

LOW-LEVEL RADIOACTIVE WASTE FORUM, INC.

2657 Bayview Drive – Ft. Lauderdale, FL 33306
(754) 779-7551 * (754) 223-7452 FAX

Disused Sources Working Group Comments

Proposed Byproduct Material Financial Scoping Study 80 *Federal Register* 46,057 (August 2, 2015)

The Low-Level Radioactive Waste Forum (LLW Forum) is a non-profit organization of representatives appointed by Governors and compact commissions that seeks to facilitate state and compact implementation of the Low-Level Radioactive Waste Policy Act of 1980 and its 1985 amendments, as well as to promote the objectives of regional low-level radioactive waste disposal compacts. In September 2011, the LLW Forum formed the Disused Sources Working Group (DSWG) to develop recommendations from the states and compacts for improving the management and disposition of disused sources.

The U.S. Nuclear Regulatory Commission (NRC) recently announced that the agency plans to conduct a financial scoping study to determine if financial planning requirements for decommissioning and end-of-life management for some radioactive byproduct material are necessary. (See 80 *Federal Register* 46,057 dated August 2, 2015.) The development of robust and comprehensive financial planning requirements for disused sources was one of the 24 recommendations contained in the DSWG's original report as issued in March 2014. (See <http://www.disusedsources.org/wp-content/uploads/2014/12/DSWG-Report-March-2014.pdf>.)

The consideration of financial planning requirements was also one of the three recommendations contained in the Radiation Source Protection and Security Task Force (RSPSTF or Task Force) report that was delivered to the President and Congress on August 14, 2015. (See <http://www.nrc.gov/security/byproduct/2014-task-force-report.pdf>.) The Task Force, which was created pursuant to Section 651(d) of the Energy Policy Act of 2005 (Public Law 109-58), is required to report every four years. The Task Force is chaired by the U.S. Nuclear Regulatory Commission (NRC) and includes members from 14 federal agencies and the Organization of Agreement States (OAS), which represents all state governments that regulate the use of radiation sources.

The DSWG developed and hereby submits for consideration by NRC the following comments in response to the agency's request for stakeholder feedback on its proposed byproduct material financial scoping study as published in the *Federal Register* on August 2, 2015.

In addition, at NRC's urging, the LLW Forum reached out to other stakeholders (i.e., users, manufacturers, industry organizations, etc.) to encourage and solicit input and feedback. Given the time constraints, the DSWG has not had an opportunity to adequately review these other stakeholder comments and therefore has included them as an Appendix for NRC's review and consideration.

Response to NRC Questions re Byproduct Material Financial Scoping Study
Comments Developed by LLW Forum's Disused Sources Working Group

1. What disposition pathways are available to various licensee types beyond the traditional disposal pathway and should be considered in any potential new financial planning requirements?

Reuse and Recycle: Although reuse and recycle is not an option for most disused sources, it can at times be an alternative to traditional disposal. Some disused sources are still valuable resources. One user's disused sources may be usable by another, or the disused sources may contain valuable radioisotopes that can be used in the manufacture of new sources. This could extend the benefits derived from the radioisotopes contained within a disused source. The Conference of Radiation Control Program Directors (CRCPD) currently provides limited information on reuse and recycle options. However, the current regulatory system does not encourage (and at times hinders) the reutilization of disused sources despite the fact that, when available, taking advantage of reuse and recycle opportunities should reduce the number of sources being generated, limit storage and preserve future disposal capacity at existing facilities. Programs that encourage reuse and recycle in other areas of commerce (e.g., tires, computers, and large appliances) could provide beneficial examples to address the responsible disposition of disused sources.

The DSWG recommends that a detailed study should be conducted to identify measures to promote opportunities for the reuse and recycling of sources. In addition, a secure "source exchange" program should be created and administered to work with licensees, source and device manufacturers, and recyclers to provide them with information about sources still having a useful life, with the goal of increasing beneficial reuse and recycle opportunities. The program could identify sources meeting the specific application requirements being sought for reuse or recycling, identify sources containing radioisotopes that can be removed and used to manufacture new sources, and assist with paperwork required for source transfer.

Due to the fact that a relatively small number of disused sources are reusable or recyclable, however, the presumption for financial planning purposes should be that disposal is necessary.

Return to Manufacturers: There is no regulatory requirement that sources be returned to manufacturers and suppliers once their useful life is over. However, at their discretion, source and device manufacturers and suppliers will often accept the return of a disused source if the user is purchasing a new replacement source from the same manufacturer or supplier. This practice—commonly referred to as a "one-for-one exchange"—is not required by federal or state regulations and is not usually an option when the user chooses not to purchase a replacement source from the manufacturer or supplier. However, in its comments to the DSWG, JL Shepherd & Associates reports that the company does take back viable sources that are candidates for recycling without requiring the purchase of a new source.

