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MEMORANDUM FOR: DOE PAAA COORDINATORS
CONTRACTOR PAAA COORDINATORS

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OFFICE OF ENFORCEMENT AND INVESTIGATION

SUBJECT: Enforcement Guidance Supplement 01-01:
Nuclear Weapon Program Enforcement Issues

Section 1.3 of the Operational Procedures for Enforcement, published in June 1998, provides the opportunity for the Office of Price-Anderson Enforcement (OE) to periodically issue clarifying guidance regarding the processes used in its enforcement activities.

This enforcement guidance focuses on the applicability of 10 CFR Part 830 to nuclear weapon programs and several related enforcement issues.

I. BACKGROUND

The Office of Price-Anderson Enforcement (OE) recognizes that there is continuing confusion on the applicability and scope of 10 CFR Part 830 to nuclear weapon programs and how this office intends to apply its enforcement discretion.

The original version of 10 CFR Part 830, with an effective date of May 5, 1994, excluded in 830.2 (c) "*activities conducted under the Nuclear Explosive and Weapons Safety Program relating to prevention of accidental or unauthorized nuclear detonations*" from the scope of the rule. Certain contractor personnel, DOE and National Nuclear Security Administration (NNSA) staff have interpreted this language to exempt all routine and emergency nuclear weapons related activities.

In Ruling 1995-1, the DOE Office of General Counsel (OGC) clarified this language as a narrow exclusion limited to those immediate actions necessary to prevent an accidental or unauthorized nuclear detonation. The OGC interpretation clarified that

routine operations related to nuclear weapon programs were not excluded from PAAA rules.

On January 10, 2001, DOE published an amended 10 CFR Part 830 Final Rule which removed the nuclear weapons exclusion effective April 17, 2001. Subsequent to its removal, OE received numerous requests for clarification concerning both rule applicability and potential enforcement discretion regarding 10 CFR Part 830 and nuclear weapon programs. The requests for clarification focused mainly on the six topics or issues noted below:

- Retroactive Enforcement
- Emergency Response
- Contractor QA Interfaces
- QA Reporting
- Off-Site Weapons Activities
- Pre-Design R&D Work

In order to address the requests for clarification, OE decided to issue this Enforcement Guidance Supplement (EGS). Section II of this EGS discusses OE's general enforcement approach and the basis for making enforcement recommendations to the Administrator, NNSA. Section III outlines OE's intent to implement a 90-day moratorium on enforcement actions involving nuclear weapon components. Attachment A addresses the six specific topics noted above and any corresponding enforcement discretion.

II. GENERAL ENFORCEMENT APPROACH

OE will continue to enforce the provisions of 10 CFR Part 830 consistent with established enforcement policy and guidance. Nuclear facilities and activities that have the potential to cause radiological harm can be the subject of enforcement actions unless (1) specifically excluded by the rule or (2) specifically excluded thru an approved exemption issued in accordance with 10 CFR Part 820. This includes NNSA facilities and activities that involve nuclear weapons and weapons related activities.

In addition, OE anticipates the use of broad discretion in its enforcement of 10 CFR Part 830 at nuclear weapon facilities and programs based on their unique mission. For example, OE anticipates little involvement in areas relative to nuclear weapons emergency response and activities on foreign soil. The use of this discretion is elaborated on in the Attachment.

The above described enforcement approach is consistent with the principles outlined in the Memorandum of Understanding (MOU) between the Administrator for the NNSA and the Assistant Secretary for EH, of January 12, 2001. The MOU is available at the OE webpage, <http://www.eh.doe.gov/enforce>.

In consideration of both the rule's applicability and the above enforcement approach, NNSA contractors, in working with the NNSA, should establish which of their facilities

and activities have the potential to cause radiological harm. Contractors should then ensure those applicable facilities and activities comply with the requirements of 10 CFR Part 830. OE does not expect that all elements of nuclear weapon programs fall under 10 CFR Part 830. For instance, components that are relied upon solely for nuclear weapon reliability would not necessarily be subject to PAAA rules. Conversely, nuclear weapon activities and components that are relied upon for nuclear or radiological safety or contain radiological material most likely have the potential for radiological harm and thus would be subject to the rule.

