From:

Iyengar, Raj

To:

Arce, Jeannette

Subject:

FW: Nuclear Energy Institute Comments on Issues Related to Development of a Draft Regulatory Basis for a Potential Rulemaking on Spent Nuclear Fuel Reprocessing Facilities 76 Fed. Reg. 34007 (June 10, 2011) Docket

ID: NRC-2010-0267

Date:

Thursday, July 07, 2011 5:36:39 PM

Attachments:

07-07-11 NRC Issues Related to Development of a Draft Regulatory Basis for a Potential Rulemaking on Spent

Nuclear Fuel Reprocessing Facilities.pdf

07-07-11 NRC Issues Related to Development of a Draft Regulatory Basis for a Potential Rulemaking on Spent

Nuclear Fuel Reprocessing Facilities Attachment.pdf

From: Rulemaking Comments

Sent: Thursday, July 07, 2011 5:02 PM

To: Iyengar, Raj; Sulima, John

Subject: FW: Nuclear Energy Institute Comments on Issues Related to Development of a Draft Regulatory Basis for a Potential Rulemaking on Spent Nuclear Fuel Reprocessing Facilities 76 Fed. Reg.

34007 (June 10, 2011) Docket ID: NRC-2010-0267

From: McCULLUM, Rodney [mailto:rxm@nei.org]

Sent: Thursday, July 07, 2011 4:51 PM

Subject: Nuclear Energy Institute Comments on Issues Related to Development of a Draft Regulatory Basis for a Potential Rulemaking on Spent Nuclear Fuel Reprocessing Facilities 76 Fed. Reg. 34007 (June

10, 2011) Docket ID: NRC-2010-0267

July 7, 2011

Ms. Annette Vietti-Cook Secretary U.S. Nuclear Regulatory Commission Washington, DC 20005-0001

Subject: Nuclear Energy Institute Comments on Issues Related to Development of a Draft Regulatory Basis for a Potential Rulemaking on Spent Nuclear Fuel Reprocessing Facilities 76 Fed. Reg. 34007 (June 10, 2011) Docket ID: NRC-2010-0267

Project Number 689

The Nuclear Energy Institute (NEI), on behalf of the nuclear energy industry, is pleased to comment on the U.S. Nuclear Regulatory Commission (NRC) staff's "Draft Regulatory Basis for a Potential Rulemaking on Spent Nuclear Fuel Reprocessing Facilities" (Regulatory Basis Document or Document). Establishing a risk-informed, performancebased and technology-neutral regulatory framework for these facilities is a vital prerequisite to national and industry decision-making regarding the development of domestic used fuel recycling capability. The Regulatory Basis Document on which the NRC is now providing the opportunity for comment is an important early step towards establishing this

framework. We strongly encourage the NRC to continue on this path to develop a regulatory framework in the most expeditious manner practicable.

In developing a risk-informed, performance-based and technology-neutral regulation, it is important that the NRC's regulatory bases assure that all requirements are consistently linked to the facility safety analysis and that this linkage is applied evenly across the full scope of the regulation. The regulations developed to address each of the regulatory gaps identified by the NRC should appropriately reflect a holistic understanding of the nexus between the hazards posed by the facility and the degree of controls necessary to be imposed in areas such as operator licensing and training, general design criteria, and technical specifications. This principle is an underlying tenet of many of our comments. It is also the reason that NEI does not support development of a safety and total risk limit for recycling facilities but rather proposes a holistic approach to assuring safety based on established Integrated Safety Analysis (ISA) methods. Because the level of hazard at non-reactor nuclear facilities is significantly less than at reactor facilities, it is not appropriate to apply reactor safety goals to non-reactor nuclear facilities.

The industry appreciated the opportunity to provide verbal feedback on the draft Regulatory Basis Document at the June 21-22 Workshop conducted in Augusta, Ga. This workshop facilitated a useful dialogue among a number of stakeholders on the Document, and exemplified the open and transparent public discourse that serves as an important foundation for any significant regulatory development effort.

These attached comments are informed by the discussion at the June 21-22 Workshop and are intended to further reinforce and clarify the industry positions stated on the record at that time. The comments are organized in the same manner as the Regulatory Basis Document, which identifies 19 regulatory "gaps" to be addressed as part of any future rulemaking governing the licensing of used nuclear fuel reprocessing (or "recycling") facilities.

As in the staff's Document, the individual gaps are organized into the following five topical areas: (1) Regulatory Framework and Definitions; (2) Safety, Risk, and Licensing Considerations; (3) Waste Management and Environmental Considerations; (4) Material Control and Accounting, Security; and (5) Financial Considerations, and are addressed below in that order. For each individual gap, the comments summarize the gap and the NRC staff's current, proposed approach, and present NEI's position and recommendations for the final Regulatory Basis Document to be submitted to the Commission. The staff's Document also requests the comments include responses to a number of specific public feedback questions or topics relating to each of the gaps. NEI is providing its current views on those questions and topics as well.

We look forward to continued interactions with the NRC staff to facilitate its development of a regulatory framework that is stable, predictable, efficient and capable of addressing all future challenges regarding the safety of spent nuclear fuel recycling facilities. In this regard, there are a number of areas (such as safety and risk assessment methodology,

general design criteria, and technical specifications) in which we believe additional focused interactions between the NRC, industry and other stakeholders will be needed to further refine this regulatory framework. We are interested in working with the staff to plan such interactions at the staff's earliest convenience. On these and other topics, please do not hesitate to contact me if you have any questions.

Sincerely,

Rod McCullum Director, Used Fuel Programs

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Rod McCullum
DIRECTOR
USED FUEL PROGRAMS

July 7, 2011

Ms. Annette Vietti-Cook Secretary U.S. Nuclear Regulatory Commission Washington, DC 20005-0001

Subject: Nuclear Energy Institute Comments on Issues Related to Development of a Draft Regulatory Basis for a Potential Rulemaking on Spent Nuclear Fuel Reprocessing Facilities 76 *Fed. Reg.* 34007 (June 10, 2011) Docket ID: NRC-2010-0267

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In developing a risk-informed, performance-based and technology-neutral regulation, it is important that the NRC's regulatory bases assure that all requirements are consistently linked to the facility

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear material licensees, and other organizations and individuals involved in the nuclear energy industry.

Ms. Annette Vietti-Cook July 7, 2011 Page 2

safety analysis and that this linkage is applied evenly across the full scope of the regulation. The regulations developed to address each of the regulatory gaps identified by the NRC should appropriately reflect a holistic understanding of the nexus between the hazards posed by the facility and the degree of controls necessary to be imposed in areas such as operator licensing and training, general design criteria, and technical specifications. This principle is an underlying tenet of many of our comments. It is also the reason that NEI does not support development of a safety and total risk limit for recycling facilities but rather proposes a holistic approach to assuring safety based on established Integrated Safety Analysis (ISA) methods. Because the level of hazard at non-reactor nuclear facilities is significantly less than at reactor facilities, it is not appropriate to apply reactor safety goals to non-reactor nuclear facilities.

