December 2024

The proposed rule: "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)," was published in the *Federal Register* on October 31, 2024 (89 FR 86918) and is also available at https://www.regulations.gov under Docket ID NRC–2019–0062. In the staff requirements memorandum (SRM) approving publication of the rule, the Commission directed the staff to conduct further interactions with stakeholders on testing fueled manufactured reactors in the factory. The preliminary draft language below is being released to support those interactions with stakeholders and the Advisory Committee on Reactor Safeguards (ACRS) as directed by the SRM. Moreover, Section VI, "Specific Requests for Comments," of the *Federal Register* notice includes questions related to the possible inclusion of provisions regulating the testing of fueled manufactured reactors in the manufacturing facility. The preliminary draft language below may also assist those choosing to respond to the specific request for comment by providing a draft example of text related to the specific questions included in the request for comments.

This language has not been subject to complete NRC management or legal review, and its contents should not be interpreted as official agency positions. Comments related to the proposed rule, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)," should be filed no later than *February 28, 2025*.

Subpart H – Licenses, Certifications and Approvals

DRAFT Section 53.1480 – Combined license supporting testing of manufactured reactors.

December 2024, Description

Proposed part 53, Subpart E, "Construction and Manufacturing Requirements," § 53.620(d), "Fuel loading," would allow and establish requirements for the loading of fuel into a manufactured reactor at the manufacturing site for subsequent transport to its final place of operation at a commercial nuclear facility that will operate the manufactured reactor pursuant to a combined license (COL). The proposed regulation would require the manufactured reactor to include at least two independent physical mechanisms, each of which is sufficient to prevent criticality assuming optimum neutron moderation and neutron reflection conditions. This requirement and other requirements described in § 53.620(d) would provide reasonable assurance that the manufactured reactor would not be capable of operations, thereby justifying

not requiring an application for and issuance of a COL under §§ 53.1416, “Contents of applications for combined licenses; technical information,” and 53.1440, “Issuance of combined licenses,” to authorize fuel loading. Therefore, the proposed part 53 rule would rely on a determination that even though fuel has been loaded, which historically the NRC has interpreted as the start of operations, the fueled manufactured reactor is not considered to be in operation due to the two independent physical mechanisms to prevent criticality. As a corollary, the proposed part 53 rule also concludes that the manufactured reactor commences operation upon initiation of the removal of one of the independent physical mechanisms to prevent criticality.

A holder of a manufacturing license (ML) that desires to perform testing of a fueled manufactured reactor in the manufacturing facility while the reactor is generating fission reactions to gather data on the performance of the fuel or other structures, systems, and components (SSCs) associated with the manufactured reactor would *per force* need to change its configuration from that required by the proposed § 53.620(d). As described above, upon initiating the physical removal of any one of the independent physical mechanisms to prevent criticality, the fueled manufactured reactor would be deemed to have commenced operation. As a result, an ML holder seeking to conduct operational testing with the reactor generating fission reactions under the proposed part 53 would need to also possess a COL for the manufactured reactor. The introduction of a COL means that different licenses will control activities at the facility at different points in time. These different licenses may involve some requirements that apply at all times and others that only apply some of the time. The NRC staff is still thinking through the logistics of which requirements apply when. The NRC staff is also considering how to establish which requirements apply at what time. For example, the NRC staff could establish this on a case-specific basis through license conditions or generally through rule text.

Compared to normal operation for energy production under a COL, testing at the manufacturing facility could involve short periods of operation and low power levels. Therefore,

not all of the current requirements for a COL application in part 53 may be necessary for a COL that only authorizes testing with the reactor generating fission reactions sufficient to gather data on the performance of the fuel or other SSCs. Accordingly, the staff has drafted for discussion purposes an additional provision in draft 10 CFR 53.1480, “Combined license supporting testing of manufactured reactors,” that could be added to part 53, either in the final rule or through a subsequent rulemaking. This section would provide an abbreviated process for issuing a COL to authorize limited operational testing (e.g., short duration, low power) to the holder of an ML. The COL and ML could be combined in one license. Implementing the proposal in draft § 53.1480 would necessitate conforming amendments to § 53.620(d) and other proposed and existing regulations that could be addressed in a future iteration of this paper. This could include consideration of proposed regulations for the holder of the COL for energy production (e.g., timing provisions for certifying decommissioning funding assurance to address receipt of a reactor containing irradiated fuel prior to operation at the site of energy production).

The draft § 53.1480 would establish a pathway and associated requirements for performing testing with the manufactured reactor generating fission reactions within a manufacturing facility prior to the transport and use of the manufactured reactor for energy production at its final place of operation at a commercial nuclear facility that will operate the manufactured reactor pursuant to a separate COL. These provisions could be included in the proposed part 53 to support the possible factory-type fabrication and testing of manufactured reactors. There are potential economic and safety benefits of allowing testing of the manufactured reactors with the reactors generating fission reactions prior to their transport to their place of operation for commercial energy production. The performance of this testing in the manufacturing facility would involve changing the configuration of the manufactured reactor required by certain provisions of § 53.620(d) and manipulating reactivity control systems to initiate fission reactions and ensure that materials, geometries, fuel properties, and other

aspects of the design would support a self-sustaining chain reaction. Such testing could allow deployment of microreactors to sites that may not have a capability to dismantle and modify the internals of a manufactured reactor.

