02	--	JL Shepherd & Associates	Industrial	General	It is our view that the inclusion of all Category 3 sources under the full security and accountability requirements of 10CFR37 would add significant costs to health care, the inspection and maintenance of the nation's infrastructure (roads and bridges), to manufacturing processes, and to federal, state and local emergency response operations.	SA	Letter	03/09/2017	ML17081A013
20.03	--	JL Shepherd & Associates	Industrial	General	As the on-going alternative technology research has not yet developed full replacement for the use of sealed sources, we anticipate that the cost of full compliance with existing Category 1 and 2 source regulations, would lead to 1) a loss of cancer treatment options, with an increase of patient mortality, 2) a decrease in infrastructure safety, with a corresponding increase of public mortality, 3) a higher cost of manufactured goods, and 4) a degradation of radiological emergency response capability, which would lead to a greater public mortality rate in the event of a radiological event.	SA	Letter	03/09/2017	ML17081A013

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20.04	--	JL Shepherd & Associates	Industrial	General	The smallest Category 3 source activity is a factor of 10 lower than the smallest Category 2 activity. The concern seems to be that an aggregated amount of Category 3 activity sources has the potential be obtained to meet a Category 2 threshold. This could be a range of 2 of the higher activity Category 3 sources to 10 of the lowest activity Category 3 sources. Therefore, we believe that a Graded Approach to the security and accountability to Category 3 sources should be considered for the preservation of public health and safety.	SA	Letter	03/09/2017	ML17081A013
20.05	--	JL Shepherd & Associates	Industrial	General	Additionally, there seems to be a question if the Categories pertain to only sealed sources or to any form of radioactive material, which should also be addressed.	SA	Letter	03/09/2017	ML17081A013
20.06	--	JL Shepherd & Associates	Industrial	FRN, General, Q1	No, we believe that current methods of license verification for Category 3 sources should not be changed to only meet the reporting methods of 10 CFR 37.31. A graded approach to this activity should be explored, as described in our comments on the philosophy of this response.	LVS	Letter	03/09/2017	ML17081A013
20.07	--	JL Shepherd & Associates	Industrial	FRN, General, Q2	We believe that there would be an increase of the source safety and security if Category 3 sources were capable of being checked in some form but not in the NRC License Verification System (LVS) or the licensees transferring authority, as LVS currently exists. Currently LVS queries the National Source Tracking System (NSTS), for source information. NSTS contains information on sources only and not all forms of radioactive materials. As part of the Graded Approach, perhaps LVS in its current format can be used for Category 1 and 2 source transactions. Perhaps a second license system that contains all radioactive materials licenses (without the NSTS query) so that verification for Category 3 and two sources and other forms of radioactive materials could be performed, would be a security asset. Alternately, requiring a regulatory concurrence of license validity would also be a security asset.	LVS	Letter	03/09/2017	ML17081A013
20.08	--	JL Shepherd & Associates	Industrial	FRN, General, Q3	License verification through LVS or transferee's license issuing authority, or any license verification system for Category 3 sources, for manufacturers or distributors should be carefully considered, and a Graded Approach might be considered. For example, if a hospital is under contract for periodic replacement of radioactive materials with the manufacturer, perhaps an annual verification of the manufacturer's license can be considered. Distributors of radioactive material may or may not have the same possession limits and security requirements in place as a manufacturer and licenses should be confirmed. As transfers can be performed between licensees, including service providers, or facilitated by service providers, license verification should be required.	LVS	Letter	03/09/2017	ML17081A013
20.09	--	JL Shepherd & Associates	Industrial	FRN, General, Q4	An addition verification of the material to be transferred, per USNRC's RIS 2014-08, Use of Aftermarket Sources, should be performed to ensure that the materials are being legally transferred to the licensee.	LVS	Letter	03/09/2017	ML17081A013
20.10	--	JL Shepherd & Associates	Industrial	FRN, NSTS, Q1	No, not all Category 3 sources should be added to the NSTS. It is our belief that a Graded Approach should be considered. Perhaps there could be a factor of 5 activity trigger of a factor of 5 (instead of 10)for inclusion in NSTS. Alternately, instead of adding Category 3 sources to the existing NSTS, perhaps a mirror NSTS for lower activity source tracking could be explored. A mirror system would not degrade the security and reporting requirements of 10CFR37 for Category 1 and 2 sources, and a Graded Approach for Category 3 sources security might be easier to implement.	LVS	Letter	03/09/2017	ML17081A013
20.11	--	JL Shepherd & Associates	Industrial	FRN, NSTS, Q2	No, the NRC should not consider the same NSTS reporting requirements for Category 3 sources, as for Category 1 and 2 sources, as we believe a Graded Approach would best serve public health and safety, while enhancing the security of Category 3 sources.	NSTS	Letter	03/09/2017	ML17081A013

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20.12	--	JL Shepherd & Associates	Industrial	FRN, NSTS, Q3	As NSTS is not a real time system, inclusion of Category 3 sources would not increase the immediacy of inclusion of these sources on the system. That being said, we believe that reporting transfers of Category 3 sources should be considered for accountability purposes.	NSTS	Letter	03/09/2017	ML17081A013
20.13	--	JL Shepherd & Associates	Industrial	FRN, NSTS, Q4	Yes there would be an increase of safety and security of Category 3 sources for including Category 3 sources in NSTS; however a cost benefit analysis should be performed. If our general philosophy comments are taken into consideration, would public health and safety be degraded and to what extent?	NSTS	Letter	03/09/2017	ML17081A013
20.14	--	JL Shepherd & Associates	Industrial	FRN, NSTS, Q5	With the increase of the number of sources entered into NSTS, there is the very real possibility of the increase of having duplicate source serial numbers. Prior to NSTS, manufacturers did not seem to be creative in serial numbering systems and we have found identical serial number systems used between manufacturers.	Cred&SysArc	Letter	03/09/2017	ML17081A013
20.15	--	JL Shepherd & Associates	Industrial	FRN, LVS, Q1	We are already registered for access to LVS. Many of our clients are not and would most likely use alternative methods of reporting; just as they do for NSTS.	LVS	Letter	03/09/2017	ML17081A013
20.16	--	JL Shepherd & Associates	Industrial	FRN, LVS, Q2	How many sources transferred is proprietary information.	LVS	Letter	03/09/2017	ML17081A013
20.17	--	JL Shepherd & Associates	Industrial	FRN, LVS, Q3	Unknown, no guidelines are established as the definition of an "established" manufacturer.	LVS	Letter	03/09/2017	ML17081A013
20.18	--	JL Shepherd & Associates	Industrial	FRN, LVS, Q4	Yes, we have online access to LVS. Many license inquiries are redirected to the issuing agency.	LVS	Letter	03/09/2017	ML17081A013
20.19	--	JL Shepherd & Associates	Industrial	FRN, NSTS licensees, Q1	We are already registered for access to NSTS. Many of our clients are using the alternative methods of reporting.	NSTS	Letter	03/09/2017	ML17081A013
20.20	--	JL Shepherd & Associates	Industrial	FRN, NSTS licensees, Q2	Any NSTS issues are resolved by the help desk. They are extremely helpful when something occurs, usually a reset of Internet Explorer.	NSTS	Letter	03/09/2017	ML17081A013
20.21	--	JL Shepherd & Associates	Industrial	FRN, LVS, AS	We are not an Agreement State, so cannot answer these questions.	LVS	Letter	03/09/2017	ML17081A013
20.21	--	JL Shepherd & Associates	Industrial	FRN, NSTS, AS	We are not an Agreement State, so cannot answer these questions.	NSTS	Letter	03/09/2017	ML17081A013
20.22	--	JL Shepherd & Associates	Industrial	FRN, Security, Q1	We believe that a Graded Approach should be taken for physical security of Category 3 sources, with a specific approach to the aggregate quantity of Category 3 sources. Perhaps there could be a factor of 5 activity trigger (instead of 10), depending on what information the NRC receives from hospitals, first responders and other entities that use different quantities of these materials. It would be much harder to accumulate 5 sources instead of duplicating and order for 2 sources.	SA	Letter	03/09/2017	ML17081A013
20.23	--	JL Shepherd & Associates	Industrial	FRN, Security, Q2	Yes, if the increase of security for Category 3 sources is determined to be beneficial and not degrading to public health and safety; then a revision of general licenses should be considered. We believe that all Category 1 and 2 sources should require a specific license and be subject to security requirements. For Category 3 sources, we believe that the cost benefit analysis should be performed, and that the benefits of the use of the material be included, not just the activity.	GLDs	Letter	03/09/2017	ML17081A013
21.01	Lynne A. Fairobent	self	Medical	General	As acknowledged in the January 9, 2017 Federal Register notice (82 FR 2399), this is not a new issue. The NRC first published the proposed rule on “Expansion of NSTS [National Source Tracking System] in the Federal Register on April 2008 (73 FR 19749).	NSTS	Letter	03/10/2017	ML17087A267

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21.02	Lynne A. Fairobent	self	Medical	General	Numerous radiation oncology facilities employ high-dose-rate remote after loader (HDR) systems in the treatment of disease, particularly for gynecological, prostate, and breast cancers. The additional tracking and potential security, beyond that currently in force through U.S. Nuclear Regulatory Commission (NRC) (10 CFR Part 37) and equivalent Agreement State regulations, would impose additional costs on these treatment facilities; costs which would result in significant increases in the cost of medical care for these patients. Many of these cancer care facilities are freestanding and it is likely that a significant number of these institutions would be forced to halt HDR treatments, denying care to many patients.	NSTS	Letter	03/10/2017	ML17087A267
21.03	Lynne A. Fairobent	self	Medical	General	Hospitals and health systems are already experiencing financial hardship due to changes in the way healthcare is delivered and paid for in this country. Adoption of this proposed regulation may make it more difficult for facilities to maintain their existing equipment and could potentially require them to purchase newer machines even though their current equipment has not outlived its usefulness. Most of the nominally equivalent replacement equipment fails to provide the quality treatments of the current equipment, and in some cases, can pose a safety hazard for patients.	SA	Letter	03/10/2017	ML17087A267
21.04	Lynne A. Fairobent	self	Medical	General	In the end, patients may have less access to the latest treatment options or they will pay dramatically more to obtain the benefits of those treatment options. Even if one presumes that third-party payers (government and commercial) will adjust their reimbursement rates to reflect these higher costs, historically it can take two years or longer for these payment adjustments to make their way through the system. In the meantime, facilities will have incurred the costs to perform the upgrade and often must wait two or more years to obtain reimbursement rates that reflect those added costs. This alone could create a significant cash-flow problem for many institutions. Oftentimes these devices and equipment are the only option for treatment of certain cancers or tumors. Imposing barriers to facilities for housing this type of diagnostic and treatment equipment will significantly reduce the physical number of these pieces of equipment which gives patients fewer options at a higher cost.	SA	Letter	03/10/2017	ML17087A267
21.05	Lynne A. Fairobent	self	Medical	FRN, General, Q1	The current regulatory system allows NRC and Agreement States to identify licensees that possess Category 3 sources, and to monitor the location and movement of the sources through the licensing and inspection program. Is it the current regulatory system that is not sufficient or is it that there are not adequate resources to establish a more rigorous pre-licensing, inspection and enforcement program to ensure licensee compliance with existing requirements without increasing the regulatory burden on the licensees. I believe that the latter is possibly true and therefore both NRC and Agreement States may need additional resources to ensure the existing regulatory system remains effective.	SA	Letter	03/10/2017	ML17087A267
21.06	Lynne A. Fairobent	self	Medical	FRN, NSTS, Q1	During the 2009 discussions on include Category 3 sources in the NSTS, the robustness of the system was raised. I continue to be concerned on whether the system can handle the additional Category 3 sources. Including Category 3 sources will increase not only the total number of sources in the system but the number of licensees needing to interact with NSTS.	Cred&SysArc	Letter	03/10/2017	ML17087A267
21.07	Lynne A. Fairobent	self	Medical	FRN, LVS, Q2	At the January 31, 201, public meeting at NRC headquarters, NRC stated there are currently approximately 1,400 Category 1 and 2 licensees representing approximately 75,000-80,000 sources. NRC staff also stated that there are approximately 5,500 Category 3 licensees of NRC and Agreement state licensees (NRC ~ 600 licensees of the 5,500 cat 3). However, this does not indicate how many additional sources would be added to the Licensee Verification System (LVS) or the NSTS.	NSTS	Letter	03/10/2017	ML17087A267

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21.08	Lynne A. Fairobent	self	Medical	FRN, NSTS, Q5	In 2009, the discussion indicated that before including Category 3 sources, a detailed impact analysis should be performed for the expansion of NSTS to include Category 3 reflecting the significantly larger number of licensees impacted. To date, I don't believe this impact analysis has been conducted nor made publicly available. Prior to a staff recommendation to the Commission is made, the results of this should be completed and provided for public comment.	SA	Letter	03/10/2017	ML17087A267
21.09	Lynne A. Fairobent	self	Medical	FRN, NSTS, Q4	If Category 3 sources are added, will the system become diluted thus masking the ability to focus on sources of risk significance.	NSTS	Letter	03/10/2017	ML17087A267
21.10	Lynne A. Fairobent	self	Medical	FRN, NSTS, Q5	It is unclear whether NRC and the Agreement State have or will have adequate resources to handle the increased workload if Category 3 sources are added to the system. It is also unclear what the resource burden would be on Category 3 licensees. More and more demands are being made to medical licensees which could impact patient safety. There has been no discussion as to how these requirements will be paid for. I urge NRC to complete a cost/benefit analysis addressing the regulatory burden prior to a final decision.	SA	Letter	03/10/2017	ML17087A267
21.11	Lynne A. Fairobent	self	Medical	FRN, NSTS, Q3	At the January 31, 2017 meeting, NRC staff stated that roughly 30 - 40 percent of category 1 and 2 licensees do not electronically upload the data. Licensees have chosen instead to fax or email their data which must then be uploaded to the system, thus causing a delay in the information and introducing errors in data entry.	Cred&SysArc	Letter	03/10/2017	ML17087A267
21.12	Lynne A. Fairobent	self	Medical	FRN, NSTS, Q5	In today's world, the issue of cyber security cannot be ignored. Although part of the argument for including Category 3 sources in to provide better traceability of radioactive sources, does it truly make sense to put all information into one database? Has an analysis of the vulnerability of the system been conducted? I urge NRC and the Agreement States to consider the potential from a cybersecurity risk and to provide the results prior to a final decision.	Cred&SysArc	Letter	03/10/2017	ML17087A267
21.13	Lynne A. Fairobent	self	Medical	General	My view on the need to include Category 3 radioactive sources in enhanced security regulations has not changed since 2009. I believe that if someone wants to circumvent any system, they may be able to. The question that needs to be answered, if the current system any less safe and secure that the proposed changes? There has not been sufficient justification provided to demonstrate the new proposed requirements would result in a more secure regulatory system.	SA	Letter	03/10/2017	ML17087A267
21.14	Lynne A. Fairobent	self	Medical	General	I believe that the current regulatory system provides for the safe use of radioactive materials. Until a true cost/benefit and risk analysis is conducted, I do not believe there is sufficient justification to implement the changes proposed.	SA	Letter	03/10/2017	ML17087A267
22.01	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	After significant consideration, the Group believes that the NRC should not revise its regulations regarding the security and accountability of Category 3 quantities of byproduct material. * *As noted below, the Group offers no comment as to the desirability of revising the NRC's regulations regarding the security and accountability of either source material or special nuclear material.	SA	Letter	03/10/2017	ML17081A018

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22.02	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	The SSA WG notes that, as described below in more detail, the NRC's approach to regulating the possession and transfer of varying quantities of radioactive material is based on extensive and recurring evaluations performed by both the International Atomic Energy Agency ("IAEA") and the NRC over the course of several decades. More specifically, the IAEA has conducted a thorough evaluation of the radioisotopes - and the quantities of those isotopes - that could pose a threat to safety and security. The IAEA's Code of Conduct on the Safety and Security of Radioactive Sources ("Code of Conduct") documents that evaluation and the conclusions therefrom. The Code of Conduct established a tiered approach to the management and regulation of certain radioactive isotopes by establishing five 'categories' which account for the risk significance of certain quantities of those radioisotopes.	SA	Letter	03/10/2017	ML17081A018
22.03	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Separately, the U.S. Department of Energy ("DOE") and the NRC reviewed the chemical, physical, and radiological characteristics of each isotope that is licensed in the United States for its attractiveness to a terrorist. This effort identified 16 isotopes that could pose a serious threat to people and the environment if used malevolently. This effort further identified the quantities (or "thresholds") of materials that could pose a terrorism risk. The DOE and NRC's findings regarding risk significance of specific quantities of each isotope closely correspond to the IAEA's findings. The NRC adopted the IAEA's Category 1 and Category 2 threshold quantities to provide consistency between domestic and international efforts for security of radioactive materials that are deemed to be attractive targets for malevolent use.	SA	Letter	03/10/2017	ML17081A018
22.04	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	In order to provide for a periodic review of the regulations in light of new developments, Congress established an inter-agency Task Force on Radiation Source Protection and Security ("Task Force) in 2005. In 2006, and every four years thereafter, the Task Force has evaluated developments regarding the security and accountability of radioactive material and the extent to which those developments counsel for revisions to the NRC's regulations regarding source security and accountability. None of the three Task Force reports that have been issued to date suggest that the NRC should revise its regulations related to the use and transfer of Category 3 quantities of radioactive material in the way that (it appears) the NRC is currently considering. * *See Radiation Source Protection and Security Task Force Report (August 2006) available at https://nrc.gov/reading-rm/doc-collections/ congress-docs/correspondence/2006/president-08-15-2006.pdf; Radiation Source Protection and Security Task Force Report (August 2010) available at Radiation Source Protection and Security Task Force Report, August 2010) available at https://nrc.gov/sccurity/byproduct/2010-task-force-report.pdf; and Radiation Source Protection and Security Task Force Report (August 2014) available at https://nrc.gov/security/byproduct/2014-task-force-report.pdf.	SA	Letter	03/10/2017	ML17081A018

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
22.05	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	The risk to public health and safety aggregating RAM was well known to the IAEA, the NRC, and the Task Force throughout all relevant periods. Despite this risk, however, the NRC has developed and maintained a regulatory structure which rightly recognizes the different risks to public health and safety arising from each category of RAM. Specifically, NRC regulations regarding the physical security of the source, the transfer of the source (and the reporting of the transfer of the source), and the manner in which the source is tracked, become more stringent as the quantity of a particular isotope becomes more risk significant. This regulatory structure accounts for increased risk to public health and safety arising from aggregation of RAM.	SA	Letter	03/10/2017	ML17081A018
22.06	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	The SSAWG is aware that recent investigations by the Government Accountability Office ("GAO") have caused the NRC to reevaluate regulations regarding the security and accountability of Category 3 quantities of RAM. The Group notes that the NRC has evaluated the risks posed by the aggregation of RAM in the past, and that the NRC has, as a result of those evaluations, established and maintained a regulatory system which promotes a balanced approach to managing those risks. The SSAWG is unaware of any fact that changes the validity of the NRC's previous evaluations or the NRC's conclusions based thereon. The Group believes that the NRC and the Agreement State regulators were aware of the risks identified by GAO and had evaluated those risks.	SA	Letter	03/10/2017	ML17081A018
22.07	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Thus, because the NRC's current regulations reflect the evaluations by the IAEA, the NRC, and the Task Force, and because the bases of those evaluations and their conclusions are still valid, the Group believes that the NRC should not revise its regulations regarding the security and accountability of Category 3 quantities of byproduct material.	SA	Letter	03/10/2017	ML17081A018
22.08	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	The SSA WG understands that the GAO's 2014-2015 investigation precipitated the NRC's current evaluation as to whether it is necessary or desirable to revise NRC regulations or processes governing source security and accountability. The SSA WG also understands that the investigation identified certain weaknesses in the application of one Agreement State's prelicensing guidance which allowed that state's regulator to issue a RAM license to the GAO investigator. The SSA WG further understands that the GAO investigator placed an order for a Category 3 source, altered the license, and placed a second order for another Category 3 source, thereby allowing the GAO investigator to acquire an aggregated Category 2 quantity of RAM.	SA	Letter	03/10/2017	ML17081A018
22.09	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Thus, the GAO identified two types of weaknesses. First, the GAO identified certain weaknesses in the application of one Agreement State's prelicensing activities. The SSA WG offers the following observations.	SA	Letter	03/10/2017	ML17081A018
22.10	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	First, the extent to which the findings of the GAO's investigation suggest a programmatic weakness in the pre-licensing activities of any regulator - Agreement State or NRC - is unclear. Rather, the GAO investigation merely identified one instance of one reviewer in one Agreement State's regulator not adhering to non-mandatory guidance regarding the performance of pre-licensing activities. The Group believes that, while the GAO investigation's findings serve as a data point which should be considered, the NRC should not understand, without more, that a programmatic weakness in regulators' prelicensing activities exists.	SA	Letter	03/10/2017	ML17081A018

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

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Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
22.11	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Second, it is important to note that regulators conduct pre-licensing activities in accordance with non-mandatory guidance, and not in accordance with a mandatory process. Accordingly, and assuming that the application of the non-mandatory guidance would prevent the regulator from issuing a RAM license to an entity which should not possess that license, the NRC and Agreement States could consider making that guidance mandatory.	SA	Letter	03/10/2017	ML17081A018
22.12	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Finally, the GAO's identification of weaknesses in a regulator's application of prelicensing guidance, no matter how prevalent, is unrelated to any activity that a licensee undertakes pursuant to its RAM license. Nonetheless, the vast majority of the NRC's Questions contemplate revisions to the NRC's regulations that, if approved, would place a burden not on the regulator, but rather on the licensee. The Group notes that it is unclear how any of the proposed revisions to the NRC's regulations contemplated by the NRC's Questions would remedy any weakness within the regulator to appropriately perform pre-licensing activities.	SA	Letter	03/10/2017	ML17081A018
22.13	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Second, the GAO identified the fact that a nefarious Category 3 licensee could alter his paper radioactive material license, and that, because transferors of Category 3 quantities of RAM are not required to verify the transferee's license via the License Verification System ("LVS"), and because transfers of Category 3 quantities of RAM are not required to be tracked with the NSTS, such a licensee could obtain RAM in quantities greater than that which is allowed by the license.	SA	Letter	03/10/2017	ML17081A018
22.14	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	In light of these findings, the GAO recommended that the NRC require that licensees track Category 3 sources in the NSTS, and that transferors of Category 3 sources verify the transferees' licenses before transferring the RAM, among other recommendations. Although these recommendations seem reasonable, there are practical difficulties with their application, as described in more detail below.	NSTS	Letter	03/10/2017	ML17081A018
22.15	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Thus, the Group believes that the revisions to the NRC's regulations that the NRC is currently contemplating are either unrelated to the weaknesses identified by the GAO, and are therefore unlikely to remedy those weaknesses, or would be practically difficult to implement.	SA	Letter	03/10/2017	ML17081A018
22.16	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	It appears that the revisions to the regulations that the NRC is considering presuppose the presence of a nefarious licensee. More specifically, it appears that those revisions are solely intended to prevent a nefarious licensee from possessing via aggregation quantities of RAM in excess of the quantities which he is otherwise licensed to possess.	SA	Letter	03/10/2017	ML17081A018
22.17	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	The Group offers the following observations. First, the SSA WG is unaware of any case - other than the cases documented in the GAO Report* -- in which a nefarious licensee has attempted to aggregate risk significant quantities of RAM by altering a RAM license and placing orders for RAM with vendors. If such an occurrence is uncommon or nonexistent, the NRC should reconsider the revising its regulations in response to the potential, but as of yet speculative, risk. *GA0-16-330, "Nuclear Security: NRC Has Enhanced the Controls of Dangerous Radioactive Materials, but Vulnerabilities Remain" (July 2016).	SA	Letter	03/10/2017	ML17081A018

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Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
22.18	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Second, if the NRC understands that there is an unacceptable risk that a nefarious licensee could take an action that is inconsistent with preserving public health and safety, the NRC should consider what additional measures regulators can and should take to prevent a nefarious person from becoming a licensee or occupying a role within a licensee to order, accept, or otherwise handle RAM. Such an approach would mitigate the potential risk to public health and safety while not additionally burdening licensees whose activities are not nefarious and who operate in accordance with the NRC's and Agreement States' regulatory frameworks.	SA	Letter	03/10/2017	ML17081A018
22.19	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Thus, the Group believes that, if the NRC is concerned with the potential activities of a nefarious licensee (or a nefarious person within a licensee who has access to RAM), the NRC should consider additional measures that the regulator can and should take to prevent that person from becoming a licensee or otherwise having access to RAM.	SA	Letter	03/10/2017	ML17081A018
22.20	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	It appears that the NRC is considering revising its regulations to require that transferors of Category 3 quantities of RAM use the LVS to verify the proposed transferee's license* and that transferors track the transfers of Category 3 sources via the NSTS.** *See, e.g., General Questions Related to License Verification, Question 1, asking "Should the current methods for verification of licenses prior to transferring Category 3 quantities of radioactive material listed in 10 CFR 30.41(d)(l)-(5), 10 CFR 40.51(d)(l)-(5), and 10 CFR 70.42(d)(l)-(5) be changed such that only the methods prescribed in 10 CFR 37.71 are allowed?" **See, e.g., General Questions Related to the NSTS, Question 1, asking, "Should Category 3 sources be included in the NSTS? Please provide a rationale for your answer."	SA	Letter	03/10/2017	ML17081A018
22.21	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	The Group offers the following observations. First, to the extent that the NRC is considering such revisions to make it more difficult for a nefarious licensee to aggregate risk significant quantities of RAM, the Group observes that the NRC must similarly revise its regulations to also require transferors to track Category 3 sources via the NSTS, as the use of just one of the systems will not create a meaningful impediment to that nefarious licensee.	NSTS	Letter	03/10/2017	ML17081A018
22.22	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Second, the Group observes that, should the NRC revise its regulations to require that transferors use the LVS to verify a proposed transferee's license, that the NRC must be able to ensure that both the LVS and the NSTS are maintained perfectly current in order to both permit authorized transfers of RAM and to prevent unauthorized transfers of RAM.	SA	Letter	03/10/2017	ML17081A018
22.23	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Third, the Group observes that, in order to be most effective at preventing the transfer of RAM to a nefarious licensee, the NRC should require that the transferor reflect the transfer of RAM in the NSTS prior to shipping the RAM to the transferee.	NSTS	Letter	03/10/2017	ML17081A018
22.24	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Finally, the Group observes that, even where the NRC requires the use of the LVS and the NSTS as described just above, a nefarious licensee could nonetheless aggregate risk significant quantities of RAM by placing orders for Category 4 quantities of RAM or by other means.	SA	Letter	03/10/2017	ML17081A018

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Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
22.25	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	As noted above, the Group believes that the NRC should not revise its regulations regarding the security and accountability of Category 3 quantities of byproduct material. Nonetheless, should the NRC revise its regulations to require that licensees use the LVS and the NSTS, it should understand that such revisions can only provide a meaningful impediment to a nefarious licensee seeking to obtain risk significant quantities of RAM via aggregation where the NRC requires the use of both the LVS and the NSTS and where both systems are maintained perfectly current.	SA	Letter	03/10/2017	ML17081A018
22.26	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	It appears that the NRC is considering revising its regulations related to the security and accountability of Category 3 quantities of RAM so as to make them more stringent regarding license verification, tracking, and physical security. It appears that the NRC is considering doing so only for the isotopes listed in 10 C.F.R. Part 37 Appendix E and 10 C.F.R Part 20 Appendix A.	SA	Letter	03/10/2017	ML17081A018
22.27	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	The Group observes that several entities in the oil & gas and petrochemical industries use either or both Cs-137 and/or Ba-133, among other isotopes. Whereas Cs-137 is listed in both appendices, and would, therefore be regulated in the more stringent fashion, Ba-133 is not listed in either appendix, and would, therefore not be regulated in a more stringent fashion. To the extent that an entity uses Cs-137 and not Ba-133, that entity would be significantly disadvantaged by the more stringent regulations as compared to an entity which uses Ba-133 and not Cs-137.	SA	Letter	03/10/2017	ML17081A018
22.28	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	Should the NRC revise its regulations related to the security and accountability of Category 3 quantities of the isotopes listed in 10 C.F.R. Part 37 Appendix E and 10 C.F.R Part 20 Appendix A so as to make them more stringent, entities that use those isotopes would likely experience a significant and disproportionate commercial burden.	SA	Letter	03/10/2017	ML17081A018
22.29	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q1	The Group believes that the NRC should not revise its regulations as described. The bases for the Group's belief are provided below. 10 C.F.R. 30.41(d)(1)-(5), 10 C.F.R. 40.51(d)(1)-(5), and 10 C.F.R. 70.42(d)(1)-(5), respectively, provide the means by which a transferor of byproduct material, source material, and special nuclear material may verify that the proposed transferee's license authorizes it to possess those materials. More specifically, these sections allow a transferor of those radioactive materials to review a copy of the transferee's license provided to him by the transferee. 10 C.F.R. 37.71 provides the means by which a transferor of Category 1 and 2 quantities of RAM may verify that the proposed transferee's license authorizes it to possess those quantities of RAM. More specifically, this section provides that a transferor of those quantities of RAM must verify the proposed transferee's license via either the LVS or alternate means, which includes the use of the NRC Form 749.	SA	Letter	03/10/2017	ML17081A018
22.30	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q1	The Group offers no comment as to the desirability of requiring that transferors of source material or special nuclear material verify the proposed transferee's license in accordance with 10 C.F.R. 37.71.	LVS	Letter	03/10/2017	ML17081A018

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<tr><th>Unique Identifier</th><th>Individual</th><th>Organization</th><th>Stakeholder Type</th><th>FRN Question</th><th>Comment</th><th>Bin</th><th>Comment Format</th><th>Date Written</th><th>Accession No.</th></tr>
<tr><td>22.31</td><td>Roland Backhaus</td><td>Pillsbury Winthrop Shaw Pittman LLP</td><td>Industrial</td><td>FRN, General, Q1</td><td>The Group, however, offers the following observations regarding the desirability of requiring that transferors of byproduct material verify the proposed transferee's license in accordance with 10 C.F.R. 37.71. First, it seems necessary that, for a transferor to verify a proposed transferee's license, the proposed transferee must in fact possess a physical license. The SSA WG observes that many entities that possess Category 3 sources do so pursuant to the general license provided at 10 C.F.R. 31.5 and the corresponding Agreement State regulations. Where a general license authorizes the use and possession of RAM, the licensee does not possess a physical license, but rather relies on the license provided in the regulation. Should the NRC require that transferors of Category 3 quantities of byproduct material verify the proposed transferee's license in accordance with 10 C.F.R. 37.71, proposed transferees would, presumably, need to become specific licensees so as to possess a physical, verifiable, license.</td><td>GLDs</td><td>Letter</td><td>03/10/2017</td><td>ML17081A018</td></tr>
<tr><td>22.32</td><td>Roland Backhaus</td><td>Pillsbury Winthrop Shaw Pittman LLP</td><td>Industrial</td><td>FRN, General, Q1</td><td>The NRC and Agreement State regulators should consider the burden to the regulator associated with the issuance of specific licenses to each entity which had previously possessed Category 3 sources pursuant to a general license. In addition, specific licensees bear additional cost and regulatory burdens not born by entities which use and possess RAM pursuant to a general license. The NRC should consider the effect of the additional cost and regulatory burden on these entities should the NRC require them to become specific licensees. The cost of applying for a RAM license varies among the regulators and depending upon the proposed use of the material. The Group notes that entities that apply for specific licenses often hire radiation safety licensing professionals to assist in the development of the license application and the related documents and programs and that the costs for these services are in addition to the fees charged by the regulator.</td><td>GLDs</td><td>Letter</td><td>03/10/2017</td><td>ML17081A018</td></tr>
<tr><td>22.33</td><td>Roland Backhaus</td><td>Pillsbury Winthrop Shaw Pittman LLP</td><td>Industrial</td><td>FRN, General, Q1</td><td>Table 1, below, provides a representative sample of the costs which could accrue to a Category 3 general licensee should the NRC require it to become a specific licensee.