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Ms. Annette Vietti-Cook July 7, 2011 Page 3

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Sincerely,

Rod McCullum

Attachment

c: Ms. Catherine Haney, NMSS, NRC

Mr. Jack Guttman, NMSS/DHLWRS/TRD, NRC

Mr. Jack R. Davis, NMSS/DHLWRS/TRD, NRC

Mr. Aby S. Mohseni, NMSS/DHLWRS/LID, NRC

NRC Document Control Desk

ATTACHMENT NUCLEAR ENERGY INSTITUTE COMMENTS ON "DRAFT REGULATORY BASIS FOR A POTENTIAL RULEMAKING ON SPENT NUCLEAR FUEL REPROCESSING FACILITIES"

A. Regulatory Framework and Definitions

- 1. Gap 1 Developing a Regulatory Framework for Fuel Reprocessing Plants
 - a. Gap 1 Summary and Staff-Proposed Approach

A reprocessing (or recycling)¹ facility is a "production facility" as defined in Section 11 of the Atomic Energy Act of 1954, as amended (AEA). As such, 10 CFR Part 50 currently would apply to the licensing of such a facility.

However, the detailed requirements in Part 50 focus, almost exclusively, on the licensing of reactor facilities, and not on reprocessing or recycling facilities. Applying Part 50 to reprocessing or recycling facilities would require numerous exemptions from requirements that should not be applied to such facilities. Regulation under the current Part 50 would be inefficient and complicated.

On the other hand, 10 CFR Part 70, applicable to the licensing of Special Nuclear Material (SNM) facilities, does not provide a complete framework for licensing and regulating reprocessing (or recycling) facilities, though it contains numerous elements that could be applied to such facilities.

See NEI's comments on Gap 2 regarding the appropriate term for, and definition of, the facilities which are the subject of the Regulatory Basis Document.

The NRC staff's basic proposed approach is to establish a new 10 CFR Part "7X" that, to the maximum extent possible, carries forward the risk-informed and performance-based approach reflected in Part 70 and incorporates appropriate elements of Part 50, while removing the current references in Part 50 to reprocessing facilities.

b. NEI Comments on Staff Proposed Approach

NEI strongly supports the staff's proposal to establish a new risk-informed, performance-based regulation "7X," which will incorporate appropriate elements of Parts 70 and 50. The staff explicitly states that "[t]he regulations should, to the extent possible, be aligned with NRC's risk-informed and performance-based philosophy towards rulemaking."

Some elements of the staff's proposals that are discussed later in these comments do not appear to conform to this risk-informed, performance-based approach. NEI's views on this and many other topics covered by the Regulatory Basis Document are set forth in detail in three White Papers, including an NEI White Paper entitled "Regulatory Framework for an NRC Licensed Recycling Facility" (ADAMS No. ML 083590114) (Regulatory Framework White Paper).

As reflected in NEI's Regulatory Framework White Paper (and in later discussion in these comments), NEI favors an approach tailored closely to Part 70, while recognizing and supporting the incorporation of appropriate elements of Part 50, and other relevant NRC regulations, into the proposed Part 7X.

It is important to note that this approach can only be effectively implemented if the regulation is also "technology neutral." It must allow for the efficient and effective licensing and regulation of the range of potentially available technologies that may be favored by various interested industry participants.

In addition, the new rule should: (1) allow for the licensing and regulation under a single Part of 10 CFR of facilities closely associated with reprocessing (or recycling) such as stabilization, fuel fabrication and solid waste storage facilities; and (2) provide flexibility for applicants to seek either a construction permit, followed by an operating license (two-step licensing process), or a single combined license, generally comparable to a Combined Operating License (COL) as authorized by 10 CFR Part 52 (one-step licensing). It should also allow an applicant to seek separate licenses under Part 7X for individual aspects of the reprocessing/recycling facility, such as used fuel storage or stabilization, if the applicant desires to proceed with the licensing process in stages. Such flexibility is essential, since it is not possible at this time to predict how any individual license applicant may wish to proceed. Further, early applicants may have different perspectives than later applicants who have had the benefit of the lessons learned from previous licensing actions.

Stabilization is used herein to describe any process that converts a liquid or gaseous waste into a solid waste form (e.g. glass, ceramic, etc.).

c. <u>NEI Comments on Public Feedback Questions³</u>

PF-1: The staff has asked for input on potential emergency planning requirements. Any emergency planning requirements or guidelines for reprocessing (recycling) facilities, including potential emergency planning zone (EPZ) provisions, must be hazards/risk-based, and must be based upon the Safety Analyses performed for the particular facility. While general guidelines can be established, areas such as the need for and scope of EPZs and the need for and scope of offsite, state and local government coordination should be based on the individual facility's hazards/risk profile. NEI endorses use of the current Part 70 framework, with application of provisions similar to Part 50, Appendix E in circumstances where the Safety Analysis demonstrates that preparedness for a General Emergency Classification is necessary.

Further analysis and consideration of this issue, including the details of NUREG-1140, are needed to provide more comprehensive comments on this issue. Additional dialogue with the NRC is also necessary.

PF2: The staff proposes use of National Fire Protection Association (NFPA) standard 801. NEI has previously discussed the potential use of NFPA 805 which is preferred by those familiar with reactor operations. Either one may be appropriate for a given facility. Therefore, we conclude that individual applicants should be permitted to propose standards appropriate for their facilities subject to NRC review and approval.

The staff's "Public Feedback" questions are designated as "PF-1", etc., below.

PF-3: The staff recommends design of reprocessing (recycling) facilities to the NRC's Seismic Category I, the most demanding seismic category, similar to nuclear power plants. NEI recommends an alternative approach which reflects a more risk-informed and performance-based philosophy.

For recycling facilities, NEI recommends adopting a graded seismic hazard design approach similar to that described in U.S.

Department of Energy (DOE) DOE STD-1020, "Natural Phenomena Hazards Design and Evaluation Criteria of Department of Energy Facilities" (DOE, 2002). DOE-STD-1020 (DOE, 2002) is a graded approach based on the hazards presented by different facilities. DOE grades facilities by assigning a Performance Category (PC) based on overall hazard. The categories range from PC-0 for facilities that require no natural phenomena hazard protection, to PC-4 for facilities with reactor-like hazards.

For a recycling facility, the approach utilized for each portion of the facility, each of which may present different risks, should be tailored to the hazards posed by that portion of the facility. As an example, PC-3 SSCs (systems, structures, and components) are those for which failure to perform their safety function could pose a potential hazard to public health, safety and the environment because radioactive or toxic materials are present and could be released from the facility as a result of that failure. PC-3 SSCs would prevent or mitigate criticality accidents,

chemical explosions and events with the potential to release hazardous materials outside the facility.

d. <u>NEI Comments on Questions for the Public</u>⁴

OP-1: With respect to the appropriate requirements to be adopted from 10 CFR Part 50, Appendix F, NEI's proposed Part 7X considered Appendix F and addresses the time period for stabilizing waste, financial assurance and decommissioning. See NEI's proposed 10 CFR §§ 7X.34 Baseline Design Criterion (BDC) 14, 7X.30(d) and (g), and 7X.38. In addition, consistent with Appendix F, recycling facilities clearly do not need to be sited on federal or state land and may be sited on private land.

QP-2: With respect to appropriate requirements for decommissioning financial assurance and planning, NEI refers the staff to its proposed Part 7X, in particular, NEI's proposed 10 CFR § 7X.38, which was based on 10 CFR § 70.25. Any requirements should reflect the recent amendments to 10 CFR § 70.25.

OP-3: As discussed above, Part 50 is not well-suited for licensing a reprocessing/recycling facility. A new risk-informed, performance-based, and technology neutral Part 7X is the best and most efficient approach.

QP-4: Further analysis and consideration of the details of NUREG-1140 are needed to provide more comprehensive comments on this issue. Further dialogue with the NRC is also necessary.