The safety of a fueled manufactured reactor during testing allowed by draft § 53.1480 would be provided by a combination of design features associated with the manufactured reactor, design features in those portions of the manufacturing facility in which testing would be performed, programmatic controls, and compliance with the relevant regulatory requirements. The manufactured reactor undergoing testing with the reactor generating fission reactions would constitute an operating reactor, which would result in the proposed treatment of the fueled manufactured reactor and portions of the manufacturing facility as a commercial nuclear plant under part 53. However, the NRC recognizes that operation of a manufactured reactor with the reactor only generating fission reactions sufficient to gather data on the performance of the fuel or other SSCs would present reduced risk compared to operations for energy production because of the smaller inventory of fission products and resulting limited levels of radioactivity and heat generated by radioactive decay. Therefore, draft § 53.1480 would establish scaled requirements for a combined license for testing of manufactured reactors (COL-TMR) by identifying specific requirements for the testing and alternatives to other requirements in part 53 that were developed for longer-term, full-power operation of a commercial nuclear plant and therefore need not be addressed by a COL-TMR applicant. The COL-TMR does not establish a new class of facilities; rather, the COL-TMR is solely a type of COL. The limited operation of the manufactured reactor under the COL-TMR would introduce byproduct materials and result in the need to provide additional controls under 10 CFR part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” during and after the testing is completed.

Consistent with the proposed § 53.620(d) that limits the loading of fuel into manufactured reactors to fresh (unirradiated) fuel, the draft § 53.1480(a) limits its use to manufactured

reactors loaded with fresh fuel. The NRC will, if needed, address the possible loading of fuel resulting from reprocessing of spent nuclear fuel or fuel that has experienced significant burnup through operations beyond the testing allowed in this section into a manufactured reactor as part of future activities. For now, limiting § 53.1480 to testing of manufactured reactors loaded with fresh fuel is consistent with the presumed low risks posed by the in-factory tests and allows the specific alternatives to certain requirements staff has included in the draft § 53.1480. These specific alternatives are consistent with the performance-based approaches in part 53.

Draft § 53.1480(a) defines the applicability of the section to COL-TMRs authorizing testing of manufactured reactors at the manufacturing facility with the manufactured reactor generating fission reactions to gather data on the performance of the fuel or other SSCs associated with the manufactured reactor. Draft § 53.1480(b) refers potential applicants to the appropriate sections in part 53 and 10 CFR part 2, “Agency Rules of Practice and Procedure,” for submitting applications for combined licenses to the NRC.

Draft § 53.1480(c) would provide the proposed Commission determinations regarding the operating state of a manufactured reactor consistent with the approach taken in proposed § 53.620(d). The manufactured reactor would either be in operation or not in operation based on the configuration of the manufactured reactor and the status of certain protections specified in proposed § 53.620(d). When certain protections specified in proposed § 53.620(d) are in place, the manufactured reactor is not in operation and is governed under the manufacturing license and materials licenses and applicable regulations. The manufactured reactor would therefore not be in operation during fuel loading, storage, and transport before and after testing is performed. In contrast, the manufactured reactor would be in operation when the licensee initiates removal of one of the independent physical mechanisms to prevent criticality (1) to perform testing within a manufacturing facility and later (2) to operate the manufactured reactor

for energy production purposes after it is installed at its final place of operation at a commercial nuclear plant.

The period following testing of the manufactured reactor under this section would be complicated by the production of byproduct material by the fission reactions associated with the testing under the COL-TMR. This draft section includes limitations to minimize the amount of byproduct materials produced during the testing operations (e.g., initial loading of fresh fuel into the manufactured reactor, low power levels under paragraph (e)(1), and restrictive safety criteria under paragraph (e)(2)). Nevertheless, the introduction of byproduct materials will result in the need to take additional precautions in areas such as radiation protection and the need to obtain licenses and follow regulations under part 30 and related NRC regulations that are either applicable or might be made applicable by conforming changes to accommodate this draft section. The regulations and related license applications under part 30 would require additional assessments and requirements for the manufactured reactor following testing, including those related to financial assurance and decommissioning funding plans, emergency preparedness, security, and transportation. The requirements resulting from the regulations and licensing process would be graded based, in part, on the estimated types and quantities of radionuclides produced during the testing of a manufactured reactor. The requirements related to the control of byproduct materials may duplicate or supplement the requirements imposed by the draft § 53.1480, 10 CFR part 70, “Domestic Licensing of Special Nuclear Material,” and other licenses and regulations for the manufactured reactor following testing and the restoration of the physical mechanisms to prevent criticality. The staff notes that additional evaluations of the applicability of, and potential modifications and additions to, various regulations, including those in part 30, and possible licenses issued under different parts of NRC regulations will be needed to address the manufactured reactor following testing under the COL-TMR if a § 53.1480 is developed for inclusion in part 53. This could, for example, include consideration of financial

protection requirements under Section 170, “Indemnification and Limitation of Liability,” of the Atomic Energy Act of 1954, as amended, (see question in Section VI, “Specific Request for Comment” section of the proposed rule regarding whether and how to apply financial protection requirements to fueled manufactured reactors under an ML).

