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Cc:	Veil, Andrea; Taylor, Robert; Shams, Mohamed; Segala, John; Beall, Bob; Reckley, William; Valliere, Nanette; RulemakingComments Resource
Subject:	[External_Sender] NEI Paper on Manufacturing License Considerations for Part 53, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)
Date:	Friday, July 16, 2021 10:47:34 AM
Attachments:	07-16-2021_NRC_Part 53 Manufacturing License Paper - Attachment.pdf

July 16, 2021

Dr. Kevin Coyne
Acting Director, Division of Rulemaking, Environmental, and Financial Support
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: NEI Paper on Manufacturing License Considerations for Part 53, *Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)*

Project Number: 689

Dear Dr. Coyne:

The Nuclear Energy Institute (NEI) and its members appreciate the Nuclear Regulatory Commission's (NRC) staff's approach to develop preliminary rule language to facilitate discussion with stakeholders on the concepts for the Part 53 rule. The NRC previously issued preliminary rule language for manufacturing licenses in Subpart E.

We have developed the attached paper on *Proposed Approach for Manufacturing License Requirements in 10 CFR Part 53* to discuss potential approaches for establishing manufacturing license (ML) requirements in 10 CFR Part 53, with the intent to inform the NRC's ongoing Part 53 rulemaking. Advanced reactors are being developed with a range of sizes and capabilities that have not previously been available in the market. As a result, new market opportunities and business models are being considered for the use of advanced reactors. This has prompted the industry to consider how the ML provisions in 10 CFR Part 53 could be developed to better support the new business models.

We would appreciate the NRC's consideration of the attached paper, and would encourage further discussion in public meetings on this topic. If you have questions concerning our input, please contact me at 202-739-8131 or mrn@nei.org.

Sincerely,

Marcus R. Nichol

Senior Director
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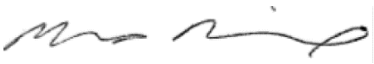
[1] The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

Sincerely,



Marcus Nichol
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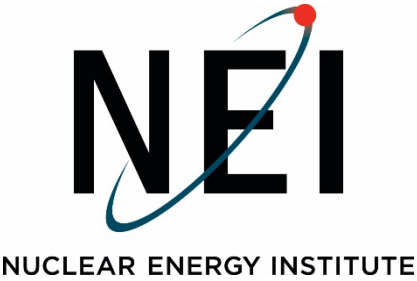

WHITE PAPER

PROPOSED APPROACH FOR MANUFACTURING LICENSE REQUIREMENTS IN 10 CFR PART 53

July 2021

ACKNOWLEDGMENT

This NEI White Paper was developed by the NEI Part 53 Task Force.

WHITE PAPER

PROPOSED APPROACH FOR MANUFACTURING LICENSE REQUIREMENTS IN 10 CFR PART 53

I. INTRODUCTION

This paper discusses potential approaches for establishing manufacturing license (ML) requirements in 10 CFR Part 53, with the intent to inform the NRC's ongoing Part 53 rulemaking. Advanced reactors are being developed with a range of sizes and capabilities that have not previously been available in the market. As a result, new market opportunities and business models are being considered for the use of advanced reactors. This has prompted the industry to consider how the ML provisions in 10 CFR Part 53 could be developed to better support the new business models.

Unlike conventional nuclear plants (i.e., large light-water reactors (LWR)) – the components of which are built at a manufacturing facility but assembled at the operating site – many advanced reactors (including micro-reactors, small modular reactors (SMR), and non-LWRs) will be built and assembled at a manufacturing facility and then shipped to the operating site. In some cases, the reactor fuel will be shipped to the plant-manufacturing facility and loaded into the reactor. In addition, an operated reactor may be later moved to a different site(s). Such activities raise novel regulatory considerations related to fuel loading at the manufacturing facility, compliance with radioactive material shipping requirements, physical security during transport, and reactor startup/reactor restart testing requirements for site-specific inspections, tests, analyses, and acceptance criteria (ITAAC).

Some of these considerations are well beyond past NRC practices, but it is important that the approaches the industry is interested in pursuing are considered in the Part 53 effort. Some of these approaches are quite aspirational, as compared to past practices, but these are enabled by the nature of the designs that some developers are pursuing. This paper does not attempt to define the specific solutions to all the industry aspirations, but rather attempts to outline the nature of these aspirations so that the NRC can account for these in the Part 53 rulemaking process.