The return of sources to manufacturers and suppliers results in fewer storage locations and increases the likelihood of beneficial reuse or recycle, thereby reducing the number of new sources that need to be manufactured. In addition, manufacturers and suppliers often have greater institutional knowledge of the product, more comprehensive oversight, and increased physical security in place. However, some source and device manufacturers and suppliers are accumulating large numbers of disused sources in storage with little possibility of reuse or recycle. To prevent the accumulation of an excessive number of sources by manufacturers and suppliers, the DSWG encourages NRC and Agreement States to require manufacturers and suppliers to dispose of those sources that have no reuse or recycle value on an annual basis.

Storage: Many source users are choosing to store their disused sources indefinitely rather than pay for the cost of disposal. This is a concern because sources in long-term storage are more likely to be subject to loss of control and accountability. The 2006 Task Force report states that two years of disuse usually reflects the lack of a plan to use material. In addition, there is a two-year timeframe in the current rules related to decommissioning. The DSWG recognizes, however, that storage for decay may be an appropriate waste management method for some sources with a short half-life and that there are cases (i.e., space propulsion, insect irradiation, some research, etc.) in which storage in excess of two years may be appropriate.

In most cases, NRC and Agreement State regulators currently lack adequate authority to require licensees to dispose of sources that have been stored for an extended period of time. At present, the NRC and Agreement State regulations limit storage for two years only for General Licenses (GL) and in the case of licensee inactivity, but enforcement of this requirement is less certain when licensees claim a potential future use of the source. In the past, it may have been difficult to enforce license storage limits due to a lack of disposal access. This is no longer a constraint for most Class A, B and C disused sources as disposal is now available for these sources throughout the United States. However, the existing regulations do not provide adequate enforcement authority to prevent the indefinite storage of disused sources.

Concentration Averaging: The NRC recently finalized revisions to the Branch Technical Position on Concentration Averaging and Encapsulation (CA BTP), which provides guidance for waste generators, processors, disposal facility operators and regulators in complying with 10 CFR Part 61 regulations as they apply to classification of waste for disposal. In particular, the document outlines acceptable methods to determine radionuclide concentrations in specific waste streams or mixtures of these waste streams and how the concentrations can be averaged over the volume or mass of the waste disposal container.

The revised draft CA BTP increases the allowed concentration and activity for certain isotopes. The NRC's analysis shows that a 130 curie (Ci) cesium-137 sealed source can be safely encapsulated and disposed in a Class C low-level radioactive waste disposal facility where previously the limit on such a source was 30 Ci. The revised draft CA BTP also includes an alternative approaches section that allows the waste generators and waste

processors to work with Agreement State regulators in the states with commercial disposal facilities to consider site-specific and waste-specific information that would allow the acceptance of wastes that would not otherwise be acceptable. This may allow for the disposal of certain higher activity sealed sources.

Government Subsidized Programs: The CRCPD's Source Collection and Threat Reduction (SCATR) program provides cost-shared support for the packaging, transport, and disposal of Class A, B, and C sources with access to a commercial disposal facility. Licensees in all 50 States and U.S. territories are potentially eligible for program participation. SCATR is funded through a grant provided by the U.S. Department of Energy (DOE) National Nuclear Security Administration (NNSA). CRCPD/SCATR is targeting a 45% cost-share amount for 2014-2015 program participants.

The Off-Site Source Recovery Program (OSRP) is a U.S. government activity sponsored by NNSA's Office of Global Material Security and managed at Los Alamos National Laboratory (LANL) through the Nuclear Engineering & Nonproliferation Division. OSRP has an NNSA sponsored mission to remove excess, unwanted, abandoned, or orphan radioactive sealed sources that pose a potential risk to health, safety, and national security. The initial scope of OSRP included any sealed sources comprising Greater than Class C (GTCC) low-level radioactive waste. However, since September 11, 2001, the mission expanded from environmental concerns to address broader public safety and national security requirements. In addition to transuranic sources, the expanded OSRP mission now includes recovery of beta/gamma emitting sources, which are of concern to both the U.S. government and the International Atomic Energy Agency (IAEA).

Although these programs continue to provide significant benefits, the DSWG advocates a reevaluation due to the availability of additional disposal access and the potential that these programs may provide an unintended disincentive to prompt disposal by licensees.

Additional Considerations: Due to the age, activity, packaging, expired certifications and condition most sources cannot be recycled, so in general financial planning should not be based on the unlikely possibility of an alternative disposal pathway. Financial planning must always take into account the possibility that a governmental agency will have to step in and arrange for disposal and in such situations there must be financial resources in place to cover the full disposal costs.