The staff's "Questions for the Public" are designated as "QP-1," etc., below.

OP-5: See NEI's comments on PF-1 above.

OP-6: See NEI's comments on PF-1 above.

2. Gap 6 – Definitions

a. Gap 6 Summary and Staff-Proposed Approach

Neither the AEA nor NRC regulations currently define the term "reprocessing." Clear terms and definitions are necessary to minimize regulatory uncertainty. The NRC staff's proposed approach is to define the term "reprocessing," and it is considering several variations including a definition that appears in the IAEA Safety Glossary (2007 Edition). It is also considering developing a separate definition for the term "recycling" and clarification of the term "high-level waste."

b. NEI Comments on Staff Proposed Approach

NEI favors replacing the term "reprocessing" throughout the regulations with the term "recycling." The NRC staff believes that "recycling" "describes an integrated lifecycle process that results in the production of a new reactor fuel from used nuclear fuel," and that in contrast, "reprocessing" is a "stage in this lifecycle process that refers to the actual mechanics of removing unwanted components from used nuclear fuel." The staff does not see a "compelling need" to replace the term "reprocessing" with recycling" in the regulations.

NEI continues to believe that "recycling" is the most appropriate term. "Reprocessing" is a term that has historically been associated with aqueous processing and, hence, connotes a specific technology rather than

the technology neutral approach needed for an effective and efficient rule.

Furthermore, "recycling" is a more comprehensive term that would clearly encompass in the regulations those facilities that would create new fuel from used nuclear fuel. In addition, even in the absence of subsequent new fuel fabrication, there is a substantial environmental benefit derived from taking americium and other fission products out of the used fuel and immobilizing them in a solid form. NEI's Regulatory Framework White Paper defines a "fuel recycling facility" as:

a facility for recycling and its associated activities such as, but not limited to, used fuel storage, vitrification, plutonium and/or minor actinides processing and fuel fabrication, waste storage and processing, and storage of new fuel to the extent such associated activities are included in the application and or license for the fuel recycling facility. A fuel recycling facility is a production facility.

See NEI's proposed 10 CFR § 7X.3. This definition, in industry's view, is descriptive as well as comprehensive, encompassing all of the various activities that might be covered by the new rule. Throughout the remainder of these comments, NEI uses the term "recycling" for consistency.

c. NEI Comments on Public Feedback Questions

PF-1: Yes. NEI believes that there are important differences between the terms "reprocessing" and "recycling" as discussed above.

B. Safety, Risk and Licensing Considerations

3. Gap 5 – Safety and Risk Assessment Methodology

a. Gap 5 Summary and Staff-Proposed Approach

The Regulatory Basis Document states that the existing Part 70 regulations "do not adequately address the potential hazards, consequences, and risks of reprocessing and recycling (R&R) facilities, including distinguishing potentially life-threatening events from lesser ones, minimization of risks, and property and environmental damage." It also states that the Integrated Safety Analysis (ISA) approach incorporated into Part 70 does not "adequately address the potentially large source terms, greater number of scenarios...and more [severe] consequences much higher than 70.61 thresholds, of R&R facilities as compared to existing fuel cycle facilities."

As a result, the NRC staff proposes to incorporate more quantitative risk assessment methods into the new rule, including Probabilistic Risk Assessment (PRA). Two basic approaches are under consideration.

The first is a "hybrid ISA-PRA approach." This would involve, among other things: use of an ISA to *identify* accident sequences and *categorize* them by consequence; use of a PRA to calculate the risk of "very high consequence events (VHCEs), (a new concept not currently in Part 70)⁵; establishment of lower, acceptable likelihood values for VHCEs; application of associated Items Relied On for Safety (IROFs) to achieve those lower likelihood values or to reduce consequences below the

Page 13 of the Regulatory Basis Document refers to application of PRA to VHCEs only, while pages 14 and 16 state that PRA should be applied to high consequence events (HCEs) as well. This inconsistency should be addressed.

VHCE thresholds; use of PRA to "rank" IROFs; and further minimization of risk below legal thresholds by application of an "As Low As Reasonably Practical" (ALARP) methodology.

The second approach under consideration is a pure PRA approach applied to all identified "significant" accident sequences, and similar to that recommend by the Advisory Committee on Reactor Safeguards (ACRS) in NUREG-1909. The staff intends to "assess both options (pros and cons) during the rulemaking process and make a recommendation at that time." The Regulatory Basis Document also contains "Proposed Performance Requirements" that identify quantitative risk thresholds for all credible events (e.g., >1E-4 to <1E-6).

b. NEI Comments on Staff Proposed Approach

NEI strongly favors use of ISA methodology, and endorses the use of quantitative risk assessment methodologies in limited, appropriate circumstances in which there is the potential for fission product releases/exposure to persons outside the controlled area⁶.

As described in NEI's ISA/PRA White Paper, an ISA provides a flexible methodology that can be tailored to the uniqueness of each facility to identify events or accidents with high or intermediate consequences and to develop the needed safety measures to prevent or preclude these events. Use of an ISA will achieve the required safety for recycling facilities, and

⁶ Such quantitative risk assessment methodologies may include use of PRA techniques. PRAs require that the facility systems are amenable to application of that methodology, and require availability of sufficient data. The basis for this position is explained in NEI's White Paper entitled "Integrated Safety Analysis: Why Is It Appropriate for Fuel Recycling Facilities?" (ISA/PRA White Paper) (ADAMS No. ML 102810587).

is the best, most cost effective option for ensuring safety at these facilities. An ISA is essentially a design methodology to assure appropriate safety controls are in place to meet performance objectives. It is not, like PRA, a tool to determine the overall risk of a facility. ISAs are useful to determine the needed safety requirements for a facility, but in contrast to a PRA, the ISA process is not intended to determine the relative increase in the off-site risk of a facility following a degraded condition.

NEI has concerns about the NRC staff's proposed approaches. The staff has proposed two approaches. The first approach is the hybrid ISA-PRA approach. This approach introduces terms, for which there is no precedent, that are not necessary to describe the potential hazards of a recycling facility and, of most concern, may create confusion in their application. This proposed approach appears to suggest three elements which the industry does not consider appropriate or warranted.

Firstly, NEI does not believe quantifying "to the extent practicable" is a workable approach. A determination of "to the extent practical" requires expert judgment. NEI's proposed Part 7X used the term "to the extent practical" in 10 CFR § 7X.30(c)(3)(i)(E) in the context of the availability of data to support quantitative analysis. This is intended to take into account a number of factors including the particular system, its design, and equipment used. Thus, what is practical will depend on the circumstances of the particular facility. It does not lend itself to a quantifiable number.

The second concern is the staff's proposal to apply PRA to very high consequence events (VHCEs) and calculate risk. NEI questions the need for and benefits of creating the entirely new concept of VHCEs and believes that the goal of adding this term (which would be unique in the NRC regulations) can be achieved in other ways.

As noted above, a high-level simplified PRA for a recycling facility could be used to provide risk insights in the context of demonstrating the margin within safety goals for certain accident scenarios from fission product releases with potential for high consequences. Such an analysis would support the conservative assumptions applied in the ISA. Such insights could be used to inform regulatory decisions including setting appropriate thresholds for use of quantitative risk analysis methodologies and ranking, and establishment of appropriate controls for certain HCEs with consequences well above the threshold for HCEs in the existing Part 70. NEI opposes deviating from the safety envelope precedent established by Part 70 by the creation of new terms that are not necessary to protect the public health and safety.