OE is also aware that the NNSA has placed certain quality assurance (QA) requirements in its contracts, including DOE Order 414.1A and the QC-1 requirements of NNSA/AL Supplemental Order 56XB. OE expects that contractor processes intended to meet those QA requirements should be sufficient to demonstrate compliance with 10 CFR Part 830 Subpart A. However, it is still incumbent on the individual NNSA contractors to review those programs and their implementation to ensure they are in compliance with Subpart A of the rule.

III. ENFORCEMENT MORATORIUM

As a result of the ongoing confusion and issues surrounding the applicability and enforcement of 10 CFR Part 830 to nuclear weapon program, this office has decided to issue a 90-day moratorium on future enforcement actions involving 10 CFR Part 830 and nuclear weapon components. During this 90-day period, contractors conducting NNSA nuclear weapon activities may take the opportunity to address the following:

- Review the enforcement guidance contained in this EGS for applicability to their activities,
- Identify contractor activities that fall within the scope of 10 CFR Part 830,
- Ensure the above identified nuclear weapon activities comply with the provisions of 10 CFR Part 830 and local implementing plans and procedures,
- Report any potential rule noncompliances for future enforcement mitigation, and
- Implement prompt corrective actions to resolve any identified noncompliances.

Nuclear weapon component related noncompliances identified and voluntarily reported during this 90-day period, and those that are promptly corrected will not be subject to OE enforcement actions. This moratorium specifically applies to nuclear weapon systems and components. Nuclear weapon facilities and supporting activities are excluded from the moratorium because, in general, they already have established and implemented PAAA programs.

For reporting purposes, the interim guidance contained and referenced in the Attachment to this EGS should be used. For identification purposes, noncompliances that do not meet reporting thresholds should be tracked locally for future enforcement mitigation credit.

This enforcement guidance will be incorporated into OE's Operational Procedures for Enforcement and will be made available on the OE webpage (<http://www.eh.doe.gov/enforce/>). If you have any questions regarding this enforcement guidance, please contact me or Peter Rodrik of my staff at (301) 903-5092.

ATTACHMENT A

SPECIFIC ENFORCEMENT ISSUES

A. Retroactive Enforcement

The majority of the nuclear weapons stockpile was designed, manufactured and placed into inventory prior to the effective date of the QA rule. If quality problems are discovered, how will OE enforce the QA rule for these problems?

Quality assurance problems that were attributed to historical design and manufacturing activities conducted prior to the establishment of PAAA rules will not be subject to enforcement actions. This also applies to quality problems associated with nuclear weapon facilities, activities, and components. By establishing an effective date for each of the PAAA rules, DOE's intent was to not "backfit" the requirements of the rules to these past activities. However, the following additional points should be recognized.

Both Subparts A and B of 10 CFR Part 830 contain requirements that currently apply to nuclear weapon programs whether or not the weapons or facilities themselves were manufactured prior to the effective date of the rule. These requirements are intended to address the ongoing management and nuclear safety of nuclear weapons and facilities (storage, stockpile surveillance, maintenance, etc.) manufactured prior to the rule.

For example, the quality improvement criterion of Subpart A requires ongoing processes to detect and correct quality problems. Failures to identify and correct safety significant quality problems with nuclear weapons or facilities that predate the rule as part of ongoing surveillance/maintenance programs could be subject to enforcement actions. Similarly, Subpart B also contains applicable requirements involving documented safety analysis (DSAs), technical safety requirements (TSRs), and USQ processes. These requirements also apply to nuclear weapon facilities and activities regardless of their design or manufacture date.

The above enforcement discretion concerning legacy quality problems is consistent with how this office addresses legacy contamination issues as outlined in

EGS 00-01, Enforcement Position Relative to the Discovery/Control of Legacy Contamination.

The following case examples are provided to help illustrate the above guidance:

Example 1: A specific software code was developed and used in the design or modeling of a weapon component in 1982. This component is currently in the stockpile. Is the responsible contractor required to go back and ensure that the software code meets current quality assurance requirements?

No. OE does not expect contractors to backfit quality requirements to processes and activities completed prior to the application date of the PAAA rules.

Example 2: A specific software code was used in the design or modeling of a component in 1982. This component is currently in the stockpile. A contractor is continuing to use this same software code for maintaining or improving the component. Is the responsible contractor required to ensure that the software or the software-generated data meets the quality assurance requirements of the rule?