This paper describes potential options for licensing, manufacture, transportation, refueling, and decommissioning of advanced reactors in light of industry's currently envisioned business models, and for consideration by the NRC as it develops the regulatory language for 10 CFR Part 53. That regulatory language will be critical to the viability of the options discussed herein, which generally appear to fall within the NRC's statutory authority under the Atomic Energy Act of 1954, as amended (AEA). One envisioned business model included in this paper, the Generic License, may require further exploration that places it beyond the current scope or schedule of the NRC's Part 53 rulemaking effort. It is nevertheless included here for completeness and to spur additional discussion of this business model.

II. LEGAL AND REGULATORY BACKGROUND

Section 101 of the AEA requires "any person within the United States" seeking "to transfer or receive in interstate commerce, *manufacture*, produce, transfer, acquire, possess, use, import, or export any utilization or production facility" to obtain "a license issued by the Commission pursuant to section

[103] or [104]."[1] AEA Section 102(a) states that "[e]xcept as provided in subsections (b) and (c), or otherwise specifically authorized by law, any license hereafter issued for a utilization or production facility for industrial or commercial purposes shall be issued pursuant to section [103] of this title."[2] Thus, AEA Section 103 governs the issuance of licenses (including MLs) for utilization or production facilities used for industrial or commercial purposes.[3]

These statutory provisions are implemented through various NRC regulations. While the NRC continues to develop Part 53, Part 50 can provide useful insight. For example, 10 CFR 50.10 provides that, absent an exemption or applicable exception, "no person within the United States shall transfer or receive in interstate commerce, *manufacture*, produce, transfer, acquire, possess, or use any production or utilization facility except as authorized by a license issued by the Commission."[4] Pursuant to 10 CFR 50.22, a facility is deemed "industrial or commercial" (and hence requires a Section 103 license) if more than 50 percent of the annual cost of owning and operating it is devoted to the production of materials, products, or energy for sale or commercial distribution, or to the sale of services other than research and development (R&D), education or training.[5]

The NRC's ML requirements were originally established as Appendix M to Part 50 in 1973. NRC licensed only one facility under Appendix M – the Offshore Power Systems Floating Nuclear Power Plants 1-8 (License ML-1) in December 1982.[6] When the NRC adopted Part 52 in 1989, it incorporated, but did not re-examine, the Appendix M regulatory scheme.[7] Appendix M provided for issuance of a license authorizing the manufacture of a nuclear power reactor that would be incorporated into a nuclear power plant under a construction permit (CP), and then operated under an operating license (OL) at a different location from the place of manufacture. Significantly, this process did not provide for NRC approval of a final reactor design as part of the issuance of an ML. Rather, the NRC would issue an ML based upon the review and approval of a preliminary design equivalent to that provided in a CP application. Issuance of the ML permitted manufacturing of the reactor to commence, but the NRC still needed to approve the final design of the manufactured reactor by license amendment before the manufactured reactor could be transported from the manufacturing facility to the operating site.

In its 2007 revisions to Part 52, the NRC substantially revised the ML provisions and moved them to a new Subpart F.[8] The revised rule required that a final reactor design, equivalent to a DC under

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1 42 USC 2131 (emphasis added).

2 42 USC 2132(a).

3 See 42 USC 2143.

4 10 CFR 50.10(b) (emphasis added).

5 *Id.* In this regard, there are allowances for Department of Energy and Department of Defense regulatory authorizations in non-commercial nuclear-technology applications. Pursuant to 10 CFR 50.22, such facilities would be deemed non-commercial (and therefore not subject to NRC regulation) provided less than 50 percent of the annual cost of owning and operating the facility is devoted to the production of materials, products, or energy that is not sold or commercially distributed, or is otherwise dedicated to R&D or education and training.

6 A copy of this license is available at NRC ADAMS Accession No. ML20070J215.

7 See Memorandum from Glenn M. Tracy, Director, Office of New Reactors to NRC Commissioners, "Staff Assessment of the Manufacturing License Requirements Issue for Small Modular Reactors" (Mar. 27, 2013) (ML13018A168); Licenses, Certifications, and Approvals for Nuclear Power Plants; Final Rule, 72 Fed. Reg. 49352, 49391 (Aug. 28, 2007) (2007 Part 52 Final Rule).