The third element proposed by the staff is the ALARP concept.

Utilization of the proposed "ALARP" concept is not necessary to minimize risk beyond established regulatory thresholds, and that the well-established "defense-in-depth" principle incorporated in Part 70 effectively achieves this objective. In general, the NRC, the regulated community, and the public are best served by not creating new

terminology and by relying instead on established and well-understood principles. It is not at all clear why introducing such terminology is needed for recycling facilities.

The second proposed staff alternative is a pure PRA approach as recommended by the ACRS (Advisory Committee on Reactor Safeguards). As described in NEI's ISA/PRA White Paper, a PRA is intended to provide a complete, quantitative risk representation of a facility and illustrate the contribution to risk of all the supporting features of the facility. In contrast, an ISA does not determine the overall quantitative risks associated with a facility. An ISA identifies events or accidents with high or intermediate consequences and then develops the needed safety controls to prevent or mitigate these events. There is a likelihood associated with the event that can be defined qualitatively, semi-quantitatively, or quantitatively. The PRA considers all the components of the facility and their contribution to risk.

Properly done, a PRA relies on extensive data bases that include information on equipment reliability, and test data for equipment performance under adverse conditions, as well as an understanding of plant operations and conditions and their relative importance to the risk at the facility. This data has been established over time at numerous reactor sites. While no reactor may be identical in every fashion, they all have similar systems.

Fuel cycles facilities rarely have similar systems and equipment.

Because of the uniqueness of the facilities and the proprietary nature of their systems, the fuel cycle industry has not created shared databases of reliability information as has the nuclear power reactor industry. For fuel cycle facilities and for recycling and reprocessing facilities, this information would need to be developed at a significant cost using scarce specialized human resources to enable PRAs. For these reasons which are more fully explained in NEI's ISA/PRA White Paper, NEI does not support application of a full PRA to recycling facilities.

In sum, "pure" use of PRA is impractical and unnecessary.

Quantitative risk assessment techniques should be limited to those circumstances where there is a potential for fission product releases/exposure to persons outside the controlled area. This is the same threshold NEI recommends for application of Technical Specifications and for Operator licensing. It is important that this regulation be internally consistent across all of these areas by assuring that each requirement is appropriately linked to the facility Safety Analysis.

As with other issues identified herein, further dialogue with the NRC on this topic is necessary.

c. NEI Comments on Public Feedback Questions

PF-1: The NRC staff has asked if there should be a safety and total risk limit to members of the public developed for recycling facilities. If so, should this safety and total risk limit apply only to VHCEs, VHCEs and HCEs, or some other grouping of accident sequences and categories?

NEI does not support development of a total risk limit to members of the public for recycling facilities. Such a risk limit does not provide useful information, since the summing of potentially numerous hypothetical but uncorrelated hazards (e.g., spills and chemical explosion hazards) is statistically meaningless (similar to collective doses associated with micro-doses to macro-populations). Furthermore, the uncertainties associated with such a total risk limit are likely to be very high and highly dependent on the availability and quantity of relevant data.

Unlike Part 50, NEI's proposed Part 7X (7X.32) contains performance requirements to provide the standard for the protection of the public health and safety. Neither Part 70 or any other NRC regulation uses the term or the concept of VHCEs.. Parts 70 and 7X in the context of defining performance requirements address HCEs which are those internally or externally initiated events that could potentially result in:

- (1) An acute worker dose of 1 Sv (100 rem);
- (2) An acute dose of 0.25 Sv (25 rem) to any individual outside the controlled area;
- (3) An intake of 30 mg or greater of uranium in soluble form by any individual located outside the controlled area; or
- (4) An acute chemical exposure to an individual that:
- (i) Could endanger the life of a worker, or
- (ii) Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area.

There is no reason to develop a limit above the HCE. Current practices and regulations on dose limits provide protection to the public health and safety and the environment.

PF-2: The staff has also asked whether the total risk to workers or

member of the work force should be assessed, and, if so, which accident sequence categories should be included in the calculations. NEI does not support development or assessment of a total risk limit to the work force for recycling facilities. Current practices and regulations on dose limits provide adequate protection to the work force.

PF-3: The staff asks if the total risk goal, for a worker and a member of the public, for recycling facilities should be the same as the goal for commercial nuclear power plants. NEI does not support development of a total risk goal for workers or members of the public for recycling facilities. Current practices and regulations on dose limits provide adequate protection for these facilities.

PF-4: The staff asked if it should consider a total risk limit, or a total risk limit and a total risk aspirational goal. NEI does not support development or assessment of a total risk limit or a total risk limit and a total risk aspirational goal for recycling facilities. In addition NEI questions what is meant by an "aspirational goal." Current practices and regulations on dose limits provide adequate protection for these facilities.

PF-5: The staff has asked if PRA methods should be used more or less extensively than the hybrid approach mentioned above. NEI strongly favors use of ISA methodology and would not oppose the use of PRA in limited, appropriate circumstances in which there is the potential for fission product releases/exposure to the offsite public and where the facility systems are amenable to application of PRA methods. As is more

fully explained in NEI's ISA/PRA White Paper, NEI does not support application of a full PRA to recycling facilities. "Pure" use of PRA is impractical and unnecessary. Quantitative risk assessment techniques should be limited to those circumstances where there is a potential for a high consequence event involving fission product releases to an individual outside the controlled area assuming the availability of sufficient data to perform the analysis. This is the same threshold NEI recommends for application of Technical Specifications and for Operator licensing. It is important that this regulation be internally consistent across all of these areas by assuring that each requirement is appropriately linked to the facility Safety Analysis.

- 4. Gap 7 Licensed Operators and Criteria for Testing and Licensing Operators
 - a. Gap 7 Summary and Staff-Proposed Approach

Under the AEA, "production facilities" must employ licensed operators. The current 10 CFR Part 55 regulations are not applicable, in whole, to operators at recycling facilities. The staff anticipates deriving applicable requirements primarily from Part 55, and using a risk-informed, performance-based approach to determine which personnel need to be licensed (e.g., persons relied on to control VHCEs) and the requirements for licensure.

b. NEI Comments on Staff Proposed Approach

NEI favors applicant certification to the NRC that operators are

technically, medically and physically competent based on an NRC-approved certification program. The NRC operator licensing process would include NRC audits and approval of the facility's certification program. The threshold for licensed operators would be to certify and license those operators whose actions are necessary to prevent or mitigate accident scenarios that involve fission product releases that could result in an HCE to an individual outside the controlled area. This would be the same threshold for establishment of Technical Specifications and use of quantitative risk assessment methods, establishing a coherent approach and consistency throughout the rule. It is important that this regulation be internally consistent across all of these areas by assuring that each requirement is appropriately linked to the facility Safety Analysis.

c. NEI Comments on Public Feedback Questions

Roles and Responsibilities

<u>PF-1</u>: The NRC's role in testing candidates should be consistent with the approach set forth in Section III.E of NEI's Regulatory Framework White Paper.

<u>PF-2</u>: NEI does not believe an auditing approach would be "problematic because tests and grading...may later be found to be deficient...." NEI's proposal includes NRC approval of the certification program, and audits and inspections are regularly used to ensure and confirm all NRC licensees comply with requirements in a wide range of areas.

Simulation Facilities

PF-1: Simulation facilities should not be required. There is, to date, insufficient justification and insufficient information on which to impose such a requirement.