The draft requirements in § 53.1480 and the COL-TMR would govern activities in the manufacturing facility, and individual manufactured reactors would be within the scope of these requirements, when a licensee is preparing for or performing testing that includes generating fission reactions while the manufactured reactor is within the manufacturing facility. This draft of § 53.1480 was developed assuming that portions of the manufacturing facility would contribute to fulfilling safety functions by providing conditions needed for testing and possibly mitigating licensing basis events by isolating the testing area. Those portions of the manufacturing facility identified as safety significant during the performance of tests would be subject to requirements in the COL-TMR and would be the common equipment and controls within the COL-TMR as different manufactured reactors were fabricated and tested. The use of a single facility license for multiple nuclear reactor units was identified as a potential licensing approach in the staff information paper, SECY-11-0079, “License Structure for Multi-Module Facilities Related to Small Modular Nuclear Power Reactors,” dated June 12, 2011 (ADAMS Accession No. ML110620459). The process in draft § 53.1480 would similarly have a single license but the multiple modules aspect would be different in that manufactured reactors would be tested one at a time. The COL-TMR would specify the number of manufactured reactors that could be tested over the lifetime of the license.

The draft § 53.1480(d) would specify that the implementation of part 53 Subparts B, “Technology-Inclusive Safety Requirements,” and C, “Design and Analysis Requirements,” safety requirements and analyses in the application for a COL-TMR can reflect the characteristics of the manufactured reactor at the time of testing in the manufacturing facility.

For example, the analyses of the manufactured reactor's response to unplanned events and the identification of safety functions required by § 53.230, "Safety functions," can reflect characteristics such as the loading and testing of unirradiated fuel and the associated amount of decay heat generated by the subsequently irradiated fuel when the manufactured reactor is under the COL-TMR. This draft provision distinguishes between the conditions and radiological hazards of the testing in the manufacturing facility and the conditions and radiological hazards introduced by extended full power operation at a commercial nuclear plant at its final place of operation. While the Subpart B and C requirements for commercial nuclear plants in part 53 would apply to the COL-TMR unless otherwise stated in draft § 53.1480(e), the results from the assessments and analyses required in those subparts, in terms of the safety-related (SR) and non-safety-related but safety significant (NSRSS) SSCs and associated controls, could reflect the lower risks of a manufactured reactor during testing operations within the manufacturing facility.

The draft § 53.1480(e) identifies special requirements for the conduct of testing under a COL-TMR and alternatives to specific requirements for COL-TMRs in other sections of part 53 that are justified given the limitations imposed by this section. The specific limitations and alternatives include:

- Section 53.1480(e)(1): The maximum reactor power during testing would be limited to a small fraction (e.g., 5 percent) of the rated thermal power for the manufactured reactor. This proposed requirement is intended to support testing at the manufacturing facility using fission reactions in the manufactured reactor to gather data on the performance of the fuel or other SSCs while also ensuring that changing the reactor configuration from that required by proposed § 53.620(d) and manipulating reactivity systems for testing would introduce only a small risk to public health and safety.

- Sections 53.1480(e)(2) and (3): Safety criteria and evaluation criteria for licensing basis events supporting the COL-TMR would be more restrictive (0.1 rem (1 mSv) over the course of a year following any licensing basis event, which corresponds to the annual dose limits for individual members of the public under § 20.1301, “Dose limits for individual members of the public,” when compared to the safety and evaluation criteria specified in proposed part 53 Subparts B and C, which address long term operation at the final place of operation. These criteria would be met using design features provided by the manufactured reactor (e.g., control rods and cooling systems) and additional design features within the manufacturing facility governed by the COL-TMR (e.g., ventilation systems for the testing room). These criteria would need to be met without reliance on human actions. The safety criteria in § 53.1480(e)(2)(i) are more restrictive for testing in the manufacturing facility to support associated alternatives to some requirements such as those related to protecting plants from various external hazards. In meeting the more restrictive criteria in (e)(2)(i), a COL-TMR application would also demonstrate that the manufactured reactor meets the criteria for a self-reliant mitigation class of reactors under § 53.800, “Facility licensees for self-reliant-mitigation facilities,” during testing under the COL-TMR. Therefore, operation of a COL-TMR would require the use of generally licensed reactor operators (GLROs) for performing testing with the reactor generating fission reactions, consistent with draft § 53.1480(f)(7).
- Section 53.1480(e)(4): In addition, the manufacturer would need to ensure that activities conducted under draft § 53.1480 do not adversely affect and are otherwise considered in the design and programmatic controls for the subsequent storage, transport and use of the manufactured reactor.

The draft § 53.1480(f) identifies specific requirements in various subparts of part 53 that would apply to a COL TMR in modified form under this draft section. The specific alternatives and clarifications specific to a COL-TMR include:

- Section 53.1480(f)(1)(i): References to a plant's lifetime as applied to the parts of the manufacturing facility under the COL-TMR would mean the period controlled by the COL-TMR. The applicability of the conditions established by the COL-TMR for individual manufactured reactors being tested would begin when the holder of the COL-TMR transitions from the requirements for storing a manufactured reactor under proposed § 53.620(d) (e.g., initiating the physical removal of any one of the independent physical mechanisms to prevent criticality required under § 53.620(d)(1)) and would end when the manufactured reactor is restored to the configuration required under proposed § 53.620(d).
- Section 53.1480(f)(1)(ii): The proposed requirements of § 53.440(j) and related analysis requirements in § 53.450(g)(2), "Aircraft impact," would not apply to the COL-TMR because of the limited inventories of radioactive byproduct materials resulting from the testing and limited radiological consequences of an aircraft impact on the manufacturing facility.
- Section 53.1480(f)(2): The proposed requirements of § 53.470, "Maintaining analytical safety margins used to justify operational flexibilities," are revised such that they apply to design basis accidents to ensure that the radiological consequences from any licensing basis event during testing of any manufactured reactor over the duration of the COL-TMR remains below the selected alternative criteria.
- Section 53.1480(f)(3): The proposed requirements of §§ 53.415, 53.480, 53.510, and 53.720 related to protecting commercial nuclear plants from external hazards, including seismic events, would not apply for the facility governed by the COL-TMR