Additionally the NRC needs to adopt waste policies that minimize the number of waste sources being transferred as usable material, particularly for the purposes of *sham recycling*. A simple test should be employed that a licensee must have a need for and be authorized and able to use a source to accept it as non-waste material. Authorization to accept waste should be a specific authorization on a license for anyone accepting waste from another licensee.

2. What should be the primary considerations in establishing and imposing appropriate and equitable financial planning requirements on radioactive sealed sources?

General Recommendations: All licensees including most currently under GL must be able to show that they understand their financial obligations and have a financial plan in place to cover disposal costs. If the disposal costs exceed available monthly discretionary funds, the licensee needs to have a funding instrument of some type in place. All licensees in possession of Category 1, 2 and 3 sources must have a written financial plan and funding instrument such as a bond or letter of credit, with the possible exceptions of isotopes with <120 day half life, and sources possessed by government entities. A letter of intent is usually sufficient for government entities.

Due to bankruptcy or other situation in which a source becomes orphaned or abandoned, no funds may be available. Accordingly, an orphan source fund of other program must be in place.

Storage vs. Disposal: The development of more stringent financial planning requirements by the NRC and the Agreement States is crucial to ensuring that licensees properly manage and promptly dispose of disused sources. After using a source for its original purpose, most licensees place it in storage or return it to the manufacturer. Often, the disused source is not reused by the licensee and is stored indefinitely. In this regard, the 2006 Task Force report acknowledges that two years of disuse usually reflects the lack of a plan to use material. This is a problem because sources in long-term storage are more likely to be subject to loss of control and accountability.¹ In addition, users of sealed sources have little or no incentive to dispose of disused sealed sources. Most sources are small and require very little space to store, so users incur very little cost or other negative consequences in storing disused sources. By comparison, disposal can be very costly. As disposal was not available for many states for some years, users are also not accustomed to including funds for disposal in their annual budgets.

Economics, Budgeting and Planning: The economics of sealed source possession do not motivate licensees to plan or budget for the management and disposal of sources they possess or plan to purchase. Although the NRC has established limited financial planning regulations, they do not apply to the vast majority of sealed source users since the regulations currently only apply to licensees who possess a very large quantity of radioactive material

¹ “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>. NUREG-1551, Final Report of the NRC-Agreement State Working Group (NRC-AS Working Group) to Evaluate Control and Accountability of Licensed Devices, October 1996. The NRC-AS Working Group examined the information provided by NRC and determined that there is a lack of licensee oversight by the regulators. According to the NRC-AS Working Group, regulators have not had an active role in ensuring that licensees maintain control over and accountability for devices, and in ensuring that licensees possess, use, and transfer devices in accordance with the regulations. The NRC-AS Working Group further determined that both general and specific licensees have demonstrated loss of control over and accountability for devices.

(greater than 100,000 curies). In addition, existing NRC financial planning requirements for sealed sources—including those for Category 1 and 2 sources—do not reflect the full cost of packaging, transport, and disposal.

Orphaned and Abandoned Sources: Another concern that must be taken into consideration when establishing and imposing appropriate and equitable financial planning requirements is the fact that the cost of dispositioning orphaned and abandoned sources often falls on the state or federal government. NRC has an orphaned and abandoned source funding agreement with the CRCPD, but it is limited in scope (\$50,000 per year for five years). The existing program is insufficient to address the orphaned and abandoned source disposition needs of the nation.

State Regulations: Several Agreement States have taken the lead in developing more stringent and comprehensive regulations to address gaps in the current NRC source regulation program. Some which have been identified by the DSWG include: Oregon's comprehensive GL requirements and possession fees for each source in a licensee's possession;² Texas' fees on licensees to cover the cost of orphaned and abandoned source recovery;³ Illinois' financial planning requirement for most sources;⁴ Florida's radiation protection trust fund covering all costs associated with licensee bankruptcy and orphaned sources;⁵ and Colorado's comprehensive GL registration and annual self-certification program and requirement for Specific Licenses (SLs) for certain Category 3 sources that are normally generally licensed. The NRC could expedite the development of revised regulations by incorporating the best practices already in use by the states, as some of the benefits of financial planning may be gained through these relatively more simple mechanisms. Revised regulations initiated by the NRC will also help states with regulatory reform to adopt compatible regulations by streamlining the economic impact review process.

CRCPD's Development of Suggested State Regulations: Finally, the CRCPD's Part S (Bonding and Surety) Committee is developing suggested state regulations related to financial surety for sealed sources. NRC should consult with and review the work of CRCPD's Part S Committee.

²Oregon comprehensive GL rule to ensure accountability Rules (Oregon Rules for the Control of Radiation in GL Devices, OAR 333-102-0115).

³Texas Financial Provisions for orphan sources (Health & Safety Code: Subtitle D, Nuclear and Radioactive Materials: Chapter 401, Radioactive Materials and Other Sources of Radiation: Subchapter H, Financial Provisions).