PF-2: Given NEI's response to PF-1 above, it is not possible or necessary to provide specific recommendations on acceptable attributes of a simulation facility.

PF-3: See NEI's comments on PF-1 above.

Licensed Personnel

<u>PF-1</u>: The decision as to which personnel should be licensed should be based upon a risk-informed, performance-based approach. It should be "driven" by the results of the Safety Analyses and limited to those individuals who perform activities or functions needed to prevent or mitigate identified and defined accident scenarios involving fission products that could result in an HCE to an individual outside the controlled area.

Senior Operators

PF-1: The NRC staff's proposed approach should not include requirements for senior operators. This is, more appropriately, a management decision and should be based on the results of the Safety Analysis. In particular, given the multiple potential recycling processes under consideration, the decision should be driven by the nature of the facility and technology and the operator's specific functions.

PF-2: See NEI's comments on PF-1 above.

PF-3: It is not clear what "increase" in training requirements the staff has in mind. Appropriate training of licensed operators will depend, to a very large degree, on the particular circumstances. Any new rule should be limited to requiring that operators be properly and adequately trained in a manner consistent with the Safety Analysis results for the particular facility. More detailed criteria should be addressed in implementing guidance, developed in parallel with the rule.

5. Gap 9 – General Design Criteria

a. Summary and Staff-Proposed Approach

Design Criteria" or GDC and Part 70 requires development and application of "General Design Criteria" or GDC and Part 70 requires development and application of "essentially synonymous" "Baseline Design Criteria" or BDC. The former apply only to nuclear power plants. The latter are, in the staff's view, too general to "comprehensively address hazards posed by...reprocessing and recycling facilities." The staff is proposing to utilize ten categories of GDC, encompassing 78 specific *potential* GDC. The GDC would be based on 10 CFR Part 72 GDC, as applicable, as well.

b. NEI Comments on Staff Proposed Approach

NEI has proposed 28 individual BDC. NEI has no objection to the concept of "categories" of GDC (or BDC) or to the development of specific, individual design criteria within those categories. However, any

such criteria must either be technology neutral or must clearly indicate which criteria are applicable to which recycling technologies.

The staff has proposed 78 potential GDC in only a brief summary manner and without providing the specific content of the proposed GDC.

NEI has proposed 28 specific, individual BDC. Without knowing the substance of the 78 GDC, it is not clear what the differences are between these approaches. This is because many of the NEI proposed BDC could be subdivided into separate topics. NEI did not include some topics that NRC has listed, because they would be covered under separate regulatory requirements such as 10 CFR § 20.1406, "Minimization of contamination", physical security, and material control and accounting provisions.

It is also important to recognize that the Part 50 GDC and proposed Appendixes were based on a deterministic system, rather than a risk-informed performance-based approach. A balance between a deterministic approach with prescriptive requirements and a risk-informed performance-based approach needs to be considered.

Development of the details of this aspect of the proposed regulatory scheme will require considerable, additional interactions among stakeholders by way of workshops, meetings, or other communication methods. This is a complex topic warranting particular additional attention before a proposed rule is published. Accordingly, further dialogue with the NRC on this topic is necessary.

c. NEI Comments on Public Feedback Questions

PF-1: See NEI's comments on the staff's proposed approach above.

PF-2: See NEI's comments on the staff's proposed approach above.

PF-3: Yes. There are clearly areas of regulation where there is no need to establish GDC because of the existence, or ability to create, separate regulatory requirements in the regulations which amply address the issue. The example referenced by the staff, 10 CFR § 20.1406 "Minimization of contamination" is an excellent example. This regulation has worked effectively and efficiently for reactor and non-reactor licensees alike, and there is no apparent need to establish GDC covering this same topic that exclusively apply to recycling facilities.

PF-4: The proposed, but never implemented, 10 CFR Part 50 Appendix P and Q GDC (which as the staff states "were not technological neutral" [sic]) should be evaluated in the same manner as the staff's proposed 78 GDC. Any decision to include specific GDC or BDC in the rule should be based upon a determination that they provide an added and necessary safety benefit needed to provide reasonable assurance of protection of public health and safety. If requirements in other parts of the regulations adequately address the topic, there is no need for duplicative GDC or BDC.

- 6. Gap 10 One-Step Licensing and Inspection, Testing and Acceptance Criteria (ITAAC)
 - a. Summary and Staff-Proposed Approach

The staff is proposing to adopt a one step licensing process similar

to the 10 CFR Part 52 COL process, including ITAAC. It will also allow for the opportunity to seek Early Site Permits (ESPs), but would not provide for standard design certifications, standard design approvals or manufacturing licenses.

b. NEI Comments on Staff Proposed Approach

NEI endorses inclusion of a Part 52-like one step licensing process in the rule. However, it is essential that the option of a two-step construction permit/operating license process also be permitted by the rule. As discussed earlier, there are various recycling technologies in various states of development. Some potential entrants into the market may wish to provide the level of design detail needed for approval of construction (which is typically less than that required for operation) in order to seek construction approval in parallel with continued design development. This is likely to particularly be the case for first-of-a-kind technologies. This approach (used in other circumstances of NRC licensing) creates no adverse health, safety or environmental issues, could potentially provide for more public participation opportunities (e.g., via hearings on a construction permit application for example), and could provide a more efficient licensing path in some circumstances. NEI believes that there is a necessary and important rationale for including this option in the rule. We envision two alternative subparts to the 7X regulation, to accommodate the two options. NEI also has no objection to the inclusion of an ESP provision.

c. NEI Comments on Public Feedback Questions

PF-1: The criteria for ITAAC for recycling facilities are provided in NEI's proposed Part 7X, using the same criteria that are used in Part 52. See NEI's 10 CFR §§ 7X.30(o) and 7X.58. It is premature to address specific ITAAC at this time. Specific ITAAC will be provided in the application if the applicant proposes a combined application.

PF-2: There is no need to have separate ITAAC for different designs because the criteria in Part 7X for ITAAC are technology neutral. Specific design ITAAC will be addressed in the applications as part of the licensing process.

PF-3: The applicant for a combined license will need to supply sufficient information so that the NRC may make the findings required for license issuance. The information and findings recommended by NEI are addressed in NEI's proposed Part 7X, Subparts B and D.

<u>PF-4</u>: Subpart B of NEI's proposed Part 7X addresses the information that should be in the applicant's final safety analysis report.

7. Gap 11 – Technical Specifications

a. Summary of Staff Proposed Approach

The staff proposes to apply Technical Specifications (Tech Specs) to VHCEs, including "accident sequences that can endanger the life of a member of the public, result in 'high consequences' as defined in Part 70 to large groups of individuals, or result in widespread contamination of land and property." It also proposes requiring effluent Tech Specs

comparable to those in 10 CFR § 50.36a. The staff is also apparently considering requiring some Tech Specs that do not have a direct nexus to VHCEs or necessary effluent release limits.

b. NEI Comments on Staff Proposed Approach

NEI recommends Tech Specs derived from the results of the Safety Analysis and from the IROFS that emerge from that analysis, based upon the need to protect against HCEs involving fission product releases to an individual located outside the controlled area – again the same threshold proposed for quantitative risk assessment and operator licensing. The need for Tech Specs should be driven by the results of the Safety Analysis. Tech Specs that do not have an appropriate nexus to the results of the Safety Analysis are inappropriate and unnecessary. Tech Specs should not be divorced from the risk-informed, performance-based analysis of consequences and likelihood envisioned to be a centerpiece of the rule. Further stakeholder/NRC interactions on this subject as well, are extremely important, in order to allow for a thorough discussion of the circumstances under which Tech Specs are needed, and of the general content and level of detail of the Tech Specs.