Table 1: Representative Sample of Costs
<table>
<tr><th>Requirement</th><th colspan="2">Cost</th><th colspan="2"></th></tr>
<tr><th></th><th colspan="2">Initial</th><th colspan="2">Annual</th></tr>
<tr><td>License Fee (NRC Gauge)</td><td>$</td><td>3,100.00</td><td></td><td></td></tr>
<tr><td>Consultant Fee or In-house Expense to Prepare Application</td><td>$</td><td>10,000.00</td><td></td><td></td></tr>
<tr><td>Radiation Survey Equipment (Acquisition and Annual Calibration, Maintenance and Replacement)</td><td>$</td><td>5,000.00</td><td>$</td><td>500.00</td></tr>
<tr><td>Staff Training and Retraining Cost</td><td>$</td><td>10,000.00</td><td>$</td><td>2,000.00</td></tr>
<tr><td>RSO Salary and Fringe</td><td>$</td><td>105,000.00</td><td>$</td><td>105,000.00</td></tr>
</table></td><td>GLDs</td><td>Letter</td><td>03/10/2017</td><td>ML17081A018</td></tr>
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22.34	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q1	Second, and relatedly, the SSA WG observes that many entities possess certain RAM pursuant to a specific license and other RAM pursuant to a general license. Should the NRC require that transferors of Category 3 quantities of byproduct material verify the proposed transferee's license in accordance with 10 C.F.R. 37.71, proposed transferees would, presumably, be required to amend their specific licenses such that those amended specific licenses would additionally authorize the use possession of the Category 3 quantities of RAM (which the specific licensee would have previously been able to possess pursuant to a general license). As noted just above, the NRC and Agreement State regulators should consider the burden to the regulator associated with the need to review the significant number of license amendment applications requesting revisions to support the possession of Category 3 quantities of RAM which they would have previously been able to possess pursuant to a general license. Also as noted just above, specific licensees bear additional cost and regulatory burdens not born by entities which possess RAM pursuant to a general license.	GLDs	Letter	03/10/2017	ML17081A018
22.35	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q1	The cost of applying for a license amendment varies among the regulators and depending upon the proposed use of the material. The Group notes that entities that apply for amendments to specific licenses often hire radiation safety licensing professionals to assist in the development of the license amendment application and the related documents and programs and that the costs for these services are in addition to the fees charged by the regulator. The NRC should consider the effect of the additional cost and regulatory burden on these entities should they be required to become specifically licensed to use and possess Category 3 quantities of RAM.	GLDs	Letter	03/10/2017	ML17081A018
22.36	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q1	Third, the Group further notes that many regulators charge periodic fees to maintain a specific license and that their reliance on the general license granted in 10 C.F.R. 31.5 and in the corresponding state regulations has allowed licensees to avoid the significant costs described above while providing for sufficient security and accountability of at-issue Category 3 sources.	GLDs	Letter	03/10/2017	ML17081A018
22.37	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q1	Fourth, because it seems that all entities which use and possess Category 3 quantities of RAM would need to become specific licensees so as to allow a transferor of Category 3 quantities of RAM to be able to verify the their licenses in accordance with 10 C.F.R. 37.71, it is not clear how the general license provided at 10 C.F.R. 31.5 could continue to exist.	GLDs	Letter	03/10/2017	ML17081A018
22.38	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q1	Finally, and as noted above, the NRC has historically regulated the use and transfer of RAM based in part on the category of radioactive material to be used or transferred. In so doing, the NRC applies a graded approach to regulation. For example, the NRC's current regulations allow a transferor of Category 3 quantities of RAM to verify the proposed transferee's license by reviewing a copy of the license provided by the proposed transferee. Should the NRC revise its regulations to require that that transferor verify the proposed transferee's license in accordance with 10 C.F.R. 37.71, the NRC would be blurring one of the distinguishing features of the historical graded approach to the regulation of RAM.	GLDs	Letter	03/10/2017	ML17081A018
22.39	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q2	The Group believes that revisions to the NRC's regulations to only allow license verification as described above would result in only a negligible increase in safety and security of Category 3 sources. Nonetheless, the Group believes that, if the NRC were to revise its regulations to require the real-time tracking of Category 3 sources in the NSTS in conjunction with the revisions described above, a modest increase in safety and security could result. The bases for the Group's belief are provided below.	NSTS	Letter	03/10/2017	ML17081A018

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22.40	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q2	As noted above, to the extent that the NRC is considering such revisions to make it more difficult for a nefarious licensee to aggregate risk significant quantities of RAM, the Group observes that the NRC must require the use of both the LVS and the NSTS, as the use of just one of the systems will not create a meaningful impediment to that nefarious licensee. For example, should the NRC revise its regulations to require only that transferors verify the proposed transferee's license via the LVS (and do not revise the regulations to also require the tracking of Category 3 sources in the NSTS), a nefarious licensee would be able to rely on his unaltered license in the LVS to acquire risk significant quantities of RAM via aggregation of Category 3 quantities of RAM. The Group further observes that even if the NRC requires the use of the LVS and the NSTS as described above, a nefarious licensee would still be able to acquire risk significant quantities of RAM via aggregation of Category 4 (or Category 5) quantities of RAM.	SA	Letter	03/10/2017	ML17081A018
22.41	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q3	The Group believes that should the NRC revise its regulations as described above, that the NRC should consider a more relaxed license verification standard for all transfers of Category 3 quantities of byproduct material where the transferor is familiar with the transferee, including, but not limited to transfers to manufacturers and distributors.	LVS	Letter	03/10/2017	ML17081A018
22.42	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q3	The bases for the Group's belief are provided below. The Group understands that the NRC is considering rev1smg its regulations to require that transferors of Category 3 quantities of RAM verify the proposed transferee's license in accordance with 10 C.F.R. 37.71. The Group also understands that the NRC is considering exempting transfers of Category 3 quantities of RAM to manufacturers and distributors, and, instead, continuing to allow those transferors to verify the manufacturer's and distributor's license as provided in 10 C.F.R. 30.41 (in the case of the transfer of Category 3 quantities of byproduct material).	LVS	Letter	03/10/2017	ML17081A018
22.43	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q3	First, the Group notes that it favors the continuation of the current graded regulatory approach regarding the verification of proposed transferees' licenses based on the Categories of RAM to be transferred. Nonetheless, the Group understands that the NRC might revise its regulations to require that transferors of Category 3 quantities of RAM verify proposed transferees' licenses in accordance with 10 C.F.R. 37.71. Should the NRC do so, the Group supports the use of a less burdensome standard, such as the method provided in 10 C.F.R. 30.41, for the transfers of Category 3 quantities of RAM to all licensees with which the transferor is familiar, including, but not limited to, manufacturers and distributors.	LVS	Letter	03/10/2017	ML17081A018
22.44	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q3	Second, the Group notes that many licensees are considered manufacturers/distributors of one type of radioactive material or device, but are not considered manufacturers/distributors of other types of radioactive material or devices. Thus, it is unclear whether the NRC is considering a less burdensome standard for transfers of RAM and devices to manufacturers/distributors regardless of whether the manufacturer/distributor originally manufactured or distributed the material or device to be transferred, or only for transfers of RAM and devices to the manufacturers/distributors which originally manufactured/distributed the specific material or device to be transferred.	LVS	Letter	03/10/2017	ML17081A018

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

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Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
22.45	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q1	The Group believes that revisions to the NRC's regulations to require licensees to track Category 3 sources in the NSTS would result in only a negligible increase in safety and security of Category 3 sources. Nonetheless, the Group believes that, if the NRC were to revise its regulations to require transferors of Category 3 quantities of RAM to verify the licenses of proposed transferees in accordance with 10 C.F.R. 37.71, a modest increase in safety and security could result.	NSTS	Letter	03/10/2017	ML17081A018
22.46	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q1	The bases for the Group's belief are provided below. First, and as noted above in the context of the whether the NRC should require the use of the LVS to verify the proposed transferee's license, to the extent that the NRC is considering such revisions to make it more difficult for a nefarious licensee to aggregate risk significant quantities of RAM, the Group observes that the NRC must require the use of both the LVS and the NSTS, as the use of just one of the systems will not create a meaningful impediment to that nefarious licensee. For example, should the NRC revise its regulations to require only that transferors reflect the transfer of Category 3 sources in the NSTS (and do not revise the regulations to also require the use of the LVS to verify the proposed transferee's license), a nefarious licensee would be able aggregate risk significant quantities of RAM in the same ways that he would be able to aggregate them absent the revision to the regulations.	SA	Letter	03/10/2017	ML17081A018
22.47	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q1	The Group further observes that even if the NRC requires the use of the LVS and the NSTS as described above, a nefarious licensee would still be able to acquire risk significant quantities of RAM via aggregation of Category 4 (or Category 5) quantities of RAM.	SA	Letter	03/10/2017	ML17081A018
22.48	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q1	Second, the Group observes that should the NRC require the use of both the LVS and the NSTS as articulated in the January 9, 2017 Federal Register Notice, both the LVS and the NSTS must be maintained perfectly current in order to both permit authorized transfers of RAM and to prevent unauthorized transfers of RAM.	NSTS	Letter	03/10/2017	ML17081A018
22.49	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q1	Third, the Group suggests that the NRC consider the ability of the NSTS to effectively track the many more sources that would be tracked in the system should the NRC require licensees to use it to track Category 3 sources.	NSTS	Letter	03/10/2017	ML17081A018
22.50	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q1	Fourth, the Group recognizes the risk to public health and safety that could arise should the security of the NSTS become compromised by cyberattack or by other means. Should the NRC require the use of the NSTS to additionally track Category 3 sources, the security of the NSTS against cyber and other threats would become even more important.	Cred&SysArc	Letter	03/10/2017	ML17081A018
22.51	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q2	The Group believes that, should the NRC require the tracking of Category 3 sources in the NSTS, it should require that licensees maintain the NSTS perfectly current, and should not permit even the delay provided in 10 C.F.R. 20.2207(f).	NSTS	Letter	03/10/2017	ML17081A018
22.52	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q2	First, and for the reasons provided above, the Group does not believe that the NRC should revise its regulations to require the tracking of Category 3 sources in the NSTS.	NSTS	Letter	03/10/2017	ML17081A018

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22.53	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q2	Second, the Group notes that the use of the LVS and the NSTS to lessen the risks associated with the aggregation of RAM by a nefarious licensee is only meaningful when both the LVS and the NSTS are maintained perfectly current. The failure to maintain both systems perfectly current could, on one hand, prevent the transfer of RAM that would be authorized absent a delay, and on the other hand, allow a transfer of RAM to a nefarious licensee that would be prevented absent the delay.	NSTS	Letter	03/10/2017	ML17081A018
22.54	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q2	Finally, the Group notes that even the delay in reporting that is permitted by 10 C.F.R. 20.2207(f) could precipitate the problems described just above.	NSTS	Letter	03/10/2017	ML17081A018
22.55	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q3	For the reasons provided above, the Group believes that the use of the NSTS to track Category 3 quantities of RAM could only promote safety and security if it was used in conjunction with the LVS and if both the LVS and the NSTS are maintained perfectly current. The Group further believes that even if the NRC requires the use of the LVS and the NSTS as described above, that only a modest increase in safety and security could result as a nefarious licensee would still be able to acquire risk significant quantities of RAM via aggregation of Category 4 (or Category 5) quantities of RAM..	NSTS	Letter	03/10/2017	ML17081A018
22.56	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q3	No.	NSTS	Letter	03/10/2017	ML17081A018
22.57	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, LVS, Q1	The Group notes that certain members of the group would consider becoming credentialed to use the LVS so long as the NRC allows sufficient time for licensees which choose to become credentialed to do so prior to requiring that those licensees use the LVS to verify the proposed transferee's license.	Cred&SysArc	Letter	03/10/2017	ML17081A018
22.58	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, LVS, Q1	The Group provides the following observations. First, the fact that it takes one month to become credentialed to use the LVS is not a concern to the Group.	Cred&SysArc	Letter	03/10/2017	ML17081A018
22.59	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, LVS, Q1	Second, the Group does not fully understand the phrase, "and NRC establishes new requirements for license verification involving Category 3 quantities of radioactive material." We assume that the NRC is asking whether, if the NRC ultimately requires license verification in accordance with 10 C.F.R. 37.71, a licensee which does not currently have access to the LVS would apply for access or use alternative methods for license verification. Based on that assumption, we again note that the use of the LVS and the NSTS to lessen the risks associated with the aggregation of RAM by a nefarious licensee is only meaningful when both the LVS and the NSTS are maintained perfectly current.	LVS	Letter	03/10/2017	ML17081A018
22.60	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, LVS, Q1	We believe that, unless the NRC was able to process the license verification requests in real time, the delay associated with the use of the NRC Form 749* could, on one hand, prevent the transfer of RAM that would be authorized absent a delay, and on the other hand, allow a transfer of RAM to a nefarious licensee that would be prevented absent the delay. * We note that the "Manual License Verification Report" is NRC Form 749, and not NRC Form 748 is identified in the NRC's question.	LVS	Letter	03/10/2017	ML17081A018

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22.61	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, LVS, Q2	The Group notes that the number of transfers of Category 3 quantities of RAM per period varies widely depending on the nature of the licensee and that licensee's business, among other factors. The Group understands that some licensees regularly conduct 10-30 such transfers per month and that other licensees conduct fewer than a single such transfer per month. Further, the Group understands that the majority of the transfers of Category 3 quantities of RAM that are not associated with storage or disposal are transfers to or from a manufacturer or distributor.	LVS	Letter	03/10/2017	ML17081A018
22.62	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, LVS, Q3	The Group believes that a transferor of Category 3 quantities of RAM should verify the proposed transferee's license prior to transferring the material. The Group further believes that the NRC's current regulations regarding the verification of a proposed transferee's license rightly recognize the different risks to public health and safety arising from each category of RAM.	LVS	Letter	03/10/2017	ML17081A018
22.63	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, LVS, Q4	No member of the Group has access the LVS; therefore, the Group cannot comment on the operability of the LVS.	Cred&SysArc	Letter	03/10/2017	ML17081A018
22.64	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS licensees, Q1	The Group notes that certain members of the group would consider becoming credentialed to use the NSTS so long as the NRC allows sufficient time for licensees which choose to become credentialed to do so prior to requiring that those licensees use the NSTS to track Category 3 sources.	NSTS	Letter	03/10/2017	ML17081A018
22.65	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS licensees, Q1	The Group provides the following observations. First, the fact that it takes one month to become credentialed to use the NSTS is not a concern to the Group.	Cred&SysArc	Letter	03/10/2017	ML17081A018
22.66	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS licensees, Q1	Second, the Group does not fully understand the phrase, "and NRC establishes new requirements for the tracking of Category 3 sources in the NSTS." We assume that the NRC is asking whether, if the NRC ultimately requires the use of the NSTS to track Category 3 sources, a licensee which does not currently have access to the NSTS would apply for access or use alternative methods for reporting transfers, such as emailing or faxing the NRC Form 748 to the NRC. Based on that assumption, we again note that the use of the LVS and the NSTS to lessen the risks associated with the aggregation of RAM by a nefarious licensee is only meaningful when both the LVS and the NSTS are maintained perfectly current.	NSTS	Letter	03/10/2017	ML17081A018
22.67	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS licensees, Q1	We believe that, unless the NRC was able to process the license verification requests in real time, the delay associated with the use of the NRC Form 748 could, on one hand, prevent the transfer of RAM that would be authorized absent a delay, and on the other hand, allow a transfer of RAM to a nefarious licensee that would be prevented absent the delay.	NSTS	Letter	03/10/2017	ML17081A018
22.68	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS licensees, Q2	No member of the Group has access the NSTS; therefore, the Group cannot comment on the operability of the NSTS.	NSTS	Letter	03/10/2017	ML17081A018
22.69	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	The Group believes that the NRC should not expand the physical security requirements for Category 1 and 2 quantities of radioactive material to additionally include Category 3 quantities of byproduct material. The Group offers no comment as to the desirability of expanding the physical security requirements for Category 1 and 2 quantities of radioactive material to additionally include Category 3 quantities of source material or special nuclear material.	SA	Letter	03/10/2017	ML17081A018

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22.70	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	The Group provides the following observations. First, and as noted above, the Group believes that, because the NRC's current regulations reflect significant evaluation by the IAEA, the NRC itself, and by the Task Force, and because the bases of those evaluations and their conclusions are currently valid, the NRC should not revise its regulations regarding the security and accountability of Category 3 quantities of byproduct material.	SA	Letter	03/10/2017	ML17081A018
22.71	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	Second, to the extent that the NRC's current interest in the potential strengthening of the physical security requirements for Category 3 quantities of RAM was precipitated by the GAO's investigation, the Group observes that the GAO did not identify any weakness in any of the requirements - or the application of those requirements - related to any category of RAM.	SA	Letter	03/10/2017	ML17081A018
22.72	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	Third, the Group notes that, to the extent that the physical security of RAM is to prevent the loss and/or theft of that material, there have been very few cases of loss or theft in the United States or abroad.	SA	Letter	03/10/2017	ML17081A018
22.73	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	Representatively: In 2012, ten significant events occurred involving the loss of Category 1, 2, and 3 sources. No Category 1 sources, three Category 2 sources, and seven Category 3 sources were lost, all of which were subsequently recovered, with the exception of one Category 3 source. The unrecovered Category 3 source was in a cardiac pacemaker that was buried with the deceased patient.* *Nuclear Material Events Database, Annual Report, Fiscal Year 2012 (February 2013) at xi, providing also "[a]ll three of the Category 2 events involved radiography exposure devices: one was lost during transportation from a job site, one was stolen from a parked truck, and the other was lost during shipment. Three of the seven Category 3 events involved the incorrect receipt of radioactive material at medical facilities; the sources were left uncontrolled for a period of time. Two of the Category 3 events involved items (a radiography exposure device and a well logging source) that were lost during transportation from jobsites. The other two Category 3 events involved cardiac pacemakers in deceased patients; one was retrieved by the funeral home before burial and the other was buried."	SA	Letter	03/10/2017	ML17081A018
22.74	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	In 2013, four significant events occurred involving the loss of Category 1, 2, and 3 sources). No Category 1 sources, ten Category 2 sources, and two Category 3 sources were lost, all of which were subsequently recovered.* *Nuclear Material Events Database, Annual Report, Fiscal Year 2013 (March 2014) at xi, providing also "[t]wo events involved the loss (and subsequent recovery) of all ten Category 2 sources (radiography sources). The sources were lost by a common carrier during shipment from a radiography source manufacturer. Two events involved the loss (and subsequent recovery) of the Category 3 sources. In the first event, a brachytherapy source was delivered to a medical facility on a Friday during non-business hours. The source remained in an unrestricted shipping/receiving area over the weekend. In the other event, a common carrier delivered a brachytherapy source to the wrong licensee	SA	Letter	03/10/2017	ML17081A018

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22.75	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	In 2014, eight significant events occurred involving the loss of Category 1, 2, and 3 sources. No Category 1 sources, five Category 2 sources, and three Category 3 sources were lost, all of which were subsequently recovered.* *Nuclear Material Events Database, Annual Report, Fiscal Year 2014 (February 2015) at xi, providing also "[f]ive events involved the loss (and subsequent recovery) of the Category 2 sources (radiography sources contained within exposure devices). Two of the devices were left unattended at temporary jobsites, one device was lost after being left on the bumper of a truck that was driven away, one device was lost when a tornado ripped the darkroom off of a radiography truck, and one device was lost by a common carrier during shipment. Three events involved the loss (and subsequent recovery) of the Category 3 sources. Two events involved common carriers delivering brachytherapy sources to the wrong addresses. On the remaining event, a plutonium-powered pacemaker was sent to a licensee that was not licensed to possess the device.	SA	Letter	03/10/2017	ML17081A018
22.76	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	In 2015, fourteen significant events occurred involving the loss of 15 Category 1, 2, and 3 sources. Two Category 1 sources, nine Category 2 sources, and four Category 3 sources were lost; all of which were subsequently recovered except one Category 3 source.* *Nuclear Material Events Database, Annual Report, Fiscal Year 2015 (March 2016) at xi, providing also "[t]wo events involved the loss (and subsequent recovery) of Category 1 sources (containers of Ir-192 source wafers/disks) during shipment by common carrier. Eight events involved the loss (and subsequent recovery) of Category 2 sources. Six of the events involved radiography devices; three devices fell from trucks en route to jobsites, two devices were left unattended by the radiographers, and one device was in a truck that was stolen. The seventh event involved the loss of two radiography sources during shipment by common carrier. The eighth event involved the abandonment of an irradiator during an eviction process. Four events involved the loss (all but one source were subsequently recovered) of Category 3 sources. Two of the events resulted from errors during shipment by common carrier. One event involved a well logging source that fell from a truck en route from a jobsite. The fourth event involved a plutonium powered pacemaker that was buried with a deceased patient; this source was not recovered. A fifteenth significant event occurred prior to Fiscal Year 2015 and was recently added to NMED. This event involved the receipt of a Category 3 brachytherapy source at a hospital on a holiday weekend; no authorized user was present. The source was not placed into a controlled area for several days.	SA	Letter	03/10/2017	ML17081A018
22.77	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	Thus, there have been no reported instances of the theft of any Category 1, 2, or 3 source in the last four years. Similarly, all of the sources which have been lost or abandoned in the last four years have been either recovered or were buried underground.	SA	Letter	03/10/2017	ML17081A018
22.78	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	Fourth, the Group notes that none of the three Task Force reports issued to date have identified any weakness in the physical security requirements associated with Category 3 quantities of RAM.	SA	Letter	03/10/2017	ML17081A018

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22.79	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	Finally, the group notes that, should the NRC revise its regulations to apply the physical security requirements for Category 1 and 2 quantities of byproduct material to also apply to Category 3 quantities of byproduct material, the cost of complying with those requirements is likely to be very high for many licensees. The actual cost of complying with those requirements varies depending on the amount of RAM a licensee might possess, the number and locations of the RAM storage locations at which the licensee possess the material, the manner in which a particular licensee uses the material, the manner in which the NRC proposes to determine whether a licensee possesses a Category 3 quantity of RAM (e.g., the use of the unity rule, or a similar rule), and on the manner in which the NRC defines the potential for several Category 4 sources (for example) to be aggregated. For example, whereas the cost associated with complying with these expanded regulations might be manageable for a licensee who is licensed to possess a single category 3 source at a single location to which only one person has access, the cost to the operator of a refinery could be extremely significant, as refineries are enormous complexes (which could be treated as a single storage location by the NRC) at which many Category 3 sources might be located, and to which many people might have access.	SA	Letter	03/10/2017	ML17081A018
22.80	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	The Group recommends that the NRC conduct significant outreach to licensees in a variety of industries to better understand the cost associated with complying with revisions to the NRC 's regulations regarding the physical security of Category 3 quantities of RAM.	SA	Letter	03/10/2017	ML17081A018
22.81	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q2	The Group believes that the NRC should not establish maximum quantities in general licensed devices, thereby reserving authorization to possess Category 1, 2, and 3 quantities of radioactive material to specific licensees.	GLDs	Letter	03/10/2017	ML17081A018
22.82	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q2	The Group provides the following observations. First, and as noted above, the Group believes that, because the NRC's current regulations reflect significant evaluation by the IAEA, the NRC itself, and by the Task Force, and because the bases of those evaluations and their conclusions are currently valid, the NRC should not revise its regulations regarding the activity permitted in generally licensed devices.	GLDs	Letter	03/10/2017	ML17081A018
22.83	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q2	Second, to the extent that the NRC's current interest in revising its regulations regarding the activity permitted in generally licensed devices was precipitated by the GAO's investigation, the Group observes that the GAO did not identify any weakness in any regulation regarding general licenses (generally) or generally licensed devices (specifically), including, but not limited to, the maximum activity permitted to be present in a generally licensed device.	GLDs	Letter	03/10/2017	ML17081A018
22.84	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q2	Finally, should the NRC revise its regulations to provide that a generally licensed device may only possess less activity than the Category 3/4 threshold activity for a particular isotope, licensees which currently use devices with Category 3 quantities of byproduct material would be required to become specific licensees. Representative costs for those companies to become specific licensees are provided in Table 1, above [Comment 22.33]. The Group notes that many licensees in the oil & gas and petrochemical industries conduct activities with Category 3 quantities of byproduct material in generally licensed devices in several states. Licensees which operate those devices in several states would, presumably, be required to become specific licensees in each of the states in which they operate. Thus, those companies would be required to bear some portion of the costs provided in Table 1, above, several times over.	GLDs	Letter	03/10/2017	ML17081A018

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22.85	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	General	After significant consideration, the Group believes that the NRC should not revise its regulations regarding the security and accountability of Category 3 quantities of byproduct material	SA	Letter	03/10/2017	ML17081A018
23.01	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	General	The OAS concurs with the Conference of Radiation Control Program Directors (CRCPD) and does not support adding Category 3 materials to the License Verification System (LVS), the National Source Tracking System (NSTS), or require increased security pursuant to 10 CFR 37.	SA	Letter	03/17/2017	ML17083A249
23.02	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	General	The OAS agrees with NRC Chairman Svinicki and Commissioner Burns that the current NRC regulations for transfers of radioactive sources are adequate to protect public health and safety, commensurate with the associated risk.	SA	Letter	03/17/2017	ML17083A249
23.03	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	General	The NRC provides no other evidence that there is a problem with transferring or authorizing possession of Category 3 materials other than the General Accounting Office (GAO) report where one individual, who did not follow procedures, allowed an illegitimate acquisition of Category 3 material. By altering the license, the GAO would have been able to acquire enough Category 3 material to exceed the threshold of Risk Significant Radioactive Materials.	SA	Letter	03/17/2017	ML17083A249
23.04	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	General	By adding Category 3 materials to LVS and NSTS, the NRC hopes that this contrived scenario can be avoided. This is an admirable goal, however, the OAS submits that it will not deter someone from obtaining materials below the Category 3 quantities (perhaps the GAO again) and altering the license to obtain more material until eventually quantities of concern may be possessed. Therefore this "fix" may eventually be proven inadequate and we may find ourselves faced with this same issue for all radioactive materials. This would clearly be impractical and counter-productive to ensuring quantities of concern are under adequate security.	SA	Letter	03/17/2017	ML17083A249
23.05	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	General	OAS believes that adding Category 3 materials to LVS and NSTS is unnecessary and over-burdensome. Agreement States do not have any evidence to share that there is a problem with the transfer or security of Category 3 sources.	SA	Letter	03/17/2017	ML17083A249
23.06	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, General, Q1	No. There is no evidence that in the current terrorist threat environment that the distribution of these sources is not already well controlled. The Agreement State consensus is that current regulations are adequate to ensure transfers occur safely. Changing the regulations to prescribe license verification for Category 3 sources would significantly impact radioactive material and radioactive waste transfers and transportation without any evidence to suggest current regulations are inadequate.	SA	Letter	03/17/2017	ML17083A249
23.07	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, General, Q2	There is no evidence that there is a security or safety issue with current Category 3 quantity radioactive source transfer practices. Additional requirements may result in delaying or impeding the completion of a transfer, thus possibly affecting patient health.	SA	Letter	03/17/2017	ML17083A249
23.08	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, General, Q3	As stated by the CRCPD, OAS believes that license verification is important for all entities transferring radioactive sources, however, for Category 3 quantities or lower, requiring LVS is not justified. If NRC choses to proceed with this requirement, the OAS believes that licensees transferring Category 3 quantities to manufacturers and distributors be excepted.	LVS	Letter	03/17/2017	ML17083A249
23.09	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, General, Q4	The NRC should supply more evidence that the current system is not adequate regarding the security of Category 3 sources and then perform a cost benefit analysis to support their position that the regulations should be revised.	SA	Letter	03/17/2017	ML17083A249

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23.10	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, NSTS, Q1	OAS does not believe that Category 3 sources should be included in the NSTS. The NRC has not provided supporting evidence of data that the existing regulatory approach to Category 3 source security is inadequate. Including Category 3 quantity sources in NSTS will be a burden on licensees and Agreement States and it is questionable that it would add to the safety and security, considering that Inspectors regularly check that inventories are within the licensing limits. The NRC estimates that there are 30,000-40,000 Category 3 sources in use or storage. The added burden to all involved is not justified by the rationale that the NRC presented.	NSTS	Letter	03/17/2017	ML17083A249
23.11	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, NSTS, Q2	No.	NSTS	Letter	03/17/2017	ML17083A249
23.12	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, NSTS, Q3	No. Existing reporting requirements are adequate. Adding additional reporting requirements for NSTS will add significantly to the regulatory burden on licensees. OAS does not believe that a possible missing source would be investigated any sooner considering normal delays in the realization of a problem and communications.	NSTS	Letter	03/17/2017	ML17083A249
23.13	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, NSTS, Q4	No. The OAS has no evidence or data to answer this question. Just as the NRC has no evidence or data to justify requiring Category 3 sources be included in NSTS. OAS believes that errors in deliveries would still occur and that common carriers do an adequate job of tracking. NSTS cannot prevent packaging errors.	NSTS	Letter	03/17/2017	ML17083A249
23.14	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, NSTS, Q5	See #4 under LVS questions. The extra cost of maintaining the larger database, and the introduction of additional errors with additional data entry are additional reasons for not including Category 3 sources in NSTS.	Cred&SysArc	Letter	03/17/2017	ML17083A249
23.15	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, NSTS, AS Q1	The fact that the NRC is asking this question makes it clear that there would be an unbearable burden if Category 3 sources were included in NSTS. The OAS agrees with Colorado and other Agreement States, that if NRC discontinued the annual inventory reconciliation, Agreement States would most likely perform the reconciliation through their inspection program. The OAS agrees with North Carolina that the purpose of NSTS is to provide a national database. The NRC is the single point of contact in maintaining the database and should remain so since it is more efficient and cost effective.	NSTS	Letter	03/17/2017	ML17083A249
23.16	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, Security, Q1	No. Part 37 requirements for physical security would be problematic for fixed gauges and for HDR licensees.	SA	Letter	03/17/2017	ML17083A249
23.17	Matthew W. McKinley, OAS Chair	Organization of Agreement States	Agreement State	FRN, Security, Q2	OAS supports the re-evaluation of the NRC's General License Program. OAS believes that Category 3 sources should be specifically licensed. General licensees are usually unaware of the applicable regulations.	GLDs	Letter	03/17/2017	ML17083A249
24.01	Charma Waring, Supervising Radiological Health Specialist	Rhode Island Department of Health	Agreement State	General	We wish to go on record as fully supporting the comments submitted with regard to Docket No. NRC-2016-0276 by the Organization of Agreement States (OAS) in their letter of 17 March 2017. We have no additional comments to offer at this time.	SA	Letter	03/23/2017	ML17087A266
25.01	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	General	The AAPM commends the NRC on its work in addressing whether it is necessary to revise NRC regulations or processes governing Category 3 source protection and accountability. The AAPM further commends the NRC for its efforts to engage stakeholders on this issue.	SA	Letter	03/10/2017	ML17101A556

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
25.02	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	General	The AAPM, however, believes the current system appropriately manages risk and balances benefits against burdens. Accordingly, the AAPM does not support the NRC's enumerated security and accountability enhancements now under consideration, including: - Verification of Category 3 licenses through the License Verification System (LVS) or the regulatory authority; - Inclusion of Category 3 sources in the National Source Tracking System (NSTS); - Expanding physical security requirements for Category 3 sources.	SA	Letter	03/10/2017	ML17101A556
25.03	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	General	Tens of thousands of patients each day benefit from radiation medicine procedures. Category 3 sources include sources used for high dose rate brachytherapy (HDR) treatments for cancer. Many patients' lives depend on the availability of diverse radioisotopes for diagnosis and treatment. The AAPM is concerned that vendors, if confronted with additional regulatory oversight and administrative burden, will choose to discontinue supplying certain radioisotopes, diminishing patient access to care. Accordingly, the AAPM urges the NRC to consider and heavily weight the enormous benefits of radioisotopes to patients when the Agency is assessing safety and security risk of sources.	SA	Letter	03/10/2017	ML17101A556
25.04	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	General	There is a tradition of safety culture in the control of medical radiation sources that has informed a long record of safe and secure use. Medical facilities are well versed in accounting, control, physical security and careful disposal of medical sources. Facilities periodically evaluate workflow, human factors, quality assurance, and provide training and education by qualified experts. Moreover, on-site inspections by state regulators and accrediting bodies further assure safety and security of medical sources.	SA	Letter	03/10/2017	ML17101A556
25.05	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, General, Q1	The NRC and Agreement States already have the ability to identify licensees that possess Category 3 sources, and to monitor the location and movement of the sources through the licensing and inspection program. The AAPM believes the same end result of the proposed enhancements could be achieved by implementation of more rigorous pre-licensing review and dedicating adequate resources for inspection and enforcement to ensure licensee compliance with existing requirements (e.g., 10 C.F.R. § 30.41) without increasing the regulatory burden on the licensees.	SA	Letter	03/10/2017	ML17101A556
25.06	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, General, Q2	The AAPM does not believe that including Category 3 sources in the enhancements under consideration would improve safety and security of those sources. Security and accountability policy should be both risk-informed and science-based.	SA	Letter	03/10/2017	ML17101A556
25.07	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, General, Q4	The AAPM is concerned about the robustness of the NRC's NSTS and LVS system and its capacity to handle the significant increase in transactions if Category 3 were added to the system. We question whether the Agency has, or will have, sufficient resources to meet this challenge.	Cred&SysArc	Letter	03/10/2017	ML17101A556
25.08	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, LVS, Q2	At the January 31, 2017 public meeting at NRC headquarters, stakeholders learned that there are currently approximately 1,400 licensees for Category 1 and 2 sources, which control 75,000-80,000 sources. Including Category 3 sources would add approximately 5,500 licensees to the data system. The NRC would need to dedicate considerable resources to ensure that its system could adequately manage all Category 1, 2 and 3 source data.	Cred&SysArc	Letter	03/10/2017	ML17101A556

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25.09	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, NSTS, Q4	We believe that if Category 3 sources are included in the NSTS, it has the potential to dilute the effectiveness of this tracking system for Category 1 and 2 sources due to the sheer volume of sources that would be added and the number of transactions that would be taking place each year.	Cred&SysArc	Letter	03/10/2017	ML17101A556
25.10	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, NSTS, Q1	The proposed enhancements indicate a gap exists where transaction information provides a level of protection that is not otherwise present. However, no vulnerability assessment has been performed to support this argument. No evidence has been provided that addition of Category 3 sources to the NSTS will generate a timely response to missing or unauthorized shipments.	NSTS	Letter	03/10/2017	ML17101A556
25.11	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, Security, Q1	If Category 3 sources are included in the Part 37 security requirements, it will most likely "lower the bar" and reduce the overall security for licensees that also possess Category 1 and 2 sources, due to the added burden and cost to implement these security requirements for a large number of sources.	SA	Letter	03/10/2017	ML17101A556
25.12	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	General	The AAPM believes the increased burden of adding Category 3 sources to the system is not supported by the risks presented by Category 3 quantities of radioactive material.	SA	Letter	03/10/2017	ML17101A556
25.13	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, General, Q1	Usability is closely related to the robustness of the NRC's reporting system. The AAPM cautions against increasing reporting requirements for Category 3 sources and urges the NRC to assess the end-user usability of their data reporting system.	Cred&SysArc	Letter	03/10/2017	ML17101A556

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25.14	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, LVS, Q1	Currently, credentialing to get direct access to either NSTS or LVS is cumbersome, and can take almost one month. At the NRC's Public Meeting in January, NRC staff advised that about 30-40 percent of licensees engage in electronic versus manual reporting. Licensees, who do not report electronically, complete Form 748, and either fax or email it to the Agency. The present delay for entering data that is provided to the NRC by fax and email is up to 24 hours, but that delay would certainly increase under the burden of Category 3 sources. The NRC's system appears to be still developing and moving toward an all-electronic platform.	Cred&SysArc	Letter	03/10/2017	ML17101A556
25.15	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, NSTS, Q5	If Category 3 sources are included, the number of covered transactions of some stakeholders would increase dramatically. One stakeholder, at the public meeting in January, stated if Category 3 is included in source tracking, his radioisotope company would double its administrative burden based on transactions per day.	NSTS	Letter	03/10/2017	ML17101A556
25.16	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, NSTS, Q5	Moreover, implementation of Category 3 security and accountability enhancements now under consideration by the NRC would likely force some licensees into using the NRC reporting system for the first time. This initial credentialing and adoption curve could be resource-laden and daunting given the current challenges presented by the reporting infrastructure.	Cred&SysArc	Letter	03/10/2017	ML17101A556
25.17	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, NSTS, Q4	Any NRC rulemaking would require analysis of cost and benefit. The AAPM questions whether there would be any benefit to gain from increasing reporting requirements for Category 3 sources.	SA	Letter	03/10/2017	ML17101A556
25.18	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	FRN, NSTS, Q5	The AAPM is concerned about the NRC enlarging its interlocking system of NSTS and LVS to incorporate Category 3 source data because of the potential increase in cybersecurity vulnerability. Including Category 3 sources in the system essentially would place "all eggs in one basket" for malicious actors, who can operate from anywhere in the world, to exploit vulnerabilities to steal information and pose new risks. The AAPM would urge the NRC to consider this cybersecurity risk in further aggrandizing and developing its NSTS and LVS system.	Cred&SysArc	Letter	03/10/2017	ML17101A556
25.19	Melissa Carol Martin, President AAPM	American Association of Physicists in Medicine	NGO	General	In summary, the AAPM does not support the security and accountability enhancements now under consideration by the NRC, including verification of Category 3 licenses, inclusion of Category 3 sources in the NSTS, or expanding physical security requirements for Category 3 quantities of radioactive material. The AAPM believes that current NRC regulations governing use of sources are appropriate and sufficient to ensure public safety and security. Accordingly, the AAPM urges the NRC not to pursue any additional rulemaking on licensing, security or tracking requirements.	SA	Letter	03/10/2017	ML17101A556