Yes. If the component or activity has the potential to cause radiological harm or if it is used to prevent radiological harm, then the PAAA rules would apply since the software code or its generated data is being used for a current activity (i.e., maintenance/improvement).

Example 3: A component was designed and placed into production in 1982. It is being monitored by way of present-day surveillance activities to ensure that it continues to meet performance expectations. The monitoring activities detect a safety significant quality-manufacturing defect with the potential to cause radiological harm. Are the contractor's monitoring and corrective action activities required to meet the quality assurance requirements of the rule?

Yes. The monitoring and corrective action activities would be subject to PAAA rules and potential enforcement actions including any failures to control and correct the safety significant defects.

B. Emergency Response

A NNSA contractor may have to take certain actions during an emergency to prevent a nuclear detonation. These actions may not be in compliance with the QA rule. How will the QA rule be enforced?

The removal of the nuclear weapons exclusion from 10 CFR Part 830 (see Section I) has resulted in questions on whether or not contractor emergency response actions could be subject to future enforcement actions.

As stated in the preamble to the October 10, 2000, Interim Final rule, the nuclear weapons exclusion was eliminated with the addition of Subpart B of the rule. Specifically, Subpart B added a "safe harbor" or process for contractors to integrate both nuclear safety and nuclear explosive and weapons surety program requirements in to a single documented safety analysis (DSA). DSAs are intended to address nuclear hazard controls including emergency response programs/requirements. The preamble also stated that any potential conflicts between the different sets of requirements should be resolved by way of a rule exemption in accordance with Subpart E of 820.

OE recognizes that in spite of the above expectations, the possibility, however unlikely, could still exist where NNSA contractors may need to take certain nuclear weapons related emergency actions that do not comply with the rule. The primary reason for taking such actions would be the prevention of an accidental or unauthorized nuclear weapons detonation and any corresponding harm to workers, the public, and the environment.

Since these types of emergency actions are intended to prevent imminent and significant harm to workers and the public, enforcement discretion would be appropriate. The following factors, similar to those outlined in 10 CFR Part 830.205 (b) for DOE nuclear facility emergency response activities, would be considered by OE when deciding to apply its discretion:

- The actions taken were needed to prevent an accidental or unauthorized nuclear weapons detonation and consistent with an overall intent to protect workers, the public, or the environment from imminent and significant harm,
- No other apparent and appropriate actions were available consistent with the requirements of 10 CFR Part 830 and corresponding implementing procedures, plans, and programs,
- The actions were authorized by the appropriate DOE/NNSA Senior Energy Official (SEO) as required,
- Follow-up corrective actions are taken as necessary to identify, report, and resolve the potential conflicts.

For noncompliances involving the above, this office will limit its enforcement authority and refrain from issuing enforcement actions.

It should be noted that this office does not intend to use its enforcement authority in a manner that inhibits or restricts contractor emergency actions essential for the protection of workers, the public, and environment from imminent and significant harm. OE also does not take enforcement action against an individual who may be involved with a PAAA noncompliance since the scope of DOE's enforcement

authority is limited to the “indemnified contractor” which is a corporate entity. The exception would be a situation where criminal wrongdoing was evident.

The purpose of the enforcement program is to promote and protect the radiological health and safety of the public and workers. Consistent with the above, this office will carefully consider the facts and will exercise appropriate enforcement discretion.

The above enforcement discretion, however, does not relieve contractors of their contractual responsibilities for the management or technical support of NNSA radiological emergency response assets. It also does not relieve contractors of their responsibility to integrate both nuclear safety and nuclear explosives and weapons surety requirements under Subpart B of the rule and to address any conflicts in accordance with Subpart E of 10 CFR Part 820.

C. Contractor QA Program Interfaces for the Design-Manufacturing-Final Assembly Cycle

The Design-Manufacture-Final Assembly (D-M-FA) cycle for nuclear weapon programs can include different NNSA prime contractors for each phase of the process. Under this arrangement, prime contractors are required to provide specialized products and services for use by other prime contractors. These prime contractors do not have contractual relationships with each other governing the QA of such services and products. How does the PAAA enforcement policy address this arrangement?