With respect to effluent Tech Specs, such Tech Specs are not needed because NEI's proposed Part 7X BDC 13 has adopted the concepts of 10 CFR § 50.36a to keep radioactive effluents as low as reasonable achievable (ALARA) and is included as part of the Safety Program the licensee is required to maintain to ensure that, among other things, the

provisions of Part 20 are met. NEI's proposed Part 7X contains reporting provisions in 10 CFR § 7x.92(a) similar to 10 CFR § 70.59 which require more frequent reporting than the provisions in 10 CFR § 50.36a.

c. NEI Comments on Public Feedback Questions

PF-1: See NEI's comments on the staff's proposed approach above.

PF-2: It is not clear in this question what is meant by the phrase "overall facility technical specifications." Given the proposal to utilize IROFS and Management Measures in a risk-informed, performance-based regulation, there will be only a limited need for Tech Specs. The requirement to establish and maintain IROFS to be available and reliable when needed obviates the need for a lengthy set of Tech Specs. Any Tech Specs should be derived from the facility Safety Analysis where there is a potential for a high consequence event. It is important that this regulation be internally consistent across all of these areas by assuring that each requirement is appropriately linked to the facility Safety Analysis. See NEI's proposed 10 CFR § 7X.40. Similarly NEI does not agree that the five "categories" of Tech Specs identified by the staff (e.g., safety limits and limiting control settings, etc.) are necessary or appropriate for recycling facilities.

C. Waste Management & Environmental Considerations

- 8. Gap 2 Independent Storage of High Level Waste
 - a. Summary and Staff-Proposed Approach

The staff is considering modifying Part 72, Subpart K to provide

for a "general license" for storage of solidified HLW at a recycling facility. It also envisions amendments to Part 72, Subpart L to provide criteria for certification of casks for HLW storage. It is NEI's understanding that storage for "operational needs" would be covered by such a general license, but that a specific license would be required for "extended" HLW storage.

b. NEI Comments on Staff Proposed Approach

NEI opposes a separate Part 72 rulemaking and favors incorporation of any necessary provisions for HLW storage into Part 7X, as a matter of clarity and to avoid potential interface issues between various Parts of the regulations.

c. NEI Comments on Public Feedback Questions

PF-1: NEI agrees that storage of solidified HLW from recycling is, as the staff has stated, "not significantly different from the storage of SNF...."

Any unique technical issues that may arise with respect to the storage of solidified HLW from recycling operations can and should be addressed in the Part 7X rulemaking.

PF-2: NEI strongly supports a general license provision in Part 7X for solidified HLW comparable to that in Part 72. We are aware of no justification for "some other [alternative and undefined] approach...."

PF-3: The staff has asked if "limits should be placed on the amount of SNF that could be stored at a reprocessing facility if a general license for storage is issued?" NEI strongly believes that the answer is no.

The amount of used fuel to be stored, even under a general license, is essentially a commercial and operational issue for the license applicant, who will need to propose possession limits in its specific recycling facility license application. Any quantity proposed must be able to be safely stored in accordance with applicable NRC requirements, and the applicant has the burden to demonstrate compliance. Indeed, in 10 CFR Part 72, Subpart K, a general licensee storing used fuel at power reactor sites may store all used fuel that the general licensee is authorized to possess at the site under its *specific* license. Subpart K demonstrates that effective general license criteria can be established without placing a specific storage limit on the licensee (again, beyond the possession limits set forth in the specific license).

9. Gap 3 – Waste Incidental to Reprocessing

a. Summary and Staff-Proposed Approach

The staff recognizes the need to distinguish, in a practical and technically sound manner, between HLW and low-level waste (LLW) resulting from the recycling of used fuel. It references, among other things, the definition of HLW in the Nuclear Waste Policy Act (NWPA) that focuses on two key phrases: "highly radioactive" material and fission products "in sufficient concentrations" – neither of which are specifically defined. The staff states that wastes that are not "highly radioactive" can be safely disposed of in a near surface disposal facility so long as compliance with 10 CFR Part 61 can be achieved.

The Regulatory Basis Document offers three options for distinguishing HLW from LLW generated at recycling facilities. These are: (1) seeking legislative changes to reduce the scope of the definition of HLW; (2) promulgating a regulation interpreting the NWPA definition of HLW (and in particular, the phrases "highly radioactive" and "in sufficient concentrations" in order to clarify the distinction between HLW and LLW); and (3) no action, resulting in *all* "highly radioactive" waste streams being considered as HLW.

While the Regulatory Basis Document itself does not select a preferred approach, at the June 21-22, 2011 NRC public meeting held by the staff in Augusta, Georgia, the staff appeared to express a preference for the rulemaking option (option 2 above) using functional, hazards-based criteria for distinguishing HLW from LLW.

The staff also states that it:

believes wastes that are not "highly radioactive" can be safely disposed of in a near-surface disposal facility as long as the waste streams in question could meet the requirements for disposal specified in 10 CFR Part 61. The NRC staff believes that there is a need to develop a practical approach to determining what materials are considered "highly radioactive" in the definition of HLW and, thus, requires [sic] deep geologic disposal, in contrast to those lower activity wastes that could be safely disposed in a near-surface facility that met the radioactive disposal requirements of Part 61.

b. NEI Comments on Staff Proposed Approach

NEI believes that the only appropriate and viable option is rulemaking to implement the relevant provision of the AEA (Option 2).

The AEA adopts the definition of "high-level waste" from the NWPA. This is the opportunity for the NRC to utilize the flexibility in the AEA and NWPA to further move away from a source-only definition and to a definition based on hazards, by defining "highly radioactive" and "in sufficient concentration." The basis for moving towards a hazard-based definition was presented in the NEI White Paper entitled "High-Level Waste Insights" (ADAMS No. ML 093030353) (Insights White Paper). The Insights White Paper provides support for this option.

Congressional legislation (Option 1) is neither needed nor well-suited for the types of technically and scientifically-informed judgments needed. These are the sorts of questions that should be addressed by way of the rulemaking function of the NRC as the expert technical agency.

Further, legislation generally takes considerable time and may never be adopted. Adoption of the rulemaking approach (Option 2) provides for regulatory certainty by establishing the ground rules up front for HLW by providing those who may disagree with the outcome with an opportunity to seek judicial review.

The "no action" option (Option 3) would result in leaving the status of waste to be resolved in the licensing process. This would place the issue in limbo, creating uncertainty that may have significant economic impacts. It would be inconsistent with one of the fundamental purposes of developing a regulatory framework, which is to provide future potential applicants with an understanding of their design needs.

NEI continues to support the position in its Insights White Paper that defined the terms of "highly radioactive" and "in sufficient concentration" in the context of waste incidental to reprocessing, or WIR. At page 13 of its Insights White Paper, NEI stated that onsite disposal was not contemplated. It is important to realize that WIR is not limited to onsite disposal. In fact, DOE uses its WIR analyses to dispose of waste at LLW disposal sites. For example, DOE/West Valley has submitted WIR determinations to dispose of waste at LLW disposal sites. NEI's proposal would require the licensee to either meet Class C concentrations under 10 CFR Part 61 or demonstrate compliance with the performance objectives in 10 CFR Part 61, Subpart C for a near-surface disposal site, based on a site specific performance assessment.