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Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
26.01	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	General	I appreciate the opportunity to emphasize the importance of ensuring and enhancing Category 3 source accountability.* As the largest Agreement State, the security and accountability of Category 3 radioactive materials is of particular concern to California because: - The malicious aggregation and misuse of high-level Category 3 quantity materials, exceeding the Category 2 threshold, could result in significant long term damage to California's environment and economy, impacting public health and safety on multiple levels. - Antiquated regulations, which can be exploited to allow access to multiple Category 3 sources, are a target of interest for "bad actors" intent on deploying a radiological dispersal device or a radiological exposure device. This higher risk profile increases the burdens placed on California regulatory, enforcement and security agencies *U.S. Nuclear Regulatory Commission, categories of radioactive sources, retrieved from https://www.nrc.gov/reading-rm/basic-ref/glossary/category-of-radioactive-sources.html. Categories for radioactive sources are defined by the IAEA's Code of Conduct. Category 1 sources (A/D > 1000), would be likely to cause permanent injury to a person who handled them or was otherwise in contact with them for more than a few minutes; Category 2 sources (A/D 10- 1000) could cause permanent injury to a person who handled them or was otherwise in contact with them for a short time (minutes to hours); Category 3 sources (A/D 1-10) could cause permanent injury to a person who handled them or was otherwise in contact with them for some hours. A/D is defined by IAEA, where A is the activity of the source and D is the minimum dangerous activity.	SA	Letter	03/10/2017	ML17101A610
26.02	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, General, Q1	Yes. Licensees in possession of Category 3 quantities of radioactive material should follow the enhanced verification standards applicable to Category 2 quantities of radioactive material.	LVS	Letter	03/10/2017	ML17101A610
26.03	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, General, Q1	The U.S Government Accountability Office (GAO), report GA0-16-3 30, recommends that NRC should take actions to improve tracking and security of Category 3 quantities and verify the legitimacy of the licenses for them. A change to the methods prescribed in 10 CFR 37 .71 would improve the tracking and security of quantities of Category 3 radioactive material.	LVS	Letter	03/10/2017	ML17101A610
26.04	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, General, Q1	Under 10 CFR 37.7 1 (d) Category 2 radioactive materials undergo an additional level of vetting that uses currently available technology. 10 CFR 37.71 (d) requires that "Any licensee transferring category 2 quantities of radioactive material to a licensee of the Commission or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification." Transfers within the same organization are exempt.	LVS	Letter	03/10/2017	ML17101A610
26.05	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, General, Q1	Vetting Category 3 materials in this way, using NRC's existing suite of digital data systems, would reduce the risk of malicious aggregation with minimal burden to all involved.	LVS	Letter	03/10/2017	ML17101A610
26.06	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, NSTS, Q1	Yes. Category 3 sources should be included in the National Source Tracking System (NSTS), License Verification System (LVS) and Web-Based Licensing (WBL) system. Advances in technology and experience demonstrate this can be accomplished at reasonable cost.	SA	Letter	03/10/2017	ML17101A610

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26.07	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, NSTS, Q1	There is a considerable amount of agreement on this. In 2009 NRC staff stated, "NSTS was designed to accommodate Category 3 sources and licensee information, and this feature can be implemented at reasonable cost."* The GA0-16-330 report advises NRC to, "... include category 3 sources in the National Source Tracking System and add agreement state category 3 licenses to the Web-based Licensing System as quickly as reasonably possible."** In a letter to the NRC Chairman regarding the GAO report, U.S. Senator Dianne Feinstein inquired about key concerns and reiterated the importance of securing radioactive materials.*** In response to Senator Feinstein's letter, former NRC Chairman Burns indicated that an NRC working group is assessing the inclusion of Category 3 sources into the NRC digital data systems (NSTS, LVS, and WBL).**** *U.S. Nuclear Regulatory Commission, SECY-09-0086 FINAL RULE: EXPANSION OF THE NATIONAL SOURCE TRACKING SYSTEM (RIN 3150-A129). Page 4, June 2009. **Id GAO-16-330 ***U.S. Senator Dianne Feinstein letter dated August 22, 2016, expressed concern to U.S. Nuclear Regulatory Commission Chairman Burns regarding the findings in a July 2016 U.S. Government Accountability Office (GAO) report GA0-16-330. ****U.S. Nuclear Regulatory Commission Chairman Burns response to U.S. Senator Dianne Feinstein inquires by letter(s) dated October 7, 2016, ML 16253A345 and ML 16253A379.	NSTS	Letter	03/10/2017	ML17101A610
26.08	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, NSTS, Q1	The International Atomic Energy Agency (IAEA) safety standards recommend the inclusion of Category 3 sources into the same national database/register as Category 1 & 2. "In view of the fact that Category 3 sources have the potential to cause severe deterministic effects, the regulatory body may also consider including them in a national register together with the Category 1 and 2 sources."* *IAEA Safety Standards, Categorization of Radioactive Sources , No. RS-G-1.9, 2005. Page 10, section 3.8. Available at http://wwwpub.iaea.org/MTCD/Publications/PDF/Pub1227 web.pdf.	SA	Letter	03/10/2017	ML17101A610
26.09	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, NSTS, Q1	NRC staff noted that the decision in 2009 not to include Category 3 sources in the NSTS was based on concerns that entering the data would be too costly and burdensome.* Advances in NRC digital data systems alleviate these concerns. The technology is now integrated at all levels. With seven years of experience operating the NSTS, integrating Category 3 sources can be accomplished much more economically, thanks to advanced data management and exchange practices. *Commissioner Baran letter to Chairman Burns, COMJMB-16-0001 PROPOSED STAFF RE-EVALUATION OF CATEGORY 3 SOURCE ACCOUNTABILITY. ML16197A229. July 2016.	NSTS	Letter	03/10/2017	ML17101A610
26.10	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, NSTS, Q1	Including Category 3 sources in NRC digital data systems will accommodate transitioning to 10 CFR 37.71(d)'s enhanced verification and methods, greatly reducing the risks of malicious aggregation of large quantities of radioactive materials.	LVS	Letter	03/10/2017	ML17101A610
26.11	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, NSTS, Q2	Yes. The requirements of 10 CFR 20.2207(f) are designed to mesh with 10 CFR 37.71(d) and the NSTS. Together, they would provide an integrated system to verify, track, report and account for radioactive sources analogous to systems in widespread use for tracking purchases from online retailers.	NSTS	Letter	03/10/2017	ML17101A610

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26.12	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, NSTS, Q4	Yes. There should be increases in safety and/or security commensurate with those for category 1 and 2 sources.	SA	Letter	03/10/2017	ML17101A610
26.13	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	FRN, NSTS, Q4	GAO was able to breach the current system because "NRC does not specifically require that the validity of Category 3 licenses be verified by the seller with NRC or the Agreement States creating risks that licenses could be counterfeited or that licensees could obtain radioactive materials in quantities greater than what is allowed by their licenses." The GAO report also observed that the current system lacks assurances or vetting that would "...prevent bad actors from altering licenses or fraudulently reporting the details of their licenses to transferors, accumulating dangerous materials by aggregation to Category 2 or larger quantities on the basis of those fraudulent licenses..." Including Category 3 sources would address these security gaps. Quantifying its impact could be done by reference to the various metrics NRC has access to by virtue of implementing the same security measures for Category 1 and 2 sources.	SA	Letter	03/10/2017	ML17101A610
26.14	Robert B. Weisenmiller, Chair	California Energy Commission	Government-State	General	I support the NRC's efforts to enhance Category 3 source accountability and appreciate the opportunity to comment on the assessment of the current regulations and processes governing source protection and accountability. I believe this assessment is essential in continuing to assure adequate protection of public health and safety. Adopting these recommendations would provide methods to verify the legitimacy of licenses and provide greater assurance that no entity could manipulate the system to acquire radioactive materials in aggregate greater than what they are authorized to possess. I recognize that other stakeholders will have differing recommendations and welcome the dialogue necessary for the development of a comprehensive regulatory basis to address radioactive source accountability and security.	SA	Letter	03/10/2017	ML17101A610
27.01	Susan M. White	The Ohio State University, Nuclear Reactor Laboratory	Medical	General	In the event that the NRC revises its regulations/processes governing source security and accountability for Category 3 sources, the OSU NRL staff propose that the NRC develop a list of nuclides and their respective Category 3 threshold activity limits. Docket ID NRC-2016-0276 states "NRC regulations do not include a definition for Category 3 but the NRC has historically considered the Category 3 threshold to be greater than 1/10th of the Category 2 threshold but less than the Category 2 threshold." The OSU NRL staff assert that the above statement does not provide enough guidance and that a list similar to Appendix A of 10 CFR 37 would be required as part of any revisions to the regulations/processes governing source security and accountability for Category 3 sources.	SA	Letter	03/06/2017	ML17101A544
27.02	Susan M. White	The Ohio State University, Nuclear Reactor Laboratory	Medical	FRN, Security, Q1	The OSU NRL staff propose that two physical barriers would be a sufficient deterrent to the loss of a Category 3 quantity of radioactive material. A requirement for continuous monitoring and detection of unauthorized entry into an area containing a Category 3 source would be an undue burden upon the Licensee.	SA	Letter	03/06/2017	ML17101A544

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28.01	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	General	The agency indicated that the scope of the evaluation is limited to Category 3 quantities of the materials listed in Appendix E of 10 CFR Part 20, as well as the materials subject to physical security requirements in 10 CFR Part 37. Therefore, a potential NRC expansion of source tracking, license verification, and physician security requirements would include Category 3 quantities of Iridium-192 sources used in High- Dose Rate (HDR) brachytherapy—the most common brachytherapy procedure.	SA	Letter	03/09/2017	ML17101A549
28.02	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	General	As a general comment, the ACR recommends that NRC use a risk-informed approach to evaluating any possible expansion of NRC's tracking, license verification, and increased physical security over Ir-192 HDR sources.	SA	Letter	03/09/2017	ML17101A549
28.03	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	General	In terms of tracking and verification, adding these sources would represent a substantial, and potentially overwhelming, increase in the volume of sealed sources handled by NRC's systems and staff. The agency would need to ensure adequate staffing and resources to support significantly expanded National Source Tracking System (NSTS), License Verification System (LVS), and Web Based Licensing (WBL) activities, including enhancing responsiveness for any newly impacted licensees.	Cred&SysArc	Letter	03/09/2017	ML17101A549
28.04	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	General	It took years to implement these programs for a relatively limited number of licensees with Category 1 and 2 quantities of the materials in question— there are potentially several thousand more Category 3 licensees. The NRC would also need to consider collaborations with Agreement States to ensure process compatibility and interoperability.	SA	Letter	03/09/2017	ML17101A549
28.05	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	General	Additionally, the ACR has serious concerns related to patient privacy (e.g., via surveillance of sources), practicality, and cost of expanding 10 CFR Part 37 physical security requirements to Ir-192 HDR sources in medical facilities.	SA	Letter	03/09/2017	ML17101A549
28.06	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	General	We urge NRC to consider risk together with other factors— including the public health benefit of patient access to HDR brachytherapy services, the unique nature of the clinical environment, and the difficulties experienced by medical licensees currently subject to Part 37 (e.g., Cesium-137 irradiators)—when determining the added value of expanding Part 37 to include Category 3 quantities of medically used isotopes such as Ir-192.	SA	Letter	03/09/2017	ML17101A549
28.07	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	FRN, General, Q3	Yes, medical licensees transferring Ir-192 HDR sources back to the manufacturer should be exempted. Typically, an ongoing, bilateral relationship would exist between a medical licensee and a manufacturer such that perpetual or even occasional license verification using these systems to return HDR sources to the manufacturer would be of unsubstantiated security benefit despite the administrative burden. Consider that these transfer verification methods are reportedly regarded as burdensome even for single source transfers at no more than a quarterly frequency between the same one or two manufacturers. Moreover, the credentialing process for medical physicists/licensee workers needing access to the LVS on behalf of licensees takes approximately one month (per NRC estimates) and is non-transferrable to the other licensees the medical physicists/workers may serve.	LVS	Letter	03/09/2017	ML17101A549

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28.08	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	FRN, NSTS, Q1	No, we believe there is insufficient evidence from NRC regarding current risk or security benefit that would outweigh the concerns of adding Category 3 quantities of Ir-192 to the NSTS at this time. HDR sources are transferred more frequently than Category 1 and 2 quantities of the materials tracked in the current version of the NSTS program, and there are significantly more of these sources. Thus, if NRC were to expand NSTS this exponentially, the agency must be cautious to ensure the NSTS program (system, processes, support, and staff) is not overwhelmed, and that licensees are not subject to administrative burden in the absence of quantifiable benefits to support any such expansion.	NSTS	Letter	03/09/2017	ML17101A549
28.09	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	FRN, NSTS, Q1	The ACR is also concerned that medical use license fees would need to increase even more vigorously that they have in recent years to fund the infrastructure, staffing, and other resources that support the NSTS and related activities, despite the indeterminate return on investment in terms of safety and security. Such costs would inevitable be passed on to patients and drive up the cost of healthcare.	SA	Letter	03/09/2017	ML17101A549
28.10	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	FRN, Security, Q1	The ACR believes that any decision to expand NRC's physical security requirements to Ir-192 HDR sources should be risk-informed and considerate of the preexisting physical security/cybersecurity realities of the healthcare setting. The NRC should account for the public benefit of HDR brachytherapy access, and consider how prohibitively expensive and misaligned security controls could ultimately discourage healthcare facilities from providing these services to patients.	SA	Letter	03/09/2017	ML17101A549
28.11	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	FRN, Security, Q1	Moreover, patients of HDR brachytherapy procedures could be directly impacted by certain physical security requirements in 10 CFR Part 37. Current NRC licensees subject to Part 37 are required to provide continuous/direct monitoring of the source with live and recorded video surveillance by qualified personnel. For some licensees this is done in collaboration with local law enforcement agencies. Surveillance systems and continuous/direct video monitoring of the sources during their use in patient care would introduce additional technological risks and cybersecurity/privacy concerns, potentially bringing NRC rules in conflict with other federal rules and protections (HIPAA, etc.) and certainly deterring healthcare facilities already beleaguered with persistent information technology threats, such as ransomware, attempted data breaches, etc.	SA	Letter	03/09/2017	ML17101A549
28.12	James A. Brink, Chair, Board of Chancellors	American College of Radiology	NGO	FRN, Security, Q1	We encourage NRC to communicate with the U.S. Department of Health and Human Services (HHS) Office of Civil Rights (OCR) to better understand the rapidly increasing frequency and scope of cybersecurity attacks on healthcare providers specifically over the past few years, and the added risk introduced by continuous/direct video surveillance monitoring/recording of patient care in progress.	SA	Letter	03/09/2017	ML17101A549
29.01	Kenny Jordan, Executive Director	Association of Energy Service Companies	NGO	General	First and foremost, let us state that as an industry, we are very sensitive to issues related to possible threats by radioactive materials in the current world we live in. NO company wants a radiological event to occur, knowing what it would mean for the entire industry if only one mistake was made. It is in all of our best interest to maintain security and control of this material at all times. We believe industry has demonstrated that commitment in the past and will continue to do so in the future.	SA	Web	03/10/2017	ML17101A570

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Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
29.02	Kenny Jordan, Executive Director	Association of Energy Service Companies	NGO	General	This Issue was Brought Forward by Lack of Governmental and Regulatory Controls to Start With: - The apparent genesis of this proposal was through a “sting” operation conducted whereby the Government Accountability Office (GAO) was able to obtain a radioactive license from the NRC by utilizing a fictitious company, the license was altered and a contract was entered into for the purchase of radioactive material in approximately 2007. In 2014 the GAO conducted a vulnerability test by setting up fictitious businesses in three states; two of those states denied licenses after site inspections, however, and one state issued a license because of lack of procedural follow up. Changes were made in that state in 2016 to strengthen the procedures for vetting licensees. We believe those changes have now only been in place approximately one year, this may very well have addressed the concerns of the regulatory offices but has it been given sufficient time to properly evaluate the changes. - The concern is now that industry, especially smaller companies that may possess only a Category 3 license and may only have 1-3 sources are being made to bear the burden of mistakes made on the regulatory side, not on the industry side. Many of these small companies are exactly that, small enterprises with probably less than 50 employees total (and in many instances smaller than that).	SA	Web	03/10/2017	ML17101A570
29.03	Kenny Jordan, Executive Director	Association of Energy Service Companies	NGO	General	Burdensome Regulations for Small Businesses: - As stated above, many of the smaller well logging companies in the US only maintain a license for Category 3 sources. Some of the larger companies may have licenses for Category 1 or 2, so the addition of Category 3 sources for those larger companies is not as burdensome to them. They already do all necessary steps for the Cat 1 and 2, so the addition of Cat 3 does not impact them to the extent that it does for smaller companies who have to possibly now (if enacted) go through the entire process and cost of implementation. - Additional cost burdens may come at a time when ALL companies involved in oil and gas exploration in the U.S. have had to cut their staffing, take capital equipment out of service, lower their price for services, and not be able to invest back into their companies due to the price of oil. It has been “survival” mode for many of these companies over the last two years. Additional costs that include personnel for tracking, security implementations, etc. would be a tremendous financial burden at a time when they are trying to recover from the worst economic slowdown in the oil and gas business there has been in the last 40 years. - One of our member companies reported that the additional cost to them for (2 locations, 14 sources, 30-40 employees) would be an initial cost set up in year one of $250,000. That included personnel, training, regulatory implementation, security systems, vehicle monitoring, etc. That did state that this was a rough estimate as they had not gone through a bidding or sourcing process for what would be all of the requirements to get specific estimates of costs.	SA	Web	03/10/2017	ML17101A570

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29.04	Kenny Jordan, Executive Director	Association of Energy Service Companies	NGO	General	Working with Industry: - In the event that it is decided to proceed with regulatory controls to industry as opposed to additional regulatory internal controls either by the NRC and Agreement States, we feel it is imperative to include industry in your discussions, especially with the smaller companies that may not feel they have a voice in the process except AFTER the proposed regulations are submitted for comment. The upstream oil and gas industry has worked effectively with OSHA in areas of safety by taking the approach of working together to formulate a regulatory environment that is more agreeable to industry once it is introduced. We only found out about this release last minute before the release of the proposal. We have encouraged all regulatory agencies to be inclusive of industry during potential rulemaking processes.	SA	Web	03/10/2017	ML17101A570
29.05	Kenny Jordan, Executive Director	Association of Energy Service Companies	NGO	General	In conclusion, we are opposed to the inclusion of Category 3 sources into the same regulatory, tracking, and security as Category 1 and 2 sources. This seems to be a regulatory industry issue that has been made into an industry issue. There have been regulatory agency changes implemented, we believe those should be given time to work, then if additional 'testing' of the process is needed, do so there. The industry perception is that the agencies involved are burdening industry to fix their own internal problems.	SA	Web	03/10/2017	ML17101A570
30.01	Alan Jackson, RSO	Henry Ford Hospital	Medical	FRN, Security, Q1	I disagree that all of these security requirements should applied to Category 3 sources. Since the hazard is much lower it makes sense to have a lower set of requirements. The requirements for category 1 and 2 sources are quite burdensome and costly to implement. For the case of High Dose Rate After loader sources it would make the practice of medicine more difficult and costly with little benefit. There is little evidence that the existing rules are inadequate.	SA	Web	03/10/2017	ML17101A572
31.01	Laura I. Thevenot, CEO	American Society for Radiation Oncology	NGO	General	In general, we believe that adding additional security requirements to Category 3 quantities of radioactive material is not necessary given existing protections.	SA	Letter	03/09/2017	ML17101A548
31.02	Laura I. Thevenot, CEO	American Society for Radiation Oncology	NGO	General	A culture of safety and quality is woven into the fabric of radiation oncology, with checks and balances at every level to ensure that the safest and most effective care is delivered to patients. Radiation oncologists and medical physicists receive extensive training in the safe use of radioactive materials. Such training involves a healthy respect for the risks and benefits of radiation, as well as strict adherence to inviolable policies and procedures that ensure secure storage and handling, use and disposal of these materials. A recent Nuclear Regulatory Commission's (NRC) analysis* found that, for 30 years, there have been no violations with actual safety or security consequences, and the nation's robust regulatory infrastructure has appropriately managed the protection of sources. *US Nuclear Regulatory Commission Report to Congress under Public Law 113-235, Effectiveness of Part 37 of Title 10 of the Code of Federal Regulations, December 2016.	SA	Letter	03/09/2017	ML17101A548

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31.03	Laura I. Thevenot, CEO	American Society for Radiation Oncology	NGO	General	Radiation oncologists generally use Category 3 sources for high dose rate (HDR) brachytherapy procedures. HDR is most commonly used to treat gynecological cancers, but can also be used for other disease sites. Category 3 sources for HDR are purchased from, and returned to, the manufacturer and cannot be purchased without first having purchased the unit that houses the source and administers the treatment. This, coupled with the fact that licensees already keep detailed records of purchases and returns of Category 3 sources, already ensures the security of these sources.	SA	Letter	03/09/2017	ML17101A548
31.04	Laura I. Thevenot, CEO	American Society for Radiation Oncology	NGO	FRN, NSTS, Q1	No, addition of these materials in the NSTS will create an administrative burden for both the licensee and the NRC, and will not add any additional security benefits. As mentioned above, medical licensees currently have systems in place to monitor and track Category 3 sources.	NSTS	Letter	03/09/2017	ML17101A548
31.05	Laura I. Thevenot, CEO	American Society for Radiation Oncology	NGO	FRN, NSTS, Q1	Additionally, cancer treatment centers that are licensed to only use Category 3 sources may find these requirements burdensome enough to stop offering these effective treatments, causing patients to have to travel to another treatment center, receive less effective treatment using a different non-radioactive modality, or forgo treatment altogether.	SA	Letter	03/09/2017	ML17101A548
31.06	Laura I. Thevenot, CEO	American Society for Radiation Oncology	NGO	FRN, NSTS, Q4	No, we do not believe that there will be an increase in safety and/or security if the regulations were changed to include Category 3 sources in the NSTS. In fact, we believe that the addition of Category 3 sources to the NSTS will be a tremendous amount of work – both on the part of the licensee and on the NRC – for no or minimal increase in security.	NSTS	Letter	03/09/2017	ML17101A548
31.07	Laura I. Thevenot, CEO	American Society for Radiation Oncology	NGO	FRN, Security, Q1	No, we believe that if these security requirements were expanded to include Category 3 quantities of radioactive material there will be an increase in administrative, financial and logistical burdens to medical licensees. The burden will be greatest for those centers who are licensed to only use Category 3 sources. These centers may find these requirements burdensome enough to stop offering these treatments.	SA	Letter	03/09/2017	ML17101A548
31.08	Laura I. Thevenot, CEO	American Society for Radiation Oncology	NGO	FRN, NSTS, Q3	Yes, automated, non-burdensome, real-time tracking of sources as they move through the supply chain – from manufacture to user to decay and disposal – will give the NRC the most up to date information about the location of Category 1 and 2 sources, allowing the agency and law enforcement, to thoroughly investigate any thefts or other malevolent acts involving these sources. We further recommend that the NRC solicit further stakeholder input on any such proposal.	NSTS	Letter	03/09/2017	ML17101A548
32.01	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, General, Q1	If the Agency decides to require the verification methods in 10 CFR 37.71 for transfers of Category 3 quantities of material, the Agency should clearly exempt the following three types of transfers: a. Transfers to an established manufacturer (e.g., the manufacturer of a sealed source); b. Transfers to established disposal facilities; and c. Transfers among parent, subsidiary or affiliate companies of the transferor.	LVS	Letter	03/10/2017	ML17101A584
32.02	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, General, Q1	For The Dow Chemical Company, the major of shipments of Category 3 radioactive material fall into two categories: d. Transfers of nuclear gauges from one licensed facility to another licensed facility within the same company, or between facilities that belong to the same corporate family (e.g., wholly-owned subsidiaries of Dow). e. Transfers of nuclear gauges to a licensed gauge manufacturing company for repair or disposal f. Transfers of nuclear gauges to a licensed disposal company.	LVS	Letter	03/10/2017	ML17101A584

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32.03	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, General, Q1	For any of these types of transfers, the risk of sending Category 3 radioactive materials to a fictitious license is exceedingly small. We know who our subsidiaries are. We know the manufacturers and disposal firms. If a terrorist rented a storefront in order to register a new, fictitious manufacturer or disposal firm, we would not transfer gauges to those companies because we do not have any established relationship with them. Consequently, in these situations the license verification requirements in 10 CFR 30.41 are adequate. Requiring an additional step to verify the license through the NRC would just add an additional administrative burden without providing any additional safety or security over the materials.	LVS	Letter	03/10/2017	ML17101A584
32.04	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, General, Q2	Most materials licensees probably perform shipping to limited numbers of organizations like we do, and are at low risk of shipping Category 3 radioactive materials to fictitious licensees. The manufacturers of these sources are the entities that are most likely to ship sources to fictitious licenses. Requiring source manufacturers to perform this type of license verification would provide some enhancement in safety and security. Requiring materials licensees to perform similar verifications would provide very little enhancement in safety and security of the sources.	LVS	Letter	03/10/2017	ML17101A584
32.05	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, General, Q3	The Dow Chemical Company believes that materials licensees transferring Category 3 quantities of radioactive material should be exempt from additional license verification requirements. Additionally, exemptions should also be in place for transfers between different licenses within the same corporate structure (e.g., the combination of a parent company and its wholly-owned subsidiaries) and transfers to licensed waste processing and disposal facilities.	LVS	Letter	03/10/2017	ML17101A584
32.06	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, NSTS, Q1	No, Category 3 sources should not be included in the NSTS. Licensees are required to maintain their inventory of radioactive materials and document where the sources are sent when they transfer the devices. There are existing requirements to report lost radioactive materials to the NRC if they cannot be accounted for. Maintaining a centralized list of many thousand Category 3 sources does not enhance the safety and security of these devices, and just imposes an additional burden on the NRC and materials licensees to keep this list up-to-date. Short timeframes for reporting these transfers only increase that burden.	NSTS	Letter	03/10/2017	ML17101A584
32.07	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, NSTS licensees, Q2	We do not currently have access to the NSTS. If new requirements for tracking Category 3 quantities of radioactive material required were implement, we would likely sign up for online access to the NSTS.	NSTS	Letter	03/10/2017	ML17101A584
32.08	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, LVS, Q1	Dow Chemical sites do not currently have access to the LVS. If new requirements for license verification for shipments of radioactive material required were implemented, most sites that possess Category 3 quantities of radioactive material would likely sign up for online access to the LVS.	LVS	Letter	03/10/2017	ML17101A584
32.09	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, LVS, Q2	Across the US, sites of The Dow Chemical Company make approximately 1-3 shipments of Category 3 quantities of radioactive material per month. More than 80% would be transfers to and from a manufacturer for repair or disposal of devices.	LVS	Letter	03/10/2017	ML17101A584
32.10	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, LVS, Q3	Requiring additional license verification when transferring to an established manufacturer would not provide any additional safety or security for Category 3 sources of radioactive material and would only impose additional burden on licensees to comply with the regulations. Additional verification beyond current requirements should not be required.	LVS	Letter	03/10/2017	ML17101A584

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32.11	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, LVS, Q4	Dow Chemical sites do not currently have access to the LVS.	LVS	Letter	03/10/2017	ML17101A584
32.12	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, Security, Q1	No. Many Category 3 sources in our industry are level gauges located in process areas and attached to structures within the facility, but do not include physical barriers that would meet the requirements for Category 1 and Category 2 quantities of radioactive material. However, these devices generally are installed in difficult-to-reach locations, cannot be removed from their installed location easily, and will set off process alarms if removed. They are also located within facilities that are subject to chemical security requirements specified by the Department of Homeland Security. Therefore, the likelihood of these devices being successfully targeted and removed from service is exceedingly low.	SA	Letter	03/10/2017	ML17101A584
32.13	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, Security, Q1	For example, consider a level gauge that is welded to a steel tank. The steel tank is on the third floor of a chemical manufacturing plant. The chemical manufacturing plant has a control room with computers where the signals from process control devices, including the level gauge, are constantly being evaluated. If the computer detects a problem with the signal, an alarm sounds. Personnel are monitoring the alarms 24 hours a day, 7 days a week. Meanwhile, the chemical manufacturing plant sits within a larger site (perhaps several square miles in size) with numerous other chemical manufacturing plants. The site has a security fence and a limited number of gates for access. Each gate is staffed with security personnel, and additional security personnel are circulating around the site at all hours of the day and night. In order for someone to steal the gauge, he or she would need to breach the perimeter security of the larger site, then somehow find exactly the right chemical manufacturing plant (without being challenged by anyone while en route), then find exactly the right tank (without being challenged by personnel at the chemical manufacturing plant, then somehow cut the welds to free the gauge from the tank (without being detected by plant personnel or site security), and disconnect the wiring. This would instantly set off an alarm, because the signal would cease. And then the thief would need to somehow escape first from the individual plant, and then from the larger site, while carrying a heavy gauge. This scenario does not appear very credible.	SA	Letter	03/10/2017	ML17101A584
32.14	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, Security, Q1	Imposing a requirement for additional physical barriers to access these devices would provide no significant increase in the security of these devices, would require major changes to the design of many of our facilities, and could create additional safety hazards for workers in the facility to be able to efficiently evacuate process area.	SA	Letter	03/10/2017	ML17101A584
32.15	James Weldy, Corporate RSO	The Dow Chemical Company	Industrial	FRN, Security, Q2	The Dow Chemical Company has very few devices across our company that are generally licensed, but contain a Category 3 quantity of radioactive material. Any changes in this area would have little impact on us.	GLDs	Letter	03/10/2017	ML17101A584
33.01	Earl Fordham	Washington State Department of Health	Agreement State	FRN, General, Q1	No, the states have successfully handled license verification. While there would be additional security by requiring 10 CFR 37.71(b), the state of Washington believes the current processes used to verify licenses are adequate for safety and security.	LVS	Web	03/10/2017	ML17101A588
33.02	Earl Fordham	Washington State Department of Health	Agreement State	FRN, General, Q2	There may be a slight increase in security if the various computer systems are up-to-date. With all LVS and related components working properly and without any delay, the new process would prevent anyone from trying to alter a license to obtain material.	LVS	Web	03/10/2017	ML17101A588

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33.03	Earl Fordham	Washington State Department of Health	Agreement State	FRN, General, Q3	No, all Category 3 transfers should be processed through LVS. Only in this manner can accountability and tracking be ensured.	LVS	Web	03/10/2017	ML17101A588
33.04	Earl Fordham	Washington State Department of Health	Agreement State	FRN, General, Q4	Category 3 tracking and transfers could potentially be very resource intensive for the licensees and the states.	NSTS	Web	03/10/2017	ML17101A588
33.05	Earl Fordham	Washington State Department of Health	Agreement State	FRN, NSTS, Q1	No. This system is hard to use and gain access to. This would place too much burden on licensees to have to verify the sources annually and when transferred and would produce very little in the way of security.	Cred&SysArc	Web	03/10/2017	ML17101A588
33.06	Earl Fordham	Washington State Department of Health	Agreement State	FRN, NSTS, Q2	No, the Category 1 and 2 reporting requirements are overly burdensome when compared to the Category 3 risk. Instead of 1 business day to report, perhaps monthly reporting balances the burden vs risk considerations.	NSTS	Web	03/10/2017	ML17101A588
33.07	Earl Fordham	Washington State Department of Health	Agreement State	FRN, NSTS, Q3	No, the NSTS reporting requirements for Category 1 and 2 sources should not be changed. Rationale for the changes is not readily apparent.	NSTS	Web	03/10/2017	ML17101A588
33.08	Earl Fordham	Washington State Department of Health	Agreement State	FRN, NSTS, Q4	No, simply adding Category 3 sources into NSTS does enhance safety and/or security. Adding Category 3 sources to NSTS will at least triple the inventory with sources of significantly lower risk. Package mishandling or shipping/delivery errors will continue to occur. NSTS can't control these types of events.	NSTS	Web	03/10/2017	ML17101A588
33.09	Earl Fordham	Washington State Department of Health	Agreement State	FRN, NSTS, Q5	With the huge increase in potential sources, if Category 3 sources were included in NSTS, existing resources would be strained. To overcome the significant burden, additional resources will be needed in an era where states are being told to do more with less.	NSTS	Web	03/10/2017	ML17101A588
33.10	Earl Fordham	Washington State Department of Health	Agreement State	FRN, LVS, AS Q1	About 180.	LVS	Web	03/10/2017	ML17101A588
33.11	Earl Fordham	Washington State Department of Health	Agreement State	FRN, LVS, AS Q2	Both. Our state program would recommend and encourage the use of LVS. However, for some licensees, we would also plan for the additional burden of manual verification.	LVS	Web	03/10/2017	ML17101A588
33.12	Earl Fordham	Washington State Department of Health	Agreement State	FRN, LVS, AS Q3	We would consider using WBL or similar computer based licensing system.	WBL	Web	03/10/2017	ML17101A588
33.13	Earl Fordham	Washington State Department of Health	Agreement State	FRN, LVS, AS Q4	The impact on our resources would be substantial. To quantify the time and money needed has not been undertaken, but estimates can be made based upon activities 10 years ago for Category 1 and 2 sources (one new FTE).	SA	Web	03/10/2017	ML17101A588