because of the limited inventories of byproduct materials, the short time intervals when testing would be underway. The underlying assumption that may need confirmation if this draft section is more fully developed is that the various restrictions included in draft § 53.1480 would limit the potential consequences of accidents and thereby justify not having special treatments related to external hazards for the manufacturing facility or manufactured reactor during testing. This would be somewhat analogous to showing that a particular reactor design or SSC is determined to be within a low seismic design category under more recent risk informed alternatives afforded by standards development organizations (e.g., American Society of Civil Engineers (ASCE)/Structural Engineering Institute (SEI) 43-19, "Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities.") and that the SSCs are therefore reasonably protected against external hazards through the use of commercial building codes (see pre-decisional draft regulatory guide "Technology-Inclusive, Risk-Informed, and Performance-Based Methodology for Seismic Design of Commercial Nuclear Plants," issued October 3, 2022, ADAMS Accession No. ML22276A149). There is also a possibility to avoid some external hazards by prudently scheduling testing and therefore the draft paragraph would include a requirement for COL-TMR holders to establish procedures prohibiting testing during conditions related to predictable external events, such as severe weather, that could adversely affect the risks introduced by the testing of a manufactured reactor.

- Section 53.1480(f)(4): This draft paragraph states that the proposed requirements of § 53.610, "Construction," would apply to any portion of the manufacturing facility that is subject to the COL-TMR.
- Section 53.1480(f)(5): The proposed requirements of §§ 53.710, "Maintaining capabilities and availabilities of structures, systems, and components," and 53.715,

"Maintenance, repair, and inspection programs," are expected to play an especially important role for conducting testing under a COL-TMR. This is because the manufacturing facility may not be continuously configured as it would be configured during testing when the manufactured reactor is generating fission reactions. This would be acceptable so long as the technical specifications and other programmatic controls adequately address the appropriate SSC configurations for testing under the COL-TMR. An example could involve a ventilation system that is designated as safety-related given its role in controlling releases from a testing room in the manufacturing facility when criticality prevention features specified in proposed § 53.620(d) for a manufactured reactor are removed to support the production of fission reactions in the manufactured reactor. In such an example, the technical specifications and maintenance programs may need to provide confidence that the ventilation system would be available and capable of performing its safety functions only when the manufactured reactors enter operation (e.g., once the licensee has started removing one of the independent mechanisms to prevent criticality).

- Section 53.1480(f)(6): The proposed requirements of §§ 53.730(a) through (e) [*human factors, concept of operations, etc.*] would apply to the areas of the manufacturing facility, the activities, and personnel relied upon to perform the testing and respond to possible problems encountered during testing.
- Section 53.1480(f)(7): The proposed requirements of § 53.730(f)(1) *[staffing plan]* would be supplemented for the COL-TMR under the draft § 53.1480 to require that the staffing plan include an individual with engineering expertise under § 53.730(f) to serve as the test engineer and another individual with engineering expertise under § 53.730(f) with specific knowledge of nuclear reactor physics. An individual meeting the requirements for and being designated as a generally licensed reactor operator (GLRO) would be required to be the individual manipulating reactivity-related

systems and conditions during testing when the reactor will be generating fission reactions. The NRC staff is considering the use of the GLRO provisions from proposed part 53 subpart F, “Requirements for Operation,” in this draft section because in order to meet the design and analysis requirements under draft § 53.1480, the applicant would demonstrate that the criteria in the proposed § 53.800 are satisfied and therefore that human actions are not essential for protecting public health and safety should a licensing basis event occur during the conduct of testing on a manufactured reactor under a COL-TMR.

- Section 53.1480(f)(8): Some proposed programs under subpart F relate to the long-term conditions of SSCs in a commercial nuclear plant producing energy (e.g., in-service inspections, integrity assessments). Because long-term operation would not be permitted at the manufacturing location, these programs would not be applicable to facilities and programs supporting the testing of manufactured reactors under a COL-TMR. However, a holder of a COL-TMR would be required under draft § 54.1480(e)(4) to ensure that any testing performed does not adversely affect the manufactured reactor and that the testing, including creation of byproduct material during testing, is duly considered in the subsequent steps of storing, transporting, and using the manufactured reactor at its final place of operation at a commercial nuclear plant such that the licensee continues to meet the requirements of § 53.620(d) as well as the requirements of the materials licenses and regulations.
- Section 53.1480(f)(9): Although a person must obtain a license to operate a commercial nuclear plant under part 53 in order to perform testing of a manufactured reactor with the reactor generating fission reactions sufficient to gather data on the performance of the fuel or other SSCs, the manufacturing facility is otherwise much like a fuel cycle facility and most of the byproduct material generated during testing would leave the manufacturing facility with the removal of each tested manufactured