⁴Illinois has strict Financial Planning Requirements for sources (Title 32: Energy Chapter ii: Emergency Management Agency Subchapter B: Radiation Protection Part 326. Title 32).

⁵Florida has a Radiation Protection Trust Fund of 5 percent of the annual licensing and inspection fee to cover the cost for abandonment of radioactive materials, default on lawful obligations and insolvency (64E-5.206 Section 404.122 and 404.131(2)).

3. Should licensees be required to specifically declare disused sources? If so, how long after a source is disused must a licensee declare it as disused?

National Source Tracking System: On May 12, 2014, NRC issued Regulatory Issue Summary 2014-04 to encourage licensees, on a *voluntary* basis, to submit additional information pertaining to sources that are identified as being in long-term storage in the National Source Tracking System (NSTS). In particular, NRC encouraged licensees to include the “use status” of their sealed sources – i.e., whether or not their sources are in use or have become disused.

In its March 2014 report, the DSWG advocated that NRC and Agreement States should enhance the NSTS to include as a *required* field the date last used of all sealed sources of concern and that these data should be validated during routine inspections. The DSWG continues to advocate the mandatory entry of such data as it does not constitute an undue burden and should be easily obtainable from use logs.

State Efforts and Interest: The Texas State Department of Health Services (TSDHS) has drafted revisions to both 25 Texas Administrative Code (TAC) §289.251 concerning exemptions, general licenses, and general license acknowledgements and 25 TAC §289.252 concerning licensing of radioactive material. Among other things, the draft revisions seek to implement a two-year limit on the storage of disused sources for both specific and general licensees. The Department of State Health Services Council approved the draft revisions. The TSDHS plans to publish the revisions in the *Texas Register* as a proposed rule along with the state’s Part 37 changes.

Several other states, including New York, have expressed interest in developing regulations to limit the storage of disused sources. In a recent survey of state radiation control program directors jointly initiated by the DSWG and CRCPD, 60% of respondents answered that their state can take initiative on policy making. However, 66.7% of respondents answered that if a rule change is required, NRC will have to change their rules first.⁶

Recommendations: Licensees should be required to declare when sources are disused so that the regulator can provide oversight and assistance geared toward safe and timely disposal of the disused sources. Licensees should have a 2 year regulatory window from the time that sources become disused until they must be disposed of or an alternative disposition found. Category 1 and 2 sources that fall into disuse must be reported within 90 days on the NSTS database, to allow governmental organizations to assist in the safe and timely dispositioning of those sources. Category 3 sources should be added to NSTS as soon as practical so that they can also be also reported on that system. All disused sources should be noted as disused on a licensees inventory so the information is available to the regulator at the time of inspection or license renewal.

⁶ For the survey results, see <http://www.disusedsources.org/wp-content/uploads/2015/05/DSWG-CRCPD-Survey-Report-May-2015.pdf>.

4. How should source characteristics be factored into establishing equitable financial planning requirements for end-of-life management?

General Recommendations: With the exception of short half-life isotopes, financial planning should cover the full disposal costs based on the activity at the time the financial planning is established. For <120 day half-life sources (ex. Ir-192), allowances can be made so that sources can decay to Class A waste levels while being properly managed prior to disposal. In some cases, decay-in-storage may be appropriate. Management of waste that was initially Category 1 or 2 should be a licensed activity performed by a manufacturer, distributor or licensed waste management company that has appropriate security in place for larger quantities of material.

Equity Considerations: In order to establish “equitable” financial planning requirements, licensees that are receiving economic benefit from the use of sealed sources should bear the cost of disposition therefore.

Source Categorization: To encourage timely disposal, the DSWG advocates that NRC should develop robust financial planning requirements for Categories 1 through 3 disused sources. The financial planning requirements should be adequate to cover the entire cost of packaging, transportation and disposal.

Manufacturer Considerations: As noted above, in many cases, disused sources are returned to manufacturers and suppliers that often have greater institutional knowledge of the product, more comprehensive oversight, and increased physical security in place. Nonetheless, the DSWG is concerned that some source and device manufacturers and suppliers are accumulating large numbers of disused sources in storage with little possibility of reuse or recycle and believes that additional regulatory oversight is needed to minimize manufacturers’ and suppliers’ inventories. Accordingly, the NRC and Agreement States should require manufacturers and suppliers to dispose of those sources that have no reuse or recycle value on an annual basis.

5. If NRC rulemaking is initiated as a result of this scoping study, how should NRC engage with and consider the impact on Agreement States? What would be the primary considerations in establishing compatibility levels for rule requirements?

Engaging with Agreement States: NRC should reach out to Agreement States via various organizations including the Organization of Agreement States (OAS), Low-Level Radioactive Waste Forum (LLW Forum) and CRCPD.