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33.14	Earl Fordham	Washington State Department of Health	Agreement State	FRN, NSTS, AS Q1	Given the NRC permits state NSTS access to perform the annual reconciliation, the additional burden would be huge and perhaps unjustifiable given the risk of Category 3 sources. The additional staff and resources necessary to accomplish the annual reconciliation, especially with Category 3 sources included, would not only burden the state, but would also necessitate a fee increase affecting licensees.	NSTS	Web	03/10/2017	ML17101A588
33.15	Earl Fordham	Washington State Department of Health	Agreement State	FRN, Security, Q1	No. The security requirements for Category 1 and 2 quantities would be an over-reaction for Category 3 sources due to their lower risk.	SA	Web	03/10/2017	ML17101A588
33.16	Earl Fordham	Washington State Department of Health	Agreement State	FRN, Security, Q2	Yes, the NRC should establish appropriate maximum quantities for GL devices. All potentially high risk GL sources should have appropriate security to prevent possible malicious use. If Category 3 sources are to be placed under more scrutiny, they need to be specifically licensed (as Category 1 and 2 quantities of radioactive materials are currently).	GLDs	Web	03/10/2017	ML17101A588
34.01	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, General, Q1	No; it would add an administrative burden to licensees following the requirements in the existing 10 CFR 30.41(c) which already requires licensees to "verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred." By restricting the pathway to perform that verification, the transfer process will be less efficient. Furthermore, there is concern that by adding Category 3 sources to the LVS it would increase the risk of malicious access to critical licensee information, since more licensees would require access and be able to see this data. Thus, overall this proposal would cause a decrease in safety and/or security.	LVS	Letter	03/10/2017	ML17101A590
34.02	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, General, Q2	Yes, they should be excepted especially for medical institutions transferring brachytherapy sources such as Ir-192 during routine source changes. This transfer process is performed on a frequent (typically quarterly) basis, with close involvement by the manufacturer and distributor of the new source; since they are providing a new source at the same time, it is nonsensical to require licensees to verify through the LVS that the company is authorized to receive the old source back.	LVS	Letter	03/10/2017	ML17101A590
34.03	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, NSTS, Q1	The safety/security of Radioactive Material in Quantities of Concern (RAMQC) is inversely proportional to the amount of data available and how secure that data is kept. Although the NSTS database is a credentialed-access site, there is still the risk of data loss as in any electronically based file. Thus there would be a decrease in safety/security overall. Similar to the response to the first question, there would also be a significant decrease in the efficiency of radioactive material transfers, due to this additional burden of recordkeeping. Furthermore, Category 3 sources are notoriously mobile sources, and maintaining a constant physical inventory database may prove to be unmanageable.	Cred&SysArc	Letter	03/10/2017	ML17101A590
34.03	Catherine Ribaudo, RSO	National Institutes of Health	Medical	General	The NIH uses cyclotrons to provide a number of radionuclides for medical research. One of the by-products of certain production lines is Co-60. The regulation specified in 10 CFR 20.1003 defines a nationally tracked source. However, this definition does not include activated material, which is present in and around all cyclotrons (in the form of Co-60 among other radionuclides). The Category 3 limit for Co-60 is 830 mCi; the Category 2 limit is 8.2 Ci. Will licensees be responsible for tracking this radionuclide under the proposed Category 3 changes if they become final? This will present real challenges both to licensees and the regulatory authority.	LVS	Letter	03/10/2017	ML17101A590

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34.04	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, LVS, Q1	The NIH already has online access capabilities for the LVS (and the NSTS) so this question is a moot point for us. However, additional individuals at the NIH will be required to have access, which increases the burden for NRC tracking as well as increases the burden of procedural requirements for NIH staff to follow. There is an annual security training requirement, for example, that must be met and tracked.	LVS	Letter	03/10/2017	ML17101A590
34.05	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, LVS, Q2	The proposed change primarily affects the clinical oncology program at the NIH, due to our use of a High Dose Rate (HDR) brachytherapy source of Ir-192. We currently perform one transfer every quarter (3 months) for a total of four transfers per year. The number of transfers that occur are exclusively to/from original equipment manufacturers (OEM).	LVS	Letter	03/10/2017	ML17101A590
34.06	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, LVS, Q3	The NIH does not believe that license verification is required in these cases. The new HDR source is delivered and installed by the OEM and the old source is removed and returned to the factory by the OEM.	LVS	Letter	03/10/2017	ML17101A590
34.07	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, NSTS licensees, Q1	The NIH already has online access capabilities for the NSTS (and the LVS) so this question is a moot point for us. However, additional individuals at the NIH will be required to have access, which increases the burden for NRC tracking as well as increases the burden of procedural requirements for NIH staff to follow. There is an annual security training requirement, for example, that must be met and tracked.	NSTS	Letter	03/10/2017	ML17101A590
34.08	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, Security, Q1	The physical security requirements should absolutely not be imposed, as they would be excessively burdensome and not at all commensurate with the risk level of Category 3 sources. If the concern is aggregation of Category 3 sources so as to approach Category 2 quantities, the NRC can track those licensees that are accumulating large quantities of Category 3 licensed material. The NRC can also establish license criteria that inhibit the accumulation of excessive amounts of Category 3 material through proper licensing conditions.	SA	Letter	03/10/2017	ML17101A590
34.09	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, Security, Q1	This specific proposal may also be contrary to other federal statutes and regulations. The NIH uses HDR units for clinical treatment of patients. If cameras and recording video are required, this may be a violation of HIPAA regulations that protect patient privacy.	SA	Letter	03/10/2017	ML17101A590
34.10	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, Security, Q1	It is difficult to envision a workable implementation of physical security controls in an active clinical setting. There is constant movement in and out of patient treatment areas, and immediate response to patient needs necessarily overrides any thought of source security. Furthermore, reactionary law enforcement response to a clinical area is always problematic, for patient, visitor, and staff well-being. Based on years of experience with implementing physical security requirements for Category 1 and 2 quantities of radioactive material, immediate police dispatch to the scene is nearly very always due to a nuisance alarm, and simply causes unnecessary concern and criticism of protocols, which erodes public trust in law enforcement activities.	SA	Letter	03/10/2017	ML17101A590

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
34.11	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, Security, Q1	Implementation of physical security controls would also necessitate a program of "trustworthy and reliability" of all individuals with the need to access the source. This would naturally add to the licensee workload to track, certify, document, renew, and annually train this population of clinical staff. This added workload would be burdensome and not lead to any increase in safety/security of the source; individuals involved in the use of an Ir-192 source for brachytherapy procedures are already held to a high ethical standard of conduct due to their direct patient interaction. Implementation of a formal T&R program for these personnel will not contribute to an increased level of safety/security but will instead be a regulatory burden on security staff and affected individuals.	SA	Letter	03/10/2017	ML17101A590
34.12	Catherine Ribaudo, RSO	National Institutes of Health	Medical	FRN, Security, Q2	It does seem prudent for the NRC to consider the continued authorization issue and setting maximum quantity limits, especially for Category 3 sources that may present a waste disposal problem to the public if not properly managed. However, it is not necessary to create massive regulatory hurdles that will adversely affect small companies whose only role with general licensed devices and quantities of radioactive material may be the storage of devices that contain unimportant quantities of radioactive material for proper device operation.	GLDs	Letter	03/10/2017	ML17101A590
35.01	--	Tracerco, Johnson Matthey Inc.	Industrial	General	Tracerco, a business unit of Johnson Matthey Inc., does not believe that the proposed regulatory revisions intended to increase the security requirements for category 3 quantities of radioactive material are either necessary or appropriate. The proposed changes do not address and will have no beneficial impact on the concerns identified in the GAO audit and investigation.	SA	Letter	03/10/2017	ML17101A612
35.02	--	Tracerco, Johnson Matthey Inc.	Industrial	General	We believe that the current security standards relating to category 3 quantities of radioactive material are adequate and do not need to be revised. The rules and requirements associated with generally licensed devices are also adequate in their present form and should remain unchanged.	GLDs	Letter	03/10/2017	ML17101A612
35.03	--	Tracerco, Johnson Matthey Inc.	Industrial	General	For Tracerco, the burden of this proposed rule change would be considerable both operationally and commercially. The proposed regulatory changes would require significant investment, out of proportion to the benefits gained, to develop and maintain a compliant security program. We are concerned that the burden of a program of this nature could unnecessarily discourages the use of devices containing radioactive material in applications for which they are both cost effective and safe.	SA	Letter	03/10/2017	ML17101A612
35.04	--	Tracerco, Johnson Matthey Inc.	Industrial	General	The risks related to category 3 quantities of radioactive material were carefully considered and assessed during the development of the current security standards. Appropriate safety and security standards were established consistent with those assessments. Those standards are effective and do not require revision.	SA	Letter	03/10/2017	ML17101A612
36.01	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, General, Q1	Although efforts have been taken to ensure that both the WBL, LVS, and NSTS are constantly updated, it is our experience that this is not the case 100% of the time. Agreement states are voluntarily providing risk-significant licenses for inclusion to the WBL. What happens when the state doesn't deem the licensee "risk-significant?" In our industry, many Generally Licensed devices are distributed in Category 3 quantities. These GL holders will not be included in the WBL or LVS since they do not have Specific Licenses.	GLDs	Web	03/10/2017	ML17101A613

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Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
36.02	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, General, Q3	The proposed relaxation of the rule does not seem clear. If the point is to track specific category 3 sources as they are transferred, what happens if the same source is transferred many times between the manufacturer/distributor and the licensee? It would appear that the M&D would report the transfer of the same source many times, this confusing the WBL, LVS, and NSTS. Additionally, would relaxation of the rule be extended to other M&Ds that are not the original M&D of the source? This clarification would be of significant important to M&Ds that are licensed to service and distribute sources from other M&Ds and also provide storage services.	LVS	Web	03/10/2017	ML17101A613
36.03	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, NSTS, Q1	Category 3 sources should not be included in the NSTS. This would impose a significant personnel, time, and financial burden on companies that log multiple transfers of category 1, 2 and 3 sources per week. Additionally it has been our experience that the NSTS database is consistently incorrect. A reason for the errors could be that multiple transferors can submit transfers to a company through the NSTS while the transferee cannot confirm each transfer.	NSTS	Web	03/10/2017	ML17101A613
36.04	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, NSTS, Q1	Another consideration is the arbitrary quantity of the category 3 thresholds. While the commensurate safety risk associated with category 1 and category 2 quantities is well documented, there is no data to support the extrapolated 10% threshold for category 3 sources would result in 10% of the risk. Rather the rule is written in order to avoid obtaining enough category 3 sources that would result in a category 2 quantity. Following this practice would result in category 4/5/6 sources also being heavily inventoried in the future.	SA	Web	03/10/2017	ML17101A613
36.05	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, NSTS, Q2	Category 3 sources should not be included in the NSTS. This would impose a significant personnel, time, and financial burden on companies that log multiple transfers of category 1, 2, and 3 sources per week. Additionally it has been our experience that the NSTS database is consistently incorrect. A reason for the errors could be that multiple transferors can submit transfers to a company through the NSTS while the transferee cannot confirm each transfer.	NSTS	Web	03/10/2017	ML17101A613
36.06	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, NSTS, Q4	Another consideration is the arbitrary quantity of the category 3 thresholds. While the commensurate safety risk associated with category 1 and category 2 quantities is well documented, there is no data to support the extrapolated 10% threshold for category 3 sources would result in 10% of the risk. Rather the rule is written in order to avoid obtaining enough category 3 sources that would result in a category 2 quantity. Following this practice would result in category 4/5/6 sources also being heavily inventoried in the future.	SA	Web	03/10/2017	ML17101A613
36.07	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, LVS, Q3	The proposed relaxation of the rule does not seem clear. If the point is to track specific category 3 sources as they are transferred, what happens if the same source is transferred many times between the manufacturer/distributor and the licensee? It would appear that the M&D would report the transfer of the same source many times, this confusing the WBL, LVS, and NSTS. Additionally, would relaxation of the rule be extended to other M&Ds that are not the original M&D of the source? This clarification would be of significant important to M&Ds that are licensed to service and distribute sources from other M&Ds and also provide storage services.	LVS	Web	03/10/2017	ML17101A613
36.08	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, NSTS licensees, Q2	Yes my company has access to the NSTS. It seems easy to confirm your annual inventory reconciliation if your inventory does not change as frequently as ours does. But if you are charged with making changes to the inventory frequently, those changes cannot be submitted online.	NSTS	Web	03/10/2017	ML17101A613

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37.01	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, General, Q1	No. Wisconsin opposes requiring use of the verification methods in 10 CFR 37.71 for Category 3 sources.	LVS	Letter	03/09/2017	ML17101A550
37.02	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, General, Q2	Requiring verification only in this way may increase safety and /or security of some transfer activities but would have no effect on others. For example, the risk of fraudulent documentation is greatest the first time a manufacturer or distributor transfers a source to licensee. License verification through LVS or manually through the recipient's regulator would directly address the risk of fraudulent documentation of a new licensee, increasing safety and/security in this case. Additionally, for regulators, a manual verification can be a benefit by notifying the regulator when the new licensee will receive radioactive material. Once a supplier-customer relationship is established, however, additional license verification would not reduce risk to the same degree. For these transfers there would be little to no increase in safety and/or security and there is considerable potential for the process to become an undue burden for licensees and regulators. Category 3 quantity sources for industrial radiography and HDR are routinely returned to manufacturers. License verification through LVS or manually does not increase safety or security for sources being shipped to the manufacturer.	LVS	Letter	03/09/2017	ML17101A550
37.03	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, General, Q3	Yes.	LVS	Letter	03/09/2017	ML17101A550
37.04	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, General, Q4	Could the same positive effects on safety and security be achieved if manufacturers and distributors were required to verify only certain requests? The biggest risks are: new license or new use (fraudulently obtained or altered license), address changes or shipping to new locations (attempt to divert sources to another location), and large orders of total activities or at a rate greater than normal (altering using a license to get a CAT 1 or 2 quantity). The verification method should address the risks (LVS and manual verification do) but if possible not interfere with well vetted and routine transactions, i.e. some analog to TSA Pre check.	LVS	Letter	03/09/2017	ML17101A550
37.05	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, NSTS, Q1	No. The current regulations are adequate for protecting public health and safety for Category 3 sources. The stated health and security risks of Category 3 sources do not warrant additional security requirements.	SA	Letter	03/09/2017	ML17101A550
37.06	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, NSTS, Q1	In addition, requiring extra tracking and license verification for iridium-192 sources until they decay to 2.1 Ci may prompt licensees (medical and industrial radiography) to delay return shipment of old sources until the sources have decayed beneath Category 3 quantities. This increases security vulnerabilities by providing an incentive to keep unused sources onsite for a longer period of time.	SA	Letter	03/09/2017	ML17101A550
37.07	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, NSTS, Q1	Wisconsin also notes that HDR sources are always exchanged by the manufacturer. Licensees cannot acquire sources from other vendors and the manufacturer will not ship extra sources that would allow a licensee to aggregate to a Category 2 quantity. Tracking HDR sources in NSTS would provide no increase in safety or security.	NSTS	Letter	03/09/2017	ML17101A550

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37.08	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, NSTS, Q2	Yes. It would add needless confusion to have different reporting requirements for different source categories.	NSTS	Letter	03/09/2017	ML17101A550
37.09	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, NSTS, Q3	There is always going to be a lag between “ground truth” and what is in NSTS. Wisconsin recommends retaining the reporting requirements as they are currently.	NSTS	Letter	03/09/2017	ML17101A550
37.10	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, NSTS, Q4	No. Including Category 3 sources in NSTS would not increase safety or security. As mentioned in a previous question, may provide an incentive to reduce security by encouraging licensees to hold on to unused sources until they decay below the Category 3 threshold.	NSTS	Letter	03/09/2017	ML17101A550
37.11	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, NSTS, Q5	No.	NSTS	Letter	03/09/2017	ML17101A550
37.12	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, LVS, AS Q1	As of September 2016, Wisconsin had 57 licenses authorized for Category 1, 2 or 3 quantities. Of these, 26 are authorized for Category 1 or 2 quantities and 31 are authorized for Category 3 only.	WBL	Letter	03/09/2017	ML17101A550
37.13	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, LVS, AS Q2	We would encourage the use of LVS.	LVS	Letter	03/09/2017	ML17101A550
37.14	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, LVS, AS Q3	We already use WBL, and all of our Category 3 licenses are included in WBL.	WBL	Letter	03/09/2017	ML17101A550
37.15	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, LVS, AS Q4	There will be an increased burden to respond to licensees who choose to pursue manual license verification.	LVS	Letter	03/09/2017	ML17101A550

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37.16	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, NSTS, AS Q1	10 CFR 20.2207 does not specify how the annual inventory reconciliation must be conducted. Wisconsin has understood annual reconciliation as the licensee's responsibility, which Wisconsin then verifies during inspection. The annual reconciliation process does not have to include mailing a hard copy of the inventory. Wisconsin does not support printing and mailing a hard copy of security-related information to the licensees for this purpose. It is reasonable to expect licensees to seek access to NSTS online. If NSTS is expected to be a real time inventory system the process of annual inventory reconciliation is antiquated. The annual inventory reconciliation was most useful when the system was first adopted but currently provides little use in keeping the system accurate. NRC should evaluate whether the annual inventory reconciliation is still necessary at all, or whether review of this information during inspection is adequate.	NSTS	Letter	03/09/2017	ML17101A550
37.17	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, Security, Q1	No. In 2009, NRC's rationale for including Category 1 and 2 sources in NSTS was based on the potential health effects due to misuse of a source. Since then, no additional threat bases have been evaluated which concluded that Category 3 sources present a significant threat. In addition, Category 3 fixed gauge sources are often in large industrial environments in places that cannot easily be segregated from other areas. Defining a security zone and controlling access to these areas would be extremely difficult, if not impossible. Subjecting Category 3 sources to Part 37 security requirements without a credible threat basis is not warranted.	SA	Letter	03/09/2017	ML17101A550
37.18	David Reindl, Nuclear Engineer	State of Wisconsin, Department of Health Services	Agreement State	FRN, Security, Q2	Yes. Generally licensed devices which are currently subject to registration should be specifically licensed.	GLDs	Letter	03/09/2017	ML17101A550
38.01	Robert Thomas, Vice President, Health Policy and Govt Affairs	Elekta, Inc.	Medical	General	Elekta is committed to ensuring the safe use of radiological sources and to working with the NRC on implementing policies that enhance safety. We are concerned that the policies proposed in the request for comment will not have a measurable impact on safety. However, these policies will result in increased administrative burdens and costs for companies and cancer care providers.	SA	Letter	03/10/2017	ML17101A582
38.02	Robert Thomas, Vice President, Health Policy and Govt Affairs	Elekta, Inc.	Medical	General	We are specifically concerned with the proposal to require Category 3 sources to be included in the National Source Tracking System (NSTS). Access to brachytherapy, a life-extending technology for cancer patients, is currently limited. Increasing undue administrative burdens and costs on companies and health care providers may further limit access to this technology for cancer patients.	NSTS	Letter	03/10/2017	ML17101A582
38.03	Robert Thomas, Vice President, Health Policy and Govt Affairs	Elekta, Inc.	Medical	General	We urge NRC to refrain from increasing administrative burdens on cancer care companies and providers and to not require Category 3 sources to be included in the NSTS.	SA	Letter	03/10/2017	ML17101A582
39.01	Eric W. Abelquist, President-elect	Health Physics Society	NGO	General	There would be little improvement in safety and security by including Category 3 sources in the security requirements of 10 CFR 37. There would however, be increased administrative and operational costs that would not improve safety while adding additional complications related to the management of such sources.	SA	Letter	03/09/2017	ML17101A547

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39.02	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, General, Q1	No, the current regulations are sufficient. The vast majority of such sources are transferred from the manufacturer to and from licensees where the source is used and subsequently returned to the manufacturer. These transactions are between organizations with an established business relation for understood purposes.	SA	Letter	03/09/2017	ML17101A547
39.03	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, General, Q2	For routine transactions replacing radioactive sources, such as those in medicine, such transfers are between licensees with an extended relationship. Such a change would increase the cost of source replacements and transfers with a limited or non-existent increase in safety and/or security.	SA	Letter	03/09/2017	ML17101A547
39.04	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, General, Q3	Licensees returning sources to manufacturers and distributors should be exempt from the requirement to verify licenses through the LVS or license issuing authority. Sources are usually returned as part of a source replacement transaction. A requirement for LVS verification would add unnecessary work and delay with no improvement in safety or security.	LVS	Letter	03/09/2017	ML17101A547
39.05	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, General, Q4	Any change to the regulations governing Category 3 sources should provide consideration to source replacement program for known licensees with established relationships. The same end result as the proposed rule could be achieved by implementation of more rigorous pre-licensing review and dedicating adequate resources for inspection and enforcement to ensure licensee compliance with existing requirements, e.g., 10 C.F.R. § 30.41, without increasing the regulatory burden on licensees.	LVS	Letter	03/09/2017	ML17101A547
39.06	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, NSTS, Q1	Category 3 sources should not be added to the NSTS. Such an addition will vastly increase the number of sources in the NSTS and the number of transactions with minimal safety and security improvements. Medical facilities and radiography companies use High Dose Rate Brachytherapy (^{192}Ir) (HDR) that are exchanged approximately four times a year throughout the year. These facilities and vendors already work together to ensure source delivery and receipt. If a shipment is not received, as expected, regulators are already promptly notified.	NSTS	Letter	03/09/2017	ML17101A547
39.07	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, NSTS, Q2	If Category 3 sources were to be included in NSTS, inventory verification would be required. However, since many of these sources are short-lived replacement sources, it would require routine changes to the inventory and identification numbers for the sources leading to an increase administrative burden to NSTS and licensee staff with little or no safety and security benefit.	NSTS	Letter	03/09/2017	ML17101A547
39.08	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, NSTS, Q3	A requirement for 'immediate' reporting for routine exchange of Category 3 sources would create an extensive administrative burden on manufactures, licensees and NSTS staff with little or no safety and security benefit. Since many of these sources are preplanned exchanges, NRC should consider prior reporting of the shipments to the licensee and the return to the manufacturer/vendor in one reporting transaction.	NSTS	Letter	03/09/2017	ML17101A547
39.09	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, NSTS, Q4	Any increase in safety and/or security would be minimal if it exists at all. The proposed rule indicates a gap exists where transaction information provides a level of protection that is not otherwise present. However, no vulnerability assessment has been performed to support this argument. No evidence has been provided that addition of Category 3 sources to the National Source Tracking System will generate a timely response to missing or unauthorized shipments.	NSTS	Letter	03/09/2017	ML17101A547

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39.10	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, NSTS, Q5	Inclusion of Category 3 sources in NSTS should be based on a comprehensive risk analysis that takes into consideration existing licensing control and an extensive history of the control of such sources. Inclusion should be based on a net increase in safety and security with system design considerations given to the additional recordkeeping transactions. If Category 3 sources are included in the National Source Tracking System, it has the potential to dilute the effectiveness of this tracking system for Category 1 and 2 sources due to the sheer volume of sources and the number of transactions.	NSTS	Letter	03/09/2017	ML17101A547
39.11	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, LVS, Q1	Many licensees would have limited need to sign-up for the LVS as most transactions are return of sources to a manufacturer. For the infrequent use, many licensees would likely prefer an option of email a verification request. For those more technologically capable, online access should be easy to request and simple to use when necessary.	LVS	Letter	03/09/2017	ML17101A547
39.12	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, LVS, Q2	Medical licensees with HDR sources and radiography companies could expect to exchange four sources per year that are received from and returned to the sealed source manufacturer.	LVS	Letter	03/09/2017	ML17101A547
39.13	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, LVS, Q3	No, that will add work and delay with no benefit. If the manufacturer shipped a new source to a licensee with a source return packet, it is reasonable to assume the manufacturer is still licensed to receive the old source. Rechecking their license with every shipment would cause unnecessary delays in returning old sources that would result in increased staff doses due to the continued presence of the old source.	LVS	Letter	03/09/2017	ML17101A547
39.14	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, NSTS licensees, Q2	Annual reconciliation of sources on the NSTS is easy to perform and efficient. However, transferring and receiving sources on the NSTS can be confusing from the multiple options for the same process, especially for transactions involving licensees out of the United States. With that said, the NSTS Help Desk has always been very helpful in guiding licensees through the process.	NSTS	Letter	03/09/2017	ML17101A547
39.15	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, Security, Q1	The physical security requirements for High Dose Rate Brachytherapy could complicate patient care with questionable safety and security benefit. HDR patient therapy is already very stressful for the patient as this treatment places high dose rate sources in contact with the patient. Existing Category 1 and 2 security requirements are inconsistent with the medical and operational needs of radiation therapy.	SA	Letter	03/09/2017	ML17101A547
39.16	Eric W. Abelquist, President-elect	Health Physics Society	NGO	FRN, Security, Q2	It would be reasonable for category 1, 2 and 3 quantities of radioactive materials to require a specific license.	GLDs	Letter	03/09/2017	ML17101A547
40.01	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	General	I reviewed the July 2016 Government Accountability Report (GAO-16-330), the staff requirements memorandum SRM-COMJMB-16-001, and other documents relevant to the topic and I participated in the January 31st Category 3 Source and Accountability Public Meeting. I understand the concern the GAO sting operation has generated and appreciate the NRC's efforts to address this concern but I don't believe expanding the scope of existing regulations to include Category 3 sources into the NSTS and LVS systems would have changed the outcome of the GAO operating The GAO obtained the license because of the lack of due diligence during the pre-licensing phase of issuing a license. The LVS and NSTS systems and the Part 37 regulations had no role in pre-licensing activities.	SA	Letter	03/07/2017	ML17101A546

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Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
40.02	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	General	I question the argument that expanding the LVS and NSTS requirements to Category 3 materials and sources would prevent a Category 3 licensee from obtaining a Category 2 quantity of materials by procuring materials from multiple suppliers. I suppose the theory is that the LVS and NSTS systems would signal to the appropriate regulator that a receiving licensee was collecting a Category 2 quantity of material when they were only licensed to possess up to a Category 3 quantity of material. As a user of both the NSTS and LVS systems I am not sure if this is a realistic assumption. When I use the LVS system to verify a license the system does not require that I input a quantity of material that is being requested. I review the license that is provided by the LVS and I verify that the quantity and form of the material being requested is authorized by the license.	SA	Letter	03/07/2017	ML17101A546
40.03	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	General	Another point made in GAO-16-330 was that of counterfeited licensees; “Further the NRC does not specifically require that the validity of category 3 licenses be verified by the seller with the NRC or the agreement states - creating the risk that licenses could be counterfeited…”. I would agree that when the LVS is used prior to conducting a transfer the validity and accuracy of the license being verified is ensured and that it would be highly unlikely to transfer radioactive materials to a counterfeited license. This being said, would the effort needed to include all of the Category 3 licenses into the WBL be justified in order to address a theoretical deficiency? There is no data to suggest that the license verification methods for Category 3 and below quantities utilizing the current regulatory requirements (§§30.41, 40.51 and 70.42) do not adequately protect the public health and safety.	LVS	Letter	03/07/2017	ML17101A546
40.04	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	General	In general, INIS does not believe expanding the WBL, NSTS and LVS systems to include Category 3 quantities of radioactive materials is warranted and we strongly discourage expansion of NSTS to include Category 3 sources. We do believe that including licenses that authorize the possession of Category 3 quantities of radioactive material into the WBL system would ensure the accuracy and validity of these licenses prior to transferring radioactive materials but the resources needed to expand and maintain this capability would need to be justified against the perceived benefits.	SA	Letter	03/07/2017	ML17101A546
40.05	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, General, Q1	No. The current methods of verifying a recipient’s license or authorization prior to transferring Category 3 quantities of radioactive materials provides a sufficient level of safety and security commensurate with the quantity of radioactive material involved. No changes to the regulator sections referenced above are warranted.	LVS	Letter	03/07/2017	ML17101A546
40.06	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, General, Q2	We do not believe there would be an increase in the level of safety and security if license verification was conducted through the LVS. We believe that the accuracy and validity of the licensee being verified would be assured but it is not clear if this would result in an increase in the level of safety or security that is currently provided by the current regulatory requirements.	LVS	Letter	03/07/2017	ML17101A546

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40.07	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, General, Q3	As proposed the exception is arbitrary and no basis is provided to support it. The intent to limit the regulatory burden on the users of Category 3 sources is understandable but a better exemption may be that license verification utilizing the LVS is not required when returning Category 3 quantities of material to the original supplier. In this scenario, the licensee returning the Category 3 quantity is confident that the receiving licensee is authorized to possess the material because the receiving licensee had originally supplied the material. It would also be important to stress that the license must still be verified in accordance with §§30.41, 40.51 and 70.42 as applicable.	LVS	Letter	03/07/2017	ML17101A546
40.08	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, General, Q4	We believe that the current methods of verifying a recipient's license prior to transferring Category 3 quantities of radioactive materials adequately protects the public health and safety. Verifying a license using the LVS system prior to transferring Category 3 quantities of radioactive materials would ensure the validity and accuracy of the license being verified and would thereby prevent the transfer of Category 3 quantities of radioactive materials to a counterfeited license. The questions now become; (1) is this a legitimate concern? And (2) does this concern justify the resources required to expand and maintain the WBL and LVS systems? We believe the answer to these questions is no.	LVS	Letter	03/07/2017	ML17101A546
40.09	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS, Q1	No, we do not believe there would be any benefit to include Category 3 sources into the NSTS. Expanding NSTS to include Category 3 sources could overwhelm the system making it counterproductive. We acknowledge that Category 3 sources could result in physical harm if mishandled but we believe that the regulatory requirements that are currently in place adequately addresses the risks associated with this level of radioactivity. It is also important to note that most if not all Category 3 sources that are in use are registered in the sealed source and device registry and are specifically listed on the end user's license and are routinely inventoried and leak tested.	NSTS	Letter	03/07/2017	ML17101A546
40.10	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS, Q2	The NSTS is a tracking system that is intended to follow high risk sources throughout their lifecycle from the time that they are manufactured until the time the sources are disposed of, destroyed or decayed below the reporting threshold. What point is there to include Category 3 sources into the NSTS if the current reporting requirements are not applied? Inclusion of Category 3 sources into the NSTS system becomes mute if the source is not tracked through the lifecycle, which is accomplished through reporting. The fact that this question is specifically being asked brings into question the rational to include Category 3 sources into the NSTS.	NSTS	Letter	03/07/2017	ML17101A546
40.11	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS, Q3	No. This question implies that the NSTS and LVS systems can be used in concert so that when the LVS system is utilized to verify a license prior to transferring Category 1 or 2 quantities of radioactive material, the LVS system would be capable of authorizing or denying the planned transfer by verifying the receiving licensee's current NSTS inventory against their possession limit. The NSTS system is a database that is intended to track high risk sources through their lifecycle and the LVS system is a database that allows the transferring licensee to verify a recipient's authorization to possess the Category 1 or 2 quantities of radioactive material that they have requested. We believe it is up to the recipient licensee to ensure that the quantity of radioactive material that they have requested is within their remaining possession authorizations.	Cred&SysArc	Letter	03/07/2017	ML17101A546

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40.12	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS, Q4	We do not believe there would be any safety or security benefit if the regulations were changed to include Category 3 sources in the NSTS. In fact, there could be a decrease in safety and security if an end user decides it is easier to place disused Category 3 sources into long term storage instead of returning a disused Category 3 source to the manufacturer or supplier for end of life management options such as recycling or disposal.	SA	Letter	03/07/2017	ML17101A546
40.13	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS, Q5	We believe the NSTS is fulfilling the US' obligation to the IAEA Code of Conduct through the establishment of a national register of radioactive sources, that at a minimum includes Category 1 and 2 sources. Going beyond this to include Category 3 sources would need to be justified with a risk assessment and cost benefit analysis. Without knowing specific details on the number of additional users that would be affected by such an expansion, we can only assume that the resources that would be necessary to expand and maintain the expansion of the WBL, NSTS and LVS systems would be significant and that these resources could be better utilized by the affected licensees and regulators.	SA	Letter	03/07/2017	ML17101A546
40.14	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, LVS, Q1	We currently utilize the LVS system.	LVS	Letter	03/07/2017	ML17101A546
40.15	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, LVS, Q2	As a source manufacturer, we consider this proprietary information and would prefer to provide answers to this question in a follow-up phone conversation.	LVS	Letter	03/07/2017	ML17101A546
40.16	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, LVS, Q3	This question appears to be addressing Objective 1.a.ii. of the NRC/Agreement State Working Group License Verification and Transfer of Category 3 Sources (ML16197A474) Charter and it is not clear if the question is intended to include Category 1 and 2 source transfers as well. It seems that the intent of the question is to reduce the regulatory burden associated with the use of the LVS. If this is the case, then why not expand this to any established licensee?	LVS	Letter	03/07/2017	ML17101A546
40.17	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, LVS, Q3	Along these same lines the §37.71 (a) and (b) requirement to verify a license utilizing the LVS "prior to" the transfer is not clear. Does the term "prior to" mean within 24 hours, within 1 week, within 30 days? If these transfers are routine, occurring several times a month to the same licensee or if the transfer is for a bulk quantity of material with deliveries staggered over a period of time is license verification required "prior to" each of the transfers made to the licensee.	LVS	Letter	03/07/2017	ML17101A546
40.18	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, LVS, Q4	Yes, I have on-line access. There are times when the "Contact Agency Alert" window appears and no explanation is given as to why the code appears, just that verification should be conducted through the regulating agency. If an incorrect amendment number was inserted or if the license number was typed incorrectly additional information could be provided to the user that would allow the person to correct the error and proceed with the verification.	Cred&SysArc	Letter	03/07/2017	ML17101A546

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40.19	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, LVS, Q4	Being able to access the system through a wireless network would be desirable. Including the Sealed Source and Device Registries into the LVS would be an improvement, so that users of sources and devices could verify that they have the most up to date SS&DR for the source and/or device in their possession.	Cred&SysArc	Letter	03/07/2017	ML17101A546
40.20	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS licensees, Q1	We currently utilize the NSTS.	NSTS	Letter	03/07/2017	ML17101A546
40.21	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS licensees, Q2	Yes, I have on-line access. Being able to make corrections to a source after it has been transferred is not possible, and correction have to be made through the help desk. Having to shut down the browser after logging off in order to log back on is annoying.	Cred&SysArc	Letter	03/07/2017	ML17101A546
40.22	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS licensees, Q2	Wireless access would be ideal. The NRC should provide guidance on the intent of the NSTS system, which should be limited to the tracking of sealed sources that are intended for or have been commercially distributed. As it is now “radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control” language found in the §20.1003 definition of a “nationally tracked source” encompasses radioactive materials that should not be included in the NSTS. For example, capsules of bulk material that will be utilized for source manufacturing, radioisotope targets, inner source capsules or incomplete sealed sources that have not been released for distribution, and if the NSTS was to include category 3 “sources” individual 1 mm x 1mm Co-60 pellets would me the §20.1003 definition of a nationally tracked source. The intent of NSTS was to track a Category 1 or 2 sealed source through its life cycle and was not intended to include all forms of radioactive materials contained in a capsule or closely bonded.	Cred&SysArc	Letter	03/07/2017	ML17101A546
40.23	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, LVS, AS Q1	No comments to the questions in this section.	LVS	Letter	03/07/2017	ML17101A546
40.24	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, Security, Q1	No. We believe that the existing safety regulations provide an adequate and appropriate level of security for Category 3 and below quantities of radioactive material.	SA	Letter	03/07/2017	ML17101A546
40.25	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, Security, Q2	We are not aware of how many such sources would be affected but it seems reasonable to establish maximum quantities of radioactive materials in generally licensed devices. Reserving the authorization to possess Category 1, 2 and 3 quantities of radioactive material to specific licensees would be warranted if data exists that indicates there are generally licensed devices containing these quantities of radioactive materials that pose a safety or security risk.	GLDs	Letter	03/07/2017	ML17101A546