reactor. Further, reactors undergoing testing are fundamentally different from reactors operating at full power, including reactors, such as research reactors, which operate at much lower power levels. Therefore, the decommissioning requirements for the holder of a COL-TMR in this preliminary draft paper refer to the need to provide a decommissioning funding plan for NRC review and approval and otherwise meeting the requirements in § 70.25(e) for the manufacturing facility instead of proposed part 53, subpart G, “Decommissioning Requirements.” Additionally, the ML holder will need to apply for and receive a license under part 30 due to the introduction of byproduct materials into the manufactured reactor during testing. The licensing provisions under part 30 would be used to ensure appropriate consideration of decommissioning of the manufactured reactor subsequent to the testing performed under the COL-TMR until it becomes the responsibility of the holder of the COL for its final place of operation, although the staff is still considering which specific provisions in 10 CFR 30.35, “Financial assurance and recordkeeping for decommissioning,” should apply and whether any additional changes are needed. The alternative requirement under draft paragraph (f)(9) for the submittal of a decommissioning funding plan would not revise the proposed financial requirements in subpart J, “Reporting and Other Administrative Requirements,” of part 53, including the need to take reasonable steps to obtain insurance to stabilize and decontaminate the plant and the plant site should an accident occur.

- Section 53.1480(f)(10): This draft paragraph states that §§ 53.1410 through 53.1461 [*Subpart H, COL application*] are applicable for applications for a COL-TMR except as the technical and programmatic requirements are revised by this draft § 53.1480.
- Section 53.1480(f)(11): Draft paragraph (f)(11)(i) would cover the inspections, tests, analyses and acceptance criteria (ITAAC) closure for the first manufactured reactor under the COL-TMR. Both the COL-TMR and the COL for operation for energy

production at the final place of operation will have associated ITAAC. Paragraph (f)(11) would specify the ITAAC for the manufacturing facility (e.g., for a ventilation system in the testing room) and ITAAC for each manufactured reactor to be tested under the COL-TMR (e.g., for a reactivity protection system). The ITAAC for the manufactured reactors could include both ITAAC included in the ML for appropriate verifications prior to performing testing under draft § 53.1480 and possibly ITAAC introduced in the COL-TMR. These ITAAC would be used to comply with the requirements and timelines specified in §§ 53.1449 and 53.1452 for the COL-TMR, including supporting the Commission's finding under proposed § 53.1452(g). Upon a 10 CFR 53.1452(g) finding for the first manufactured reactor under the COL-TMR, the associated ITAAC for the portions of the manufacturing facility under the COL-TMR would no longer constitute regulatory requirements and would not need to be repeated for testing of subsequent manufactured reactors under the COL-TMR, and the COL-TMR ITAAC specifically associated with the first manufactured reactor would no longer constitute regulatory requirements for that reactor.

- Sections 53.1480(f)(12) and (f)(13): Draft paragraphs (f)(12) and (f)(13) would cover the ITAAC closures for the initial as well as subsequent manufactured reactors under the COL-TMR. The factory-style manufacture and testing of manufactured reactors warrants special provisions for the testing of each manufactured reactor. The manufacturing, loading of fuel, and testing would be governed under multiple NRC regulations and licenses including the part 70 license for special nuclear material, the manufacturing license, and the COL-TMR. Although there is some semblance of routine and repetitive actions similar to refueling at existing nuclear plants, each set of tests for a new manufactured reactor with the reactor generating fission reactions involves an initial criticality or approach to criticality and use of SSCs associated with each manufactured reactor such that requirements are needed to verify that the new

manufactured reactor has been constructed and will be operated as required. The ITAAC for the manufacturing facility are addressed under paragraph (f)(11) and requirements on the manufacturing facility for subsequent tests are governed by the COL-TMR, including technical specifications, and other sections in part 53. The draft paragraph (f)(12) would require the verification of the relevant ITAAC for each manufactured reactor and the completion of the associated submittals, notices, and findings before testing with the reactor generating fission reactions could proceed. The need to address ITAAC and associated processes defined for COLs in the Act and NRC regulations will introduce some possible scheduling-related challenges for factory-type fabrication and testing of manufactured reactors. For example, holders of a COL-TMR may invoke the provisions in § 53.1449(c)(3) for reporting uncompleted ITAAC more than large-LWR licensees have invoked equivalent provisions. Depending on the schedules for manufacture and testing, it is possible that all ITAAC for some manufactured reactors would be addressed using § 53.1449(c)(3). The requirements in draft § 53.1480(f)(13) for the NRC to publish notices, conduct hearings if needed, and make ITAAC-related findings to allow testing of specific manufactured reactors with the reactors generating fission reactions refer to §§ 53.1449 and 53.1452

Separate from the ITAAC and related requirements in the COL-TMR for testing in the manufacturing facility, additional ITAAC for the deployment of the manufactured reactor to its final place of operation at a site having a COL for energy production will include ITAAC defined for the ML, the site-specific COL, and potentially for a design certification. Each of these ITAAC are established to ensure that the installation and operation of the manufactured reactor is consistent with the design, analysis, and interface requirements for the manufactured reactor and other portions of the specific

commercial nuclear plant. The proposed § 53.1452 requires a licensee to notify the NRC of scheduled fuel load and requires the related NRC publication of a notice of intended operation and opportunity for a person to request a hearing on whether the facility as constructed complies, or on completion will comply with the ITAAC. In the case of a manufactured reactor deployed at its final place of operation for energy production, upon installation of the manufactured reactor, the initiation of physical removal of one of the independent mechanisms to prevent criticality is equivalent to fuel load in COLs not using a factory-fueled manufactured reactor.