Compatibility Level Considerations: As noted above, in a recent survey of state radiation control program directors, 60% of respondents answered that their state can take initiative on policy making. However, 66.7% of respondents answered that if a rule change is required, NRC will have to change their rules first. (For additional information, see footnote 6.)

General Recommendations: The NRC should engage with the states and consider the impact on the states during all phases of rulemaking. Some proposed financial planning solutions

may be too labor intensive for smaller state programs, so in that case these states may need to opt into a federal program rather than have their own.

Any new financial planning rule should remain compatibility C so that states can choose to adopt equivalent programs of their own choosing and retain the ability to adopt or retain stricter rules than the NRC's.

6. When necessary, what mechanism should be used to administer financial planning requirements on general licensees?

Background: In 2010, the OAS petitioned NRC to increase the regulatory control over certain GL sources.⁷ When this 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.

A previous NRC-Agreement State Working Group (NRC-AS Working Group) determined that there is a lack of oversight of GL licensees by the regulators.⁸ The NRC-AS 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.⁹ Subsequently, NRC and Agreement States have implemented registration and annual reporting requirements for GL sources. However, there remains a time lag in reporting information and limited regulatory oversight of GL sources.

General Recommendations: Financial planning requirements need to be applied to persons who are currently generally licensed. Since financial planning is not consistent with the GL concept, general licensees who possess sources that require financial planning should be required to be specifically licensed.

At a minimum all Category 3 GL devices should be specifically licensed, but to adequately address financial planning the Commission should consider a lower activity threshold such as 10% of Category 3, Category 4, or the current activities that require registration. Alternatively generally licensed devices should be done away with altogether.

⁷ 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-A1 33), December 2, 2010. In addition to OAS, nine Agreement States also supported this position.

⁸Final Report of the NRC-AS Working Group to Evaluate Control and Accountability of Licensed Devices (NUREG-1551).

⁹ 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.

- 7. What are the ideal characteristics and qualifications for an entity that will act as the custodian for any funds earmarked for long-term management of disused sealed sources? For instance, what characteristics and qualifications should be taken into consideration regarding the custodian's relationship to the licensee (e.g., the ability of the custodian to access the funds, or the custodian's independent financial viability)? In the event that there is a residual amount remaining in the fund following payment of disposition cost, what should be the fate of the residual funds?**

Because the costs are highly variable and licensee specific, it is first important that the burden for obtaining financial assurance be weighted based on the costs. Some existing financial planning methods such as letters of credit or bonds are very effective and can continue to be used for private licensees with the greatest liability. For licensees with lower disposal liability, it is better to pool their funds in some fashion.

A single, small leaking source can cost \$250,000 or more to clean up and a radiological dispersal device (RDD) made from even a Category 3 source can potentially cost billions of dollars to clean up and have significant economic impacts for decades. There is a need for all licensees, even those with Category 4 sources, to have the ability of covering the costs of a contamination incident. In addition, there is a need for a pooled fund and/or insurance mechanism to cover these contingencies, noting that no company or existing fund could likely cover the full cost of the worst case RDD incident. Such a fund can also be used for orphaned and abandoned sources or sources from bankruptcies.

Such funds can be part of the state or federal entity; however, distribution of funds can be difficult if not properly set up and may require special legislation. Such a fund may be more effectively administered by a private entity that has government or industry funding. If the insurance option were selected, American Nuclear Insurers may be a good model or a candidate to fill that role.

- 8. What are the key characteristics of a tracking system for byproduct material (sealed sources) subject to financial planning requirements? Which of these characteristics are not available as part of the NSTS?**

Sources do not necessarily need to be part of NSTS for the NRC to effectively study financial planning. Most of the licensees that are not in NSTS but need to consider financial planning are specifically licensed already, so regulators should know the number and activity of sources in their possession.

GLs in possession of large sources or a large number of sources should be converted to SLs so that they may be tracked more effectively.

Appendix One re Byproduct Material Financial Scoping Study *Comments Developed by Other Stakeholders*

* *The below comments were provided by stakeholders in response to a request from the DSWG for input on NRC's request for feedback on its proposed byproduct material financial scoping study as published in the Federal Register on August 2, 2015. Given time constraints, the DSWG has not had an opportunity to collectively review the below comments and therefore takes no position on them at this time. Instead, the DSWG is providing the comments as a courtesy in response to NRC's request for additional stakeholder feedback.*

1. What disposition pathways are available to various licensee types beyond the traditional disposal pathway and should be considered in any potential new financial planning requirements?

JL Shepherd & Associates: As a general statement, JL Shepherd & Associates comments as follows:

The comments contained herein have been developed by JLS&A and are our opinions based upon the nature of the products and services offered to our clients. In some instances, the users and uses of our high level sources in our irradiators have been designated as "Classified" and we can only discuss some issues in relationship to unclassified publically available material in the comments below. There are some DOD and DOE applications which cannot be discussed.