8 *See* 2007 Part 52 Final Rule, 72 Fed. Reg. at 49391-94.

Part 52 or an OL under Part 50, be submitted and approved before issuance of an ML.[9] The application also must address proposed procedures governing the preparation of the manufactured reactor for shipping to the site operation, the conduct of shipping, and verification of the condition of the manufactured reactor upon receipt at the site.[10] Subpart F remains in effect today.

Under Subpart F of Part 52, an ML applicant may reference a standard design certification (SDC) or a standard design approval (SDA) in its application. An ML authorizes "the manufacture of nuclear power reactors but not their construction, installation, or operation at the sites on which the reactors are to be operated."[11] A Part 50 CP or Part 52 combined license (COL) is required for those activities. Further, a nuclear power reactor manufactured under an ML only may be transported to and installed at a site for which either a CP or COL has been issued.[12] Note that Appendix N of Part 52 allows one or more applicants to seek COLs to construct and operate nuclear power reactors of identical or common design to be located at multiple sites. Such applications may reference an SDC or "the use of a reactor manufactured under subpart F of [Part 52]."[13]

As noted, 10 CFR Part 50, Appendix M was used to license the Offshore Power Systems floating reactor in 1982, authorizing the manufacture of eight reactors. However, none of those reactors was ever manufactured, and no further applications for MLs under Part 50, Appendix M were submitted. The NRC has not received any ML applications under Part 52, Subpart F, although the NRC and prospective applicants have engaged in some pre-application discussions.

In view of this history and the current regulatory framework in Parts 50 and 52, the Manufacturing License requirements in 10 CFR Part 53 must be significantly different to accommodate the new business models envisioned by the industry (as discussed in Section III below), which will require much greater flexibility and ease of implementation.

III. ADVANCED REACTOR BUSINESS MODELS

Most grid-scale advanced reactors are likely to follow the traditional business model for nuclear power reactors. That is, the owner (i.e., an electric utility) will finance the project, have a contract

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9 Thus, a significant portion of the ML application focuses on the reactor design and operation and must include the same technical information required in an OL or COL final safety analysis report related to the design of a reactor. The application also must address the applicant's ability to manufacture and transport the proposed reactor with sufficient quality assurance, the site parameters required for installation of a reactor, and the required interface conditions between the manufactured reactor and the remainder of the plant.

10 10 CFR 52.157(f)(26)(iv).

11 10 CFR 52.1. As the NRC explained in its 2007 Part 52 rulemaking, "[u]nlike [a] design certification, which is an approval of a 'paper design,' the NRC's proposed concept of a manufacturing license is pre-approval of the procurement, manufacturing, and quality assurance processes that translates the approved reactor design into a manufactured assembly in a controlled environment, with the capability to optimize techniques and procedures based upon feedback." 2007 Part 52 Final Rule, 72 Fed. Reg. at 49393.

12 10 CFR 52.153(a). *See also* 10 CFR 51.167(c)(1) ("A holder of a manufacturing license may not transport or allow to be removed from the place of manufacture the manufactured reactor except to the site of a licensee with either a construction permit under part 50 of this chapter or a combined license under subpart C of this part. The construction permit or combined license must authorize the construction of a nuclear power facility using the manufactured reactor(s).").

13 10 CFR Part 52, Appendix N, ¶ 3. The final safety analysis report for each application must either incorporate by reference or include the final safety analysis of the common design, including, if applicable, the final safety analysis report for the referenced design certification or the manufactured reactor. The application may incorporate by reference a single environmental report on the environmental impacts of the common design.

with the engineering, procurement, and construction companies to perform their scope of the work, and will be the license holder for the construction and operation of the plant. This business model is suitable for larger plants that have a large amount of on-site construction, and with advanced reactor customers that wish to sell the energy. Notably, while the Part 52 design certification provisions streamline the process for seeking operating licenses, Part 52 still requires that a CP or COL be obtained before transporting and installing the reactor at an approved site.