Specific Request for Comment in Part 53 Federal Register Notice (89 FR 86918)

> The following specific request for comment is included in Section VI of the *Federal Register* notice (89 FR 86918) associated with the proposed rule, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors." The staff encourages stakeholders to submit comments on the proposed rule via www.regulations.gov using Docket ID "NRC-2019-0062."

Part 53, Subparts E and H – Manufacturing Licenses; Question 13. The NRC is seeking comment on whether provisions regulating the testing of fueled manufactured reactors in the manufacturing facility should be included in part 53 and, if so, what would be practical for the holder of an ML while also providing adequate protection of public health and safety. One possibility could be COLs that would be issued to the holders of an ML to cover low power (e.g., <5% rated thermal power) nuclear physics testing of fueled manufactured reactors within the manufacturing facility prior to the manufactured reactors being transported to and incorporated into a commercial nuclear plant for the purpose of energy production. The NRC recognizes configuration changes are needed to perform nuclear physics testing and is seeking comment on what requirements should apply to the manufactured reactors and the manufacturing facility during such testing (e.g., limiting power levels). If a comment indicates that the regulations should address limited operations at manufacturing facilities, please describe the likely scenarios that would need to be addressed and suggest what would be appropriate requirements for such scenarios.

While an ML holder could accomplish nuclear physics testing by applying for a COL under the proposed subpart H of part 53, stakeholders have indicated that many of the requirements would likely be unnecessary, given the reduced risk profile posed by such activities. Therefore, the NRC is seeking comment on what requirements in subpart H of part 53 should apply to applicants for a COL who would perform testing of fueled manufactured reactors at the manufacturing plant. Examples of proposed requirements that might be relaxed or

modified for applications for low power testing at manufacturing plants include those related to selection of LBEs to reflect limited inventory of radionuclides and decay heat, aircraft impact assessments, and earthquake engineering.

Additionally, the NRC is seeking comment on whether several other requirements in part 53 could be modified for applications for a low power testing COL at a manufacturing facility. For example, the NRC is seeking comment on how portions of the ML facility used to support testing should fall within the requirements for construction activities under § 53.610; whether §§ 53.710 and 53.715 (SSC configuration control) must be implemented to ensure portions of the ML facility relied on to limit potential radiological consequences from LBEs are available to perform their safety functions; and whether the requirements of § 53.730 could be modified to reflect the conditions of low power physics testing. If a comment indicates that some design and analysis requirements and related application requirements in subpart H of the proposed part 53 are not needed for the testing of fueled manufactured reactors, please provide a rationale supporting your comment and, if applicable, what alternate requirements would be appropriate.

Moreover, the licensing mechanism for the facility could present unique challenges. One option could be to issue a low power testing COL for each fueled manufactured reactor to be tested. This would comport with the agency's practice of issuing one license per reactor but could prove prohibitive from a cost standpoint and may provide very little safety benefit if all manufactured reactors are the same. Alternatively, one low power testing COL could be issued for the portions of the ML facility used to test the fueled manufactured reactors and allow multiple fueled manufactured reactors to be completed and tested over the course of the ML. Under this approach, any ITAAC related to testing of the fueled manufactured reactors would need to be closed after they were manufactured but prior to testing, and the NRC would issue a notice of intended operation and provide the public an opportunity to request a hearing on whether each fueled manufactured reactor as constructed complies, or on completion will

comply, with the acceptance criteria of the license. The NRC is seeking comment on the potential benefits and issues with having a COL for each fueled manufactured reactor to be tested versus having a COL cover the testing of multiple fueled manufactured reactors. If a comment indicates a preference for a particular approach, please provide a rationale supporting the comment and describe the specific scenarios that the regulations need to address.

DRAFT RULE TEXT LANGUAGE:

Subpart H—Licenses, Certifications and Approvals

§ 53.1480 Combined license supporting testing of manufactured reactors.

This section applies when applicants for or holders of a manufacturing license apply for a combined license to authorize operation of a manufactured reactor at a manufacturing facility solely for testing with the reactor generating fission reactions to gather data on the performance of the fuel or other structures, systems, and components (SSCs) associated with the manufactured reactor. The combined license for testing with the manufactured reactor generating fission reactions (COL-TMR) issued under this section is separate and distinct from the licenses issued for commercial operation of the manufactured reactors at the final place of operation. A COL-TMR is limited to the testing of manufactured reactors loaded with unirradiated fuel in a facility governed by a manufacturing license. This testing must be performed under conditions established for staffing as provided under this section and the facility for testing, and the manufactured reactor must include SSCs with the capabilities to confine radioactive materials in the event of unplanned events as provided under this section.

(a) The provisions of this section apply to applications under this part for a COL-TMR to be issued to an applicant for or holder of a manufacturing license. The COL-TMR will authorize testing of reactors manufactured under a manufacturing license issued in accordance with § 53.1287 that have been loaded with unirradiated fuel in accordance with a license issued under 10 CFR part 70, as described in § 53.620(d).

(b) Each application for a COL-TMR pursuant to this section must be submitted as specified in §§ 53.1410 through 53.1419 and 10 CFR 2.101, with the additional clarifications and exceptions provided in § 53.1480(d), (e) and (f).

(c)(i) The Commission has determined that any fueled manufactured reactor in which the two independent physical mechanisms to prevent criticality required under § 53.620(d)(1) have been installed is not in operation.