There are many and diverse uses of the sealed sources and devices which we manufacture, and we have tried to convey some of these uses in the context of these comments concerning this draft.

We fully acknowledge that there are some problem licensees and manufacturers that have caused the rationale for this draft; however we believe that there can be unintended consequences for the majority of the responsible licensees, whether they are governmental, private or commercial.

This response seems to be based on the premise that sealed sources are in constant or continuous use. This is simply not the case for many types of sources and devices that we manufacture. I was at a meeting where NASA addressed this issue. Some space projects are years in planning and ensuing execution of space exploration. Some sealed sources used for specific phases of missions are not in constant use. NASA is worried that "Storage" may be defined to include these types of sources. We can definitely see where the definition of "Storage of Disused Sources" could impact long term Defense and Aerospace mission projects, and in medical research where a research study may need to be reconfirmed in the midst of a pre-clinical or clinical trial. In the

areas where insect irradiation for sterile release to protect humans or crops is seasonal, the irradiator may have periods of down time. If an insect sterilization program is successful, the facility would need to remove the irradiator under this proposal, it would not be available if an outbreak occurred, and the economic recovery cost could be enormous. In a Biosafety Lab (BSL), irradiators are used to deactivate dangerous biologics and pathogens for research into therapies or medical interventions. If a BSL irradiator needed to be removed because it wasn't in constant use, where would be the response for research emergent or mutated biologics either naturally occurring or manipulated as a weapon of mass destruction? Why should people and troops die or be put in harm's way because the irradiator was removed from service because a gauge manufacturer or radiographer didn't play right? In a calibration laboratory, instruments are calibrated periodically, in cycles, or less frequently if it is a "special use" instrument, potentially denying the cal lab of specialized instrumentation.

We believe that there should be some way to approach the problem in a phased, important to safety type and safety culture type approach, that would be fair to the responsible licensees and would like to work with the Group in either exploring this approach or introducing the Group to various types of licensees who could have the potential be adversely affected.

In regard to the DSWG's statement that, "some source and device manufacturers and suppliers are accumulating large numbers of disused sources in storage with little possibility of reuse or recycle," JL Shepherd & Associates comments as follows: "How will it be determined if there is little possibility?" If the source isn't approved for that manufacturer's devices, could be 1 criteria. Or recycling to other manufacturers could be another."

The DSWG's formal comments state that, "To prevent the accumulation of an excessive number of sources by manufacturers and suppliers, the DSWG encourages NRC and Agreement States to require manufacturers and suppliers to dispose of those sources that have no reuse or recycle value on an annual basis." In response, JL Shepherd & Associates writes as follows: " ANNUAL might be good for large volume, small source manufacturers, but is too restrictive for small volume, capital equipment, large source manufacturers. For instance, it might take 5 years to accumulate the correct activity assortment to be able to combine viable sources into a larger source. There should be provision for small volume viable source accumulation. It also does not take into account funding cycles, as some capital equipment projects can take +5 years to obtain funding, depending upon the economic climate. Who will decide if the source has no reuse or recycle value? The manufacturer/distributor or the regulator?"

In response to the DSWG's statements on "Storage" in response to Question 1, JL Shepherd & Associates writes as follows: "Storage is different than period use, but this response contains no provision for periodic use, which could be misconstrued as storage ... We've discussed some periodic uses which could also be potential future use. If the replacement cost is a capital expenditure and the disposal cost for is also a capital expenditure (such as an

irradiator with a Cat 1 or 2 source), this could be perceived as a waste of resources." JL Shepherd & Associates continues as follows: "If ... the source is a Type B shipment, transportation container options are extremely limited, due to wattage or Curie limitations for Cs-137 & Co-60. With the current Summer 2015 suspension of 2 Models of Type B packages, transportation options are even scarcer. Of even more importance, is the scarcity of Type B packages that can ship sealed sources direct to a commercial waste disposal site, without an on-site source transfer into a burial container (LANL/OSRP shipments excepted from this statement)."

In response to the DSWG's comments on "Concentration Averaging" in response to Question 1, JL Shepherd & Associates writes as follows: "30 Ci. Cs-137, if in Special Form or a A₁ quantity was shippable in a Type A package. The A₁ quantity for Cs-137 is currently 54 Curies & the A₂ (Normal Form) is 16 Curies. The lack of Type B shipping containers that are approved for sealed sources (per above) is a drawback here, but some additional sources could now be readily disposed of."

In response to the DSWG's comments on the Off-Site Source Recovery Program (OSRP) in response to Question 1, JL Shepherd & Associates states as follows: "But OSRP does not permit source recycling, even if the bid is \$0 or no cost to the tax payer, as we have bid on several projects. OSRP is now denying source recovery requests if there is a commercially available land disposal, regardless of the lack of a viable Type B transport container, but not for recycling." JL Shepherd & Associates goes on to point out that "There is the Type B shipping container that can be used to ship to disposal sites that is a huge issue here."