Smaller reactors (especially micro-reactors less than 10 MWe) enable new business models in three main ways: (1) they will utilize a high degree of factory construction; (2) the customers for smaller reactors may wish to be only energy users, not energy sellers; and (3) the reduced costs of these reactors allow a vendor to build them before receiving customer orders. Smaller reactors will require little, if any, on-site construction, and in some cases may be transported in a fully assembled configuration. For customers that wish to be only energy users, the advanced reactor developers also may be the reactor owners and operators, supplying energy under power purchase agreement. Having pre-fabricated reactors ready to ship as soon as an order is placed would significantly reduce time to market, a key consideration for many customers.

The following are the specific activities being envisioned for these new business models. Note that a company may combine different activities within a given business model.

1. **Prospective Manufacture of Reactor Modules without a Customer Order** – In the past, some SMR developers have discussed manufacturing reactor modules prospectively and storing those modules until a specific customer (and hence a host site) is identified. The NRC's current Part 50/52 regulations permit such an approach under an ML, although we encourage the NRC to clarify its position regarding the ability of an SDC or SDA holder to prospectively manufacture reactor modules prior to receiving an order from a customer with a COL. Regardless, this paper discusses options for the Part 53 ML requirements to ensure that an ML is a possible pathway to prospectively manufacture reactor modules up to and including fully assembled reactors.

2. **Fully Assemble an Operable Reactor at the Factory** – Some advanced reactor developers, especially micro-reactor developers, will fully assemble the reactor at the factory. In this context, "fully assemble" means the assembly of all the structures, systems and components of an operable reactor module, excluding reactor fuel. If a particular reactor requires a significant amount of on-site construction before the reactor could operate, then it would not meet the definition of "fully assembled". Thus, the developer may become the ML holder and be responsible for the factory fabrication and assembly activities. Alternatively, the developer may contract with an appropriate manufacturer who will manufacture and assemble the reactor, i.e., "build to print". The details of which entity (developer or manufacturer) would be the ML holder would be addressed through contractual arrangements and application to the NRC for the ML. We emphasize that in this scenario, there would be no fuel loaded into the reactor and, in fact, there would not be any fuel at the factory.

   This approach would allow the licensee to own or control (e.g., through subcontracts) all necessary facilities for the manufacture and testing (unfueled) of the reactor. (These facilities may or may not be co-located.) Assembly in a factory setting would support conducting ITAAC or ITAAC-like inspections and tests to ensure the reactor has been fabricated and assembled consistent with the license and applicable regulations. Security requirements for these facilities would be consistent with security for commercial

manufacturing facilities supporting the nuclear industry. Fitness for duty requirements also would be consistent with those used in commercial manufacturing facilities.

3. **Fuel a Fully-Assembled Reactor at the Factory** – While not feasible for large reactors, fully assembling and fueling a reactor module at the factory is envisioned for a transportable reactor, e.g., a micro reactor, which eliminates onsite fueling. This activity can be performed under a Part 70 *possession license*, which may draw in other requirements, e.g., Parts 26, 30, 40, 70, 73, 74 and 75, etc., under which the primary function is to assure radiological safety and that the reactor is maintained subcritical at all times. Performing reactor fueling at the factory would be more efficient for reactors that are manufactured in large numbers and reduce the burden of doing these activities in numerous remote locations. This activity is separated from critical testing at the factory and transporting a fueled reactor to the operating site (separate activities described below).

4. **Testing a Fully-Assembled Reactor at the Factory** – After fully assembling an operable reactor module at the factory, some developers may wish to perform criticality and power ascension testing. We distinguish this activity from the above-described activities, which do not include control manipulation and criticality testing. Enabling this type of testing would clearly require significant changes from the existing regulatory framework and facilities, controls, and oversight. In fact, under the current regulatory framework, such activities generally require a utilization facility license, since the criticality prevention requirements for a Part 70 possession license (which governs the licensing of special nuclear material) would specifically preclude this type of testing. Thus, this activity would need the utilization license to either be included with the ML or obtained through a separate and limited Part 53 operating license. Fueling and testing a reactor involves a number of NRC regulations, which may include Parts 26, 30, 40, 55, 70, 73, 74 and 75. The benefit of performing fueled criticality tests at the factory is that such tests could be performed more efficiently for reactors that are manufactured in large numbers, thereby reducing the burden of doing these activities at numerous separate locations.

