

## Summary of Stakeholder Outreach and Comments

The Staff Requirements Memorandum for COMJMB-16-0001, "Proposed Staff Re-Evaluation of Category 3 Source Accountability," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16292A812) directed the U.S. Nuclear Regulatory Commission (NRC) staff to "collaborate with its Agreement State partners, non-Agreement States, regulated entities, public interest groups, industry groups such as those in the medical and industrial fields, and the reactor community, to fully assess the regulatory impact for any recommendations made in the notation vote paper." This enclosure describes the outreach activities conducted by the Category 3 Source Security and Accountability Working Group (C3WG) to obtain stakeholder input and summarizes the feedback received as a result of those outreach activities.

### *Stakeholder Outreach Activities*

In order to fully assess the regulatory impact of recommendations considered as part of the source security and accountability re-evaluation of Category 3 quantities of radioactive material, the C3WG actively sought feedback from the wide array of stakeholders who could be impacted by regulatory changes related to the control of Category 3 quantities of radioactive material. The C3WG's efforts included issuing a *Federal Register* Notice (FRN) with more than 20 questions to inform the evaluation; hosting a series of public meetings at both the NRC headquarters and offsite in locations where large concentrations of radioactive materials licensees are present; sending letters to affected entities to encourage feedback; and providing presentations at meetings and conferences to increase awareness of the C3WG's effort. Specific details of these outreach activities are provided below.

- **Federal Register Notice.** The C3WG published an FRN with specific questions for stakeholders to consider regarding Category 3 sources. The FRN was published for a 60-day comment period on January 9, 2017 (82 FR 2399), with a subsequent correction published on January 17, 2017 (83 FR 4938).
- **Public Meetings/Webinars.** The C3WG held five public meetings to facilitate feedback on the Category 3 re-evaluation effort. Two meetings were held outside the Washington, D.C. area – in Boston, Massachusetts and in Houston, Texas – in order to facilitate receipt of feedback from medical and industrial (e.g., well logging) licensees. The offsite meetings consisted of two sessions each to maximize the opportunity for public participation. Table 1 identifies the meeting dates and locations and provides reference to meeting summaries and transcripts.

*Table 1: Public Meetings/Webinars Held as Part of the Source Security and Accountability Re-Evaluation of Category 3 Quantities of Radioactive Material*

<b>Meeting Date</b>	<b>Meeting Location</b>	<b>Meeting Type</b>	<b>Meeting Summary ADAMS Accession No.</b>	<b>Meeting Transcript ADAMS Accession No.</b>
January 31, 2017	Rockville, MD	Public meeting/ webinar	ML17045A379	ML17045A353
February 21, 2017	Rockville, MD	Webinar	ML17080A254	ML17079A125
February 23, 2017	Boston, MA	Public meeting/ webinar (2 sessions)	ML17081A364	<u>Session 1:</u> ML17079A131 <u>Session 2:</u> ML17080A113
February 28, 2017	Houston, TX	Public meeting/ webinar (2 sessions)	ML17083A165	<u>Session 1:</u> ML17080A462 <u>Session 2:</u> ML17080A472
March 2, 2017	Rockville, MD	Webinar	ML17081A301	ML17079A140

- **Outreach Letters, Publications, and Postings.**
  - The C3WG distributed letters to the following organizations to promote participation in the public meetings and webinars, and to facilitate response to the questions posed in the FRN:
    - American Association of Physicists in Medicine (AAPM)
    - American Brachytherapy Society
    - Association of Energy Service Companies
    - American Society for Nondestructive Testing (ASNT)
    - American Society for Radiation Oncology
    - Conference of Radiation Control Program Directors (CRCPD)
    - Health Physics Society (HPS)
    - International Source Suppliers and Producers Association
    - Low Level Waste (LLW) Forum
    - Nondestructive Testing Management Association (NDTMA)
    - Nuclear Energy Institute
    - National Registry of Radiation Protection Technologists
    - Society of Petroleum Engineers
    - Society of Petrophysicists and Well Log Analysts
    - National Organization of Test, Research, and Training Reactors
  - The C3WG published articles in the following periodicals:
    - HPS Health Physics News (ADAMS Accession No. ML17038A563)
    - CRCPD Newsbrief (ADAMS Accession No. ML17062B000)
    - Office of Nuclear Material Safety and Safeguards News Link (ADAMS Accession No. ML17073A068)