Products developed and supplied for use among different NNSA prime contractors in general represent activities performed for the DOE/NNSA. Section 830.1 of the rule states "*This part governs the conduct of DOE contractors, DOE personnel, and other persons conducting activities (including providing items and services) that affect, or may affect, the safety of DOE nuclear facilities.*" These shared products, including technical services and weapon components, are thus subject to the requirements of 10 CFR Part 830.

The NNSA, through its contracts and directives, establishes prime contractor roles and responsibilities for products used within the nuclear weapons D-M-FA cycle. Each prime contractor is therefore responsible for the quality of their NNSA specified products used within the D-M-FA cycle including the development of a QA Program per 10 CFR Part 830.

Based on the above arrangements, OE recognizes the potential for events to occur at one prime contractor site that discloses potential rule noncompliances caused by a different prime contractor at another site. For example, a design flaw with a component could go undetected until the manufacturing phase of the D-M-FA cycle. As a result, OE will consider the following before determining whether or not an enforcement action is appropriate and for which specific prime contractor(s).

- Where in the D-M-FA cycle did quality noncompliances arise and which contractor(s) are/were responsible for introducing and correcting the deficiencies?
- Did the contractor(s) involved conduct the activities consistent with the requirements of the rule and their designated NNSA contractual responsibilities?
- Did the involved contractor(s) identify and voluntarily report any potential noncompliances consistent with established OE reporting guidance?
- Did the contractor discovering the issue notify other appropriate parties (other impacted contractors and NNSA/DOE officials) in a timely manner and assist in the review and corrective actions, as appropriate?
- Did the contractor responsible for the noncompliances initiate prompt and effective corrective actions?

OE also recognizes that in the contractor's delivery of products for use in the D-M-FA cycle, both formal and informal exchanges of technical support, information, and services do occur between prime contractors. In some cases, this technical exchange can have quality assurance implications that can affect the nuclear safety of NNSA activities, including lessons learned or other similar quality related information.

It is not the intent of OE to implement its enforcement authority so as to discourage technical exchanges and communications that improve the quality of nuclear weapons services. However, because some of these technical services could significantly affect the nuclear safety of NNSA activities, contractors need to manage these services consistent with rule requirements. Contractors responsible for the generation and subsequent use of technical services must ensure they meet, in a graded approach based on safety significance, the requirements of their QA programs and the rule. This is required by the rule even if 10 CFR Part 830.122 (g) Criterion 7-Performance/Procurement is not applicable due to the lack of contractual processes between prime contractors.

The following case examples are provided to help illustrate the above guidance:

Example 1: A defect that affects nuclear safety requirements is identified in a weapon component at a NNSA production site. In evaluating the root cause of the defect, it is determined that the production site followed all quality system requirements and the deficiency was the result of a design performed by a national laboratory. In evaluating potential PAAA enforcement issues, OE will address the following lines of inquiry:

- What was the root cause of the deficiency? Was there a failure of a contractor's quality system that allowed this failure and, if so, where did this failure occur?
- Did the production site appropriately identify the defect, perform appropriate root cause analysis, and communicate the deficiency to the design lab?

- Did the design lab perform appropriate root cause analysis, reporting, and corrective action?

If the result of these questions confirmed failure at the design laboratory, then any potential enforcement actions would be assessed against the design laboratory. The manufacturing site's quality system worked correctly in identifying the defect and communication occurred between design and production contractors as desired by both NNSA and OE.

Example 2: A defect that affects nuclear safety is identified in a component produced by a supplier subcontracted by a NNSA production site. A national laboratory provided the design requirements for the component. In evaluating the root cause of the defect it is determined that the supplier produced the defect, however the suppliers qualification and acceptance process was insufficient to prevent the defect.

In evaluating potential PAAA enforcement issues, OE will evaluate the following lines of inquiry:

- Was the design adequate? Was the design correctly provided to the NNSA production site?
- Did the production site effectively transmit design and production QA procurement requirements to the supplier?
- Was there a failure in the suppliers QA process that allowed the defective component to be purchased by the production site?
- Did the production site's quality acceptance process perform correctly in identifying the defect?
- Was there communication and cooperation between the design and production sites in identifying, reporting, and correcting the deficiency?

OE could assess potential enforcement actions against the suppliers failed quality control program, dependent on the responses to the above questions.

Example 3: A defect that affects nuclear safety is generated during the manufacturing process at a production site. The defect is not detected by the production site's QA program and is shipped to an assembly plant where the defect is detected during assembly. The assembly plant follows their work direction in identifying the non-conformance to the production site.