NEI also recommends inclusion of the language in the proposed Appendix D to Part 50 Paragraphs 6 and 7 stating that other types of waste, such as radioactive hulls and other hardware and solid waste resulting from reprocessing operations, could be disposed of in licensed waste burial facilities on land owned by the Federal or State governments. We believe a detailed discussion of this definition should take place in future meetings with stakeholders.

Finally, NEI strongly agrees with the staff's statements that wastes meeting Part 61 requirements are not "highly radioactive" and can and should be disposed of in a near-surface facility, and that a "practical approach" to waste classification is needed.

c. NEI Comments on Public Feedback Questions

PF-1: The staff has asked "[w]hat waste disposal options should NRC consider for the management of waste generated by a commercial SNF reprocessing facility?" Public decisions about available waste disposal options (such as development of a geologic repository) represent policy questions to be decided by other governmental entities and should not be part of the proposed 7X rulemaking. HLW will go to whatever facilit[ies] are ultimately designated by the Government and LLW will go to suitable near-surface disposal facilities subject to compliance with applicable Part 61 requirements. This question is beyond the scope of the proposed rulemaking.

10. Gap 15 – Waste Confidence for Reprocessing Facilities

a. Summary and Staff-Proposed Approach

The NRC's Waste Confidence Rule (10 CFR § 51.23) applies only to used fuel generated in a reactor. The staff states that the NRC could expand the Waste Confidence Rule to encompass the environmental impacts of on-site storage of solidified HLW from recycling, but also cites a number of reasons for declining to do so.

Instead, the staff's currently proposed approach is to require individual recycling facility license applicants to address these environmental impacts in their Environmental Reports (ERs) submitted as part of their license applications, and for the NRC to address those impacts in an Environmental Assessment (EA) or Environmental Impact Statement

(EIS) under the National Environmental Policy Act (NEPA) on a case-bycase basis.

b. NEI Comments on Staff Proposed Approach

NEI strongly opposes "opening up" the existing Waste Confidence Rule in 10 CFR § 51.23, and in this regard, we agree with the NRC staff. However, NEI also does not endorse case-by-case consideration of the environmental impacts of storage of solidified HLW from recycling. The NRC specifically recognized the benefits of generic treatment of waste confidence determinations in its recent reactor findings (75 Fed Reg 81032-33, December 23, 2010). NEI believes that it is premature to conclude that the "scope and magnitude of existing knowledge gaps currently prevents NRC staff from having reasonable assurance" regarding long-term storage of HLW from recycling facilities. The NRC has not gone through the formal rulemaking process to enable it to determine if adequate information exists to make such a determination. Furthermore, while the Regulatory Basis Document, on the one hand, generally refers to limited licensing experience and a lack of scrutiny of relevant technical bases, it also correctly states that there is "substantial experience...worldwide" on dry storage of HLW from recycling, and that the "existing technical requirements for safe long-term storage of SNF might encompass the requirements for safe long-term storage of HLW from [recycling]."

Therefore, NEI encourages the NRC to further consider the

practicability and benefits of a "Waste Confidence" regulation limited to long-term storage of HLW from recycling facilities. NEI believes that there is a substantial base of knowledge that can be marshaled in support of such a generic approach, and would be pleased to provide further information in support of this recommendation.

c. NEI Comments on Public Feedback Questions

<u>PF-1</u>: Yes. See NEI's comments on the staff's proposed approach above.

PF-2: The information on SNF dry storage may bound the storage of HLW from recycling facilities. This should be the subject of additional consideration and NRC/stakeholder interactions.

11. Gap 16 – LLW Waste Classification

a. Summary and Staff-Proposed Approach

Depending upon the technology, some recycling facilities may produce waste streams that contain radionuclides not considered in the Waste Classification tables in 10 CFR § 61.55. There is a rulemaking currently underway to modify 10 CFR Part 61 to evaluate LLW streams to be disposed of in near-surface facilities using a risk-informed, performance-based approach. The rulemaking draft is expected to be provided to the Commission in 2011. The staff appears to favor completion of this rulemaking as the basis for addressing potential recycling facility LLW streams and their waste classification, and does not appear to believe that separate action under proposed Part 7X is necessary.

b. NEI Comments on Staff Proposed Approach

The ongoing Part 61 rulemaking should be completed because it will assure protection of the public health and safety regardless of the classification of the LLW streams from recycling. Consequently at this time, no action under proposed Part 7X appears necessary. Nevertheless, NEI believes that conforming changes to 10 CFR Part 61 should be included as part of the development of the Part 7X regulatory framework to assure that waste that conforms to Part 61 concentration limits or waste that meets Part 61 performance objectives (as demonstrated by a site specific performance assessment) are not treated as HLW.

c. NEI Comments on Public Feedback Questions

<u>PF-1</u>: The staff will be seeking public comments on the waste classification issue as part of the Part 61 rulemaking process. NEI will continue to provide its input through this process.

12. Gap 19 – Effluent Controls and Monitoring

a. Summary and Staff-Proposed Approach

10 CFR Part 70 does not adequately address effluent controls and monitoring for recycling facilities. The staff is proposing to use 10 CFR § 50.34a as the basis for developing specific design and operating requirements for radioactive effluents at such facilities, but also to apply a risk-informed, performance-based approach to establish such requirements. The 10 CFR § 50.34a requirements are technology neutral.

The staff is also proposing to develop GDC based upon those found in 10 CFR Part 50, Appendix A on control and monitoring of radioactive releases.

b. NEI Comments on Staff Proposed Approach

The NEI approach in Part 7X is a workable and appropriate approach for addressing effluent controls and monitoring. Contrary to the NRC statement, NEI's proposed Part 7X does address 10 CFR § 50.36a. This is done by incorporating in BDC 13 provisions of section 50.36a as well as requirements from Part 50 GDC 60. This is further described in NEI's response to GAP 11 regarding why effluent technical specifications are not needed.

NEI does not support developing 10 CFR Part 50, Appendix I type regulations regarding ALARA for recycling facilities. An Appendix I type regulation is not needed since Part 20 requires releases to be ALARA and to be in compliance with 40 CFR Part 190. Consideration should be given to the fact that a comprehensive review and update of 40 CFR Part 190 that accounts for current health physics knowledge and industry standards should be conducted in parallel with this effort. NEI's proposed Part 7X provides for keeping releases ALARA consistent with Part 20. As noted above, Part 7X BDC 13 has adopted the concepts of 10 CFR § 50.36a to keep radioactive effluents ALARA, and is included as part of the Safety Program the licensee is required to maintain to ensure that, among other things, the provisions of Part 20 are met. The applicant is also

required to describe the expected effluents and the licensee must submit periodic reports.

Appendix I for reactors has been developed to support ALARA for light water reactors. The materials and the material forms are similar across the technologies to which the regulation applies. This would not be the case for recycling facilities. The different technologies currently proposed would require different criteria to adequately address the different chemical forms and their various physical properties and environmental effects. Any effort to apply an Appendix I type regulatory process could be inconsistent with having a technology neutral rule. Moreover, there is no safety purpose or benefit in requiring this additional regulatory burden for recycling facilities.

c. NEI Comments on Public Feedback Questions

PF-1: No. An Appendix I type regulation is not needed since Part 20 requires releases to be ALARA and to be in compliance with 40 CFR Part 190. NEI's proposed Part 7X provides for keeping releases ALARA consistent with Part 20. As noted above, NEI's proposed Part 7X BDC 13 adopts the concepts of 10 CFR § 50.36a to keep radioactive effluents ALARA, and is included as part of the Safety Program the licensee is required to maintain to ensure that, among other things, the provisions of Part 20 are met. The applicant is also required to describe the expected effluents and the licensee must submit periodic reports. Setting specific effluent limitations in the regulations may be inconsistent with having a

technology neutral rule.