- The C3WG developed flyers to promote participation in the public meetings/webinars and FRN feedback (ADAMS Accession No. ML17048A103) and distributed them to the NRC Regions and Agreement States.
- The C3WG also leveraged web-based outreach mechanisms by creating a dedicated page on the NRC's public Web site: <https://www.nrc.gov/security/byproduct/category-3-source-security-accountability-reevaluation.html>, and writing a post on re-evaluating source protection and accountability of Category 3 quantities of radioactive material for the NRC Blog: <https://public-blog.nrc-gateway.gov/2017/01/17/re-evaluating-category-3-source-protection-and-accountability/>.
- Finally, the NRC staff provided presentations at numerous external meetings and conferences (see Table 2).

*Table 2: External Meetings during which the NRC Provided Presentations on the Source Security and Accountability Re-Evaluation of Category 3 Quantities of Radioactive Material*

<b>Meeting Date</b>	<b>Meeting Location</b>	<b>Organization</b>	<b>Meeting Type</b>
January 23, 2017	Rockville, MD	HPS	Mid-year meeting
February 16, 2017	Las Vegas, NV	NDTMA	Annual conference
March 14, 2017	Jacksonville, FL	ASNT	Research symposium
March 14-16, 2017	Rockville, MD	NRC	Regulatory Information Conference poster
March 20, 2017	New Orleans, LA	AAPM	Spring clinical meeting
April 25, 2017	Denver, CO	LLW Forum	Meeting
April 26, 2017	Rockville, MD	Advisory Committee on Medical Uses of Isotopes	Semi-annual meeting
May 10, 2017	Scottsdale, AZ	CRCPD	Annual conference
May 17, 2017	Piscataway, NJ	HPS New Jersey Chapter	HPS Chapter Meeting

### *Summary of Stakeholder Comments*

As a result of the stakeholder outreach activities outlined above, the C3WG received approximately 1,015 comments. This includes both comments obtained from 54 individual letters and comments provided during the public meetings and webinars. All of the comments are available in a separate table (ADAMS Accession No. ML17191B140) and on <https://www.regulations.gov> under Docket ID NRC-2016-0276.

After reviewing the comments, the C3WG binned them into six categories:

1. Comments related to the License Verification System (LVS);
2. Comments related to the National Source Tracking System (NSTS);
3. Comments related to the Web-Based Licensing (WBL) System;
4. Comments related to credentialing and general system architecture;
5. Comments related to the assessment of safety and security; and
6. Comments related to general licenses (GLs).

Once the comments were binned by category, they were further grouped by stakeholder type. The six stakeholder types were as follows:

1. *Agreement States* – Comments were received from the Organization of Agreement States (OAS) and 16 Agreement States;
2. *Non-Governmental organizations (NGOs)* – Comments were received from 10 NGOs;
3. *Medical stakeholders* – Comments were received from 16 medical stakeholders;
4. *Industrial stakeholders* – Comments were received from 26 industrial stakeholders;
5. *Academic stakeholders* – Comments were received from 3 academic stakeholders; and
6. *Government stakeholders* – Comments were received from 3 government stakeholders.

The following tables provide a summary of the comments received in each of the six comment categories by stakeholder type.