In evaluating Potential PAAA enforcement issues, OE would evaluate the production site's quality system, the failure of the quality system to identify the defect, root cause analysis, and corrective actions taken subsequent the notification of the defective component. OE would note that the assembly plant's QA program

performed correctly in identifying the defect and in communicating the defect to the originator for corrective action.

D. QA Reporting

The nuclear weapons complex has established QA processes for identifying, documenting, evaluating, and reporting nonconforming items. Are all of these nonconformance reports (NCRs) considered to be PAAA NTS reportable noncompliances?

OE recognizes that weapon programs have established processes to identify nonconformances to quality requirements. These processes identify quality deficiencies for weapon components and services concerning both product reliability (fit, form, and function) as well as nuclear or radiological safety. Consequently, only some of the NCRs may represent PAAA rule noncompliances and only a sub-set of these more significant noncompliances would meet the thresholds for PAAA NTS reporting.

Safeguards and Security classified information should not be included in the NTS report. The information in the NTS report should be provided so as to identify that a potential PAAA noncompliance has occurred without compromising sensitive or classified information.

In determining whether or not an NCR represents a noncompliance that should be considered for PAAA NTS reporting, the following screening criteria should be considered.

- The NCR involves a component that has the potential for radiological harm, including specific weapon design or operational characteristics,
- The nonconformance deficiencies represent a noncompliance with a requirement of a PAAA rule,
- The noncompliance represents a programmatic or recurrence issue, or
- The noncompliance represents a willfulness or intentional violation of the rule.

OE also recognizes that its current reporting guidance contained in the OE Operational Procedure - *Identifying, Reporting, and Tracking Nuclear Safety Noncompliances Under Price-Anderson Amendments Act of 1988* may not be sufficient for determining the reportability of nuclear weapon program related noncompliances. Therefore, OE would like to receive additional input on reporting thresholds for nuclear weapon activities from both NNSA contractor and federal staff. This input should be coordinated through the applicable site's or program office PAAA coordinator(s) and be provided by the close of the 90-day moratorium on enforcement discussed in Section III of this EGS. Upon closure of the 90-day moratorium, OE will review and incorporate the new reporting threshold guidance in its operational procedure.

In the interim, contractors should use the guidance and reporting thresholds contained in the OE Operational Procedure - *Identifying, Reporting, and Tracking Nuclear Safety Noncompliances Under Price-Anderson Amendments Act of 1988*. The following case examples are provided to help illustrate how PAAA NTS reporting interfaces with nuclear weapon program NCR processes:

Example 1: A reservoir vessel is produced to contain tritium gas in a weapons assembly. A nonconformance with the reservoir vessel is detected during acceptance testing activities associated with the contractor's QC-1 program. The nonconformance involves an out-of-spec dimension that is an isolated case (i.e. not a reoccurring nor programmatic issue) that was detected by the functioning contractors QA program. Although the nonconformance is reported under the NNSA weapons QC-1 program, it would not be PAAA NTS reportable.

Example 2: The same reservoir vessel is produced as noted above to contain tritium gas in a weapons assembly. A nonconformance that could create a potential for tritium gas release to a worker or the atmosphere is detected by the contractor's QC-1 program. The nonconformance has been repetitive in nature indicating an ongoing concern with the QA of the seals. The nonconformance should be considered (using the screening criteria and reporting threshold guidance noted above) for PAAA noncompliance reportability in addition to any NCR.

E. Off-Site Weapons Activities

NNSA contractor nuclear weapons program support may be required at DOD facilities and within other countries where the NNSA contractor may have no control over the facilities or conditions. How will 10 CFR Part 830 be enforced in these situations?

In determining whether enforcement discretion would be appropriate for the above circumstances, OE considered the following:

Subpart B of 10 CFR Part 830 is limited to DOE facilities and, therefore, would not apply at non DOE/NNSA facilities, including those operated by the DOD or a government of another country.

Subpart A of the rule, however, is not limited to activities performed at DOE nuclear facilities. In the Preamble (Page 1811) to 10 CFR Part 830, Final Rule, dated January 10, 2001, DOE states the following in discussing its intent in choosing not to limit the applicability of the rule to "on-site activities".