(ii) A COL-TMR issued under this section governs a commercial nuclear plant that consists of the—

(A) manufactured reactors for which the configuration required under proposed § 53.620(d) will be altered to allow testing using fission reactions within the manufactured reactor, and

(B) any areas of the manufacturing facility that are used or relied on to perform the testing and limit the release of radioactive materials that could result from any licensing basis event.

(iii) Notwithstanding the requirements in § 53.620(d)(1)(iv), upon a Commission finding that the acceptance criteria in the COL-TMR are met in accordance with § 53.1452(g), the holder of the COL-TMR may remove the independent physical mechanisms to prevent criticality and perform testing of the manufactured reactors in accordance with the COL-TMR and the applicable regulations in this part.

(iv) Upon initiating the physical removal of any one of the independent physical mechanisms to prevent criticality, the fueled manufactured reactor has commenced operation, and

(v) Upon restoration of a fueled manufactured reactor to the configuration required by § 53.620(d), the manufactured reactor is not in operation and the manufacturing license and associated licenses under 10 CFR parts 30 and 70 authorize and govern possession and storage of the fueled manufactured reactor.

(d) The implementation of safety requirements in Subpart B of this part and related design and analyses requirements in Subpart C of this part must reflect the characteristics of

the manufactured reactor and portions of the manufacturing facility governed by the COL-TMR at the times testing will be performed in the manufacturing facility.

(e) A COL-TMR authorizing testing with the reactor generating fission reactions to gather data on the performance of the fuel or other SSCs associated with the manufactured reactors at the manufacturing facility is subject to the requirements in this chapter for COLs issued under 10 CFR Part 53 with the following clarifications and modifications:

(1) The operation of the manufactured reactor under the COL-TMR is limited to performing testing of the reactor and operational testing of reactor systems such that—

(i) The power level in all cases must not exceed five percent of the rated thermal power of the manufactured reactor as defined in the manufacturing license for when the manufactured reactor is operated for energy production at its final place of operation at a commercial nuclear plant, and

(ii) The estimated types and quantities of byproduct materials produced by the testing is consistent with the supporting analyses and 10 CFR part 30 license.

(2)(i) Rather than meeting the safety criteria of § 53.210 for design basis accidents and § 53.220 for licensing basis events other than design basis accidents and the evaluation criteria in § 53.450(e) for specific licensing basis events, all of the analyses required under §§ 53.450(e) and 53.450(f) must demonstrate that the dose at the boundary of the exclusion area does not exceed 0.1 rem (1 mSv) over the course of a year following any licensing basis event.

(ii) Licensing basis events associated with testing a manufactured reactor under the COL-TMR issued under this section must be mitigated (without reliance on human actions) by design features included in the manufactured reactor, as adjusted to address testing configurations, and additional design features and functional design criteria within the manufacturing facility governed by the COL-TMR.

(3) The design features and related functional design criteria required in §§ 53.400, 53.410, 53.420, 53.425, and 53.430 must include for the COL-TMR those capabilities included

in the manufactured reactor, as adjusted to address testing configurations, and additional design features and related functional design criteria for SSCs in the manufacturing facility governed by the COL-TMR.

(4) The holder of the COL-TMR under this section must ensure that the testing of each manufactured reactor does not adversely affect, and is otherwise considered in the design and programmatic controls for, the subsequent storage, transport and use of the manufactured reactor at its final place of operation at a commercial nuclear plant. In making this showing, the COL-TMR holder must demonstrate that the manufactured reactor will continue to meet the provisions in § 53.620(d), the 10 CFR part 70 license referenced in § 53.620(d), and § 53.1279(d) after the testing is complete. In meeting the design requirements in § 53.440, the design covered by the COL-TMR under this section must reflect the characteristics of the manufactured reactors at the time of testing in the manufacturing facility.

(f) The specific requirements in various subparts of part 53 are revised as follows for a COL-TMR under this section:

(1)(i) References to a “plant’s lifetime” in § 53.440(a) refer to those SSCs in the manufacturing facility included in the COL-TMR and means the duration of the COL-TMR for each facility. The “plant’s lifetime” for the individual manufactured reactors being tested under this section and the COL-TMR covers the times beginning when the holder of the COL-TMR transitions from the requirements for storing a manufactured reactor under proposed § 53.620(d) and ending when the manufactured reactor is restored to conditions required under § 53.620(d) after testing is complete.

(ii) The requirements of § 53.440(j) and related analysis requirements in § 53.450(g)(2) *[aircraft impact]* do not apply to the COL-TMR for testing of a manufactured reactor.

(2) The requirements of § 53.470 *[alternate evaluation criteria]* are extended to design basis accidents, such that if an applicant adopts alternative criteria more restrictive than those specified in paragraph (c)(2) of this section for the COL-TMR, the radiological consequences

from any licensing basis event during testing of any manufactured reactor over the duration of the COL-TMR remains below the selected alternative criteria.

(3)(i) The requirements of §§ 53.415, 53.480, 53.510, and 53.720 *[external events, earthquake engineering, design basis external hazard levels, response to seismic events]* do not apply to the COL-TMR for testing of manufactured reactors.

(ii) The holder of the COL-TMR must establish procedures to prohibit testing during conditions under which predictable external events, such as severe weather, could adversely affect the risks introduced by the testing of a manufactured reactor.

(4) The requirements of § 53.610 *[construction]* apply to any portion of the manufacturing facility that is subject to the COL-TMR.