*Table 3: Summary of Comments related to the License Verification System*

Agreement States	<ul style="list-style-type: none"> <li>• OAS and most Agreement States were opposed to requiring license verification through the LVS or the regulator for transfers of Category 3 quantities of radioactive material.</li> <li>• Most Agreement States commented that there is not a clear safety and security basis for a change and that such a change would be an over-reaction to the Government Accountability Office (GAO) findings.</li> <li>• One State indicated that while it believes the current regulations are adequate, the state could see a benefit to license verification through the LVS or the regulator for licenses authorizing Category 3 quantities of radioactive material, because of the GAO findings.</li> <li>• Most Agreement States commented that if the NRC requires license verification through the LVS or the regulator for licenses authorizing Category 3 quantities of radioactive material, they would encourage their licensees to use the LVS.</li> <li>• OAS and most Agreement States indicated that if the NRC requires license verification through the LVS or the regulator for licenses authorizing Category 3 quantities of radioactive material, then exemptions should be considered for licensees returning sources to the manufacturer.</li> <li>• One State suggested the consideration of exemptions for well-established, known licensees such as manufacturers and distributors (M&amp;Ds), waste processors, and commercial disposal sites.</li> <li>• One State suggested that the NRC consider these exemptions be applied to license verification for licenses authorizing Category 1 and Category 2 quantities of radioactive material in a similar manner.</li> <li>• One State suggested that the working group consider recommendations that will make licenses more difficult to alter or forge.</li> </ul>
NGOs	<ul style="list-style-type: none"> <li>• Most NGOs were opposed to requiring license verification through the LVS or the regulator for transfers of Category 3 quantities of radioactive material. These NGOs commented that there is not a clear safety and security basis for the change and that such a change would be an over-reaction to the GAO findings.</li> <li>• One NGO commented that the current requirements are adequate when considering the strong safety and security history for radioactive materials. However, the NGO noted that it could see a benefit to the change because of the GAO findings regarding falsification of a license.</li> <li>• One NGO commented that if license verification for licenses authorizing Category 3 quantities of radioactive material is required through the LVS or the regulator, then all licenses should be verified with no exemptions.</li> <li>• One NGO commented that licensees returning sources to an M&amp;D should be exempt since these sources are usually returned as part of a source replacement transaction.</li> <li>• Some NGOs stated that the NRC should consider exemptions beyond just source returns to manufacturers. One NGO stated that licenses for a known, established licensee such as a power reactor, fuel facility, waste processor, or commercial disposal facility, should not need to be verified.</li> </ul>

Medical Stakeholders	<ul style="list-style-type: none"> <li>• Most stakeholders were opposed to requiring license verification through the LVS or the regulator for transfers of Category 3 quantities of radioactive material.</li> <li>• These stakeholders commented that such a change would only add administrative burden (thus increasing medical care costs) with no real benefit to security.</li> <li>• Several stakeholders mentioned that they would have to increase the number of credentialed individuals if license verification requirements were expanded to include Category 3 radioactive materials.</li> <li>• One stakeholder commented that increasing the number of LVS users and sources presents a cyber security risk as more and more individuals have access to the system and can view license images.</li> <li>• Regarding LVS usage, some licensees said that they would use the LVS, while others indicated that with infrequent transfers, manual license verification would be simpler.</li> <li>• Several stakeholders suggested that license verification exemptions be provided for source exchanges with manufacturers.</li> <li>• One stakeholder, while agreeing with a broader exemption, stated that the NRC should at least consider exemptions for medical institutions because they must be properly vetted and approved by health departments and other State agencies before treating patients.</li> <li>• Several stakeholders provided estimates on the number of monthly transfers involving Category 3 quantities of radioactive material and the percentage of those transfers that involve the M&amp;D.</li> </ul>
Industrial Stakeholders	<ul style="list-style-type: none"> <li>• Most stakeholders were opposed to requiring license verification through the LVS or the regulator for transfers of Category 3 quantities of material.</li> <li>• Several stakeholders mentioned that they would have to increase the number of credentialed individuals.</li> <li>• One stakeholder commented that increasing the number of users and sources presents a cyber security risk as more individuals have access to the system and can view license images.</li> <li>• Some licensees said that they would use the LVS, while others indicated that with infrequent transfers, manual license verification would be simpler.</li> <li>• Overall, these stakeholders were not against the concept of exemptions, but wanted the NRC to provide a clear description of when an exemption would apply and what limitations would exist.</li> <li>• Three stakeholders recommended that the NRC expand exemptions beyond source returns (i.e., to include transfers to known waste processing and disposal facilities).</li> <li>• Several stakeholders commented that the NRC should implement a graded approach to license verification requirements, taking into consideration standard uses for Category 3 devices and radioactive materials.</li> <li>• Several stakeholders provided estimates on the number of monthly transfers involving Category 3 quantities of radioactive material and the percentage of those transfers that involve the M&amp;D.</li> </ul>

Academic Stakeholders	<ul style="list-style-type: none"> <li>One commenter was in favor of requiring license verification through the LVS or the regulator for all radioactive material transfers.</li> </ul>
Government Stakeholders	<ul style="list-style-type: none"> <li>Two commenters were in favor of requiring license verification through the LVS or the regulator for transfers of Category 3 quantities of radioactive material.</li> <li>One commenter was opposed to the change and highlighted how it would significantly impact their operations.</li> </ul>