In response to the DSWG's comments on "Additional Considerations" in response to Question 1, JL Shepherd & Associates comments, "This statement depends on the isotope, original specific activity and also does not include changes to current regulations."

In response to the final paragraph of the DSWG's comments on "Additional Considerations" in response to Question 1, JL Shepherd & Associates adds the following: "And DISTRIBUTE. If an entity can't distribute a sealed source, then they have no viable option for recycling."

Southwestern Low-Level Radioactive Waste Compact Commission: Upon review of the JL Shepherd & Associates comments to the DSWG, Kathy Davis (Executive Director of the Southwestern Low-Level Radioactive Waste Compact Commission) responded as follows: "Mary Shepherd's comments are an example of how important it is to have input by 'users' of various products and without that input, negative impacts will be imposed by regulators which will hurt the business climate of this industry ... I agree with Shepherd's comment about the use of the word 'storage' and 'period use' and 'disused.' This should be strongly considered and perhaps some clarification of terms could be useful."

Davis continues as follows: "My comment, which has been expressed a number of times by my Commissioners is-2 years is not enough time for research uses. It will cause unnecessary disposal, and then repurchasing a few years later."

Davis also states, "I believe we should encourage the NRC to reach out to users and manufactures prior to any final document."

2. What should be the primary considerations in establishing and imposing appropriate and equitable financial planning requirements on radioactive sealed sources?

JL Shepherds & Associates: In response to the DSWG's comments regarding the need for an orphan source fund or other program, JL Shepherd & Associates writes: " I believe that this was the original intent of the LANL OSRP program, which now accepts sources from any entity that does not want them, regardless of their ability or inability to pay. Perhaps this mission funding can be re-allocated for real orphans and not for anyone who asks for a free disposal at taxpayer expense."

The DSWG commented as follows: "The development of more stringent financial planning requirements by the NRC and the Agreement States is crucial to ensuring that licensees properly manage and promptly dispose of disused sources." JL Shepherd & Associates responds, "Perhaps or no longer needed -- perhaps a definition is needed to address different kinds of disuse."

The DSWG commented as follows: "There is a problem because sources in long-term storage are more likely to be subject to loss of control and accountability." JL Shepherd & Associates responds, "Is this really a problem for Cat 1 & 2 sources? It seems that this is more of a Cat 3 & 4 source problem."

The DSWG commented as follows: As disposal was not available for many states for some years, users are also not accustomed to including funds for disposal in their annual budgets." JL Shepherd & Associates responds, " With the Type B transport package problems, this is still the case for greater than A₁ or A₂ quantities."

In response to the DSWG's comments on "Economics, Budgeting and Planning" in response to Question 2, JL Shepherd & Associates states as follows: " With the sun-setting of the 20WC packages, an inexpensive, easy to maintain Type B package, with a history of NO RELEASE, with inner packages only limited to a Type A or 2R package, it is almost impossible to determine a packaging and transport cost. Although attempts have been made, there are no direct replacement packages to date that encompass the shipping scope of these sun-setted package. The time and cost to bring a new Type B package into existence is staggering, as has been discussed at several meetings, and much too long to discuss here."

Southwestern Low-Level Radioactive Waste Compact Commission: Kathy Davis states that, "shipping containers and their future availability is the major concern for affordable disposal cost."

3. Should licensees be required to specifically declare disused sources? If so, how long after a source is disused must a licensee declare it as disused?

JL Shepherd & Associates: In response to the DSWG's comments on the "National Source Tracking System" in response to Question 3, JL Shepherd & Associates states as follows: "See my comment above concerning long term NASA, Defense Aerospace, Agricultural, BioSafety Labs & medical research projects. A last date used, does not necessarily constitute a disused source in these applications and could cause mission interruption at a later date. Perhaps wording could be refined to include these types of mission applications. Unless there is specific language, we've seen too many times where "Verbatim" compliance is required."

In response to the DSWG's comments on "State Efforts and Interest" in response to Question 3, JL Shepherd & Associates writes as follows: "Again, a disused source might not be a source that is not needed in a long term mission. Maybe New York does not have these types of licensees, and maybe other States are not aware of the potential issues. Just because there are problems with some licensees, including manufacturers, doesn't mean that there is a problem with the majority of the licensees. From the meeting I've attended and the presentations that I've heard, the Group is trying to address how to deal with the few bad apples or miscreants across a broad spectrum of uses in the industry and government that has accumulated and occurred over many years of licensing regulation that didn't actually address the issues being presented. Instead of taking a broad-brush approach that will affect all licensees, even the responsible licensees, with unintended consequences, perhaps there are other ways to look at the problem. For example problems with radiographers or gauges may not be the identical problems encountered with universities, hospitals or government entities. There should be some way to approach the problem with the bad apples in a phased, important to safety type approach, that would not leave responsible licensees scrambling to justify their irradiator usage or periodic lack thereof. There is no mechanism in this draft that would preclude a subjective denial by a regulator for an irradiator which use is periodic in nature, even for safeguarding public health and safety.