(5) The requirements of §§ 53.710 and 53.715 *[SSC configuration control]* must be implemented to ensure that safety-related SSCs and non-safety-related but safety significant (NSRSS) SSCs limiting the potential radiological consequences from licensing basis events for the facility and manufactured reactor subject to the COL-TMR are capable and available to perform their safety functions during the testing of any manufactured reactor.

(6) The requirements of §§ 53.730(a) through (e) *[human factors, concept of operations, etc.]* apply to the areas of the manufacturing facility, the activities, and personnel relied upon to perform the testing of a manufactured reactor and to limit the radiological consequences from licensing basis events identified for the COL-TMR under this section.

(7) The requirements of § 53.730(f)(1) *[staffing plan]* are supplemented for the COL-TMR under this section to require that the staffing plan include, at a minimum, the following individuals to be present during the testing of each manufactured reactor:

(i) an individual meeting the criteria for engineering expertise under § 53.730(f) with specific expertise in nuclear core design or nuclear reactor physics

(ii) an individual meeting the criteria for engineering expertise under § 53.730(f) to serve as the test engineer responsible for the overall performance of the test and the condition of the manufactured reactor, and

(iii) an operator licensed by the NRC under § 53.810 *[GLRO]* of this part

(8) The program requirements in §§ 53.870 and 53.880 *[ISI/IST, Integrity assessments]* are not applicable to COL-TMR holders under this section.

(9) In lieu of the requirements in Part 53, subpart G, the holder of a COL-TMR under this section must provide a decommissioning funding plan for NRC review and approval and otherwise meet the requirements in § 70.25(e) of this chapter for the manufacturing facility and § 30.35 of this chapter for the manufactured reactors to address the period between completion of testing under this section and receipt and acceptance of the manufactured reactor by the COL holder for its final place of operation .

(10) Sections 53.1410 through 53.1461 *[Subpart H, COL application]* are applicable to applications for a COL-TMR under this section, except that the content of applications and other specific requirements referred to therein must reflect the revised technical and programmatic requirements described under this section.

(11)(i) For the first manufactured reactor subject to testing with the reactor generating fission reactions, the pertinent ITAAC that must be satisfied prior to testing are the ITAAC for the manufacturing facility in the COL-TMR and the ITAAC in the COL-TMR for each manufactured reactor (including ITAAC from the manufacturing license for verifications needed prior to conducting testing with the reactor generating fission reactions on each manufactured reactor). In accordance with § 53.1452(g), the licensee must not begin initiating the physical removal of any one of the independent physical mechanisms to prevent criticality required under § 53.620(d)(1) for the first manufactured reactor to be tested with the reactor generating fission reactions until the Commission makes a finding that the acceptance criteria in the COL-TMR are met for both the manufacturing facility and the first manufactured reactor to be tested.

(ii) For subsequent manufactured reactors subject to testing with the reactor generating fission reactions, the pertinent ITAAC that must be satisfied prior to initiating the physical removal of any one of the independent physical mechanisms to prevent criticality required under § 53.620(d)(1) are the ITAAC in the COL-TMR for each manufactured reactor (including the ITAAC from the manufacturing license for verifications needed prior to conducting testing with the reactor generating fission reactions on each manufactured reactor).

(12)(i) The licensee must follow § 53.1449 for each manufactured reactor to be tested under the COL-TMR. Updates to the ITAAC schedule under § 53.1449(a) and ITAAC closure notifications under § 53.1449(c) may address multiple manufactured reactors that are under fabrication or planned to be fabricated under the ML and tested under the COL-TMR.

(ii) For the purpose of meeting § 53.1452 when performing testing of individual manufactured reactors under a COL-TMR, the date for initial loading of fuel in § 53.1452 means the date the licensee plans to change the configuration of the manufactured reactor from that specified in § 53.620(d) for the individual manufactured reactor being tested.

(iii) For manufactured reactors that are tested after the first manufactured reactor to be tested, the licensee must not initiate the physical removal of any one of the independent physical mechanisms to prevent criticality required under § 53.620(d)(1) for any manufactured reactor until the Commission makes a finding under § 53.1452(g) that the acceptance criteria in the COL-TMR are met for the manufactured reactor to be tested.

(13)(i) The NRC must meet the requirements of § 53.1449(e) for each individual manufactured reactor being tested.

(ii) The NRC must publish notice of intended operation in the *Federal Register* as required by § 53.1452(a) for each manufactured reactor to be tested under the COL-TMR. The NRC must address any requests for hearing resulting from the notice of intended operation under § 53.1452(c), (d) and (e).

Note that the addition of draft § 53.1480 would result in conforming changes to other sections in the proposed part 53. Possible examples include:

§ 53.620(d)(1)(i) An ML may authorize possession of a manufactured reactor into which the licensee has loaded fresh (unirradiated) fuel pursuant to a license issued under part 70 of this chapter and fuel that has been irradiated during the testing allowed under § 53.1480 only if the manufactured reactor is configured during its loading, storage, and transport with at least two independent physical mechanisms in place, each of which is sufficient to prevent criticality assuming optimum neutron moderation and neutron reflection conditions.

§ 53.1452 (g) The licensee must not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under § 53.1440(a)(2). If the combined license is for a modular design, each reactor module may require a separate finding as construction proceeds. If the combined license is for testing of manufactured reactors under § 53.1480, each manufactured reactor is required to have a separate finding before testing may proceed.