*Table 4: Summary of Comments related to the National Source Tracking System*

Agreement States	<ul style="list-style-type: none"> <li>OAS and most Agreement States were against the expansion of NSTS to include Category 3 sources.</li> <li>Agreement States generally commented that there is no clear safety and security basis for expansion of NSTS.</li> <li>OAS and Agreement States were not in favor of taking over the responsibility of administering the annual inventory reconciliation (AIR). Some commented that if the NRC passed the responsibility onto them, they would conduct the AIR as part of inspection activities.</li> <li>Two Agreement States questioned the continuing need for the AIR and suggested removing it from regulations and conducting it as part of inspections.</li> <li>OAS and most Agreement States were against changing the current NSTS reporting requirements as they did not see a basis for the change.</li> <li>One State suggested revising the reporting requirement for entering source transactions into NSTS to be by the next day, including over weekends.</li> <li>One State suggested revising the reporting requirement for Category 1 source transfers to be reported on the same day of the transfer.</li> <li>Two States suggested allowing additional time for reporting Category 3 sources to NSTS based on the lower associated risk.</li> </ul>
NGOs	<ul style="list-style-type: none"> <li>Most NGOs were against the expansion of NSTS to include Category 3 sources.</li> <li>The NGOs generally commented that there is no clear safety and security basis for expansion of NSTS, and that the number of sources and transactions would vastly increase, resulting in significant burden on both, the regulator and the licensee.</li> <li>One NGO questioned the continuing need for the AIR and suggested removing it from regulations and conducting AIR as part of its inspections.</li> <li>Most NGOs were against changing the current NSTS reporting requirements, stressing that the current reporting requirements are adequate and changes would not provide any meaningful additional safety or security benefits.</li> <li>One NGO suggested that routine preplanned exchanges between the manufacturer and user licensee be considered as one reportable transaction (for both sending and returning).</li> </ul>

	<ul style="list-style-type: none"> <li>• Another NGO suggested more real-time reporting to NSTS since shipping papers are completed prior to shipment.</li> </ul>
Medical Stakeholders	<ul style="list-style-type: none"> <li>• Most stakeholders were against the expansion of NSTS to include Category 3 sources.</li> <li>• These stakeholders provided information on how most medical facilities have one high dose rate (HDR) afterloader device, and source replacement is conducted in a manner where they do not store and aggregate these sources to Category 2 quantities. Also, sources are received from, and returned to, the same manufacturer.</li> <li>• They commented that such an expansion would only add administrative burden (thus increasing medical care costs) with no real benefit to security.</li> <li>• Six stakeholders commented that the GAO audit highlighted a pre-licensing and licensing issue, which is the regulator responsibility, not a problem with the industry management of Category 3 sources.</li> <li>• One stakeholder commented that expanding the system to include more sources and users only adds additional burden to regulator staff to ensure the integrity of all the information, including Category 3 sources, which dilutes the regulator's focus on Category 1 and Category 2 radioactive material.</li> <li>• One stakeholder commented that increasing the number of users and sources presents a cyber security risk as more and more individuals have access to the system and the information within it.</li> <li>• Some licensees said that they would use the NSTS if Category 3 sources were included, while others indicated that with infrequent transactions, fax and e-mail would be easier.</li> <li>• Two stakeholders commented that Agreement States should not take over the responsibility of administering the AIR for their licensees because Agreement States do not need another unfunded mandate and that the process the NRC uses is good.</li> <li>• Several stakeholders said that current NSTS reporting requirements and shipment planning activities are adequate.</li> </ul>
Industrial Stakeholders	<ul style="list-style-type: none"> <li>• Ten stakeholders were against the expansion of NSTS to include Category 3 sources, citing the rationale that current requirements are adequate and such an expansion would only add administrative burden to both the regulator and the licensee with no increase in security.</li> <li>• Two stakeholders were in favor of expanding NSTS to include Category 3 sources. These stakeholders stated that Category 3 sources are dangerous, and having Category 3 source information readily available in NSTS could provide assistance with response actions, such as fire or other emergencies at facilities.</li> <li>• Several stakeholders commented that the number of sources and transactions would increase significantly and questioned whether the additional resources needed by the regulators to ensure that Category 3 source information is up-to-date and correct would be better utilized elsewhere.</li> <li>• One stakeholder noted that only real-time reporting could result in some additional security benefit.</li> <li>• Some stakeholders commented that increasing burden on licensees would discourage use of devices for applications where they are both cost-effective and safe.</li> </ul>