"In adopting this option to cover offsite activities, we noted that the scope of the rule would apply not only to prime contractors responsible for a nuclear facility, but also

subcontractors, suppliers, and other contractors including those who provide items ... or services ... that affect, or may affect, the nuclear safety of DOE nuclear facilities."

The DOE General Council (GC) in its Ruling 1995-1 provided the following interpretation:

Although the requirements of Parts 830 and 835 apply to arrangements other than contracts, civil penalty assessments are authorized only for a "...person who may conduct activities under contract with the Department of Energy..." and any subcontractor or supplier thereto. Civil penalties are not authorized for activities conducted under a cooperative agreement, grant, or work-for-others arrangement, as distinguished from a contract.

The DOE Enforcement Policy of 10 CFR Part 820 Appendix A, Section IX. b. 9, Exercise of Discretion states:

"DOE will not issue a Notice of Violation for cases in which the violation discovered by the DOE contractor cannot be reasonably linked to the conduct of that contractor..."

Based on the above, OE has determined it will generally refrain from issuing enforcement actions for 10 CFR Part 830 noncompliances involving off-site weapons support activities for the following reasons:

- Subpart B of the rule would not be applicable
- DOE's original intent for expanding the scope of Subpart A was to capture off-site activities that could affect the nuclear safety of DOE facilities versus regulating all off-site activities such as work at non-DOE/NNSA sites involving other agencies or governments.
- The DOE GC's 1995-1 Ruling prohibits the issuance of civil penalties involving cooperative agreements or work-for-other arrangements.
- Contractor support work at non-DOE/NNSA sites typically includes conditions that are beyond the contractor's control.

F. Pre-Design R&D Work

During the research and development stage conceptual designs are evaluated and not all quality assurance requirements are applied. At what point in the R&D design process will OE start to enforce QA requirements?

Pre-design testing and engineering activities could have a significant impact on later design selection and its safety adequacy. Because of this, the requirements of 830 were written to address the QA of design items and processes including pre-design selection activities. Specifically, 830.122 (f) (5) states "Verify or validate work before approval and implementation of the design." It is also recognized that not all QA

requirements of the rule would apply to all of the varying types of pre-design testing and selection activities.

Based on the above, there exists no consistent or defining point in the design process for commencing implementation of the QA rule or enforcement actions. Contractors should therefore consider the use of a graded approach versus defining a specific point (design approval) for commencing QA rule implementation. The graded approach should be based on the impacts the pre and post-design selection activities have on the safety adequacy of the final design selected and implemented.

Consistent with the above-described approach, OE intends to only investigate and issue enforcement actions concerning design-related noncompliances with safety related consequences. In general, OE will therefore limit its enforcement actions to only noncompliances involving implemented designs (post design selection failures). It should be noted, however, that even though the enforcement action may be issued for a post design selection failures, the noncompliance cited could be based on a pre-design selection failure such as that described in 830.122 (f) (5) (see above).

Discussed below are various anticipated design related failures/deficiencies and the manner in which OE would assess these events (in recognition of above rule applicability and graded approach) for potential QA rule noncompliances and enforcement actions.

Post-design selection and implementation failures: A weapon component fails and the component is one that is critical to preventing significant radiological harm. The component failure was attributed to an inadequate design caused by inadequate safety related performance tests conducted during the pre-design selection process. OE would consider this type of failure for potential enforcement actions due to a noncompliance involving a failure to verify/validate work (inadequate testing) prior to design approval and the event consequences (significant radiological harm).

Pre-design selection component QA failures/deficiencies: Several prototype vessels are being considered for use in a future weapon to contain a radioactive gas. The components have different sealing designs and are being subject to leak testing using a surrogate non-radioactive gas. Several of the designs fail the leak test and do not meet the quality performance criteria established for the test. None of the failed prototype designs were selected for further use. The testing was conducted in a non-nuclear and non-radiological facility. OE would not consider the above types of events for potential enforcement actions since the failed prototype activity was not part of the design process for components to be used in a nuclear weapon, facility, or activity.

Pre-design selection activity failures/deficiencies: Design R&D activities are being conducted involving neutron flux testing on prototype components using a research reactor. The describe R&D activities would be subject to potential enforcement

actions since the R&D involves nuclear activities with the potential to cause radiological harm (i.e., flux testing using a nuclear reactor).