   Testing in a factory setting also would permit addressing ITAAC or ITAAC-like testing and inspection requirements. Performing these ITAAC or ITAAC-like tests and inspections, combined with those that would be conducted in fully assembling the reactor, would reduce the scope of on-site inspection and testing activities. This activity is separated from transporting a fueled reactor to a site (see next item), since some developers may wish to do fueled testing at the factory but not transport a fueled reactor (due to the desire to streamline transportation or to keep only a single set of fuel on-site that is used to test multiple reactors). Another option would be to fuel the reactor at the factory but not perform any criticality or power ascension testing, deferring that testing until after the reactor has been installed at the approved site.

5. **Transporting a Fueled Reactor from the Factory** – Some companies may wish to transport a fueled reactor to the site at which it will be operated. This will trigger other requirements, including those in 10 CFR Part 71. The developer may wish to transport the fueled reactor by barge, rail, truck, and possibly by air. The transport of a fueled reactor is intended to eliminate or minimize the amount of testing and inspection required at the operating location to facilitate more rapid reactor deployment. For those situations where the ML holder also is the OL/COL holder, control of the reactor once it is at the approved site (including any storage before installation) would be consistent with the terms of the respective licenses. The OL/COL would govern any interim storage of the reactor on the approved operating site and related security requirements. If the ML holder and OL/COL

holder are different entities, then provisions for transferring control of the reactor from the ML holder to the OL/COL holder would be addressed by contractual agreement. The ML holder would be required to ensure the safety and security of the reactor until control of the reactor is transitioned to the OL/COL holder. Any interim storage site, if different from the approved operating site, would require prior approval by the NRC based on relevant safety, security, and environmental considerations.

6. **Multiple Operating Locations** – Developers of advanced reactors that require very little site infrastructure to operate may want the ability to move the reactor to an alternate site one or more times during the lifetime of the reactor. For example, a micro-reactor that could be operated for 60 years might operate at mining site X for 30 years, and then be moved to mining site Y to operate for an additional 30 years. In another case, the micro-reactor might be moved to a new location every 5 years. This "Multiple Location" scenario presumes that a site-specific license will be needed for each new location prior to transporting the reactor to that location.

7. **Defueling and Refurbishing Operated Reactor at a Factory** – Some developers (especially those that pursue a multiple location approach) may want to return the reactor to a refurbishment center during fuel reloads. This scenario raises regulatory issues associated with the transport of a reactor containing used fuel. The refurbishment center may or may not be the original factory at which the reactor was assembled. The refurbishment center likely would remove the used fuel and reload with new fuel. (Note that some designs have fuel that will last 10 to 20 years before refueling is required.) However, there may be some approaches that involve fuel unloading and loading at the operating location. The refurbishment center may also perform routine reactor maintenance, but doing so would be pursuant to the OL/COL, not an ML. For refurbishment centers that remove used fuel, interim storage of used fuel may be necessary, although this would be governed by a Part 72 license and not part of the ML. Finally, the refurbishment center might decommission the reactor. While the refurbishment center concept offers a number of advantages, some organizations may choose a more traditional approach, whereby the reactor would be defueled and decommissioned at the operating site, and the used fuel and defueled reactor would be transported offsite. These options should be available to the OL/COL holder.

8. **General License** – Some developers may want the ability to supply advanced reactors to customers, with a technically justified approach that avoids the need for site-specific licensing. From a process perspective, this concept is similar to the general license approach used by NRC in other regulatory contexts. For example, an NRC general license for dry storage of used fuel allows the use of dry storage casks, and the preparation of the storage site, for Part 50/52 licensees without prior NRC approval. (Note that such licensees must notify the NRC prior to using the general license.) The concept of an advanced reactor general license might involve use of a reactor certificate of compliance (CoC) that specifies the critical attributes of the reactor (similar to a design certification), the site parameter envelope where it is licensed for use, and any conditions for the qualification of the reactor owner/operator. The developer could manufacture and sell reactors for use consistent with the CoC. While prior NRC approval would not be required, the NRC would be notified prior to the use of each reactor. The benefit of the General License approach is that it would substantially reduce deployment times. It also could allow the option of delivering a reactor to a site, operating it for an unspecified period of time, and then moving it to a different operating site. This operate-and-move process could be used multiple times, including in emergency situations (e.g., providing power after a natural disaster). This option may require further evaluation that places it outside the scope of the current Part 53 rulemaking.