	<ul style="list-style-type: none"> <li>• Seven stakeholders commented that the GAO audit highlighted a pre-licensing and licensing issue, which is the regulator responsibility, not a problem with the industry management of Category 3 sources.</li> <li>• One stakeholder noted that an NSTS expansion would not have prevented GAO's outcome during the audit. This stakeholder further compared NSTS to a checkbook ledger; it keeps track of items and cannot prevent theft of material.</li> <li>• One stakeholder commented that reporting requirements for Category 3 sources should be similar to Category 1 and Category 2 sources.</li> <li>• Two stakeholders advocated applying a graded approach to reporting requirements for Category 3 sources.</li> <li>• Three stakeholders said current NSTS requirements are adequate; two of these stakeholders pointed out that since licensees can fax or e-mail information, data entry introduces a delay, and information is not in the system in real time. As a result, the stakeholder felt that there would be no improved security benefit from revising the reporting times.</li> </ul>
Academic Stakeholders	<ul style="list-style-type: none"> <li>• All three stakeholders opposed expanding NSTS to include Category 3 sources.</li> <li>• One stakeholder questioned how this change would be consistent with the Atomic Energy Act mandate to impose the minimum amount of regulations to research and test reactors.</li> <li>• Another stakeholder commented that there is no safety and security basis for such an expansion.</li> </ul>
Government Stakeholders	<ul style="list-style-type: none"> <li>• Two stakeholders supported the expansion of NSTS to include Category 3 sources.</li> <li>• One stakeholder opposed the expansion of NSTS to include Category 3 sources because it would significantly impact their operations.</li> <li>• One stakeholder commented that Category 3 is risk-significant and should be treated similar to Category 1 and Category 2, and that malicious aggregation and misuse could result in significant long term damage to the environment and economy, and impacts to public health and safety.</li> <li>• One stakeholder commented that Category 3 should be treated similar to Category 1 and Category 2 and noted that Category 3 quantities of radioactive material can be assembled into Category 1 or Category 2 quantities. The stakeholder also pointed out that some sources at the upper threshold of Category 3 pose more risk than other sources at the lower threshold of Category 2.</li> </ul>

*Table 5: Summary of Comments related to the Web-Based Licensing System*

Agreement States	<ul style="list-style-type: none"> <li>• Agreement States indicated that they would voluntarily provide their licenses authorizing Category 3 quantities of radioactive material to be included in WBL, similar to what they currently do for licenses authorizing Category 1 and 2 quantities of radioactive material.</li> <li>• Two States indicated that they already use WBL.</li> <li>• Several States indicated that they have no plans to adopt WBL.</li> <li>• One State indicated that they would consider transitioning to WBL.</li> <li>• Some States provided information on their number of licenses authorizing Category 3 quantities of radioactive material.</li> </ul>
NGOs	<ul style="list-style-type: none"> <li>• One NGO indicated that there is a significant backlog of States waiting to use WBL, and that the NRC should make it a priority to work with States to evaluate potential opportunities to expand the use of WBL to increase regulatory efficiency and consistency.</li> </ul>
Medical Stakeholders	<ul style="list-style-type: none"> <li>• These stakeholders did not provide any comments related to this topic.</li> </ul>
Industrial Stakeholders	<ul style="list-style-type: none"> <li>• These stakeholders did not provide any comments related to this topic.</li> </ul>
Academic Stakeholders	<ul style="list-style-type: none"> <li>• These stakeholders did not provide any comments related to this topic.</li> </ul>
Government Stakeholders	<ul style="list-style-type: none"> <li>• One stakeholder supported including licenses authorizing Category 3 quantities of radioactive material in WBL.</li> </ul>