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41.01	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	General	There would be little improvement in safety and security by including Category 3 sources in the security requirements of 10 CFR 37 but there would however, be increased administrative and operational costs that would add complications related to the management of such sources.	SA	Web	03/07/2017	ML17101A545
41.02	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, General, Q1	No, the current regulations are sufficient. The vast majority of such sources are transferred from the manufacturer to and from licensees where the source is used and subsequently returned to the manufacturer. These transactions are between organizations with an established business relation for understood purposes.	SA	Web	03/07/2017	ML17101A545
41.03	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, General, Q2	For routine transactions replacing radioactive sources, such as those in medicine, such transfers are between licensees with an extended relationship. Such a change would increase the cost of source replacements and transfers with a limited or non-existent increase in safety and/or security.	LVS	Web	03/07/2017	ML17101A545
41.04	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, General, Q3	Licensees returning sources to manufacturers and distributors should be exempt from the requirement to verify licenses through the LVS or license issuing authority. Sources are usually returned as part of a source replacement transaction. A requirement for LVS verification would add unnecessary work and delay with no improvement in safety or security.	LVS	Web	03/07/2017	ML17101A545
41.05	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, General, Q4	Any change to the regulations governing Category 3 sources should provide consideration to source replacement programs for known licensees with established relationships. The same end result as the proposed rule could be achieved by implementation of more rigorous pre-licensing review and dedicating adequate resources for inspection and enforcement to ensure licensee compliance with existing requirements without increasing the regulatory burden on licensees.	SA	Web	03/07/2017	ML17101A545
41.06	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, NSTS, Q1	Category 3 sources should not be added to the NSTS. Such an addition will vastly increase the number of sources in the NSTS and the number of annual transactions with minimal safety and security improvements. Medical facilities performing 192Ir High Dose Rate Brachytherapy (HDR) have sources that are exchanged approximately four times a year. These facilities and vendors already work together to ensure source delivery and receipt. If a shipment is not received, as expected, regulators are already promptly notified.	NSTS	Web	03/07/2017	ML17101A545
41.07	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, NSTS, Q2	If Category 3 sources were to be included in NSTS, inventory verification would be required. However, since many of these sources are short-lived replacement sources, it would require routine changes to the inventory leading to an increase administrative burden to NSTS and licensee staff with little or no safety and security benefit.	NSTS	Web	03/07/2017	ML17101A545

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41.08	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, NSTS, Q3	A requirement for 'immediate' reporting for Category 1 and 2 source transfers within 24 hours would seem reasonable. Same day would likely create an extensive administrative burden on licensees with little or no safety and security benefit. Since many of these sources are preplanned exchanges, NRC should consider prior reporting of the shipments to the regulatory authority as sufficient.	NSTS	Web	03/07/2017	ML17101A545
41.09	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, NSTS, Q4	Any increase in safety and/or security would be minimal if it exists at all.	SA	Web	03/07/2017	ML17101A545
41.10	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, NSTS, Q5	Inclusion of Category 3 sources in NSTS should be based on a comprehensive risk analysis that takes into consideration existing licensing control and an extensive history of the control of such sources. Inclusion should be based on a net increase in safety and security with system design considerations given to the additional recordkeeping transactions. If Category 3 sources are included in the National Source Tracking System, it has the potential to dilute the effectiveness of this tracking system for Category 1 and 2 sources due to the sheer volume of sources and the number of transactions.	NSTS	Web	03/07/2017	ML17101A545
41.11	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, LVS, Q1	Many licensees would have limited need to sign-up for the LVS as most transactions are the return of sources to a manufacturer which should be an exception to the verification process. Due to infrequent use, many licensees would likely prefer an option of emailing a verification request. For those more technologically capable, online access should be easy to request and simple to use when necessary.	LVS	Web	03/07/2017	ML17101A545
41.12	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, LVS, Q2	Medical licensees with HDR sources and radiography companies could expect to exchange four sources per year that are received from and returned to the sealed source manufacturer.	LVS	Web	03/07/2017	ML17101A545
41.13	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, LVS, Q3	No, that will add work and delay with no benefit. If the manufacturer shipped a new source to a licensee with a source return packet, it is reasonable to assume the manufacturer is still licensed to receive the old source. Rechecking their license with every shipment would cause unnecessary delays in returning old sources that would result in increased staff doses due to the continued presence of the old source.	LVS	Web	03/07/2017	ML17101A545
41.14	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, LVS, Q4	No. But I have had nothing but trouble getting online access to the NSTS system so I would anticipate issues with the LVS system as well.	Cred&SysArc	Web	03/07/2017	ML17101A545

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41.15	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, NSTS licensees, Q1	As stated above, I have had nothing but trouble getting online access to the NSTS system due to firewall issues. The help desk has not been able to resolve the problem. I would use the e-mail method.	NSTS	Web	03/07/2017	ML17101A545
41.16	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, NSTS licensees, Q2	No. Yes. See above. On my last call with the NSTS help desk in December 2016, after receiving an e-mail from NSTS reminding me I had online access and that my annual reporting information would be coming soon, they acknowledged that the e-mail went out to everyone - even those like me who they know don't have access. So if they can't even get their e-mails to go out correctly to the 1200 licensees that have Category 1 and 2 sources, how are they going to be able to deal with 5000 licensees if Category 3 sources are added?.	NSTS	Web	03/07/2017	ML17101A545
41.17	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, Security, Q1	The physical security requirements for High Dose Rate Brachytherapy could complicate patient care with little if any safety and security benefit. HDR patient therapy is already complicated and very stressful for the patient as this treatment places high dose rate sources in contact with the patient. Adding Category 1 and 2 security requirements would be a burden on the medical and operational needs of HDR radiation therapy.	SA	Web	03/07/2017	ML17101A545
41.18	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, Security, Q2	It would be reasonable for Category 3 quantities of radioactive materials to require a specific license.	GLDs	Web	03/07/2017	ML17101A545
42.01	James A. Gresham, Manager, Regulatory Compliance	Westinghouse Electric Company	Industrial	General	Westinghouse has several licenses that are maintained under Agreement State arrangements and the licensees would be impacted by the proposed changes. Westinghouse disagrees that further protection and accounting for Category 3 sources is needed and provides responses to the questions below (not all Federal Register Notice questions are addressed).	SA	Letter	03/10/2017	ML17101A581
42.02	James A. Gresham, Manager, Regulatory Compliance	Westinghouse Electric Company	Industrial	FRN, General, Q1	No, Westinghouse believes that the transfer of material regulations in Part 30, Part 40, and Part 70 are adequate as currently written.	LVS	Letter	03/10/2017	ML17101A581
42.03	James A. Gresham, Manager, Regulatory Compliance	Westinghouse Electric Company	Industrial	FRN, General, Q2	Currently, Westinghouse uses a state regulator approved method to verify licenses prior to transfer. Generally, transfers performed by Westinghouse are with entities with whom Westinghouse has a long working relationship. Westinghouse believes that the current license verification process is acceptable and does not pose an undue safety or security risk.	LVS	Letter	03/10/2017	ML17101A581

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42.04	James A. Gresham, Manager, Regulatory Compliance	Westinghouse Electric Company	Industrial	FRN, NSTS, Q1	Inclusion of Category 3 materials in the NSTS could pose a significant complication to our work. Westinghouse receives shipments of Category 3 materials which are subsequently divided into smaller samples for testing and archiving. An example of this would be surveillance capsules which arrive from operating plants and are opened in our hot cells (resulting in a single source becoming more than 100 sources). These are subsequently destructively tested, which again multiplies the number of sources. Since this is all irradiated metal, these individually tested pieces may still constitute Category 3 materials. Some of this material will be archived indefinitely, while others are scrap material for disposal.	NSTS	Letter	03/10/2017	ML17101A581
42.05	James A. Gresham, Manager, Regulatory Compliance	Westinghouse Electric Company	Industrial	FRN, NSTS, Q1	Using the surveillance capsule example, this Category 3 material is divided into many individual samples making it very difficult to track the samples. All work with the surveillance capsules is performed in the hot cell. Therefore, for tracking purposes, the samples would need to be remotely identified (in the hot cell) with a bar-code or other tracking number which could be read remotely (through the hot cell windows).	NSTS	Letter	03/10/2017	ML17101A581
42.06	James A. Gresham, Manager, Regulatory Compliance	Westinghouse Electric Company	Industrial	FRN, NSTS, Q1	Westinghouse currently tracks the total inventory (isotopically) on a receipt/shipment basis, but any finer tracking would require significant changes including large capital investments and time. The material in question is currently controlled as radioactive materials quantities of concern (RMQC) from the time it enters inventory as an aggregate source, so there is no added benefit to the security of the material with Category 3 level tracking.	NSTS	Letter	03/10/2017	ML17101A581
42.07	James A. Gresham, Manager, Regulatory Compliance	Westinghouse Electric Company	Industrial	FRN, NSTS, Q2	Westinghouse disagrees that Category 3 materials should be included in NSTS and therefore disagrees that the Category 1 and 2 source requirements be imposed. However, if NRC so deems the inclusion into NSTS necessary, a graded approach should be applied due to the low (comparative) risk to Category 1 and 2 sources.	NSTS	Letter	03/10/2017	ML17101A581
42.08	James A. Gresham, Manager, Regulatory Compliance	Westinghouse Electric Company	Industrial	FRN, LVS, Q2	At one Westinghouse location, they perform approximately two to three shipments per month of Category 3 materials, of which, transfers directly to/from a manufacturer are very infrequent.	LVS	Letter	03/10/2017	ML17101A581
42.09	James A. Gresham, Manager, Regulatory Compliance	Westinghouse Electric Company	Industrial	FRN, NSTS licensees, Q2	NSTS, or the alternative process to email the information, works reasonably well for the sources that are currently tracked in it. Materials reported in NSTS are easily reconciled and tracked. However, using the system for tracking Category 3 materials would add significant administrative burden prior to every shipment.	NSTS	Letter	03/10/2017	ML17101A581
42.10	James A. Gresham, Manager, Regulatory Compliance	Westinghouse Electric Company	Industrial	FRN, Security, Q1	No, Westinghouse believes that the physical security requirements for Category 3 materials are acceptable.	SA	Letter	03/10/2017	ML17101A581

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43.01	Michael Albanse	Qal-Tek	Industrial	General	I order to balance stakeholder resources to improve protection and accountability what if: 1) license reviewer perform background checks for each applicant and one other individual in the entity asking for the license/renewal or amendment. 2) license cannot be issued until facilities and applicant are inspected 3) licensees disposing or transferring Cat. 1,2 or 3 sources must document LVS, regulator check or certification like in Part 37.71 prior to shipment, this should include manufacturers and distributors. 4) Cat. 3 sources shouldn't require Part 37 security but should be double locked when mounted or in storage to deter being an easy target 5) GL limits should be established	SA	Web	03/10/2017	ML17101A593
44.01	Michael E. Klebe	Michael Klebe & Associates, Inc.	Industrial	FRN, Security, Q2	The fundamental question posed by the NRC in this FRN is the last one. Question 2 in the “Other Questions” section reads...[FRN, Security, Q2] My response to this question is yes, the NRC should require the specific licensing of Category 1, 2 and 3 quantities of radioactive material. The main reasons for requiring licensing for Category 1, 2 and 3 quantities include: - The International Atomic Energy Agency (IAEA) has determined Category 3 sources and quantities to be dangerous - General licensees have no training in radiation safety - Dangerous discrete sources and quantities should be possessed by persons properly trained.	GLDs	Letter	03/10/2017	ML17101A611
44.02	Michael E. Klebe	Michael Klebe & Associates, Inc.	Industrial	FRN, Security, Q2	The IAEA has established, for certain radioisotopes, a normalizing factor to define the associated risk. For each isotope they have determined a “D” factor which is the activity corresponding to a dangerous source. The IAEA defines a dangerous source as: “A dangerous source is defined as a source that could, if not under control, give rise to exposure sufficient to cause severe deterministic effects. A deterministic effect is defined as a health effect of radiation for which generally a threshold level of dose exists above which the severity of the effect is greater for a higher dose. Such an effect is described as a severe deterministic effect if it is fatal or life threatening or results in a permanent injury that reduces the quality of life.”* The threshold for Category 3 sources is at the D value. Category 2 source threshold is 10 times the D value while Category 1 source threshold is 1,000 time the D value. Category 3 radioactive sealed sources are considered dangerous by the IAEA. *IAEA “Categorization of Radioactive Sources”, Safety Guide No. RS-G-1.9, 2005, pg. 43.	GLDs	Letter	03/10/2017	ML17101A611

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

<table>
<tr><th>Unique Identifier</th><th>Individual</th><th>Organization</th><th>Stakeholder Type</th><th>FRN Question</th><th>Comment</th><th>Bin</th><th>Comment Format</th><th>Date Written</th><th>Accession No.</th></tr>
<tr><td>44.03</td><td>Michael E. Klebe</td><td>Michael Klebe & Associates, Inc.</td><td>Industrial</td><td>FRN, Security, Q2</td><td>There is no real competency standard or verification required for a general license. With regard to generally licensed devices, the NRC states on their website:
“The device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience. Consequently, the general license simplifies the licensing process so that a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary.”*
Some generally licensed devices contain Category 3 radioactive sealed sources. Persons who possess these devices do not need radiation safety training or experience. There is no demonstration of competency to a regulatory authority. There are no follow-on compliance inspections. There are minimal requirements for general licensees which are contained in 10 CFR 31.5.

*https://www.nrc.gov/materials/miau/general-use.html</td><td>GLDs</td><td>Letter</td><td>03/10/2017</td><td>ML17101A611</td></tr>
<tr><td>44.04</td><td>Michael E. Klebe</td><td>Michael Klebe & Associates, Inc.</td><td>Industrial</td><td>FRN, Security, Q2</td><td>Regardless of the inherent safety of the device, it still contains a Category 3 radioactive sealed source. Dangerous sources and quantities should require management by persons who are properly trained. In determining the D values, the IAEA used the following dose criteria:
Table I.1. Reference doses for D-values*
<table>
<tr><th>Tissue</th><th>Dose criteria</th></tr>
<tr><td>Bone marrow</td><td>1 Gy in 2 days</td></tr>
<tr><td>Lung</td><td>6 Gy in 2 days from low LET radiation 25 Gy in 1 year from high LET radiation</td></tr>
<tr><td>Thyroid</td><td>5 Gy in 2 days</td></tr>
<tr><td>Skin/tissue (contact)</td><td>25 Gy at depth of 2 cm for most parts of the body (e.g., from a source in a pocket) or 1 cm for the hand for a period of 10 hours</td></tr>
<tr><td>Bone marrow</td><td>1 Gy in 100 hours for a source that is too big to be carried</td></tr>
</table>
*IAEA “Categorization of Radioactive Sources, IAEA-TECDOC-1344, July 2003, pg. 12.</td><td>GLDs</td><td>Letter</td><td>03/10/2017</td><td>ML17101A611</td></tr>
<tr><td>44.05</td><td>Michael E. Klebe</td><td>Michael Klebe & Associates, Inc.</td><td>Industrial</td><td>FRN, Security, Q2</td><td>The potential doses used to determine the threshold for a dangerous source can result in a significant health impact. As the NRC staff mentioned in SECY-08-0137, these Category 3 sealed sources can be aggregated to a higher IAEA Category quantity. This increases the potential hazard.</td><td>GLDs</td><td>Letter</td><td>03/10/2017</td><td>ML17101A611</td></tr>
<tr><td>44.06</td><td>Michael E. Klebe</td><td>Michael Klebe & Associates, Inc.</td><td>Industrial</td><td>FRN, Security, Q2</td><td>The potential hazards associated with Category 3 radioactive sealed sources or quantities are significant. A person wanting to possess these items should have to demonstrate a basic knowledge of the hazard and demonstrate the competence to safely manage the risk. It should take more than a checkbook and a pulse to secure a Category 3 sealed source.</td><td>GLDs</td><td>Letter</td><td>03/10/2017</td><td>ML17101A611</td></tr>
<tr><td>44.07</td><td>Michael E. Klebe</td><td>Michael Klebe & Associates, Inc.</td><td>Industrial</td><td>FRN, Security, Q2</td><td>If the determination is made that Category 3 sources can continue to be secured through a general license then the rest of the FRN is immaterial. It doesn’t make much sense to place the same requirements for Category 1 and 2 radioactive sealed sources on material that can be acquired through a general license.</td><td>GLDs</td><td>Letter</td><td>03/10/2017</td><td>ML17101A611</td></tr>
</table>

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44.08	Michael E. Klebe	Michael Klebe & Associates, Inc.	Industrial	FRN, Security, Q1	Ideally, the answer to this questions is yes. However, from a practical standpoint given all the various devices that use Category 3 sealed sources (or lower category sealed sources aggregated to a Category 3 quantity) it may be difficult or impossible to achieve the same level of access control. A specific license issued to cover the possession of Category 3 sealed sources and quantities can address the physical security requirements on a case-specific basis with the goal of being as close to same requirements as required for Category 1 and 2 sealed sources.	SA	Letter	03/10/2017	ML17101A611
44.09	Michael E. Klebe	Michael Klebe & Associates, Inc.	Industrial	FRN, General, Q4	The FRN asked several general questions related to the use of the License Verification System (LVS) for the transfer of Category 3 sealed sources. Using the LVS to verify a transferee's authorization to receive a Category 3 source is a good idea. However, the success of using the LVS is subject to the specific licensing of Category 3 sealed sources, the NRC and Agreement State's use of the NRC's Web Based License (WBL) system for these licenses and the inclusion of Category 3 sealed sources in the National Source Tracking System (NSTS) .	Cred&SysArc	Letter	03/10/2017	ML17101A611
44.10	Michael E. Klebe	Michael Klebe & Associates, Inc.	Industrial	FRN, General, Q4	The LVS is a front-end verification system that relies on the associated components of the WBL and NSTS. At the time of source transfer, the transferor will use the LVS to verify a transferee's ability to receive a Category 3 sealed source. The LVS will query the WBL to return a copy of the license and the NSTS to determine the current sealed source inventory. Since some Category 3 sealed sources are generally licensed, there will be no license in the WBL for the system to query. In addition, if Category 3 sealed sources are not reported to the NSTS, the LVS will not be able to indicate the transferee's current inventory.	LVS	Letter	03/10/2017	ML17101A611
44.11	Michael E. Klebe	Michael Klebe & Associates, Inc.	Industrial	FRN, General, Q4	The use of the LVS streamlines the verification process. It reduces the workload on the regulatory agency to verify each transfer of a Category 3 sealed source and speeds the process for the transferor. But the use of the LVS to verify a recipient's ability to receive a Category 3 source requires specific licensing for Category 3 sealed sources and reporting Category 3 sealed sources to the NSTS.	LVS	Letter	03/10/2017	ML17101A611
44.12	Michael E. Klebe	Michael Klebe & Associates, Inc.	Industrial	FRN, NSTS, Q5	The FRN posed several general questions related to reporting Category 3 sealed sources to the NSTS. As mentioned in the previous section, reporting Category 3 sealed sources to the NSTS is critical to the use of the LVS for the transfer of Category 3 sealed sources. The reporting requirements should be the same as currently required for Category 1 and 2 sealed sources. Consistency in reporting requirements will aid the regulatory programs as they verify the information reported.	NSTS	Letter	03/10/2017	ML17101A611
44.13	Michael E. Klebe	Michael Klebe & Associates, Inc.	Industrial	FRN, NSTS, Q5	It is difficult to define the increase in safety and security associated with the inclusion of Category 3 sealed sources in the NSTS. The primary increase in safety and security is the ability for the NRC or Agreement State program to have immediate access to information on the inventory of sealed sources at the facility. There are times that this prompt knowledge can assist with response actions such as a fire or other emergency at the facility.	NSTS	Letter	03/10/2017	ML17101A611
44.14	Michael E. Klebe	Michael Klebe & Associates, Inc.	Industrial	FRN, NSTS, Q5	Reporting source transfers to the NSTS should be completed as close to the time of transfer as possible. This keeps the inventory of the NSTS current and accurate.	NSTS	Letter	03/10/2017	ML17101A611
44.15	Michael E. Klebe	Michael Klebe & Associates, Inc.	Industrial	General	The FRN has a series of specific questions for licensees and Agreement State Programs on the level of effort associated with the issues discussed above. I represent neither category and therefore am not providing a response to those specific questions.	NSTS	Letter	03/10/2017	ML17101A611

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45.01	Maegon Barlow, Director, Office of Radiological Security	National Nuclear Security Administration	Government-Federal	General	We commend the NRC on the measures it has taken to improve the safety and security of Category 1 and 2 sources, including implementation of 10 CFR 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, and the development of the National Source Tracking System (NSTS), the Web-Based Licensing System (WBL) and the License Verification System (LVS). These measures have reduced the risk associated with the use, transfer, and storage of these sources. Furthermore, because Category 3 sources pose risks as well, we believe that it is appropriate to include these sources in the NSTS and to include Category 3 licenses in the WBL.	SA	Letter	03/09/2017	ML17101A592
45.02	Maegon Barlow, Director, Office of Radiological Security	National Nuclear Security Administration	Government-Federal	General	As you know, Am-241, Cs-137, Co-60, and Ir-192 together account for over 99 percent of the sealed sources that pose the highest security risk,* and at the Category 3 level these sources are widely used for: calibration, industrial radiography, fixed industrial gauges, well logging, brachytherapy, and portable gauges.** *U.S. Nuclear Regulatory Commission, "The 2014 Radiation Source Protection and Security Task Force Report: Report to the President and the U.S. Congress Under Public Law I 09-58, The Energy Policy Act of 2005," August 2014 (ADAMS Accession No. ML14219A642). **U.S. Nuclear Regulatory Commission, "Interagency Working Group Report on Financial Assurance for Disposition of Category 1, 2, and 3 Radioactive Scaled Sources," March 2010 (ADAMS Accession No. ML100050105).	SA	Letter	03/09/2017	ML17101A592
45.03	Maegon Barlow, Director, Office of Radiological Security	National Nuclear Security Administration	Government-Federal	General	Additionally, the International Atomic Energy Agency (IAEA) considers Category 3 sources to be sufficiently dangerous to warrant increased safety and security measures. However, these sources are not currently subject to the security requirements of Part 37, nor are they tracked in the NSTS.	SA	Letter	03/09/2017	ML17101A592
45.04	Maegon Barlow, Director, Office of Radiological Security	National Nuclear Security Administration	Government-Federal	General	As the GAO noted in its 2014 Report on radiological source security, many of these sources are used in portable devices and stored in close proximity to one another when not in use.* Many of these sources contain material near the upper Category 3 threshold. For example, this is often the case with Am-241 sources used in portable well-logging devices. As a result, aggregation of these sources remains a concern. *Government Accountability Office, Nuclear Nonproliferation: Additional Actions Needed to Increase the Security of U.S. Industrial Radiological Sources, 2014 (GA0-14-293).	SA	Letter	03/09/2017	ML17101A592

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45.05	Maegon Barlow, Director, Office of Radiological Security	National Nuclear Security Administration	Government-Federal	General	In many cases, only two Category 3 sources are required to create a Category 2 quantity of material. The National Research Council noted that: "Sources that fall into Category 3 and lower can be assembled into Category 2 or 1 quantities of radioactive material. Further, it may be the case that some radiation sources near the upper threshold for Category 3 pose more serious risks than other sources that fall near the lower threshold of Category 2 in scenarios other than those used to create the source categorization system." * The NRC chaired 2014 Federal interagency Radiation Source Protection and Security Task Force Report cited similar concerns.** *National Research Council, Committee on Radiation Source Use and Replacement, "Radiation Source Use and Replacement, Abbreviated Version," 2008. **U.S. Nuclear Regulatory Commission, The 2014 Radiation Source Protection and Security Task Force Report, Report to the President and the U.S. Congress Under Public Law 109-58, The Energy Policy Act of 2005, August 2014 (ADAMS Accession No. ML14219A642).	SA	Letter	03/09/2017	ML17101A592
45.06	Maegon Barlow, Director, Office of Radiological Security	National Nuclear Security Administration	Government-Federal	General	Furthermore, the regulatory and administrative controls over generally licensed devices are not nearly as stringent as those required for specifically licensed sources. In its 2009 recommendation to the Commission to include Category 3 sources in the NSTS, NRC concluded that "[a]dding Category 3 sources to the NSTS with its inventory and tracking requirements will provide increased accountability of these dangerous sources due to timely knowledge of source whereabouts and an ability to confirm an individual licensee's account of its nationally tracked sources within one business day of a transaction." * *US Nuclear Regulatory Commission, SECY -09-0086, "Final Rule: Expansion of the National Source Tracking System (RIN 3150-A129), June 10, 2009.	SA	Letter	03/09/2017	ML17101A592
45.07	Maegon Barlow, Director, Office of Radiological Security	National Nuclear Security Administration	Government-Federal	General	We concur with both the reasoning and the recommendation. Inclusion of Category 3 sources in the NSTS is an effective and efficient way to provide increased security and accountability of dangerous material.	NSTS	Letter	03/09/2017	ML17101A592
45.08	Maegon Barlow, Director, Office of Radiological Security	National Nuclear Security Administration	Government-Federal	General	We appreciate the opportunity to provide input to the important issue and encourage the NRC to proceed with rulemaking.	SA	Letter	03/09/2017	ML17101A592
46.01	Daniel Januseski, RSO	Virtua	Medical	General	We operate a licensed facility that sends and receives Category 3 sources three times per year for a high dose rate afterloading system utilizing a single vendor. This vendor ships us a source and we return our current source to them for disposal. Since we utilize a single pathway and exclusive vendor due to the make/model of our HDR brachytherapy unit, it is unreasonable to require us to spend additional time entering information in the License Verification System (LVS) and the National Source Tracking System (NSTS) for no perceivable security benefit.	LVS	Letter	03/10/2017	ML17101A580

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46.02	Daniel Januseski, RSO	Virtua	Medical	General	Our license does not permit us to possess Category 2 amounts of the Category 3 sources we receive, and to acquire them in aggregate through intentional or unintentional means would take a profoundly unique and unrealistic set of circumstances. We have specific policies in place that were included in our license application that prevent us from possessing Category 2 amounts. In the unlikely event that we would receive an unexpected source that would put us over the Category 2 amount, our response plan it to immediately return the source to the vendor as per our license commitment.	LVS	Letter	03/10/2017	ML17101A580
46.03	Daniel Januseski, RSO	Virtua	Medical	FRN, Security, Q1	The possibility of imposing Part 37 physical security requirements on Category 3 sources would introduce a profound burden to facilities with HDR brachytherapy. Current requirements for source security are sufficient to protect these sources. These sources are secured in controlled areas that a limited amount of staff can access. These staff members have already had background checks conducted in order to gain employment at our facility.	SA	Letter	03/10/2017	ML17101A580
46.04	Daniel Januseski, RSO	Virtua	Medical	FRN, Security, Q1	Requiring us to implement Part 37 requirements would cause us to invest significant resources in security upgrades, development of new policies and procedures, and credentialing of our staff that we do not believe would increase the security of our sources and does not rise to the level of risk perceived by the enhanced security.	SA	Letter	03/10/2017	ML17101A580
47.01	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	General	NRC's proposal to require a higher degree of oversight for Category 3 sources in order to prevent a breakdown of current requirements may be necessary only because there was a failure with the current system.	SA	Letter	03/10/2017	ML17101A552
47.02	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	General	The Pennsylvania Department of Environmental Protection (DEP) wishes to convey that, in our opinion, appropriate requirements for proper security and accountability are already in place. Nevertheless, due to the Government Accountability Office (GAO) investigation, NRC is proposing two additional requirements for Category 3 sources.	SA	Letter	03/10/2017	ML17101A552
47.03	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	FRN, NSTS, Q4	The first requirement [NRC is proposing] necessitates entering Category 3 source licensees into the National Source Tracking System (NSTS) and, second, to then track these licensees within the License Verification System. DEP believes that the first requirement would not necessarily resolve the problem that occurred with the issuance of a license to an unauthorized entity. Specifically, requiring the input of Category 3 sources into the NSTS would not have prevented the GAO from obtaining a license illegally.	NSTS	Letter	03/10/2017	ML17101A552
47.04	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	FRN, NSTS, Q1	In addition, including Category 3 sources in NSTS would double, or possibly triple, the number of trackable sources. Further, tracking sources as low as Category 3 activities would necessitate quarterly updates rather than annual reconciliations to ensure effectiveness. Quarterly updates would be extremely taxing on licensees as well as regulators.	NSTS	Letter	03/10/2017	ML17101A552
47.05	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	FRN, General, Q2	The more optimal response to resolve this liability may be the suggestion to input Category 3 sources into the License Verification System. It should be noted that this would be added work for regulators, especially Agreement States that do not utilize Web-based Licensing, such as Pennsylvania. Nevertheless, it is achievable.	LVS	Letter	03/10/2017	ML17101A552
47.06	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	FRN, General, Q4	Another suggestion that may help to resolve this accountability issue is to require all Radiation Safety Officers for Category 3 licenses to be screened for trustworthy and reliability criteria, similar to Part 37 licensees. This recommended requirement would provide an additional check on the validity of a license applicant.	Cred&SysArc	Letter	03/10/2017	ML17101A552

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47.07	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	FRN, Security, Q2	The NRC should also strongly consider eliminating certificate-level General Licenses (GL) and instead treat these GLs similar to specific licenses. This would eliminate what has been the largest liability NRC and Agreement States encounter. It is DEP's opinion that the vast majority of these certificate-level GLs need a higher degree of oversight by the regulator.	GLDs	Letter	03/10/2017	ML17101A552
47.08	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	FRN, LVS, AS Q1	Pennsylvania has a total of 628 radioactive material licenses and tabulates all Categories 1 and 2 together as Part 37 licensees, formally known as Increased Control licensees. Separating them reveals 32 Category 1 licensees and 31 Category 2 licensees. The remaining (Categories 3, 4, and 5) are treated as specific licensees with Category 3 totaling 91 licensees. As for GLs, there are 179 certificate-level licensees ranging from 6 mCi levels to 4,000 mCi. Pennsylvania has 3 curie and 4 curie americium-241 sources requiring only a GL certificate.	WBL	Letter	03/10/2017	ML17101A552
47.09	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	FRN, LVS, AS Q2	Utilizing the LVS would be a burden for Pennsylvania because it would require entering new and amended Category 3 licenses into the system. However, because we anticipate that verification through the LVS or the transferee's license issuing authority will be a requirement for transfers involving Category 3, we will plan for it and encourage the use of LVS among our licensees.	LVS	Letter	03/10/2017	ML17101A552
47.10	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	FRN, LVS, AS Q3	DEP currently employs its custom eFACTS database, and this department-wide permitting database must be used for all radioactive materials licensing actions. For this reason, the NRC's WBL would be duplicative and so would not be a consideration for Pennsylvania.	LVS	Letter	03/10/2017	ML17101A552
47.11	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	FRN, LVS, AS Q4	DEP believes the NRC regulations, which Pennsylvania incorporated by reference, are currently sufficient for Category 3 licensees. Conversely, it is strongly suggested to eliminate GLs and convert them to specific licenses. This would not have a major impact on Pennsylvania's program and would provide a higher degree of oversight, while eliminating a potential liability.	GLDs	Letter	03/10/2017	ML17101A552
47.12	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	FRN, NSTS, AS Q1	As previously noted, inputting Category 3 sources into NSTS would be a tremendous burden for licensees and Agreement States. For Pennsylvania, it would require one full-time employee to perform this oversight. Adding Category 3 sources to NSTS would also mean increasing the number of entries from 63 to approximately 220 licenses. In addition, annual inputs would need to be increased to quarterly to be effective.	NSTS	Letter	03/10/2017	ML17101A552
47.13	Patrick McDonnell, Acting Secretary	Pennsylvania Department of Environmental Protection	Agreement State	General	In conclusion, DEP wishes to reaffirm that the current regulations are sufficient for preventing the unauthorized issuance of a materials license. Nevertheless, if regulatory amendments are necessary, DEP recommends the consideration of the following three additional requirements: 1. Include Category 3 licenses into the License Verification System. 2. Require trustworthy and reliable screening for Category 3 Radiation Safety Officers. 3. Require all General Licenses be converted to Specific Licenses.	SA	Letter	03/10/2017	ML17101A552
48.01	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	General	The Bureau agrees with NRC Chairman Kristine Svinicki that the current regulatory requirements for transfer of radioactive sources are adequate for safety and security and there is no need to include Category 3 sources in the same requirements as required for Category 1 and 2 sources.	SA	Letter	03/10/2017	ML17101A591

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48.02	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	General	The NRC has not adequately demonstrated the need for additional security requirements for category 3 sources. From 2007-2009, the Government Accountability Office (GAO) had tested the NRC and Agreement State licensing processes and identified vulnerabilities. In response to the GAO's findings, the NRC and Agreement States developed, and implemented a more robust review of applicants, moved away from the good faith presumption, and the NRC recommend inclusion of Category 3 sources in the National Source Tracking System (NSTS) (proposed rulemaking package). As indicated in the background section of this June 2009, FRN the Commission did not reach a decision on the proposed rulemaking (2-2 split vote), and the final rule was not approved. Some of the Commission votes indicated that "further expansion of the NSTS should be based upon a vulnerability assessment, built off an interagency risk study for sources, and that the original recommendation lacked a risk-informed foundation for the proposed regulatory action".	NSTS	Letter	03/10/2017	ML17101A591
48.03	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	General	More recently, item 4 of the October 18, 2016, SRM requires the NRC staff to undertake; "A vulnerability assessment which identifies changes in the treat environment between 2009 today that argue in favor or against expansion of the NSTS to include Category 3 sources." We are unaware that NRC has conducted any such vulnerability assessment. Therefore, we cannot effectively assess what constitutes an acceptable level of burden that would be associated with the inclusion and tracking of Category 3 sources in the NSTS in the absence of a full risk assessment. The acceptable level of burden added should be commensurately offset with the level of risk reduction to be achieved.	SA	Letter	03/10/2017	ML17101A591
48.04	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, General, Q1	No. We consider the current verification of licenses prior to transfer for Category 3 sources to be adequate for safety and security.	LVS	Letter	03/10/2017	ML17101A591
48.05	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, General, Q2	This would not appear to cause any increase in safety or security. It would have the net effect of defeating someone's efforts to acquiring a quantity of material that exceeds valid license limits (either inadvertently or with malicious intent).	SA	Letter	03/10/2017	ML17101A591
48.06	Stephen Gavitt, Director, Bureau of Environmental Radiation	New York Department of Health	Agreement State	FRN, General, Q3	No risk based evidence has been presented to warrant verification. However, if such a requirement is being considered, the different types/uses of Category 3 sources should be considered separately. For example- High Dose Rate afterloader sources are effectively accounted for between the end user and distributor.	SA	Letter	03/10/2017	ML17101A591