PF-2: The NRC should, in coordination with the EPA, develop release limits for carbon-14 and tritium. This should be done in concert with a comprehensive review and update of 40 CFR Part 190, which will revisit and modify limits for radionuclides already addressed (e.g. iodine-129 and krypton-85) that accounts for current health physics knowledge and industry standards.

D. Material Control and Accounting and Security

- 13. Gap 8 Risk-Informing 10 CFR Part 73 and 10 CFR Part 74
 - a. Summary and Staff-Proposed Approach

The staff states that the current quantity-based categorization scheme in the existing regulations may pose an undue regulatory burden on operating recycling facilities. Risk-informing Parts 73 (Physical Protection) and 74 (Material Control and Accounting) is needed to prevent unintended consequences at a recycling facility. The staff has received Commission direction on separate, specific proposed rulemakings for Parts 73 and 74. The risk-informing of those regulations will be handled in that context, and not as part of a Part 7X rulemaking. These efforts will be completed on a "different timeline than the rest of the [recycling facility regulatory] gaps."

b. NEI Comments on Staff Proposed Approach

NEI supports addressing the process of risk-informing Parts 73 and

74 separately from the proposed Part 7X rulemaking. NEI does, however, have two principle concerns.

The first is that the schedule for completion of the Part 73/74 rulemakings not lag behind the proposed Part 7X rulemaking, and thus create uncertainty and delay in moving forward with recycling facility applications. Second, as discussed below under Gap 4, the staff intends to remove the exclusion of recycling facilities from the Part 74 definition of a Category I facility. This change should not take effect in the absence of the promulgation of risk-informed changes to Part 74.

c. NEI Comments on Public Feedback Questions

PF-1: The staff has asked "[w]hat problems, if any, are created by development of the regulatory basis for risk-informing 10 CFR Part 73 and 10 CFR Part 74 separately from the regulatory basis for a potential rulemaking for licensing of reprocessing facilities?" Except for the timing issues discussed above, NEI is not currently aware of any significant problem with the staff's planned approach.

14. Gap 4 – Exclusion of Irradiated Fuel Processing Facilities in 10 CFR74.51

a. Summary and Staff-Proposed Approach

10 CFR § 74.51 currently excludes irradiated fuel recycling facilities from Category I MC&A requirements. A recycling facility would possess Category I quantities of SNM. The Commission has directed the staff to remove this exclusion during the Part 74 rulemaking

effort. This is being done and no action under proposed Part 7X on this matter is contemplated by the staff.

b. NEI Comments on Staff Proposed Approach

See NEI comments on Gap 8 above. No further comments.

c. NEI Comments on Public Feedback Questions

The staff has posed no further questions in this area.

15. Gap 17 – Diversion Path Analysis Requirements

a. Summary and Staff-Proposed Approach

There are no existing requirements for a diversion path analysis (DPA) under 10 CFR Part 74. A DPA is a "systematic process for generating, documenting, and analyzing diversion paths throughout a facility as a measure of the overall effectiveness of the safeguards system." The staff proposes to include in proposed Part 7X a requirement for the applicant to perform a DPA, and intends to produce a guidance document to assist license applicants in implementation.

b. NEI Comments on Staff Proposed Approach

NEI has no objection to the inclusion of appropriate and reasonable DPA requirements in proposed Part 7X. However, the development of implementation guidance is essential and must proceed in parallel with the rulemaking for two important reasons.

First, the rule itself should not contain the detailed criteria for the

performance of a DPA. But to ensure that the regulatory requirement is practical and workable, the basic acceptance criteria must be developed in the implementing guidance, in parallel with the general requirement in the rule. Second, this same parallel process is needed to ensure that the DPA requirement is technology neutral, in other words, that it can be practicably and efficiently implemented in connection with the range of anticipated recycling technologies. Industry participation in these efforts by those familiar with potential designs are essential to ensuring a workable approach.

c. NEI Comments on Public Feedback Questions

<u>PF-1</u>: The details of a DPA should be developed in implementation guidance in accordance with NEI's comments above.

PF-2: See NEI's comment on PF-1 above.

16. Gap 18 – Approaches Toward Material Accounting Management

a. Summary and Staff-Proposed Approach

The staff states that existing, predefined material accounting limits and timeliness requirements in 10 CFR Part 74 could pose a challenge for recycling facilities, due to large material throughputs, measurement uncertainties, and limitation of various measurement methods. The staff proposes to undertake a rulemaking specific to recycling facilities, but separate from and in parallel with, the proposed Part 7X rulemaking, in order to modify inventory goal quantities and timeliness requirements, and

to add requirements for a holdup management program to facilitate more accurate accountability measurements.

b. NEI Comments on Staff Proposed Approach

NEI has no objection to the staff's proposed approach, so long as implementing guidance is developed in parallel with the rulemaking, in a manner similar to that discussed above under Gap 17.

c. NEI Comments on Public Feedback Questions

<u>PF-1</u>: The process of developing implementing guidance should provide an appropriate forum for further consideration of MC&A statistical limits.

E. Financial Considerations

17. Gap 12 – Financial Protection Requirements and Indemnity Agreements (10 CFR Part 140)

a. Summary and Staff-Proposed Approach

The Price-Anderson Act establishes the required amount of primary financial protection for production facilities (including recycling facilities) as the maximum amount of liability insurance available from private sources. It also provides for NRC indemnification for the amount of liability in excess of the primary financial protection, up to the maximum of \$560,000,000.

The NRC's implementing regulations in 10 CFR Part 140: (1) do not establish the required amount of private liability insurance for production facilities; (2) do not set fees for executing an indemnity

agreement; and (3) do not contain a standard form for nuclear liability policies for production facilities. The staff proposes to amend Part 140 to address these items in the rule.

b. NEI Comments on Staff Proposed Approach

NEI agrees with the need to amend the existing Part 140 requirements. However, the ultimate financial protection requirements must be commercially viable and should be subject to further stakeholder interaction.

c. NEI Comments on Public Feedback Questions

The staff has posed no further questions in this area.

18. Gap 13 – Schedule of Fees (10 CFR Part 170)

a. Summary and Staff-Proposed Approach

The staff proposes to revise 10 CFR Part 170 to include the applicability of 10 CFR § 170.2 to recycling facilities.

b. NEI Comments on Staff Proposed Approach

NEI agrees with the need to amend the existing Part 170 requirements. Fees must be appropriate and reasonable in accordance with applicable statutory requirements.

c. NEI Comments on Public Feedback Questions

The staff has posed no further questions in this area.

19. Gap 14 – Annual Fees (10 CFR Part 171) NEW VERSION

a. Summary and Staff-Proposed Approach

The annual fee provisions of 10 CFR Part 171 do not currently list recycling facilities as subject to such fees, or specify the applicable annual fees for such facilities. The staff proposes to revise Part 171 to include these items in the rule.

b. NEI Comments on Staff Proposed Approach

NEI agrees with the need to amend the existing Part 171 requirements. Fees must be appropriate and reasonable in accordance with applicable statutory requirements.

c. NEI Comments on Public Feedback Questions

The staff has posed no further questions in this area.