*Table 6: Summary of Comments related to Credentialing and System Architecture*

Agreement States	<ul style="list-style-type: none"> <li>• One State recommended linking NSTS and WBL to share basic licensee information to improve data integrity and efficiency.</li> <li>• One State indicated that credentialing will be a barrier for licensees authorized for Category 3 quantities of radioactive material to verify licenses, so the majority of these licensees will use the manual license verification process instead of the LVS.</li> <li>• Some States were concerned with the data security and potential for hacking of the systems if regulations were changed.</li> <li>• Some States indicated that there would be an extra cost associated with maintaining a larger database and could introduce additional errors with the added data entry.</li> </ul>
NGOs	<ul style="list-style-type: none"> <li>• Some NGOs had concerns as to the capabilities of NSTS and LVS to handle the inclusion of Category 3 sources and the verification of licenses.</li> <li>• Some NGOs indicated that credentialing would be cumbersome, so more licensees would use the manual license verification process and manual reporting to NSTS, which could present a delay in the information getting into the systems.</li> <li>• Some NGOs were concerned with the cyber security of the systems and data integrity.</li> <li>• One NGO was concerned with fields in State databases that might be different from fields in the Federal databases that are not interconnected, resulting in duplicative efforts and an extra cost.</li> </ul>
Medical Stakeholders	<ul style="list-style-type: none"> <li>• These stakeholders did not provide any comments related to this topic.</li> </ul>
Industrial Stakeholders	<ul style="list-style-type: none"> <li>• One stakeholder requested more information on the message displayed by the LVS to contact the regulatory agency when a license verification cannot be completed.</li> <li>• One stakeholder requested that the systems be accessible using Wi-Fi.</li> </ul>
Academic Stakeholders	<ul style="list-style-type: none"> <li>• These stakeholders did not provide any comments related to this topic.</li> </ul>
Government Stakeholders	<ul style="list-style-type: none"> <li>• These stakeholders did not provide any comments related to this topic.</li> </ul>

*Table 7: Summary of Comments related to Assessment of Safety and Security*

Agreement States	<ul style="list-style-type: none"> <li>• OAS and all Agreement States who provided comments opposed the expansion of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 37 requirements to include Category 3 quantities of radioactive material because of the significant burden associated with implementing those requirements, and that current requirements are adequate to ensure the safety and security of radioactive materials.</li> <li>• One State commented that if the NRC expands security requirements to include Category 3 sources, their recommendation would be a limited application of 10 CFR Part 37 such as conducting a trustworthy and reliability determination on the radiation safety officer of licensees authorized to possess Category 3 quantities of radioactive material.</li> <li>• One State suggested that if the NRC expands security requirements to include Category 3 sources, then the NRC should consider limiting the expansion to portable Category 3 devices.</li> <li>• One State commented that the NRC should change 10 CFR Part 37 to compatibility category C to allow States the flexibility to add more stringent requirements.</li> <li>• Some States suggested that applying the 10 CFR Part 37 security requirements would be problematic for fixed gauges and HDR licensees.</li> </ul>
NGOs	<ul style="list-style-type: none"> <li>• Most NGOs opposed expanding 10 CFR Part 37 security requirements to include licensees possessing Category 3 quantities of radioactive material.</li> <li>• Several NGO comments focused on how Category 3 sources are used in medical settings and why an expansion to 10 CFR Part 37 would not provide any real improvement to safety and security.</li> <li>• Several NGOs commented that additional security requirements could either conflict with patient privacy laws or cause significant costs to ensure compliance with both NRC requirements and patient privacy laws.</li> <li>• Several NGOs commented that the additional regulatory oversight, cost, and administrative burden may cause some licensees to stop offering treatments and that patient access to care would be diminished.</li> <li>• One NGO said that expanding security requirements would most likely lower the bar and reduce overall security for licensees that also possess Category 1 and Category 2 quantities of radioactive material due to the added burden and cost to implement.</li> </ul>

Medical Stakeholders	<ul style="list-style-type: none"> <li>• Most stakeholders opposed expanding 10 CFR Part 37 security requirements to include licensees possessing Category 3 quantities of radioactive material.</li> <li>• Several stakeholders questioned the benefits and the safety and security basis for an expansion of 10 CFR Part 37.</li> <li>• One stakeholder raised concerns about the use of security cameras and video recordings, which may affect patient privacy.</li> <li>• One stakeholder commented that they were not aware of any past events that would justify imposing 10 CFR Part 37 security requirements on Category 3 quantities of radioactive materials. However, they noted that additional guidance on the NRC's expectations for implementing 10 CFR 20.1801 and 20.1802 for Category 3 quantities of radioactive materials would be beneficial to the medical community.</li> <li>• Several stakeholders provided comments about patient privacy laws and how additional security could either conflict with these laws or cause significant costs to ensure compliance with both NRC requirements and patient privacy laws.</li> </ul>
Industrial Stakeholders	<ul style="list-style-type: none"> <li>• Most stakeholders opposed expanding 10 CFR Part 37 security requirements to include licensees possessing Category 3 quantities of radioactive material. They questioned the benefits and the safety and security basis for an expansion of 10 CFR Part 37.</li> <li>• Two stakeholders agreed with expanding 10 CFR Part 37 to Category 3 quantities of radioactive material but did not agree with applying all of the security requirements of Category 2 to Category 3 quantities of radioactive material.</li> <li>• One stakeholder stated that the NRC should consider uses of the material when developing requirements, and another stated that the NRC should implement requirements somewhere between 10 CFR Part 20 and 10 CFR Part 37 for Category 3 quantities of radioactive material.</li> <li>• One stakeholder suggested that the NRC consider a graded approach to Category 3 quantities of radioactive material.</li> <li>• Most stakeholders focused on how Category 3 devices and radioactive materials are used in industrial settings and why the expansion of 10 CFR Part 37 to Category 3 quantities of radioactive material will not provide any real improvement to safety and security.</li> <li>• One stakeholder commented this would have a disproportionate effect on small businesses.</li> </ul>