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48.07	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, General, Q4	Please conduct a full risk assessment and actively involve the states in that assessment.	SA	Letter	03/10/2017	ML17101A591
48.08	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, NSTS, Q1	There is insufficient information to make a determination. What reduction in risk would be achieved by requiring the inclusion of Category 3 sources in the NSTS.	NSTS	Letter	03/10/2017	ML17101A591
48.09	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, NSTS, Q2	We do not believe Category 3 sources should be included in NSTS.	NSTS	Letter	03/10/2017	ML17101A591
48.10	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, NSTS, Q3	If such was implemented what dates would NRC track in NSTS? Would it include the shipment date, anticipated arrival date, and actual arrival date. And if so who wound monitor this information? There is no basis for such a change.	NSTS	Letter	03/10/2017	ML17101A591
48.11	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, NSTS, Q4	The answer to the question is best answered following a full risk assessment.	SA	Letter	03/10/2017	ML17101A591
48.12	Stephen Gavitt, Director, Bureau of Environmental Radiation	New York Department of Health	Agreement State	FRN, NSTS, Q5	The answer to the question is best answered following a full risk assessment.	SA	Letter	03/10/2017	ML17101A591
48.13	Stephen Gavitt, Director, Bureau of Environmental Radiation	New York Department of Health	Agreement State	FRN, LVS, AS Q1	Approximately 100.	LVS	Letter	03/10/2017	ML17101A591

Comments Received from Category 3 Source Security and Accountability Public Meetings and *Federal Register* Notice (82 FR 2399)

Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

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48.14	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, LVS, AS Q2	Although we would encourage the use of any database over manual processes, we understand that the LVS is only as good as the information it contains, i.e., current licenses/amendments. The most accurate means would be manual- contact the licensing authority for the most recent information.	WBL	Letter	03/10/2017	ML17101A591
48.15	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, LVS, AS Q3	The issue of Category 3 source tracking has no bearing or effect on our decision to use or not to use the WBL application. Our program is undergoing efforts to create a single regulatory database that will include radioactive material licensees, x-ray equipment registrants and incident/event tracking. We do not intend to implement the WBL unless it meets our overall program needs.	WBL	Letter	03/10/2017	ML17101A591
48.16	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, LVS, AS Q4	A full risk based analysis is needed before we can comment on the value of source tracking and the verification methods that could be used.	SA	Letter	03/10/2017	ML17101A591
48.17	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, NSTS, AS Q1	The annual reconciliation process is not administered by the NRC on behalf of the Agreement States. Rather, the Agreement States assist the Commission with the annual reconciliation in the specific situation where the license fails to supply the required information by the January 31 deadline. The responsibility for the NSTS rests with individual licensees and the NRC only. We have no plans to adopt an NRC responsibility.	NSTS	Letter	03/10/2017	ML17101A591
48.18	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, Security, Q1	Absolutely not. However, the compatibility category for Part 37 should be changed to "C" to allow states to expand upon the equivalent of Part 37 requirements, in whole or part. This would allow a state to choose to include Category 3 sources, add requirements for global positioning systems, etc.	SA	Letter	03/10/2017	ML17101A591
48.19	Stephen Gavitt, Director, Bureau of Environmental Radiation Protection	New York Department of Health	Agreement State	FRN, Security, Q2	Yes. NYS DOH has set the threshold for material possessed under a general license for certain devices containing gamma emitters, strontium-90 and transuranic nuclides to below one millicurie.	GLDs	Letter	03/10/2017	ML17101A591

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49.01	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, General, Q1	The License Verification System, when up-to-date, provides a licensee (manufacturer & distributor or other transferor) the access to a controlled original copy of an issued radioactive materials license for ensuring the intended recipient of a sealed source is authorized to possess said source. In theory, extending the use of the LVS/Part 37.71 verification methods to include Category 3 licenses would provide a transferor the insurance that the intended recipient is duly authorized, which could have potentially mitigated the second half of the 2014-2016 GAO 'performance audit'.	LVS	Letter	03/09/2017	ML17101A554
49.02	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, General, Q2	If the NRC were to extend the use of LVS and Part 37.71 verification methods to include Category 3 licenses, QSA Global suggests that a graded approach be applied; we see a very small potential security benefit for M&D use of Part 37.71 verifications for Category 3 quantity transfers, but we do not see any security benefit to having a licensee perform a verification when returning a source to a manufacturer/distributor.	LVS	Letter	03/09/2017	ML17101A554
49.03	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, NSTS, Q1	It is our opinion that the addition of Category 3 sources to the national source tracking system would place a significant additional burden on both industry and the NRC for a questionable I negligible safety and security benefit. With regard to the 2014-2016 GAO performance audit, neither the lack of due diligence by the issuing regulator, nor the modified license used by GAO would have been detected by the inclusion of Category 3 quantities in NSTS.	NSTS	Letter	03/09/2017	ML17101A554
49.04	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, NSTS, Q1	Due to the high volume of daily transactions that we generate, QSA Global has automated the majority of our NSTS transactions, and even with this automation we expend approximately 1/2 a Full-Time Equivalent in staff hours on NSTS related issues. If the NSTS role were to be expanded, it is my understanding that there is estimated to be a greater than four-fold increase in sources that would potentially need to be included. We would anticipate a similar increase in staffing effort as a result. The distributed effort to all impacted licensees would likely be proportionate.	NSTS	Letter	03/09/2017	ML17101A554
49.05	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, NSTS, Q1	Additionally, for industries that currently handle no more than Category 3 quantities (oil well logging industry, for example), the NRC and these licensees would each be burdened with a repeat of the initial inventory upload, registration, and credentialing efforts experienced by Category 1 and 2 licensees at the onset of the NSTS. The additional administrative burden for both regulators and industry, in our opinion, is not justified by the unquantified security benefit.	NSTS	Letter	03/09/2017	ML17101A554
49.06	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, NSTS, Q2	The current reporting requirements for Category 1 and 2 sources we feel are adequate and do not require an increase in the immediacy of information availability. Category 1 transfers require significant advanced planning and coordination with intermediate authorities and receiving licensees. Domestic transactions for Category 2 sources are primarily with established and vetted customers and manufacturers, and international transactions involving Category 1 and 2 sources already require a minimum of 24 hours (for export) or 7 days (for import) advance notice to the Office of International Programs. We have not been presented with any evidence that suggests a need for more immediate information availability.	NSTS	Letter	03/09/2017	ML17101A554
49.07	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, LVS, Q1	Members of QSA Global staff are credentialed for use of LVS, but we still make use of both Form 748 and direct regulatory contact due to the current lag in LVS updates by various Agreement State regulatory agencies. Additionally, as stated earlier, we do not see a safety or security benefit to requiring a transferor to use Part 37.71 verification processes when transferring a source to a manufacturer.	LVS	Letter	03/09/2017	ML17101A554

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49.08	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, LVS, Q2	We prefer not to provide transaction volume information; however, our transfer transactions are over 90% Category 2 quantities, whereas our receipts (discounting aggregation) are roughly 75% Category 3 discrete sources.	LVS	Letter	03/09/2017	ML17101A554
49.09	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, NSTS licensees, Q2	Members of QSA Global staff are credentialed for us of NSTS, but our primary interaction with NSTS is in the form of automated batch data uploads. Discrepancies are handled through correspondence with the NSTS Help Desk. On infrequent occasions a staff member will log in to NSTS to enter or modify a transaction.	NSTS	Letter	03/09/2017	ML17101A554
49.10	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, NSTS licensees, Q2	One improvement that we feel would be beneficial is the ability to provide notifications of Alerts to multiple staff members. We are a multi-license organization; the ability to set up Alert notifications to the respective RSO would alleviate a single point of failure for response.	NSTS	Letter	03/09/2017	ML17101A554
49.11	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	General	QSA Global understands the need for, and absolutely endorses, ensuring the security and safety of radioactive materials. The potential for the mal-use of commercially available radioisotopes is very real. We feel, however, that a blanket approach to applying security measures places undue burden on both regulators and industry with little to no increased benefit, as the relative usefulness of a source for nefarious acts varies widely.	SA	Letter	03/09/2017	ML17101A554
49.12	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	General	The development of source categorization by the IAEA was based on multiple factors, including use in industry, deterministic effects, chemical and physical form, etc. If a similar approach were used to develop safety and security implementation measures, perhaps a more reasonable program may be realized. As a specific example, if a focus of the safety and security measures is to ensure that radioactive material is not acquired for an end use as a radiological dispersal device, the physical form of the radioactive material should be taken into consideration in addition to the radioactive content. The registered form for encapsulated Ir-192, for example, is either metallic wafers or pellets, neither of which are practical forms for dispersal. As such, tracking and control of Ir-192 sources may not require the same level of diligence as for a Cs-137 sealed source (whereas currently the Category 2 threshold for Ir-192 is lower than that of Cs-137).	SA	Letter	03/09/2017	ML17101A554
49.13	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	General	QSA Global believes that based on experience currently available data, expansion of the ISMP to encompass Category 3 quantity sealed sources is not warranted; the increased regulatory and industry burden outweighs the perceived threat.	SA	Letter	03/09/2017	ML17101A554
50.01	John E. Hearne	Hearne Wireline Service	Industrial	General	I operate a very small oil field cased hole logging business in a very remote area. I use 2 each 3 ci (Cat. 3) Am241be sources in my business, and have no (0) Cat.1 or Cat.2 sources, so this would involve creating a system to monitor, and track sources above the systems that I have in place to secure the Cat. 3 sources. The cost could be higher than $200,000 for this.	SA	Web	03/10/2017	ML17101A571

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50.02	John E. Hearne	Hearne Wireline Service	Industrial	General	I am very concerned about radioactive material being used for illicit purposes, and take care to assure that my sources are secured and will not be taken by someone with bad intentions. The security, tracking and monitoring of these sources under Cat.2 level would require more personnel than I employ in normal operations, and would be a burden that will not increase public safety in any way. A very large cost with no benefit.	SA	Web	03/10/2017	ML17101A571
50.03	John E. Hearne	Hearne Wireline Service	Industrial	General	There has been no case where an Oil Field Service Company has had a source lost or sold one in a way that it could be used for illicit purposes, and we as an industry, and individual operators of businesses have procedures to prevent this form happening.	SA	Web	03/10/2017	ML17101A571
50.04	John E. Hearne	Hearne Wireline Service	Industrial	General	The case that this is bases on was a failure of an Regulatory Agency, not the Well Logging Industry. The additional regulatory burden on these agencies will overtax their overworked, understaffed operations that regulate and oversee enforcement of the industry. The additional burden will hinder their ability to properly oversee our industry.	SA	Web	03/10/2017	ML17101A571
51.01	William Pate	University of Texas Medical Branch	Medical	General	In response to the GAO investigation being a reason for implementing additional controls for Category 3 sources: The problem with any state issuing a license to a non-valid entity will not be fixed by imposing additional constraints on licensees. A non-valid entity could still receive a license, if not properly vetted by the delegated authority.	SA	Letter	03/10/2017	ML17101A551
51.02	William Pate	University of Texas Medical Branch	Medical	General	In response to the Government Accountability Office (GAO) investigation revealing the ability to acquire an aggregated quantity of Category 2 material: It currently takes a general license or specific license to obtain radioactive material, so any concern about aggregating Category 3 materials to Category 2 levels will not be resolved by instituting additional requirements on existing licensees. This is an administrative issue which must be resolved by the NRC or Agreement State.	SA	Letter	03/10/2017	ML17101A551
51.03	William Pate	University of Texas Medical Branch	Medical	FRN, NSTS, Q1	In response to the rationale for including Category 3 sources in the National Source Tracking System (NSTS): Has there been a demonstrated, credible threat posed by Category 3 sources not being included in the NSTS? Additionally, prior to including Category 3 sources, it would be useful to address who must enter updates to the system and the timing of those updates. For instance, for high dose-rate (HDR) sources that are changed out quarterly, there is a source that is incoming from the vendor and a source that is outgoing from the licensee/vendor, usually with FedEx as the courier. Would the NSTS update occur when each source is handed to FedEx and then again when the licensee and vendor each take control of the source? Again, clarification of who is required to update and the timing of those updates would be useful.	NSTS	Letter	03/10/2017	ML17101A551
51.04	William Pate	University of Texas Medical Branch	Medical	FRN, NSTS, Q1	In response to whether or not the NRC should consider expanding physical security requirement to Category 3 sources: The burden would be significant while the benefits seem limited. Example 1: Implementing Part 37 security requirements for Category 3 sources would create a tremendous burden in terms of money, time, and other resources for our institutions. If additional security controls are applied to HDR, an exponentially larger number of people would be added to the vetting process currently only required of Category 1 & 2 sources. There would be no measurable increased safety or security, given that there are already stringent security rules in place for these sources.	SA	Letter	03/10/2017	ML17101A551

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51.05	William Pate	University of Texas Medical Branch	Medical	FRN, Security, Q1	Additional concerns with including HDR units are: a. Given that the HDR units are often (and necessarily) portable for the purpose of positioning patients, how would security features such as the radio-frequency identification (RFID) be implemented? b. At our institution, we have 9 therapeutic medical physicists and radiation oncology physicians authorized to conduct HDR treatments. These individuals would need to be vetted as Trustworthy & Reliable. This does not include the numerous dosimetrists, nurses, therapists, residents, and fellows and other support staff who may also be involved in these types of treatments. All of these individuals would have already undergone extensive background checks by the nature of their job in healthcare, and thus substantial additional effort and cost would be expended to fingerprint, investigate and T&R all of these individuals based upon rules currently in place under Part 37. c. As an academic medical center responsible for training medical students and residents, requiring these individuals to become deemed T&R prior to having unescorted access to an HDR source could delay their educational program d. The cost of installing and maintaining the additional security features for our HDR suite will be considerable. In addition, due to the location of our HDR suite and the fact that we are located on a barrier island, we are required to relocate our HDR source to higher ground when there is the potential for a hurricane. Installing these additional security features in this secondary location would involve considerable cost with no discernable benefits. e. Our campus police department (UTPD) force is required to respond to each and every alarm for the Increased Control units. These alarms are easily tripped accidentally. In non-sterile treatment areas, police responding to accidentally triggered alarm will interrupt in-progress treatment in an HDR suite. Treatments in progress could potentially be interrupted.	SA	Letter	03/10/2017	ML17101A551
51.06	William Pate	University of Texas Medical Branch	Medical	FRN, Security, Q1	Costs: Possible cost to UTMB for T&R process: 50 people x $50 per person = $2,500.00 Possible cost to UTMB for implementation of complete security requirements for each room (primary location & hurricane relocation area = $100,000 x 2 locations = $200,000.00. These costs do not include the costs of additional staffing for vetting, security checks, alarm response, etc. It also does not include the costs in lost time, lost revenue, and patient treatment interruptions while the systems are being installed.	SA	Letter	03/10/2017	ML17101A551
51.07	William Pate	University of Texas Medical Branch	Medical	General	Although the requirement to track Category 3 sources via the NSTS may not be overly burdensome, additional clarification is needed as to the timeframe required for HDR sources that are changed out on a quarterly basis. The implementation of additional security requirements (increased controls) for Category 3 radioactive materials would be overly burdensome, negatively impact patient care and educational programs, and result in limited benefits.	SA	Letter	03/10/2017	ML17101A551

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52.01	Craig H. Piercy, Co-Chair	Source Security Working Group	NGO	General	In general, Category 3 commercial sources have a long record of safe and secure usage. Over the past decade, a total of 37 Category 3 sources have been reported lost, abandoned or stolen, excluding irretrievable well-logging events, with only three not recovered.* It is our understanding that two of these three were plutonium-powered pacemakers buried with the deceased, and the third is currently at the bottom of the Gulf of Mexico. Additionally, as the NRC notes, "there has been no overall increase in the number or types of suspicious activities tracked by the NRC that are related to the use of radioactive materials" at facilities which contain them.** *SECY-16-0050 Enclosure: "Nuclear Material Event Database: Annual Report." U.S. Nuclear Regulatory Commission, March 2015, p 6. https://www.nrc.gov/docs/ML1606/ML16060A360.pdf **"Effectiveness of Part 37 of Title 10 of the Code of Federal Regulations." U.S. Nuclear Regulatory Commission, December 2016, p 14. https://www.nrc.gov/docs/ML1634/ML16347A398.pdf	SA	Letter	03/10/2017	ML17101A568
52.02	Craig H. Piercy, Co-Chair	Source Security Working Group	NGO	General	A significant thrust of NRC's request for comments is aimed at quantifying the "increase in safety and/or security" of the various enhanced accountability measures proposed in the notice. Given that this notice was prompted in large part by the 2015 GAO-16-330 "sting" audit, we interpret these safety and security benefits to refer to reductions in public risk from illicitly-obtained Category 3 sources for use in terrorist acts. To this end, SSWG agrees with the conclusion of the National Research Council: "It is not possible to monetize the terrorism risks because we do not have a firm basis for predicting the relationship between particular radiation source uses and the expected costs of terrorism. While it may be possible to identify representative scenarios of RDD deployment or other acts of terrorism involving radiation sources, it is not possible to quantify the probabilities of these scenarios or how any particular type of radiation source contributes to them."* *"Radiation Source Use and Replacement." Committee on Radiation Source Use and Replacement, National Research Council, National Academies of Science, 2008.	SA	Letter	03/10/2017	ML17101A568
52.03	Craig H. Piercy, Co-Chair	Source Security Working Group	NGO	General	As such, any identified benefit of a proposed change should be considered a "qualitative factor" for purposes of NRC consideration, and use of that qualitative factor should be as limited as possible in order to "make every reasonable effort to apply alternative tools that can provide a quantitative perspective…concerning the value of the proposed action."* *NUREG/BR-0058, Rev 4: "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," U.S. Nuclear Regulatory Commission, September 2004, p. 24. https://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/br0058r4.pdf	SA	Letter	03/10/2017	ML17101A568
52.04	Craig H. Piercy, Co-Chair	Source Security Working Group	NGO	General	Given the lack of proposed methodology and data to measure these benefits, the inherent uncertainties in qualifying the benefits of proposed changes should also be taken into account within the NRC's analysis. Any analysis should also take care to "distinguish the effects that are likely to be significant enough to warrant serious consideration by decision-makers from those that are likely to be minor."5 It is the opinion of the SSWG that any benefits qualified by NRC analysis are likely to fall into the latter category.	SA	Letter	03/10/2017	ML17101A568

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52.05	Craig H. Piercy, Co-Chair	Source Security Working Group	NGO	FRN, NSTS, Q1	We do not support inclusion of Category 3 sources in the NSTS, or any additional rulemaking on security or tracking requirements at this time. The SSWG believes that current security, tracking, and verification requirements for Category 3 quantities of radioactive material are safe, effective, and appropriate given the level of risk for Category 3 sources as compared to Category 1 and 2, and as proven by the positive historical safety and security record of use, handling and transport of these sources.	SA	Letter	03/10/2017	ML17101A568
52.06	Craig H. Piercy, Co-Chair	Source Security Working Group	NGO	FRN, NSTS, Q4	Given the risk level involved, it is difficult to quantify any meaningful or tangible benefits that may accrue by including Category 3 sources in the NSTS. Conversely, the increased burden to both industry and regulators is easier to measure. Including Category 3 sources in the NSTS would result in increased costs and time spent by both industry and regulators ensuring compliance. Further, significant resources would be required by NRC to: 1) ensure NSTS is robust enough to manage the ongoing and very significant influx of Category 3 source data while not decreasing its capability to properly and adequately manage Category 1 and 2 source data; 2) physically manage the administration of NSTS physically; and 3) monitor, analyze and take appropriate action derived from information in the NSTS. This increased burden is not in line with the risks Category 3 quantities of radioactive material may pose.	NSTS	Letter	03/10/2017	ML17101A568
52.07	Craig H. Piercy, Co-Chair	Source Security Working Group	NGO	FRN, General, Q2	Although we do not support further tracking and security requirements in general, specifically including Category 3 sources in a License Verification System (LVS) in order to verify licensees before transfer, may provide an increase in safety and security for users and regulators. Again, the benefit is difficult to quantify, but verifying licensees before transfer would not be as burdensome as full implementation of both NSTS and LVS systems for industry and regulators.	LVS	Letter	03/10/2017	ML17101A568
52.08	Craig H. Piercy, Co-Chair	Source Security Working Group	NGO	FRN, General, Q2	However, while including Category 3 sources in LVS would help prevent license forgery, LVS as currently structured would not prevent bad actors from aggregating quantities of material in excess of their licensed limit from multiple providers simultaneously.	LVS	Letter	03/10/2017	ML17101A568
52.09	Craig H. Piercy, Co-Chair	Source Security Working Group	NGO	FRN, NSTS, Q3	We do not support any changes to the NSTS reporting requirements for Category 1 and 2 to increase the immediacy of information available. Current reporting requirements are safe and effective, and changes to the requirements would not provide any meaningful additional safety or security benefits.	NSTS	Letter	03/10/2017	ML17101A568
53.01	Aida Guzman-Crawford	Texas Department of Transportation	Government-State	General	This new rule would impact our operations. We currently have on inventory close to 400 Nuclear Density Gauges (NDG). These NDG's are stored in over 119 permanent sites STATE-WIDE. We currently track our NDG's four ways. 1. MES - Inventory number assigned to the NDG. 2&3. SN, make and model are tracked in Calibration Manager. Calibration assigns an ID# to the NDG's. 4. We conduct 6 month inventory reporting not to exceed 6 month's. In addition when transferring or relocating an NDG we complete a form to show the traceability of the NDG at all times. With al of these tools in place there is no need to add another method of tracking. We currently do not have the man-power to comply with this rule.	GLDs	Web	03/10/2017	ML17101A573
54.01	James M. Phillips, Managing Attorney	The University of Texas System	Medical	FRN, Security, Q1	We respectfully caution against such an expansion. The burden would be significant while the benefits seem limited.	SA	Letter	03/10/2017	ML17101A583

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54.02	James M. Phillips, Managing Attorney	The University of Texas System	Medical	FRN, Security, Q1	Example 1: Implementing Part 37 security requirements for Category 3 sources would create a tremendous burden in terms of money, time, and other resources for U.T. System institutions. Existing requirements to that regulate Gamma Knife use under the increased control regulations is already a huge inconvenience for staff and patients alike. If additional controls are applied to HDR, a far more common modality, an exponentially larger number of people would be added to the vetting process. There would be no measurable increased safety or security, given that there are already stringent security rules in place for these sources.	SA	Letter	03/10/2017	ML17101A583
54.03	James M. Phillips, Managing Attorney	The University of Texas System	Medical	FRN, Security, Q1	Additional concerns with including HDR units are: a. Given that the HDR units are often (and necessarily) portable for the purpose of positioning patients, how would security features such as the radio-frequency identification (RFID) be implemented? b. At one of the U.T. System institutions, there are approximately 110 therapeutic medical physicists and radiation oncology physicians authorized to conduct HDR treatments. These individuals would need to be certified as Trustworthy & Reliable. This does not include the numerous dosimetrists, residents, and fellows who may also be involved in these types of treatments. c. The cost of installing and maintaining the additional security features for each HDR suite will be considerable. d. At one U.T. System facility, we currently have six suites, including one in a special operating room (OR). The device in the OR suite is currently locked in a secure cabinet when not in use. If additional security requirements are instituted, then Part 37 security features would be required. This would require any nurse, surgeon, or technician, using that room for other types of surgical patients to be fully vetted. This would be burdensome to our medical institutions.	SA	Letter	03/10/2017	ML17101A583
54.04	James M. Phillips, Managing Attorney	The University of Texas System	Medical	FRN, Security, Q1	Example 2: Sources used for calibrating exposure rate meters fall into Category 3. Storage areas or facilities where these sources are used will be required to meet Part 37 regulations. This seems unnecessary, given that existing security and training has been adequate in the past.	SA	Letter	03/10/2017	ML17101A583
54.05	James M. Phillips, Managing Attorney	The University of Texas System	Medical	FRN, Security, Q1	Example 3: Implementation of IC requirements for Category 3 sources would adversely impact two teaching laboratories at one UT System institution alone. Given the frequent turnover of students and teaching assistants, it would not be possible to certify these individuals as T&R in a timely manner. This would reduce the educational opportunities for the students. If the students and teaching assistants have to be escorted by T&R certified faculty and staff, it would a place a burden on the institution to hire additional T&R certified staff.	SA	Letter	03/10/2017	ML17101A583
54.06	James M. Phillips, Managing Attorney	The University of Texas System	Medical	FRN, Security, Q1	The cost to implement changes across the U. T. System will be prohibitive. Possible cost to one U.T. System medical institution will be: 200 people x $50 per person = $10,000.00. Possible cost for implementation of complete security requirements for each room at a U.T. System Medical institution = $100,000 x 6 additional locations = $600,000.00 These costs do not include the costs of additional staffing for vetting, security checks, alarm response, training, writing security plans, or monitoring at dispatch locations. These will be recurring costs. It also does not include the costs in lost time, lost revenue, or patient treatment interruptions while the systems are being installed.	SA	Letter	03/10/2017	ML17101A583

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Unique Identifier	Individual	Organization	Stakeholder Type	FRN Question	Comment	Bin	Comment Format	Date Written	Accession No.
55.01	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, General, Q1	Does NRC have an estimate of the number of NRC and Agreement State licensees that solely possess Category 3 sources?	WBL	Transcript p18	01/31/2017	ML17045A353
55.02	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, General, Q1	Does NRC have an estimate of the number of NRC and Agreement State licensees that solely possess Category 3 in aggregate?	WBL	Transcript p18	01/31/2017	ML17045A353
55.03	Janet Schlueter	Nuclear Energy Institute	NGO	FRN, General, Q1	When will NRC staff complete their vulnerability assessment for Category 3 sources and what will the assessment consider?	SA	Transcript p19	01/31/2017	ML17045A353
55.04	Janet Schlueter	Nuclear Energy Institute	NGO	FRN, General, Q1	Will NRC conduct public meetings about the Category 3 vulnerability assessment?	SA	Transcript p19	01/31/2017	ML17045A353
55.05	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, General, Q2	Is the License Verification System active?	LVS	Transcript p21	01/31/2017	ML17045A353
55.06	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, General, Q2	As a Category 3 licensee, not familiar with the License Verification System, how does it function?	LVS	Transcript p21	01/31/2017	ML17045A353
55.07	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, General, Q2	As a Category 3 licensee, not familiar with the License Verification System, how long does it take to be credentialed?	Cred&SysArc	Transcript p22	01/31/2017	ML17045A353
55.08	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, General, Q2	As a Category 3 licensee, not familiar with the License Verification System, is the system available 24/7?	LVS	Transcript p22	01/31/2017	ML17045A353
55.09	Lynne A. Fairobent	self	Medical	FRN, General, Q2	Is the License Verification System widely used by Agreement State Licensees?	LVS	Transcript p23	01/31/2017	ML17045A353
55.10	Lynne A. Fairobent	self	Medical	FRN, General, Q2	Are all Agreement State licenses in LVS? Or just Category 1 and 2 material?	WBL	Transcript p23	01/31/2017	ML17045A353
55.11	Lynne A. Fairobent	self	Medical	FRN, General, Q2	Would Agreement State licenses for Category 3 have to be added to NSTS?	NSTS	Transcript p24	01/31/2017	ML17045A353
55.12	Lynne A. Fairobent	self	Medical	FRN, General, Q2	Is the License Verification System robust enough to handle the increase associated with real time verification of Category 3 licenses?	Cred&SysArc	Transcript p24	01/31/2017	ML17045A353
55.13	Lynne A. Fairobent	self	Medical	FRN, General, Q2	Has there been any estimate or verification that the system can handle the additional burden of content?	Cred&SysArc	Transcript p25	01/31/2017	ML17045A353
55.14	Lynne A. Fairobent	self	Medical	FRN, General, Q2	There are concerns from the end-user standpoint, putting all the "eggs in one basket", regarding expanding NSTS and WBL to accommodate Category 3 sources and licenses, security, and cybersecurity. If someone wants to defeat the system they can, no system is 100 percent secure.	Cred&SysArc	Transcript p26	01/31/2017	ML17045A353

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55.15	Lynne A. Fairobent	self	Medical	FRN, General, Q2	There are concerns from the end-user standpoint regarding the usability.	Cred&SysArc	Transcript p26	01/31/2017	ML17045A353
55.16	Lynne A. Fairobent	self	Medical	FRN, General, Q2	My comments are on record from 2009, I'd prefer that you pull those comments.	Cred&SysArc	Transcript p25	01/31/2017	ML17045A353
55.17	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, General, Q2	Does the NRC have a methodology to quantify the increase in safety and security for tracking of Category 3 materials?	SA	Transcript p27	01/31/2017	ML17045A353
55.18	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, General, Q2	Can NRC share this methodology with the public?	SA	Transcript p27	01/31/2017	ML17045A353
55.19	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, General, Q2	Industry could provide the costs associated with the increased tracking of Category 3 materials (i.e. time spent by licensees.) However, industry is challenged by estimating the benefit. It is not clear what level of benefit is truly being gained, other than a couple of GAO stings there's been no other publicly reported incidents of attempting to purchase radioactive material with a falsified license.	SA	Transcript p28	01/31/2017	ML17045A353
55.20	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, General, Q3	Clarify NRC's expectations regarding question 3.	NSTS	Transcript p30	01/31/2017	ML17045A353
55.21	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, General, Q3	Not certain how the manufacturer and distributor could be the only entity verifying licenses. There's liability being transferred and uncertainty if the recipient would be comfortable with the M&D doing all the verification. M&Ds use often, but once at Category 3 and there are many end users that will be sending shipments back to customers or distributors. It will be more complex than it is now, not in favor of using surrogates to make verifications for another licensee.	LVS	Transcript p31	01/31/2017	ML17045A353
55.22	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, General, Q3	Clarify the situation that NRC is envisioning with question 3. Is NRC envisioning the situation where the licensee is only purchasing sources from a one vendor and returning those sources back for disposal, would that situation be exempted? For example, Category 3, this would include HDR Ir-192 sources, depending on the manufacturer of the device there may be only one supplier. Basically, for that device, the licensee has a back and forth relationship with the supplier, is this the circumstance that you would consider an exemption?	LVS	Transcript p32	01/31/2017	ML17045A353
55.23	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, General, Q3	General question, does this effort apply only to the radionuclides listed in Part 37 or NSTS? Or is NRC considering expanding this to other radionuclides?	SA	Transcript p34	01/31/2017	ML17045A353
55.24	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, General, Q3	There's a flaw in the verification requirements regarding timeliness. As an M&D, Cat 1, 2 or 3 sources could be shipped to the same customer multiple times per week or month. How long is a license verification good for? Does it have to be done prior to every transfer? Once a month, or every 30 days, if transferring to the same customer? The timeliness of verification should be considered too.	LVS	Transcript p35	01/31/2017	ML17045A353

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55.25	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS, Q1	No, Category 3 sources should not be included in NSTS. The number of sources the NRC would be collecting data on would be overwhelming. In accordance with existing NRC regulations, licensees have in place requirements for maintaining inventories. These existing requirements are adequate to track Category 3. It is not clear what increase in safety and security will be gained by the effort expended by licensees to report to NSTS. This licensee considers NSTS like a checkbook ledger, it keeps track of items. There is no way to prevent a theft with NSTS. The licensee or NRC might be able to put together some steps and maybe find out where something might be missing if it isn't received in time, but insofar as the effectiveness of an increase in the safety and security for Category 3, NSTS doesn't provide that benefit.	NSTS	Transcript p37	01/31/2017	ML17045A353
55.26	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, NSTS, Q1	How many instances has NSTS identified a lost or stolen source? This is the basis for considering expanding NSTS to Category 3. If the NSTS hasn't identified this situation for Category 1 and 2 sources, it doesn't appear to be a benefit to expand NSTS to Category 3 sources.	SA	Transcript p37	01/31/2017	ML17045A353
55.27	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, NSTS, Q1	How many licensees are involved with the tracking of Category 1 and 2? How does this compare to the 5,500 being added in by expanding to Category 3?	NSTS	Transcript p38	01/31/2017	ML17045A353
55.28	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS, Q2	In addition to being an M&D, one company also recycles dis-used sources. Many sources received are just above Category 2 thresholds and then they decay to Category 3 quantities prior to disassembly. What would happen to Category 2 sources that decay below the threshold? Are those still within NSTS? If NSTS, expands to Category 3, would NRC return those sources to NSTS? And would the licensee that last held those sources be given a spreadsheet to identify whether the sources still exist? Because, at this M&D they've received thousands of sources that have decayed below Category 2, they still possess some and others have been transferred.	Cred&SysArc	Transcript p41	01/31/2017	ML17045A353
55.29	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS, Q2	Category 3 sources should not be included in NSTS. However, if NRC intends to expand NSTS to include Category 3, a graded approach should be applied to the reporting requirements. Category 3 are much less of a safety and security risk than Category 1 and 2 sources. So, the current NSTS reporting requirements should not be applied to Category 3. For example, the NRC should consider a longer time or longer grace period to report to NSTS.	NSTS	Transcript p43	01/31/2017	ML17045A353
55.30	Lynne A. Fairobent	self	Medical	FRN, NSTS, Q2	There are two ways to report to NSTS - electronic or through submittal of the form. Does NRC know the percentage of licensees are doing electronic reporting versus sending the form? This could impact the usability of NSTS as additional sources or licensees are added into the system. Additionally, what is the delay for data entry, for those that are not automatically entered in? Receiving an email or faxed form demonstrates that NSTS is not real time.	Cred&SysArc	Transcript p44,45	01/31/2017	ML17045A353
55.31	Michael Fuller, Director, Regulatory Affairs/Quality Assurance	QSA Global	Industrial	FRN, NSTS, Q2	Based on the volume of Category 1 and 2 sources one M&D licensee already reports to NSTS, this licensee estimated that their administrative burden would double if NSTS expanded to include Category 3 sources. This licensee estimates that they are expending 0.5 FTE and expanding to Category 3 would double the effort. The M&D estimated that expanding to Category 3 would mean reporting 30-60 additional transactions per day.	NSTS	Transcript p46,47	01/31/2017	ML17045A353