IV. RULEMAKING OPTIONS FOR ENABLING THE NEW BUSINESS MODELS

As reflected in Section III above, there are some activities that are closely aligned with the current Part 52 Manufacturing License requirements, and there are some activities that would involve other regulations, including, for example, Part 70 for fuel-related activities, and Part 71 for transporting a fueled reactor. Thus, the following three rulemaking options for enabling these activities are considered:

1. **Part 53 Only Option** - Part 53 would address all applicable requirements: design and design approval processes; manufacturing processes (with appropriate references to QA and consensus standards rather than detailed requirements); system-level testing (fueled or unfueled); transportation (fueled or unfueled); refueling; storage of used fuel; and decommissioning. Relevant provisions from Parts 70, 71, and 72 would be incorporated into Subpart E. However, only pointers or cross-references to Parts 26, 30, 40, 55, 73, 74, and 75 would be included, as appropriate.

2. **Part 53-Centric Option** - Part 53 would address requirements for design and design approval processes and specific aspects of Part 70 addressing fuel and criticality safety. Pointers to other aspects of Part 70, QA requirements, consensus standards, and Parts 26, 30, 40, 55, 73, 74, and 75, as appropriate, would be included.

3. **Part 53 Limited Option** – Part 53 would address all activities associated with approving the safety of the reactor for delivery, i.e., a reactor FSAR. A Part 70 possession license would be used to address any fuel fabrication and handling activities, including reactor assembly. If criticality or power ascension testing were to be performed, it would be done under a Part 50, 52, or 53 license. Pointers to other aspects of the regulations, including QA requirements, consensus standards, and Parts 26, 30, 40, 55, 73, 74, and 75, would be included, as appropriate. While this option requires both a Part 50, 52, or 53 license and a Part 70 license, it provides the clearest regulatory structure for accommodating the various in-factory activities described above.

V. KEY CONSIDERATIONS TO INFORM THE NRC'S APPROACH TO MANUFACTURING LICENSES IN 10 CFR PART 53

The NRC's Part 53 manufacturing license regulations should enable the new business models for producing and using new reactors that are flexible enough to accommodate the manufacturing and business strategies described herein.

In evaluating the rulemaking options in Section IV, Option 3 appears to be the most appropriate for Part 53. It would involve the least amount of effort, making it easier to accomplish in the timeline for the Part 53 rulemaking. While it would result in a more complicated licensing scheme, potentially requiring a Part 53, 50, 70, 71 and 72 licenses, such complexity could be simplified through well-developed guidance. It would permit other rule changes, for example requirements in Part 71, to be pursued in separate rulemaking. Since it would be most similar to the Parts 50/52 ML paradigm, these other rulemakings would benefit the pursuit of new business models through those parts. While some of the envisioned activities (such as criticality testing in the factory) are novel, they can be done under current NRC authorities granted in the AEA, although some of these provisions would require changes to existing regulations.

The following discussion focuses on the development of the Option 3 regulatory paradigm under Part 53. The requirements for manufacturing licenses should be limited to aspects that must be regulated by the NRC to protect public health and safety. Thus, the following considerations should inform the scope of requirements for MLs:

1. The Part 53 ML should focus on enabling prospective manufacturing and fully assembling a reactor in the factory (activities #1 and #2). Part 53 should permit movement of the manufactured reactor, or major portions thereof, to multiple facilities under the licensee's control (either directly or via subcontract) to make use of specialized capabilities in the manufacturing and testing processes (this is currently not permitted by the NRC's preliminary Part 53 rule text).
    a. Thus, Part 53 should focus on the safety of the design and its operations, which is consistent with scope in Part 50 (e.g., section 50.34) and Part 52 (e.g., Subpart F).
    b. Part 53 must address generally applicable requirements, such as QA processes, applicability of consensus codes and standards, and Part 21 reporting. In addressing such requirements, the NRC should rely principally on pointers or cross-references to the relevant regulations in other parts of 10 CFR and avoid duplicating those requirements in Subpart E to Part 53.
    c. It is noted that the NRC's initial preliminary rule text for Manufacturing Licenses (related to design and operations) in Subpart E is largely focused on QA requirements. Part 53 should clarify where requirements in other subparts (e.g., Subparts A and B) apply to the ML, with Subpart H to contain the provision to issue the ML license and authorize manufacturing. The NRC will also need to clarify that not all manufacturing is regulated by the NRC, as indicated in the NRC's preliminary definition of manufacturing being limited to only those activities explicitly to be conducted under an ML.
2. A Part 70 possession license, which may draw in requirements from Parts 30 and 40, should be utilized for use of fuel (activity #3).
    a. This would require compliance with Part 26 (FFD), Part 73 (Security - including pending revisions thereto), Part 74 (MC&A) and Part 75 (Safeguards).
    b. It is noted that the NRC Part 53, Subpart E preliminary rule text includes requirements that would enable Part 53 to authorize possession of fuel at the factory, in part by pointing to relevant requirements (e.g., Parts 30, 40 and 70). Significant flexibilities in licensing, transporting, and operating micro-reactors would be obtained by including language in Part 53, Subpart E to address factory fueling and factory refueling options. Possession of materials is also one of the more straightforward activities to incorporate into a ML; therefore, the option of addressing this in Part 53 merits further discussion.
3. A Part 50/52/53 OL or COL should be used to enable criticality testing at the factory (activity #4). Part 53 requirements should be developed in a manner conducive to issuing a limited scope OL/COL for criticality testing at the factory.
4. Part 71 should be used to regulate the transportation of a fueled reactor (activities #5 and #7). Pending revisions to Part 71 (if warranted), a licensee may need to rely on 10 CFR 71.41(c) (which allows for NRC approval of environmental and test conditions different from those specified in sections 71.71 and 71.73) or 10 CFR 71.41(d) (which allows for NRC approval of special package authorizations). Transportation of an unfueled and uncontaminated reactor, and assessment of any transportation accidents, while not directly

governed by Part 71 regulations, would draw on Part 52 ITAAC or receipt inspection and testing under the licensee's QA program, initial test program, or both.

   a. Transportation of a fueled reactor with both fresh fuel and used fuel also warrants further consideration and may require revisions to Part 71. Namely, some specific aspects of Part 71 may not be consistent with micro-reactor fuels and the need to transport micro-reactors shortly after they are taken out of service. Additionally, the prescriptive qualification testing protocols in Part 71 may not be relevant to some micro-reactors. Use of exemptions under sections 71.41(c) or 71.41(d) could provide an interim solution, but resolution of the issue via Part 53 or a revision of Part 71 is the preferred approach.

5. Part 72 should be used to regulate the storage of used fuel at the factory (activity #7)
6. Part 51 environmental review considerations would be limited to the facilities covered by the ML. The site selected for siting/operating the manufactured reactor would address environmental considerations through a CP or COL process for that site.
7. The industry and NRC should develop guidance to address:
   a. How the Part 53 ML would interact with a Part 50, 52 or 53 CP/OL or COL for use at a site, including the use at multiple sites (activity #6) and whether an SDC or SDA could be used to perform the intended business activities of prospective manufacturing, and manufacturing a fully assembled reactor at a factory (activities #1 and #2).
   b. How an applicant would combine multiple licenses (e.g., Part 53, 70) to address multiple activities, such as fuel loading and testing at the factory (activities #3, #4).
   c. How the transportation of fueled advanced reactors can satisfy Part 71 requirements (activity #5).

VI. NEXT STEPS

The above-described business models and proposed options for optimizing the usefulness of a manufacturing license process are considerably different from those underlying the NRC's current ML framework. Addressing these models and options likely will necessitate requirements in Part 53 that differ significantly from those in Part 52, Subpart F. Therefore, we recommend focused engagement with the NRC to determine which activities under the industry's new business models should be specifically addressed by the ML requirements in Part 53 (as opposed to pointers to other NRC regulations), and to develop the seven scope topics identified in Section V above. The major issues that will need to be addressed as part of this effort include Part 70 and fueling a reactor in the factory; criticality testing in a factory; transportation of a fueled reactor with either fresh or used fuel; factory re-fueling; and decommissioning. Additionally, the industry and NRC should develop guidance to clarify the various licenses and licensing processes that would be needed for the various deployment activities discussed in this paper. Further guidance or rulemaking also may be necessary to apply Part 71 to a micro-reactor during transport.