Academic Stakeholders	<ul style="list-style-type: none"> <li>• All of the stakeholders opposed expanding 10 CFR Part 37 requirements to include Category 3 quantities of radioactive material.</li> <li>• One stakeholder questioned how this action would be consistent with the Atomic Energy Act mandate to impose the minimum amount of regulations to research and test reactors.</li> <li>• Another stakeholder commented that the NRC has not demonstrated any basis for such an expansion.</li> <li>• One stakeholder commented that the NRC has not identified the quantities below Category 2 thresholds that require additional security. This stakeholder also commented that increasing security on Category 3 quantities of radioactive materials would be a significant burden.</li> </ul>
Government Stakeholders	<ul style="list-style-type: none"> <li>• Two stakeholders were in favor of expanding 10 CFR Part 37 to include Category 3 quantities of radioactive material because of the risk that this material poses and stated that the increase in safety and/or security would be commensurate with those for Category 1 and Category 2 sources.</li> <li>• One stakeholder opposed the expansion and highlighted how it would significantly impact their operations.</li> <li>• One stakeholder commented that Category 3 is risk-significant and should be treated similar to Category 1 and 2, and that malicious aggregation and misuse could result in significant long term damage to the environment and the economy, and could impact public health and safety.</li> <li>• One stakeholder noted that the National Research Council reported that Category 3 quantities can be assembled into Category 1 or Category 2 quantities, and that some sources at the upper threshold of Category 3 pose more risk than other sources at the lower threshold of Category 2.</li> </ul>

*Table 8: Summary of Comments related to General Licenses*

Agreement States	<ul style="list-style-type: none"> <li>• OAS and Agreement States commented that if the NRC decides to expand the LVS, NSTS, and 10 CFR Part 37 to include Category 3 sources, then all Category 3 generally licensed devices should be specifically licensed.</li> <li>• States commented that it is too difficult to conduct oversight activities on GLs.</li> <li>• Several States said the NRC should reconsider its GL program and believe radioactive material should be either specifically licensed or exempt.</li> <li>• Two States commented that the NRC should reconsider the GL program and limit the maximum amount of radioactive material that could be in a generally licensed device.</li> <li>• OAS commented that general licensees are typically unaware of the applicable regulations.</li> <li>• One State commented that the concept of a GL is flawed because it allows untrained, unmonitored personnel to use and possess radioactive material based on the potential radiation dose received in a year.</li> </ul>
NGOs	<ul style="list-style-type: none"> <li>• Three NGOs commented that if the NRC expands 10 CFR Part 37 to include Category 3 sources, then all Category 3 generally licensed devices should be specifically licensed.</li> </ul>
Medical Stakeholders	<ul style="list-style-type: none"> <li>• Four stakeholders commented that if the NRC expands 10 CFR Part 37 to include Category 3 sources, then all Category 3 generally licensed devices should be specifically licensed.</li> </ul>
Industrial Stakeholders	<ul style="list-style-type: none"> <li>• Three stakeholders opposed converting Category 3 GLs to specific licenses.</li> <li>• Two stakeholders commented that if the NRC expands 10 CFR Part 37 to include Category 3 sources, then Category 3 generally licensed devices should be specifically licensed.</li> <li>• Two stakeholders commented that the NRC should limit the quantities permitted in a generally licensed device and that Category 3 generally licensed devices should be specifically licensed.</li> </ul>
Academic Stakeholders	<ul style="list-style-type: none"> <li>• These stakeholders did not provide comments related to this topic.</li> </ul>
Government Stakeholders	<ul style="list-style-type: none"> <li>• One stakeholder opposed converting Category 3 GLs to specific licenses and highlighted how the conversion would significantly impact their operations.</li> </ul>