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55.32	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, NSTS, Q3	No. Prior to transferring Category 1 or 2, the licensee is required to coordinate the shipment arrival times with the receiving licensee. For Category 1 transfers, this also includes notifications and routing and time estimate. Reporting to NSTS prior to the shipment is problematic, shipments don't always leave the M&D facility at the originally scheduled time. The value of revising the reporting times to NSTS as suggested, isn't clear.	NSTS	Transcript p49	01/31/2017	ML17045A353
55.33	Lynne A. Fairobent	self	Medical	FRN, NSTS, Q5	Credentialing of a user only applies to individuals accessing the system? Is credentialing required for faxing the information or sending an email? This is an important point for Category 3 licensees understand. There's an increased burden for licensees to go through the credentialing process. It should be clear that they can avoid this process if they choose to submit information by another means.	Cred&SysArc	Transcript p53	01/31/2017	ML17045A353
55.34	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, LVS, Q1	The online access is limited. LVS or NSTS cannot be accessed using a wireless connection. This is something Category 3 licensees should consider.	Cred&SysArc	Transcript p56	01/31/2017	ML17045A353
55.35	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, LVS, Q1	Is the credentialing process specific to an individual? Could it be specific to the licensee, such that the only the licensee goes through the credentialing process?	Cred&SysArc	Transcript p57	01/31/2017	ML17045A353
55.36	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, LVS, Q1	As a medical licensee, Category 3 sources are typically being exchanged once per quarter per device. On average licensees have 1 or 2 devices. So every quarter the license would be conducting verification. Most likely the medical physicist or RSO would be involved in the verification process, these individuals do change, not frequently. The credentialing process could be a huge burden especially given the infrequency of verification. The credentialing process would be unlikely for medical licensees - because of the low verification frequency and the use of a single vendor - it's basically a "paperwork" shuffle. Don't see any benefit to this.	Cred&SysArc	Transcript p58	01/31/2017	ML17045A353
55.37	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, Q1	Believe its likely that most Category 3 users would use the manual system instead of the credentialing process. NRC should consider the impact, both to NRC and Agreement States, for more licensees to be conducting manual verification. Manual verification requires more time for the NRC staff, their Help Desk, and Agreement State staff.	Cred&SysArc	Transcript p60	01/31/2017	ML17045A353
55.38	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, Q1	Medical physicists who could be interacting with LVS because of HDR applications, will work for a variety of licensees, but may not have their own radioactive material license. Does such an individual need to be credentialed with each licensee, or would it be just one credential?	Cred&SysArc	Transcript p62	01/31/2017	ML17045A353
55.39	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, Q1	Note, a hospital can have a number of medical physicists that work there at any time, so it would be an increased burden for licensees to do the employment verification every time.	Cred&SysArc	Transcript p63	01/31/2017	ML17045A353

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55.40	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, LVS, Q1	Is there a cost associated with the credentialing process? Provide clarification on the token.	Cred&SysArc	Transcript p65	01/31/2017	ML17045A353
55.41	Cindy Tomlinson	American Society for Radiation Oncology	NGO	FRN, LVS, Q1	Do you have to do the license verification each time you submit?	LVS	Transcript webinar notes	01/31/2017	ML17045A353
55.42	Jack Tway	New Jersey	Agreement State	FRN, LVS, Q1	Why aren't LVS and NSTS combined into one system? NJ Jenny Goodman	Cred&SysArc	Transcript webinar notes	01/31/2017	ML17045A353
55.43	Lowre Young, University of Illinois, Urbana Champagne	self	Academic	FRN, LVS, Q1	Is the LVS and NSTS the same login?	Cred&SysArc	Transcript webinar notes	01/31/2017	ML17045A353
55.44	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, LVS, Q3	Why does this question specifically call out manufacturers and not other well-known entities?	LVS	Transcript p70	01/31/2017	ML17045A353
55.45	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, LVS, Q3	This falls back to the previous comment about there being a flaw in the timeliness of the verification. Is quarterly good enough.	LVS	Transcript p70	01/31/2017	ML17045A353
55.46	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, Q3	In addition to reducing the burden for M&Ds, consider reducing the burden for Part 50 licensees, power reactors, and Part 70, fuel cycle facilities. These are well known entities.	LVS	Transcript p72	01/31/2017	ML17045A353
55.47	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, LVS, Q4	International Isotopes has on-line access to LVS and uses the system regularly. At times, the encounter the "contact the regulator" message. There's no reason to be receiving that message, why is it happening? Is something entered incorrectly? When using LVS, the information about the amount being transferred isn't being entered into LVS, that done in NSTS. Not understanding why the system is returning a message that the possession limit is exceeded. It would be helpful to have more to the error message than "contact the regulator."	Cred&SysArc	Transcript p73	01/31/2017	ML17045A353
55.48	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, Q4	Does the NRC have an estimate for how many times, or percentage, the error message "contact the regulator" pops up? If there's a significant number of error messages, "contact the regulator", that could produce a significant burden to Agreement States and NRC.	Cred&SysArc	Transcript p74	01/31/2017	ML17045A353
55.49	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, NSTS licensees, Q1	Medical licensee has one category 1 source which is fixed. This licensee uses the emailing of the form to NSTS and not online access. Have had some issues in the past where have not received a confirmation that my reporting to NSTS was correct. Could see a real issue with NSTS transitioning to sources that are infrequently replaced.	Cred&SysArc	Transcript p76	01/31/2017	ML17045A353

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55.50	Ralph Lieto, RSO, St. Joseph Mercy Health Systems	St Joseph, Ann Arbor Michigan	Medical	FRN, NSTS licensees, Q1	Is the credentialing process the same for LVS and NSTS? If they are separate, will it take 2 months for someone to be credentialed?	Cred&SysArc	Transcript p77	01/31/2017	ML17045A353
55.51	Cindy Tomlinson	American Society for Radiation Oncology	NGO	FRN, NSTS licensees, Q1	How long is the online credential valid?	Cred&SysArc	Transcript p78	01/31/2017	ML17045A353
55.52	Karen Sheehan, Fox Chase Cancer Center	self	Medical	FRN, NSTS licensees, Q1	If someone retires how do they notify NSTS or end their credentialing? Do they have to send their token back?	Cred&SysArc	Transcript webinar notes	01/31/2017	ML17045A353
55.53	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, AS Q1	Does NRC want to know the individual sources that are Category 1, 2 or 3 or do you want to know the aggregate quantities?	NSTS	Transcript p81	01/31/2017	ML17045A353
55.54	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, AS Q1	There's a difference between authorization and actual possession. An Agreement State can answer the question about quantities of materials authorized, it is more difficult to answer the question for the number of sources out there that are in Category 3 quantities. Many Agreement States don't keep that level of detail in the actual licenses.	WBL	Transcript p82	01/31/2017	ML17045A353
55.55	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, LVS, AS Q2	Would it be possible for NRC to provide to Agreement States the number of licensees in each state that are using the LVS as opposed to manual license verification? Agreement States could possibly extrapolate from this information.	Cred&SysArc	Transcript p85	01/31/2017	ML17045A353
55.56	Steve Harrison	Virginia Office of Radiological Health	Agreement State	FRN, LVS, AS Q2	Virginia has 37 Category 1 and 2 versus 27 Category 3 licensees. Virginia would be almost doubling the manual burden if LVS is expanded to Category 3 material.	LVS	Transcript p86	01/31/2017	ML17045A353
55.57	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, AS Q3	If NRC went to tracking of Category 3 and requiring LVS for Category 3, would NRC require Agreement States to submit Category 3 licenses to WBL?	WBL	Transcript p90	01/31/2017	ML17045A353
55.58	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, LVS, AS Q3	To clarify, NRC will request Agreement States to submit Category 3 licensees to WBL, but not mandate it?	WBL	Transcript p91	01/31/2017	ML17045A353
55.59	Phillip Scott	California Department of Public Health	Agreement State	FRN, LVS, AS Q3	To clarify is it NRC's intent to require WBL be adopted by Agreement States? Or is NRC encouraging use of WBL by not requiring Agreement State adoption of it?	WBL	Transcript p92	01/31/2017	ML17045A353
55.60	Lynne A. Fairobent	self	Medical	FRN, NSTS, AS Q1	Returning to the 5,500 number of additional licensees for Category 3, what percent are NRC versus Agreement States? This question could also be flipped to what the increased burden for NRC licensees?	WBL	Transcript p96	01/31/2017	ML17045A353

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55.61	Phillip Scott	California Department of Public Health	Agreement State	FRN, NSTS, AS Q1	Is NRC considering requiring Agreement States to do the annual inventory? If so, Agreement States would have to do an evaluation as the cost - for time and resources? Could NRC provide information regarding licensees in NSTS and LVS to the Agreement States, to support this evaluation?	NSTS	Transcript p97	01/31/2017	ML17045A353
55.62	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS, AS Q1	From the big picture, what is the continued need for the annual inventory reconciliation? It is a significant amount of work to conduct this reconciliation, it is not clear what safety issue is being addressed with reconciliation. In particular, when most of the errors seem to be typographical, administrative items.	NSTS	Transcript p99	01/31/2017	ML17045A353
55.63	Nima Ashkeboussi, Sr. Project Manager	Nuclear Energy Institute	NGO	FRN, NSTS, AS Q1	Question the need for reconciliation of Category 1 and 2, in light of having a graded approach, would recommend excluding Category 3 from the reconciliation.	NSTS	Transcript p99	01/31/2017	ML17045A353
55.64	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, NSTS, AS Q1	What authority does the NRC have to require the Agreement States to conduct the annual inventory reconciliation?	NSTS	Transcript p100	01/31/2017	ML17045A353
55.65	Lynne A. Fairobent	self	Medical	FRN, NSTS, AS Q1	How does it work for a medical physicist who provides services to more than one licensee and has one token, one sign-on, one password? Has NRC given thought to when this individual stops consulting for hospital A, but still consulting for hospitals B and C?	Cred&SysArc	Transcript p102	01/31/2017	ML17045A353
55.66	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, Security, Q1	No. The NRC should consider the risk. What is posed with Category 3 versus Category 1 and 2? If you look a the table, there are certainly hazards associated with Category 1 quantities, but the existing safety regulations provide the level of security needed to control this material. When transferring Category 3 or less, license verification is still done. If the recipient doesn't receive their material, reporting of lost material is required. When looking at levels of activity, there's a line that should be drawn before requiring additional security enhancements. Category 3 doesn't seem to cross that line. The existing safety regulations, both NRC and DOT, provide enough security to control Category 3 quantities.	SA	Transcript p105	01/31/2017	ML17045A353
55.67	John J. Miller, RSO and Radiation Compliance Officer	International Isotopes Inc.	Industrial	FRN, Security, Q1	Looking at what this exercise is trying to solve, maybe issuing licenses for licensees that possess a Category 3 quantity might be a little more robust. License verification is a possibility that might improve security. But a question to ask, what are the unintended consequences. A consequence of expanding to Category 3 in LVS and NSTS - from a source manufacturer perspective is limited. Source manufacturers are already using these systems, adding Category 3 is just another burden. Currently there are many licensees that are unfamiliar with the enhanced requirements on Category 2, because they typically return the source when it has decayed to Category 3 without issue. Now that end user has to go through hoops to make an NSTS transaction, do a license verification, this licensee could store the source until it's below Category 3 thresholds. Sources could be collecting in a closet waiting for decay to avoid NSTS and LVS. This is a consequence that should be considered.	SA	Transcript p106	01/31/2017	ML17045A353
55.68	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q2	Provide clarification on this question. It is not clear what the NRC's thinking is behind it.	GLDs	Transcript p107	01/31/2017	ML17045A353

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55.69	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q2	The practical effect of this question is that companies that previous operated under a general license would be required to be specifically licensed?	GLDs	Transcript p108	01/31/2017	ML17045A353
55.70	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q2	If NRC is looking at general licensees that could aggregate to a Category 3 quantities, requiring those entities to obtain specific licenses would affect a large number of companies.	GLDs	Transcript p110	01/31/2017	ML17045A353
55.71	Phillip Scott	California Department of Public Health	Agreement State	FRN, Security, Q2	Recommend that a maximum quantity in a GLD such as under 31.5 be established. But NRC should also consider how this will affect the registration component of 31.5, and possibly 40.25. NRC should consider some type of grandfathering process until all the licensing can be completed. This does create more licensing, so what is NRC's expected workload increased for transitioning GLDs to specific licenses.	GLDs	Transcript p112	01/31/2017	ML17045A353
56.01	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, General, Q1	How is the new executive order on regulations going to impact the progress on this specific rule activity?	SA	Transcript p20	02/21/2017	ML17079A125
56.02	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, General, Q2	Question 2 - No, I do not think that this will increase safety or security.	SA	Transcript p26	02/21/2017	ML17079A125
56.03	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, General, Q3	Question 3 - Yes licenses should be exempted.	LVS	Transcript p27	02/21/2017	ML17079A125
56.04	Clive Townsend, Reactor Supervisor, Purdue University	self	Academic	FRN, General, Q4	How does this change the timeline for a request? Worried about it taking much longer... Does the timeline shorten with the change?	LVS	Transcript p27	02/21/2017	ML17079A125
56.05	Daniel Eavenson, First Alert, Inc.	self	Industrial	FRN, NSTS, Q1	Is there any consideration to differences of shipments when the radioactive material is already installed in a complex machine or in a shielded device?	SA	Transcript p29	02/21/2017	ML17079A125
56.06	Clive Townsend, Reactor Supervisor, Purdue University	self	Academic	FRN, NSTS, Q1	Are the complete slides available somewhere on the NRC website?	NSTS	Transcript p29	02/21/2017	ML17079A125
56.07	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, NSTS, Q1	As far as the increase in security if implemented I find nothing in your background information that would have prevented those events if this was in place.	SA	Transcript p30	02/21/2017	ML17079A125

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56.08	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, General, Q3	Question 3 - clarification - When returning decayed sources to the manufacturer that shipped the "fresh" source in the first place, licensees should not have to verify the license every time. Perhaps, simply including the manufacturers license number and expiration date with new sources would be an easy way to make NRC happy.	LVS	Transcript p30	02/21/2017	ML17079A125
56.09	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, NSTS, Q1	I would think this would be overly burdensome to licensees without any added security benefit.	SA	Transcript p30	02/21/2017	ML17079A125
56.10	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, NSTS, Q1	I would be concerned about the cyber security of this process. Cat 3 in NSTS - all of it	Cred&SysArc	Transcript p31	02/21/2017	ML17079A125
56.11	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, NSTS, Q1	Since the NSTS is not a live inventory system and one main source in hospitals is exchanged 4 times a year, the NSTS would constantly be very outdated. I do not see a benefit to including these sources in NSTS.	NSTS	Transcript p31	02/21/2017	ML17079A125
56.12	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, general, Q4	Questions 1, 2, 3 and 4 refer to “transfers of category 3 quantities”. Does this include transferring packages containing smaller category 4 sources that would aggregate up to category 3 quantities?	NSTS	Transcript p31	02/21/2017	ML17079A125
56.13	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, NSTS, Q2	I think the next business day should be relaxed if Cat 3 is included. Some of these may happen in the field and need a bit more time to login.	NSTS	Transcript p34	02/21/2017	ML17079A125
56.14	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, NSTS, Q2	#4. I would be interested to learn of any experiences the NRC can point (is aware of) to that indicate that there would be an increase to security if this change was in place	SA	Transcript p36	02/21/2017	ML17079A125
56.15	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, NSTS, Q4	I am not convinced that there would be an increase in safety/security if cat 3 sources were included in the NSTS.	NSTS	Transcript p37	02/21/2017	ML17079A125
56.16	Thomas Jones, GE Healthcare	self	Medical	FRN, NSTS, Q5	Question 5. Please consider additional guidance for Surface Contaminated Object aggregation. Most of the assumptions assume discrete sources.	SA	Transcript p38	02/21/2017	ML17079A125

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56.17	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, NSTS, Q5	NSTS reporting requirements of within a day or two does not take into account smaller organizations where the RSO may not be available to make those entries at those times (i.e. vacations, illnesses)	NSTS	Transcript p38	02/21/2017	ML17079A125
56.18	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, LVS, Q1	Consider will there be any actual increased source security with proposed regulations or is it all just aiding in the appearance of increased security?	SA	Transcript p40	02/21/2017	ML17079A125
56.19	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, LVS, Q1	Will there be any cost-benefit analysis done?	SA	Transcript p40	02/21/2017	ML17079A125
56.20	Thomas Jones, GE Healthcare	self	Medical	FRN, NSTS, Q5	Question 5. Please consider consolidating the Part 37 source list and NSTS Appendix E listing into a single list.	SA	Transcript p41	02/21/2017	ML17079A125
56.21	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, LVS, Q1	Clarification: If you have credentials for NSTS you would NOT have to reapply for LVS, correct?	Cred&SysArc	Transcript p41	02/21/2017	ML17079A125
56.22	Thomas Jones, GE Healthcare	self	Medical	FRN, LVS, Q2	Question: Since the GAO investigation seemed to point to a weakness in the Agreement State licensing process, what is being proposed as part of this evaluation for strengthening that process?	SA	Transcript p42	02/21/2017	ML17079A125
56.23	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, LVS, Q2	Transfer 4 x's a year and 100% are returned to the manufacturer.	LVS	Transcript p44	02/21/2017	ML17079A125
56.24	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, LVS, Q2	License verification should not be required when transferring to an established manufacturer.	LVS	Transcript p45	02/21/2017	ML17079A125
56.25	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, LVS, Q1	Related to question 1, would access to LVS require the same type of firewall breaching that is required to access NSTS online system? This is the main reason so many licensees don't use the NSTS on-line system.	Cred&SysArc	Transcript p45	02/21/2017	ML17079A125

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56.26	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, LVS, Q2	Question 2 - for HDR, 4 -5 times a year back to the vendor.	LVS	Transcript p46	02/21/2017	ML17079A125
56.27	Thomas Jones, GE Healthcare	self	Medical	FRN, LVS, Q3	Question 3. No. Current acceptable methods of verifying licenses (current copy, etc) especially when dealing with established or recurrent licensees.	LVS	Transcript p49	02/21/2017	ML17079A125
56.28	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, NSTS licensees, Q1	If cat 3 is included in NSTS, I'd try NSTS on-line access again.	Cred&SysArc	Transcript p49	02/21/2017	ML17079A125
56.29	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, NSTS licensees, Q2	I did go through getting on-line access years ago, but had issues with employers firewalls and have used fax/e-mail for NSTS annual updates. I appreciate today's feedback that the on-line system has since changed.	Cred&SysArc	Transcript p50	02/21/2017	ML17079A125
56.30	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, NSTS licensees, Q2	I use NSTS online and have only had early issues with using the product on a MAC.	Cred&SysArc	Transcript p50	02/21/2017	ML17079A125
56.31	Michael N. Stephens, Environmental Program Health Consultant	Florida Department of Health	Agreement State	FRN, LVS, AS Q1	Does this include license authorizations for small category 4 sources that would aggregate to category 3 quantities?	LVS	Transcript p51	02/21/2017	ML17079A125
56.32	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, LVS, AS Q1	As an agreement licensee, I'd try LVS as this would be a significant burden on an already taxed agreement state organization.	LVS	Transcript p54	02/21/2017	ML17079A125
56.33	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, LVS, AS Q4	I am in a state that licenses a source manufacturer. I can't imagine our current State program being able to handle the large number of Cat 3 transfers that are occurring.	LVS	Transcript p56	02/21/2017	ML17079A125
56.34	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, NSTS, AS Q1	This would bring the process to a halt...Agreement states are underfunded and understaffed. Another unfunded mandate is the last this our Agreement State programs need.	NSTS	Transcript p58	02/21/2017	ML17079A125

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56.35	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, NSTS, AS Q1	I remember the nightmare of reconciliation when NSTS began and that has been corrected. If my state had to perform this task, I do not have confidence that they have the resources to complete reconciliations the way NSTS does.	NSTS	Transcript p58	02/21/2017	ML17079A125
56.36	Clive Townsend, Reactor Supervisor, Purdue University	self	Academic	FRN, NSTS, AS Q1	General thought: also want to make sure that this is the best way to meet the AEA of 1954 for Research Reactors... "impose the minimum amount of such regulations and terms of license as will permit the commission to fulfill its obligations." . . . I would not consider controlling 11 kg of 1% uranium at the same level as 2.1 kg of Plutonium (for example) as being the minimum level of regulation necessary.	SA	Transcript p58	02/21/2017	ML17079A125
56.37	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, Security, Q1	NO! I see no benefits	SA	Transcript p61	02/21/2017	ML17079A125
56.38	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, Security, Q1	NO NO NO. Physical security requirements should not be expanded to include Cat 3 sources.	SA	Transcript p61	02/21/2017	ML17079A125
56.39	Clive Townsend, Reactor Supervisor, Purdue University	self	Academic	FRN, Security, Q1	No, they shouldn't be expanded.	SA	Transcript p62	02/21/2017	ML17079A125
56.40	Linda Kroger, RSO, University of California, Davis Medical Center	self	Medical	FRN, Security, Q1	Nationally, this would be a tremendous financial burden.	SA	Transcript p62	02/21/2017	ML17079A125
56.41	Thomas Jones, GE Healthcare	self	Medical	FRN, Security, Q1	Other Questions: Question 1. Since the majority of security concerns appear to be related to Ir-192 (radiography) related according to the NRC's effectiveness review, is this tightening down on all Category 3 sources unnecessary and incorrectly targeted?	SA	Transcript p62	02/21/2017	ML17079A125
56.42	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, Security, Q1	Let's not forget that we in the radiation safety security roles are doing more for security and safety if we are doing just that and not filling out forms that have no identified benefit.	SA	Transcript p64	02/21/2017	ML17079A125
56.43	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	FRN, Security, Q2	If you decide that Cat 3 sources are to be covered under Part 37, then they should NOT be covered under general licenses. General licensed devices and come and go without the RSO's knowledge - if the material is THAT dangerous, it should not be under a general license.	GLDs	Transcript p65	02/21/2017	ML17079A125

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56.44	David Brown	National Institute of Standards and Technology	Academic	General	General Comment: In my opinion the LVS is the only redeeming feature of this entire inquisition. I have for a long time felt that there should be an official source for license verification for all radioactive materials transfers that require a license. On the subject of NSTS registrations and increased security for Cat 3 sources, The NRC has already performed a thorough analysis of this for Cat 3 sources and found no need for increased security. I truly do not see any basis or justification for a different conclusion at this point.	SA	Transcript p66	02/21/2017	ML17079A125
56.45	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	General	Licensees routinely converse among themselves that the current Part 37 merely provides a means for the NRC to point the finger to the licensees if there is ever an event and provides no true increase in security.	SA	Transcript p67	02/21/2017	ML17079A125
56.46	Daniel Eavenson, First Alert, Inc.	self	Industrial	General	If the requirements of Cat 1&2 are extended to 3 will there be a reevaluation of the quantities for Cat 3 because of the increased security and licenses security requirements?	SA	Transcript p68	02/21/2017	ML17079A125
56.47	Clive Townsend, Reactor Supervisor, Purdue University	self	Academic	General	Can you review, in short, why this movement started? I heard very briefly about the GAO investigation but missed most of it. A short summary would be appreciated... Since we have time.	SA	Transcript p68	02/21/2017	ML17079A125
56.48	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	General	How long are ones credentials for NSTS or LVS good for. How often must they be renewed?	Cred&SysArc	Transcript p71	02/21/2017	ML17079A125
56.49	Kendall Berry, RSO, Hahneman University Hospital	self	Medical	General	If a terrorist wants our sources, they'll get them despite systems in place. Most hospitals do not have armed response security forces on site and nor should they be required to. Further if a terrorist wants the sources there are plenty of ways to go about getting a license and getting a source delivered to them, beyond methods that the GAO has already tested. This whole system is insane and reduces the credibility of the NRC with Hospital administration when such unfunded mandates are imposed. The cost of doing business as a hospital has been getting tougher and tougher for all hospitals, more unfunded mandates that do not actually improve security should not be imposed.	SA	Transcript p72	02/21/2017	ML17079A125
56.50	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	General	I think the renewal process should be reevaluated. It should have some connectivity to the T&R process. If I lose access to Cat 1&2 because my T&R process (10 year renewal) identifies a issue, that person should not have NSTS or LVS access either....	SA	Transcript p74	02/21/2017	ML17079A125
57.01	Mike Welling	University of Virginia	Medical	FRN, General, Q3	Please elaborate on what safety and security you are asking about. Would this be public safety, worker safety or other?	SA	Transcript p29	02/23/2017 meeting1	ML17079A131
57.02	Mike Welling	University of Virginia	Medical	FRN, NSTS, Q1	Does the NRC have a time study for Category 1 and 2 source entry into NSTS which can be used for this question?	NSTS	Transcript p32	02/23/2017 meeting1	ML17079A131

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57.03	Mike Welling	University of Virginia	Medical	FRN, NSTS, Q1	I asked the question about time study, because I'm looking at using that information. If anyone has given you anything from a Category 1 or 2 user standpoint, if that can be used for Category 3 people to say how much time and energy they're going to have to put in for all their Category 3 sources? The Category 3 licensees have no understanding of how much entry or what's required to do NSTS. So if the Category 1 and 2 users along with the NRC staff has any information to count as to how long the entries take, then could pass it along to the Category 3 users to try and understand and document how much time and energy they're going to have to put towards entries in NSTS for their past resources.	NSTS	Transcript p33	02/23/2017 meeting1	ML17079A131
57.04	Mike Welling	University of Virginia	Medical	FRN, NSTS, Q1	Suggest putting the burden estimates for filling out the Form 748, especially to those Category 3 manufacturers and distributors such as HDRs. They're going to have to do that for every source exchange quarterly.	NSTS	Transcript p35	02/23/2017 meeting1	ML17079A131
57.05	Jack Preist, Radiation Control Program Director	Massachusetts Department of Public Health	Agreement State	FRN, NSTS, Q2	If the Category 3 reporting limits are only one percent of the Category 1, does it make sense to have the same reporting timeline for sources that are, I'll say less risk-significant? I do not agree with an annual, but I think maybe a 30-day reporting time frame or something light that might be workable and useful to tracking rather than wait until the end of the year before - or annually until you realize that you had a missing source or unaccountable source.	NSTS	Transcript p37	02/23/2017 meeting1	ML17079A131
57.06	Jack Preist, Radiation Control Program Director	Massachusetts Department of Public Health	Agreement State	FRN, LVS, AS Q1	Massachusetts has approximately 60 licensees for 1, 2, and 3 categories. And we have 43 current licensees for Categories 1 and 2.	WBL	Transcript p54	02/23/2017 meeting1	ML17079A131
57.07	Jack Preist, Radiation Control Program Director	Massachusetts Department of Public Health	Agreement State	FRN, LVS, AS Q2	Massachusetts would encourage licensees for the use of LVS among our licensees. We would not recommend the plan for additional burden imposed by the manual license verification process.	LVS	Transcript p55	02/23/2017 meeting1	ML17079A131
57.08	Jack Preist, Radiation Control Program Director	Massachusetts Department of Public Health	Agreement State	FRN, LVS, AS Q3	Massachusetts would ask our licensees to voluntarily provide your Category 3 similar to what Massachusetts, which is an Agreement State., does now for Category 1 and 2 licensees. Massachusetts has not yet adopted web-based licensing system.	WBL	Transcript p57	02/23/2017 meeting1	ML17079A131
57.09	Marvin Lewis	Public	Public	FRN, LVS, AS Q3	Appreciate this chance to have my say. Thinking a lot of this class 3 stuff is going through our cities and going into areas that are not well protected, not safe, and where the first responders are first responders, volunteers, and we don't need radioactives going out into the general public or near the general public. And I don't hear people saying, well, how can we minimize the impact of radiation on the general public or people, the individual person. I want to hear a little more of what the NRC's charter says about protect the health and safety of the public. I sure don't hear it. Thank you for allowing me this comment.	SA	Transcript p59	02/23/2017 meeting1	ML17079A131
57.10	Jack Preist, Radiation Control Program Director	Massachusetts Department of Public Health	Agreement State	FRN, LVS, AS Q4	We've done some time study estimates based on our current number of licensees that we have for category 1 and 2. And we feel the additional category 3 for training, tracking, regulatory oversight, for that part of the program, we estimated 1.5 full time equivalent for that additional burden.	LVS	Transcript p61	02/23/2017 meeting1	ML17079A131

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57.11	Michael Welling	University of Virginia	Medical	FRN, Security, Q2	Would this be under a Part 37 revision or an order until Part 37 would be revised?	SA	Transcript p66	02/23/2017 meeting1	ML17079A131
58.01	Jennifer T. Opila, Radiation Program Manager	Colorado Department of Public Health and Environment	Agreement State	FRN, General, Q2	The NRC staff has the impression that the Agreement States are not against expanding NSTS to Category 3, but instead are concerned about the impact. This regulator does not believe that summary is accurate. A lot of Agreement States have not had the opportunity to comment yet, and there is one week left in the comment period. In general, including Colorado, many Agreement States are not in favor of expansion of the requirements to Category 3.	NSTS	Transcript p22	03/02/2017	ML17079A140
58.02	Mary Shepherd	JL Shepherd & Associates	Industrial	FRN, General, Q2	My concern and comments on this is for Category 3 sources, those in some areas a GL license. And so you would have to promulgate regulations on the GL side to be more in conformance with the specifically licensed device sources for devise. And this could be very expensive. And I'm not sure how well it will work. I don't do GLs as part of our business model. But I think it will be very cumbersome on the MT&E testing, you know, the non-destructive testing facility license - GL type licensing. And that should be looked at.	GLDs	Transcript p23	03/02/2017	ML17079A140
58.03	Joseph Rizzi	Westinghouse Electric Company	Industrial	FRN, General, Q2	When referring to “Category 3 sources” sometime “Category 3 quantities” is used, so is the source related only to sealed sources or any source of radioactivity?	NSTS	Transcript p24	03/02/2017	ML17079A140
58.04	Clayton Bradt	New York Department of Health	Agreement State	FRN, General, Q2	The root problem has to do with the ease of company formation in the United States. There are no barriers for malevolent actors to form a legitimate corporation in any state. Once incorporated, there is no way to deny a license to such a company. In addition, any potential terrorist group with sufficient funding and acquire a legitimate business. How will NRC's proposed actions eliminate these possibility?	SA	Transcript p26	03/02/2017	ML17079A140
58.05	James Mattern	National Institutes of Health	Medical	FRN, General, Q2	Some of the comments that were brought up earlier give basically - reflect our position also. Once of the comments was on the aggregate of byproduct material. We have set the time units. Licensing came up here with regard to byproduct material and how these regulations would affect that. The NRC's position is that it's not specifically sealed sources and the like. But these amounts generated would not necessarily be in one specific location. I mean, they maybe in, you know, a few different targets or, you know a couple of different roles or facility locations. So how would this affect operations here? Do you have any guidance on that?	SA	Transcript p28	03/02/2017	ML17079A140
58.06	James Mattern	National Institutes of Health	Medical	FRN, General, Q2	The question came up, because there's a certain cyclotron procedure that could produce some Co-60. Start pushing the 800, I guess, military limits for Category 2. But that would push it up into a Category 3 if it covers over that. And plus, if I'm at 600 in one room and 600 in another room, then it starts getting kinds of muddied a bit. All of a sudden do we have to start reporting all this Co-60 that's being produced? And it seems strange, entering back into the NRC realm after being in an Agreement State area for awhile. It's not we're producing to manufacture or distribute, it's just the nature of the beast.	NSTS	Transcript p30	03/02/2017	ML17079A140
58.07	Clayton Bradt	New York Department of Health	Agreement State	FRN, General, Q2	If I understand Duncan's response to my question, closing the regulatory gaps that enabled the GAO sting to succeed is not the intent of NRC's proposed actions. Please verify.	SA	Transcript p32	03/02/2017	ML17079A140
58.08	Joseph Rizzi	Westinghouse Electric Company	Industrial	FRN, General, Q2	Is there going to be a reporting requirement for non-sealed source Cat 3 material?	SA	Transcript p34	03/02/2017	ML17079A140

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Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

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58.09	Mary Shepherd	JL Shepherd & Associates	Industrial	FRN, General, Q2	With the adoption of Category 3, there is a concern regarding the medical isotopes used in diagnostic and therapeutic treatment. And if Category 3 is adopted, there's also patient care and patient, potential patient restrictions that need to be looked at also.	SA	Transcript p34	03/02/2017	ML17079A140
58.10	David Huber, RSO, Baker Hughes Oilfield Operations	self	Industrial	FRN, General, Q3	Would a corporation holding licenses with NRC and multiple agreement states be required to verify transfers between licenses held by that corporation?	LVS	Transcript p36	03/02/2017	ML17079A140
58.11	Craig Stone, South Texas Project	self	Industrial	FRN, General, Q3	If NRC goes down to Category 3 in regulating this, its going to be a large burden on reactors. Practically everything that is sent off site from the reactor is going to meet the Category 3 definition. And reactors are sending stuff to, places like burial sites that have three million curies available to them. And you know, the LVS, from my experience, have not been able to make it work. Routinely, I am contacting the Agreement State regulator every time I send the materials. If NRC is considering exemptions, reactors should be considered - large generators like us that send to places with huge licenses - or license quantities available.	LVS	Transcript p38	03/02/2017	ML17079A140
58.12	Brian Dodd, President, BD Consulting	self	Public	FRN, General, Q3	Was at IAEA when the source classification system was developed. Was one of the independent consultants for Part 37 review. Reminding people that the IAEA tried to classify the instances. But Category 3 sources are regarded as dangerous. That means that they are capable of causing severe deterministic effects if they are in an uncontrolled environment. There should be a graded approach, not exactly the same as Category 1 and 2, but graded system security associated with Category 3. And certainly should include in the NSTS and the LVS. As I mentioned, graded according to less than Category 2 but more than what is generally done under Part 20.	SA	Transcript p39	03/02/2017	ML17079A140
58.13	Scott J. Winters, Radiation Safety Specialist	VEGA Americas, Inc.-Nuclear Services	Industrial	FRN, General, Q3	There needs to be a consideration for a variance in the security criteria. Particularly, for Category 3 for looking at trying to make it universal, that would be a burden that we would anticipate for a lot of the people that we distribute to either under a general license or a specific license. Basically, when discussing fixed gauges. Adding another chain with a lock around something that's there's already mounted to a vessel that already has a preliminary and secondary security systems seems over redundant and not effective.	SA	Transcript p41	03/02/2017	ML17079A140
58.14	James Mattern	National Institutes of Health	Medical	FRN, General, Q3	The NRC asked if there should be an exemption, and yes, we would recommend an exemption. The primary Category 3 source that we're looking at is for an ACR unit which uses Ir-192. And the only transactions that only occur we get our source from the manufacturer. And then the manufacturer comes and takes out the decayed source that has been used. And packages it and puts in the new source. And we ship off the old source back to the manufacturer. So as far as having to get on LVS and all this, we think that yes, there should be an exemption for that.	LVS	Transcript p42	03/02/2017	ML17079A140
58.15	Clayton Bradt	New York Department of Health	Agreement State	FRN, NSTS, Q1	You should consider that bad people can get valid licenses.	SA	Transcript p45	03/02/2017	ML17079A140
58.16	David Huber, RSO, Baker Hughes Oilfield Operations	self	Industrial	FRN, NSTS, Q3	Including Cat 3 in NSTS would engage approximately 60 small well logging companies and at least three majors that have not previously used NSTS.	NSTS	Transcript p47	03/02/2017	ML17079A140