The DSWG comments state, "Licensees should have a 2 year regulatory window from the time that sources become disused until they must be disposed of or an alternative disposition found." JL Shepherd & Associates responds, "This is fine for a Type A₁ or Type A₂ quantity – for a Type B quantity, due to the dearth of Type B transport containers, this is unrealistic. For example, the ES 10-160B (of which there is 1 available for commercial shipments) can be booked up to a year in advance, from part experience using this package."

4. How should source characteristics be factored into establishing equitable financial planning requirements for end-of-life management?

JL Shepherd & Associates: The DSWG states, "In order to establish 'equitable' financial planning requirements, licensees that are receiving economic benefit from the use of sealed sources should bear the cost of disposition therefore." JL Shepherd & Associates responds, "Most Cat 1 or 2 source manufacturers or distributors would need a license amendment to accept and store 'Waste' from clients as opposed to accepting a viable source for storage for

recycling. If a source is to be used for recycling, it is no different than a newly purchased source and should not be considered 'Waste.'"

The DSWG writes, "In order to establish 'equitable' financial planning requirements, licensees that are receiving economic benefit from the use of sealed sources should bear the cost of disposition therefore." JL Shepherd & Associates questions, "How would 'equitable' be achieved? If the use of the source is directly tied to 'sales,' would that be fair compared to the use of a source used as part of a manufacturing process or 'overhead?'"

The DSWG comments, "the NRC and Agreement States should require manufacturers and suppliers to dispose of those sources that have no reuse or recycle value on an annual basis." JL Shepherd & Associates replies, "I know that the Group is trying to address problems at some manufacturers, but this should not become a burden for responsible manufacturers."

5. If NRC rulemaking is initiated as a result of this scoping study, how should NRC engage with and consider the impact on Agreement States? What would be the primary considerations in establishing compatibility levels for rule requirements?

No additional stakeholder comments.

6. When necessary, what mechanism should be used to administer financial planning requirements on general licensees?

No additional stakeholder comments.

7. What are the ideal characteristics and qualifications for an entity that will act as the custodian for any funds earmarked for long-term management of disused sealed sources? For instance, what characteristics and qualifications should be taken into consideration regarding the custodian's relationship to the licensee (e.g., the ability of the custodian to access the funds, or the custodian's independent financial viability)? In the event that there is a residual amount remaining in the fund following payment of disposition cost, what should be the fate of the residual funds?

JL Shepherd & Associates: The DSWG comments, "Some existing financial planning methods such as letters of credit or bonds are very effective and can continue to be used for private licensees with the greatest liability." JL Shepherd & Associates responds, "In our experience, Financial Surety planning methods can be iffy at best, especially if the method required runs afoul of FDIC banking requirements, which happened to us when CA started their 1st round of financial surety."

The DSWG states, "There is a need for all licensees, even those with Category 4 sources, to have the ability of covering the costs of a contamination incident." JL Shepherd & Associates replies, "It would be nice if the Price Anderson Act could be amended to include all licensees who possess materials. How does the Group propose to force the insurance industry, which is notoriously phobic when it comes to radioactive materials and insuring threats of terrorism to cover these types of incidents?"

The DSWG writes, "If the insurance option were selected, American Nuclear Insurers may be a good model or a candidate to fill that role." JL Shepherd & Associates comments as follows: "They would need to be persuaded to add to their core mission at some reasonable cost. The Group is proposing to add entities who may not be able to add this cost to their ratepayers or their clients. In the medical area, this could impose even higher costs for medical procedures or bringing drugs and therapies to market. Many US Governmental Departments and Agencies, for example, the DOD, VA, NRO & Intelligence agencies, NIH, NIST, EPA, and even State Agencies such as the State & Local Emergency Management Agencies and Radiation Protection Agencies, are licensees themselves and the DOE itself has many high level irradiators and sources, identical to private entities. We know this because they are our clients. How do you propose funding that government al entity insurance be differentiated from funding private entity insurance for the exact same materials? Why should the Government, including the DOE, be treated differently? This is why I suggested an amendment to Price Anderson for all radioactive materials, a vehicle already in place, or perhaps a new federal funding vehicle."

8. What are the key characteristics of a tracking system for byproduct material (sealed sources) subject to financial planning requirements? Which of these characteristics are not available as part of the NSTS?

No additional stakeholder comments.