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58.17	Kelley Richardt, Regulatory and QA manager, Source Production and Equipment C.	self	Industrial	FRN, NSTS, Q3	We currently report 20-30 transfers every day in NSTS, adding Cat 3 would raise that by about one third.	NSTS	Transcript p47	03/02/2017	ML17079A140
58.18	Christopher Perry, Radiation Safety Manager, Weatherford International	self	Industrial	FRN, NSTS, Q3	Just for our operations, the amount of sources that would have to be added to NSTS would be approx 5 times as many as currently required.	NSTS	Transcript p48	03/02/2017	ML17079A140
58.19	Richard Karrmann, GE Inspection Services	self	Industrial	FRN, NSTS, Q3	When a Category 2 source decays below threshold, there's no action that's done - no action to be taken by the licensee? The source is in NSTS, it just doesn't appear in the licensees inventory any more. Category 3 reporting to NSTS, would the same apply? Again, the information still remain in NSTS or - and then just fall out of a licensee's inventory. If/when a cat 2 source decays below the cat 2 threshold, would licensees be required to take any additional actions in NSTS?	NSTS	Transcript p48	03/02/2017	ML17079A140
58.20	Greg Schrad, Plant Engineer	Gilberton Power Company	Industrial	FRN, NSTS, Q5	With NSTS we don't report, we're just Category 3. We our sources for a level indication. And we're not in NSTS at all. Has NRC looked at the increased traffic that you guys are going to have to take in based off of the people who have never used NSTS? And everyone try to apply to get access to it?	NSTS	Transcript p49	03/02/2017	ML17079A140
58.21	Joseph Rizzi	Westinghouse Electric Company	Industrial	FRN, NSTS, Q5	What is NRC's position on the increase in safety and security?	SA	Transcript p53	03/02/2017	ML17079A140
58.22	Clayton Bradt	New York Department of Health	Agreement State	FRN, NSTS, Q5	No study has been done on the efficacy of the NSTS has been conducted.	NSTS	Transcript p54	03/02/2017	ML17079A140
58.23	Kelley Richardt, Regulatory and QA manager, Source Production and Equipment C.	self	Industrial	FRN, NSTS, Q5	Has NRC considered scaling back on current requirements to verify receipt of Cat 1 or Cat 2 sources to both to the shipper and in NSTS?	NSTS	Transcript p54	03/02/2017	ML17079A140

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58.24	Kelley Richardt, Regulatory and QA manager, Source Production and Equipment C.	self	Industrial	FRN, LVS, Q2	We understand that there are approximately 4000-5000 HDR source transfers annually (that would require NSTS, LVS, etc).	LVS	Transcript p58	03/02/2017	ML17079A140
58.25	Joseph Rizzi	Westinghouse Electric Company	Industrial	FRN, LVS, Q2	If a licensee has an aggregate amount of a Cat 3 radioactive material and they transfer a quantity which brings them below the Cat 3 amount, is that reportable?	LVS	Transcript p59	03/02/2017	ML17079A140
58.26	Craig Stone, South Texas Project	self	Industrial	FRN, LVS, Q2	Most of them are from M&Ds, the power sector has different concerns. It would go down to aggregate quantities on almost 90 percent, 80 percent of the shipments we make. And these shipments would be going to the basically the same licensees over and over again. Verification for an established manufacturer or and established source that we send it to continuously, should be part of the graded approach.	LVS	Transcript p61	03/02/2017	ML17079A140
58.27	Craig Stone, South Texas Project	self	Industrial	FRN, LVS, Q4	LVS does not work for the places that I send material to. So, I've had to go to the issuing authority every single time and the Help Desk. Basically, I put a trouble ticket in six months ago. It still doesn't work and nothing has happened. So I've had issues with it.	Cred&SysArc	Transcript p61	03/02/2017	ML17079A140
58.28	Glenn Rogers, Regional Environmental Manager, Pactiv	self	Industrial	FRN, LVS, Q2	Most of the transfers we have are to and from us (the customer) to the manufacturer. If, all of our transfers are less than the Cat 3 threshold amounts would we be required to report?	LVS	Transcript p62	03/02/2017	ML17079A140
58.29	Karen Sheehan, RSO Fox Chase Cancer Center	self	Medical	FRN, LVS, Q2	I agree with the comment about the receipt and shipment of the Iridium -192 sources for the HDR treatment units. The reporting of transfers and receipt each time will be a burden for the facilities who use these sources. They are exchanged each quarter. I do not think that this source exchange process is a safety risk. It would be easier for the facilities to hold the sources until they decay to a category 2 quantity. I think this poses more of a risk than sending them directly back to the manufacturer that day.	LVS	Transcript p62	03/02/2017	ML17079A140
58.30	Douglas Miskell, RSO, Applus RTD USA, Inc.	self	Industrial	FRN, NSTS licensees, Q1	When using form 749, there is a line requesting the quantity of the radioactive material. However, when using LVS online, there is no way to report the quantity of material being transferred. How does this affect the process of verifying through NSTS?	NSTS	Transcript p65	03/02/2017	ML17079A140
58.31	Christopher Perry, Radiation Safety Manager, Weatherford International	self	Industrial	FRN, NSTS licensees, Q1	We hold numerous licenses throughout the US. The majority of our monthly transfers, 10-15 per month, are internal transfers within the company from one location to another. Would we be required to use LVS?	LVS	Transcript p64	03/02/2017	ML17079A140

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58.32	Clayton Bradt	New York Department of Health	Agreement State	FRN, NSTS licensees, Q2	Is the NSTS secure from hacking by state sponsored actors? Consider that the previous system whereby Agreement States kept paper records of radioactive sources was impossible to hack into. If security were an issue, then the NSTS clearly is a step down from the previous method of tracking sources. That data is most secure which is not collected. NRC has never explained why it needs the NSTS. The best improvement may be to shut it down.	Cred&SysArc	Transcript p67	03/02/2017	ML17079A140
58.33	Richard Karrmann, GE Inspection Services	self	Industrial	FRN, NSTS licensees, Q2	Our company purchases new PC's/Lap Tops on 2-3 year intervals for each individual. The security scripts on our coreload program do not cooperate well with the security scripts in the NSTS. It can be quite difficult to install the NSTS scripts on the new computer each time.	Cred&SysArc	Transcript p68	03/02/2017	ML17079A140
58.34	Kelley Richardt, Regulatory and QA manager, Source Production and Equipment C.	self	Industrial	FRN, NSTS licensees, Q2	We use NSTS, and find it cumbersome (ie every time you want to go the main menu, it asks whether you really want to go back.) You have to go into the item detail to another screen to obtain important information.	NSTS	Transcript p68	03/02/2017	ML17079A140
58.35	Douglas Miskell, RSO, Applus RTD USA, Inc.	self	Industrial	FRN, LVS, AS Q2	It has been my experience that the manual LVS process can take anywhere from a few hours to a few days.	LVS	Transcript p72	03/02/2017	ML17079A140
58.36	Kelley Richardt, Regulatory and QA manager, Source Production and Equipment C.	self	Industrial	FRN, LVS, AS Q2	For industrial radiography, decayed sources are normally transferred to whoever manufactured the new source.	LVS	Transcript webinar notes	03/02/2017	ML17079A140
58.37	Greg Schrad, Plant Engineer	Gilberton Power Company	Industrial	FRN, Security, Q1	We're a very, very, small quantity of Category 3, I don't even know how physical security would actually be applied on us. And if we have to put any additional staffing, that would be a huge burden for us if we had to do any staffing to help do any physical security requirements above and beyond what we're already doing.	SA	Transcript p76	03/02/2017	ML17079A140
58.38	Kelley Richardt, Regulatory and QA manager, Source Production and Equipment C.	self	Industrial	FRN, Security, Q1	I don't know whether Cat 3 licensees know what the Part 37 requirements consist of, but complying with Part 37 for some isolated Cat 3 sources would be difficult for us.	SA	Transcript webinar notes	03/02/2017	ML17079A140

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59.01	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q1	For question 1: The question uses the word "quantities" and not "sources", for example. Does this question contemplate the transfer of individual sources each of which is Category 3, or the transfer of sources which, in aggregate, exceed the Category 3 threshold? If the question contemplates aggregation, is the aggregation 'per transfer', 'per billing cycle', 'per month', or per some other period?	LVS	Transcript p26	02/28/2017 meeting1	ML17080A462
59.02	Rob O'Donel, Radiation Safety Consultant, President, Suntrac Services	Suntrac Services	Industrial	FRN, General, Q1	To clarify, if there was a shipment of six sources that were 500 millicuries, that would be 3,000 millicuries, so that's … aggregate is above the Category 3 threshold. So you would have to do - you possibly would have to do the National Source Tracking System with one shipment?	NSTS	Transcript p27	02/28/2017 meeting1	ML17080A462
59.03	Rob O'Donel, Radiation Safety Consultant, President, Suntrac Services	Suntrac Services	Industrial	FRN, General, Q1	(continued from previous) so license verification yes, but NSTS, no?	LVS	Transcript p27	02/28/2017 meeting1	ML17080A462
59.04	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q1	For question 2: It seems that any increase in safety and security would stem from the fact that it would prevent the aggregation of RAM that resulted from the forging of hard copy licenses. How much of a problem is the forging of hard copy licenses to obtain potentially dangerous quantities of RAM? Does the NRC collect data on the number of forgeries / attempted forgeries that occur in a particular period?	SA	Transcript webinar notes	02/28/2017 meeting1	ML17080A462
59.05	Rob O'Donel, Radiation Safety Consultant, President, Suntrac Services	Suntrac Services	Industrial	FRN, General, Q3	Agree with the question or the statement, and that would less the burden on the licensees.	LVS	Transcript p30	02/28/2017 meeting1	ML17080A462
59.06	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, General, Q3	Can NRC define the manufacturer more clearly, please? For example, if a company is a manufacturer and a distributor but not necessarily the manufacturer and distributor on the sealed source device registry for that source, would that still fall in this category?	LVS	Transcript p31	02/28/2017 meeting1	ML17080A462
59.07	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, General, Q3	To provide more information without getting too specific, about 40 to 50% of our business is specifically for storage and disposal of radioactive material for a wide variety of customers. And we are considered a manufacturer and distributor on our license, but specifically for those sources.	LVS	Transcript p32	02/28/2017 meeting1	ML17080A462
59.08	Sandra Jimenez, RSO	University of Texas MD Anderson Cancer Center	Medical	FRN, General, Q3	Working in a medical facility, this will be a big burden on the licensee, specifically for the HDR sources. It would probably be more impactful for the manufacturer or the vendor to handle this type of work, since in most cases they are handling some paper work for shipping. It just seems like it would go hand in hand.	LVS	Transcript p33	02/28/2017 meeting1	ML17080A462
59.09	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, General, Q3	For Question 3: Presumably, this concession is designed to lessen the license verification burden to licensees transferring RAM to well-known companies with which the transferor has had regular dealing. If so, should a similar concession apply to other well-known companies with which the transferor has had regular dealing but which might not be a manufacturer or distributor?	LVS	Transcript p35	02/28/2017 meeting1	ML17080A462

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59.10	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, General, Q3	As for putting the burden on the manufacturer/distributor to be exclusively responsible for the transactions I would make the following comment. I would be concerned that any inaccuracy around accountability may then fall on the licensee who if not involved in the process would not have any knowledge or recourse. This sounds like a potential for the licensee to be subject to possible enforcement for lost/missing/sources. If there is going to be accountability and a licensee is going to be held accountable then the licensee MUST be involved in all transactions.	LVS	Transcript p35	02/28/2017 meeting1	ML17080A462
59.11	Rick Jacobi, Jacobi Consulting	self	Medical	FRN, General, Q3	1. I want to be sure I understand this proposal: If a licensee ships individual devices containing, for example, a single 500 mCi Cs-137 source, then that licensee is not required to report the shipment in the National Source Tracking System. But, if that licensee is warehousing a dozen of these devices for an aggregate of 5 Ci, then that licensee would be required to implement a physical security system.	LVS	Transcript p37	02/28/2017 meeting1	ML17080A462
59.12	Jerry Sullivan	self	Industrial	FRN, General, Q3	After analyzing reports, it appears that there is an issue with the licensee vetting and not security of the Category 3 business sites. That is the issue that should be addressed. Personally, I am in full support of increase the application requirements for Category 3 sources. The KDHE is very diligent in vetting process and working closely with the licensee to ensure safety and security for these minimal user/owners. By them saying Category 3 and forcing those to a Category 2 license, you will only eliminate small businesses who cannot afford the additional financial burdens of extra security. A Category 2 license appears to only have additional security requirements and still does not address the issue of the requirement.	SA	Transcript p39	02/28/2017 meeting1	ML17080A462
59.13	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q1	How many Category 3 sources are currently regulated by either the NRC or the Agreement States?	NSTS	Transcript p42	02/28/2017 meeting1	ML17080A462
59.14	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, NSTS, Q1	In our experience with NSTS, there's a lot of back and forth to correct the inventory. And so if we are adding a multitude of more sources, we just think that's going to multiply, and so, yes, that 's our rationale for our answer to decline on that.	NSTS	Transcript p43	02/28/2017 meeting1	ML17080A462
59.15	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, NSTS, Q1	There's a lot of back and forth because - especially since we're not the only one inputting the information into NSTS. DOE or other people are going into our inventory.	NSTS	Transcript p43	02/28/2017 meeting1	ML17080A462
59.16	William Lorenzen, RSO, Boston Children's Hospital	self	Medical	FRN, NSTS, Q1	They should NOT be included. No justification on how this would improve security. No history of issues regarding licensee accountability; large financial burden on licensee.	NSTS	Transcript p44	02/28/2017 meeting1	ML17080A462
59.17	John Hageman, RSO, Southwest Research Institute	self	Industrial	FRN, NSTS, Q2	Q.2. For transfer or disposal of multiple sources, the process should be expedited by using a batch entry method.	NSTS	Transcript webinar notes	02/28/2017 meeting1	ML17080A462

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59.18	Rick Jacobi	Jacobi Consulting	Industrial	FRN, NSTS, Q3	For general licensees, if the distributor distributes a device to a general licensee, it is required to report that distribution on a quarterly basis on Form 653 or equivalent. So this new distribution or tracking system -- reporting system would simply require them to that more frequently? Is that -- or additional reporting, twice often as the 653 form?	GLDs	Transcript p46	02/28/2017 meeting1	ML17080A462
59.19	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q3	Suggest to the panel or to the phone folks that it might be that someone who has a follow up question to remarks made by Duncan White following Q3	NSTS	Transcript p48	02/28/2017 meeting1	ML17080A462
59.20	Sylvia Revell, RSO, University of Texas Southwestern Medical Center	self	Medical	FRN, NSTS, Q3	How would you propose to capture that information?	NSTS	Transcript p49	02/28/2017 meeting1	ML17080A462
59.21	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS, Q3	Follow-up question for Q1 and Q3, If a specific licensee for example is transferring Category 4 quantity material to some who has a - that's generally licensed, how can that specific licensee through the license verification or otherwise, know how much that transfer had?	NSTS	Transcript p50	02/28/2017 meeting1	ML17080A462
59.22	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, LVS, Q2	Comment about possible more lenient reporting period for Category 3 transfers. If tracking Category 3 is important, then track it. If it's not important then stop tracking Category 3. But it seems that a problem is introduced by having a lenient reporting period during which additional transfers could be made against the licensee. In the long run, I'm not sure of the benefits.	LVS	Transcript p58	02/28/2017 meeting1	ML17080A462
59.23	Rick Jacobi	Jacobi Consulting	Industrial	FRN, LVS, Q2	Generally, I think the LVS would be an improvement in the license verification process. I don't see any downside to implementing it as a requirement.	LVS	Transcript p59	02/28/2017 meeting1	ML17080A462
59.24	Carlos Rincon	NSSI/Sources & Services Inc.	Industrial	FRN, LVS, Q2	The quantities for the monthly, it could be anywhere - pertaining to our company - from 10 to 30 items going or coming into our facility. And it would be from licensee to licensee; it wouldn't be to a manufacturer.	LVS	Transcript p60	02/28/2017 meeting1	ML17080A462
59.25	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, LVS, Q4	Rarely use LVS. Only used LVS when making large shipments to disposal site, which WCS, but setting the limits to Category 3 threshold would require us to use it at a definitely much more frequent interval.	Cred&SysArc	Transcript p63	02/28/2017 meeting1	ML17080A462
59.26	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, LVS, Q4	Used the LVS manual verification the fist time last year. Nothing online yet. But NSSI is approved with the NSTS; have the PIN and token, so it would just be another permission to request. So NSSI would use LVS online.	Cred&SysArc	Transcript p63	02/28/2017 meeting1	ML17080A462
59.27	Rick Jacobi	Jacobi Consulting	Industrial	FRN, NSTS licensees, Q1	It seems that anytime I can do something electronically, its much easier and much more efficient for me. And the questions you have about using email or fax or postal service, is NRC pushing back going to electronic reporting? It seems to be the prudent thing.	Cred&SysArc	Transcript p66	02/28/2017 meeting1	ML17080A462
59.28	Rick Jacobi	Jacobi Consulting	Industrial	FRN, NSTS licensees, Q1	Do not have experience with NSTS, but when you transfer specifically license material to another person, you have to verify that they're licensed to receive it early on. If there was a database, an electronic system, it just seems that it would be more efficient and much more reliable. And not understand why anyone would object to electronic reporting.	Cred&SysArc	Transcript p69	02/28/2017 meeting1	ML17080A462

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59.29	Gamaliel Torres, Radiological Manager	NSSI/Sources & Services Inc.	Industrial	FRN, NSTS licensees, Q1	It seems easy to verify inventory is it doesn't change, online, super simple. But if you do have changes - and people were doing it incorrectly - if your inventory does change from year to year, in Category 1, Category 2, you still have to print it out and will still have to submit the changes by other means, not necessarily online. So it seems if someone has a large number of transactions, online may not be the best way submit or track changes.	NSTS	Transcript p70	02/28/2017 meeting1	ML17080A462
59.30	Sandra Jimenez, RSO	University of Texas, MD Anderson Cancer Center	Medical	FRN, NSTS licensees, Q1	Used NSTS for the annual verification, but there is still an option to use the email or fax. And tend to go with the email, even though I've gone on line and submitted that way. But tend to still use the email, for some reason, don't know why. So maybe it because the option is still there and people are more comfortable with using the email option. It's easier.	NSTS	Transcript p70	02/28/2017 meeting1	ML17080A462
59.31	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, NSTS licensees, Q1	One of the unintended consequences of greatly increasing the number of interactions with the system is that licensees will credential more people and it could be that sheer increase of users could muddy the information in the system. Create more difficulties, more problems.	Cred&SysArc	Transcript p71	02/28/2017 meeting1	ML17080A462
59.32	Sandra Jimenez, RSO	University of Texas, MD Anderson Cancer Center	Medical	FRN, Security, Q1	Agree, no. This is for those that already have Category 1 and Category 2, they already had the administrative burden on them as well as the cost for maintaining these systems as well as security that also has to be included, working with the local PD. Now adding an additional category will also add more financial burden and more administrative burden. Don't know of any past Category 3 type of emergencies that would require such security safeguards in place.	SA	Transcript p81	02/28/2017 meeting1	ML17080A462
59.33	Sandra Jimenez, RSO	University of Texas, MD Anderson Cancer Center	Medical	FRN, Security, Q1	There's already some security involvement with the sources in general. Now if you want to be more specific in terms of how you want those sources secured without having to add all the additional security requirements in place for Category 1 and 2, that might be an option to look into. So I know you specifically state how they have to be secured, other than it has to be secured. That's some additional comments that could be made for that.	SA	Transcript p82	02/28/2017 meeting1	ML17080A462
59.34	Sandra Jimenez, RSO	University of Texas, MD Anderson Cancer Center	Medical	FRN, Security, Q1	My facility is quite large, so we have both medical and research type Cat1 and 2 already in place, so this would be more of an issue for clinical areas, and added T&R, which is already a full time job for most people. Luckily we have HR that do help us out, but for a lot of other smaller institutions, it's the RSO that's having to help with this type of security process. We would have a much larger number of people to process and we already have a large program in place.	SA	Transcript p83	02/28/2017 meeting1	ML17080A462
59.35	Rick Jacobi	Jacobi Consulting	Industrial	FRN, Security, Q1	Asked earlier if you had a device with 500 millicuries of Cs-137 per device, but you had 10-12 of these devices, so that you're now exceeding Category 3 threshold. I asked earlier if you would have to have a physical security program, and I thought the answer earlier was no, although I think the rules of the proposal the answer should be yes.	SA	Transcript p85	02/28/2017 meeting1	ML17080A462
59.36	Rick Jacobi	Jacobi Consulting	Industrial	FRN, Security, Q1	Misunderstood you earlier. Follow up question. If you have a license authorizing 10 devices containing 500 millicuries of Cs-127, but you only actually possess 2 of them which is less than a Category 3 quantity. Are the requirements based on license possession limits or on actual possession of material?	SA	Transcript p85	02/28/2017 meeting1	ML17080A462

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Bins: LVS: License Verification System NSTS: National Source Tracking System WBL: Web-Based Licensing System SA: Assessment of Safety and Security Cred&SysArc: Credentialing and General System Architecture GLDs: Generally Licensed Devices

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59.37	Rick Jacobi	Jacobi Consulting	Industrial	FRN, Security, Q1	Work a lot in the oil and gas industry in Texas. Companies that distribute devices used in industry, metering devices, for instance, may have an individual device that only has 200-300 millicuries of Cs-137 in it. But the distributor at his location might have a warehouse where there is nine, ten or twelve of these sitting ready to be distributed, either imported or exported, or distributed domestically. And so he would exceed in Category 3 in aggregate, but once he sold them - that goes to the general licensee. The general licensee might also possess you know 15 or 20 of those devices. Some would be sunk in the Gulf of Mexico, some would be in pipelines offshore, and some would be in warehouses, so that they would be distributed and not aggregated all in one place. But it would be easy, and I think it would be common for general licensees to have Category 3 quantities. That they actually possess Category 3 in aggregate, even though the individual device is low. And then the distributor would certainly exceed a Category 3 quantity. There are commercial implications of this proposal.	SA	Transcript p89	02/28/2017 meeting1	ML17080A462
59.38	Rick Jacobi	Jacobi Consulting	Industrial	FRN, Security, Q1	Understand that they currently don't have physical security requirements. Appreciate the comments that the physical security requirements would be more or less what's targeted for Category 1 and Category 2, based on these discussions.	SA	Transcript p91	02/28/2017 meeting1	ML17080A462
59.39	Rob O'Donel, Radiation Safety Consultant, President, Suntrac Services	Suntrac Services	Industrial	FRN, Security, Q1	If this goes through, Category 3 not only as a single sources, but as aggregate at a facility. If the facility secures the sources similar to the increased controls requirements, they would secure all of their sources would they be exempt from Part 37?	SA	Transcript p92	02/28/2017 meeting1	ML17080A462
59.40	Rob O'Donel, Radiation Safety Consultant, President, Suntrac Services	Suntrac Services	Industrial	FRN, Security, Q1	If you could clearly explain aggregation. MD Anderson said that their facility would be increasing the number of people that go through the T&R. By putting Category 3 quantities into Part 37 - facilities that are currently not doing T&R and have no idea what T&R is --- and some of these facilities are large, maybe upwards of 8000 people that have access basis and unescorted access to these sources - mainly fixed gauges in the petrochemical industry. So it would be a huge impact to those facilities.	SA	Transcript p93	02/28/2017 meeting1	ML17080A462
59.41	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q1	Heard three different elements in response to Mr. Jacobi's question regarding the extent to which oil and gas industry, for example, would need to comply with Part 37. Think I heard that the license must authorize for that Category 3 threshold, the licensee must be licensed for some greater number than the Category 3 threshold, and material possessed must be collocated in such a way that no aggregation could occur.	SA	Transcript p94	02/28/2017 meeting1	ML17080A462
59.42	Monty Pope	Tracerco, Johnson Matthey Inc.	Industrial	FRN, Security, Q2	Comment transcends both 1 and 2. Leaning towards letting the regs stand as they are. That will have a significant impact on us commercially and operationally, and I'm still having a hard time seeing the justification for upping it, and the risk associated with it versus significant costs	SA	Transcript p98	02/28/2017 meeting1	ML17080A462

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59.43	Rick Jacobi	Jacobi Consulting	Industrial	FRN, Security, Q2	Reinforce what Mr. Pope just said. The severe commercial implications of requiring generally licensed companies to become specifically licensed for the same devices. Going back to the oil and gas industry, when distributors in Texas and elsewhere are distributing devices to companies like Chevron or Exxon that may have huge quantities of these devices that, in aggregate, probably exceed Category 3 quantities. If you went to those companies and said, now you have specific devices that are subject to a safety plan, and on, and on, and on, these companies would be surprised and probably look at other ways to do gauging and metering and monitoring.	GLDs	Transcript p98	02/28/2017 meeting1	ML17080A462
59.44	Rick Jacobi	Jacobi Consulting	Industrial	FRN, Security, Q2	Currently distributors have to report their distribution in Texas, and in some cases, depending on the quantity of the device, general licensees have to file general license acknowledgements in Agreement States or others, perhaps the NRC as well. Maybe even those reports could be beefed up a bit instead of requiring a special license. Requiring a special license would be extremely expensive and not well received.	GLDs	Transcript p99	02/28/2017 meeting1	ML17080A462
59.45	Rick Jacobi	Jacobi Consulting	Industrial	FRN, Security, Q2	With the general licensee, if distribution reports could be done electronically, that would help business	GLDs	Transcript p100	02/28/2017 meeting1	ML17080A462
59.46	Roland Backhaus	Pillsbury Winthrop Shaw Pittman LLP	Industrial	FRN, Security, Q2	How is it that a specific license to a manufacturer or distributor can verify quantities that company which hold the device generally. Why can't the distributor determine the amount of material his customer, the general licensee has. Large companies with some large number of generally licensed devices don't have as stringent safety standards as specifically licensed device. How can a specific licensee verify quantities that his customers would have, when that customer has sources and an additional transfer might have them go over Category 3 quantities.	GLDs	Transcript p100	02/28/2017 meeting1	ML17080A462
60.01	Jeff Pettigrew, Weatherford International	self	Industrial	FRN, General, Q2	Wouldn't the LVS prevent the sting? I'm referencing the GAO sting on Texas, etc. OK, I am referencing the altered paper license.	LVS	Transcript p23	02/28/2017 meeting2	ML17080A472
60.02	Jeff Pettigrew, Weatherford International	self	Industrial	FRN, NSTS, Q1	Does NRC currently have proper funding to audit within 24 hrs the transfer of Cat 1 or Cat 2 sources?	NSTS	Transcript p28	02/28/2017 meeting2	ML17080A472
60.03	Jeff Pettigrew, Weatherford International	self	Industrial	FRN, NSTS, Q4	Does NRC currently have proper funding to audit within 24 hours the transfer of Category 1 or Category 2 sources? If not, what is the purpose of needing this information if it can't be acted upon?	NSTS	Transcript p31	02/28/2017 meeting2	ML17080A472
60.04	Jeff Pettigrew, Weatherford International	self	Industrial	FRN, LVS, Q1	How is the NSTS system secured from hacking considering what happened to the OPM? Having all the data in one place makes NSTS a more desirable target to bad actors.	Cred&SysArc	Transcript p35	02/28/2017 meeting2	ML17080A472
60.05	Jeff Pettigrew, Weatherford International	self	Industrial	FRN, NSTS licensees, Q1	Would LVS be available for export licensing under Part 110?	LVS	Transcript p41	02/28/2017 meeting2	ML17080A472
60.06	Jeff Pettigrew, Weatherford International	self	Industrial	FRN, LVS, AS Q4	Would NSTS source tracking be required when dispatching to temporary job sites such as in well logging and radiography?	NSTS	Transcript p47	02/28/2017 meeting2	ML17080A472
60.07	Jeff Pettigrew, Weatherford International	self	Industrial	FRN, Security, Q2	Would a oilfield yard with pumping units each having a GLD slurry gauge attached, be subject to the aggregation rule, when each gauge is secured to each truck?	GLDs	Transcript p54	02/28/2017 meeting2	ML17080A472

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61.01	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	General	My comments are coming from a background related to the use of gauging devices used in heavy industry, many of which are generally licensed. The GAO audit referenced in the Federal Register Notice addressed obtaining a license, not the diversion of devices from an existing legitimate licensee. There appears to be a problem within the NRC, rather that with a legitimate licensee. The failure of a licensing agency to do what they are supposed to do should not result in burdensome requirements on licensees.	GLDs	Letter	03/06/2017	ML17096A265
61.02	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	General	In general, there is a lack of awareness of the widespread use of radioactive sources in gauging devices by the general public; It would behoove the NRC and the agreement states to maintain this low level of awareness on the part of the public in order to reduce the potential for diversion of these devices for malevolent purposes.	GLDs	Letter	03/06/2017	ML17096A265
61.03	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	General	Another general comment is that most gauging devices are not that easy to remove from the gauge frame or their installation, removal will usually cause someone to notice that the gauge is not doing what it is supposed to do, in many cases, an attempt to removal will alert nearby personnel of a potential "safety" hazard, and the installations are typically "controlled" areas in which an "outsider" would be confronted, if only for safety reasons.	GLDs	Letter	03/06/2017	ML17096A265
61.04	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	General	In general, there should be minimal economic impact on transferors validating that a transferee is licensed to receive a Category 3 source. This is actually a requirement in Part 30 for specifically licensed sources and should not be that much of a hardship for generally licensed devices.	GLDs	Letter	03/06/2017	ML17096A265
61.05	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	General	There also should not be that much of an economic impact for requiring Category 3 sources to be included in the NSTS, provided the NRC finds that this is necessary. As stated in the first paragraph, gauging devices are probably of a low risk of diversion. In the case of generally licensed Category 3 sources, they are currently required to be registered with the NRC or an agreement state under Part 31.5(c)(13)(i), so registering in NSTS should not be much of a problem.	NSTS	Letter	03/06/2017	ML17096A265
61.06	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, General, Q1	While this may be an easy task for a manufacturer, it is not that easy for a licensee, especially a GL attempting to dispose of a source. The NRC's databases are not very "user friendly." There should be an easier way for Category 3, e.g., receiving a current copy of the broker's license or a declaration that they are licensed to receive the sources. In the case of a transfer to a non-disposal licensee, a copy of new licensee's license and a call to the licensing agency to verify the license authorization should suffice.	LVS	Letter	03/06/2017	ML17096A265
61.07	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, General, Q2	There may be an increase in security, however, as explained in 1 above, for a licensee, it can be difficult to work through the NRC's database. I cannot see where there would be any increase in safety requiring your proposal versus what I have suggested.	SA	Letter	03/06/2017	ML17096A265
61.08	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, General, Q3	Yes. But also include licensed disposal brokers.	LVS	Letter	03/06/2017	ML17096A265
61.09	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, General, Q4	See 1 above.	LVS	Letter	03/06/2017	ML17096A265

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61.10	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, NSTS, Q1	The NSTS system is relatively easy to deal with for someone such as a RSO for a specific licensee; however, it can be confusing for a GL, in terms of registering. Does the NRC have any data to show that Category 3 sources would cause real harm if diverted, other than psychological panic if used in a "dirty bomb?" The real hazard is the explosion. In terms of a gauge sealed source capsule, has the NRC tried to blow up a sealed source device? Was the capsule blown apart, releasing the radioactive material, or just ejected out of the housing.	SA	Letter	03/06/2017	ML17096A265
61.11	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, NSTS, Q2	No. We are dealing with much smaller and less dangerous sources. Additionally, in many gauge facilities, especially those that are GL, you are dealing with a real lack of radiation safety knowledgeable personnel. If you want to require 20.2207(f), then require the transferor to perform the registration for the GL and even for a small specific licensee with a few Category 3 gauges.	GLDs	Letter	03/06/2017	ML17096A265
61.12	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, NSTS, Q3	If you do decide to require this for Category 2 sources, the transferor should bear the responsibility, especially in the case of a new licensee. An alternative would be to have a representative of the licensing agency work with the licensee to perform the registration. From personal experience, some licensing agencies have been remiss in notifying the NSTS of a new license in a timely manner. If the licensing agencies cannot get their act together, should you really expect more from licensees?	NSTS	Letter	03/06/2017	ML17096A265
61.13	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, NSTS, Q4	No comments.	NSTS	Letter	03/06/2017	ML17096A265
61.14	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, NSTS, Q5	No comments.	NSTS	Letter	03/06/2017	ML17096A265
61.15	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, LVS, Q1	The NRC has a poor response time in granting licenses, often 3 months or more. If you add Category 3 sources, how will this affect license verification? You are likely to delay the transfer and use of needed devices, especially if you add the license approval time to the license verification time, it could seriously delay the installation of needed gauges. If I go to a licensed gun dealer and buy a gun, it takes minutes to an hour to get verification from the FBI. Perhaps the NRC should learn from the FBI.	LVS	Letter	03/06/2017	ML17096A265
61.16	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, LVS, Q2	In terms of Category 3 sources, 4 per year. Typically, 1 per year from a manufacturer, and three per year to a broker for disposal.	LVS	Letter	03/06/2017	ML17096A265
61.17	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, LVS, Q3	No. This should also include licensed disposal brokers.	LVS	Letter	03/06/2017	ML17096A265
61.18	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, LVS, Q4	See 1 above.	LVS	Letter	03/06/2017	ML17096A265

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61.19	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, NSTS licensees, Q1	No it doesn't. I got a client credentialed in one day. However, as indicated in 1 under the specific questions for license verification, is your system capable of handling the number of Category 3 sources? Does the NRC even know how many Category 3 sources are possessed by NRC and agreement state licensees? If it is taking a month to get credentialed for Category 1 and 2, it is likely the system will be swamped with Category 3.	Cred&SysArc	Letter	03/06/2017	ML17096A265
61.20	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, NSTS licensees, Q2	No problems.	NSTS	Letter	03/06/2017	ML17096A265
61.21	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, Security, Q1	No. Has the NRC been able to justify that there is a real hazard from diverted Category 3 sources?	SA	Letter	03/06/2017	ML17096A265
61.22	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, Security, Q2	Yes. This should have been done years ago. However, the limit should be at Category 2, or at a level well above the activities in commonly used gauging devices. Again, there are a multitude of gauging sources that would meet the Category 3 limits, either singly or aggregated, which have been used safely and without any security incidents over the years. The cost in terms of both time and money to force these GL's to become specific licensees (license costs, personnel costs in terms of license application preparation, survey meter purchases, training, lost time due to inspections, etc.) all come with no real increase in safety or security to the public. Thus, the cost-benefit ratio is astronomical.	SA	Letter	03/06/2017	ML17096A265
61.23	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	FRN, Security, Q2	I believe the Canadian government ran some tests a few years ago in which sources/devices containing source were deliberately blown up. If I remember correctly, the extent of the contamination was minimal. Has the NRC ever tried to reproduce these tests, and if not, why not? Instead of further burdening the regulated community without any proof of real hazards, the NRC should show the hazard is real.	SA	Letter	03/06/2017	ML17096A265
61.24	A. LaMastra, CHP	Health Physics Associates, Inc.	Industrial	General	It is doubtful the NRC will ever modify it's linear non-threshold and ALARA philosophy even though there is increasing scientific thought that they are not in the best interests of society; forcing the wasteful expenditure of scarce resources for a minimal hazard. This should not be another process in which over-reaction, and the resultant wasting of limited financial and personnel resources are expended without showing there is a real problem.	SA	Letter	03/06/2017	ML17096A265