THIRD WAY

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Unleashing Innovation: A Comparison of Regulatory Approval Processes

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In the 1970s, the Nuclear Regulatory Commission was created to license and regulate commercial nuclear power plants with a mission to protect the public health and safety. In the decades since, it has done an excellent job at this mission—no member of the public has ever been injured in an accident from an American nuclear plant. But now, the NRC faces a renewed challenge – private sector nuclear innovators in the United States are developing the next generation of advanced reactors to help address climate change and growing global energy demand. The NRC needs to be prepared to regulate for innovation and to make sure these emerging technologies operate safely. It's time to build a 21st century NRC. To do this, both Congress and the NRC must consider:

1. **Making the licensing costs for first movers more cost-effective;**
2. **Building on available knowledge to ensure efficient and effective licensing;**

3. **Developing a streamlined, risk-informed pathway for the construction of demonstration reactors.**

Modernizing the Nuclear Licensing Process

When it comes to innovation, the old adage of 'If it ain't broke, don't fix it' misses the point. A better axiom is: 'If things change, adapt.' This is particularly apt in the case of the Nuclear Regulatory Commission (NRC) and the licensing and regulation of 21st century nuclear technology.

With nearly 50 companies and organizations already working to develop the next generation of reactors, the NRC is facing a moment of truth. [1] Advanced nuclear companies are being developed and funded because innovators see a chance to improve energy generation and investors see profit in creating an answer to the global energy paradox. Right now there are 1.3 billion people in the world without access to reliable electricity, but the climate crisis means they simply must not get it from dirty sources. Advanced reactors can provide scalable, affordable electricity without carbon emissions. [2] These promising innovations are attracting both startups and big-name investors like Bill Gates, who are placing bets on a nuclear comeback, hoping to get the technology in position to win in an increasingly carbon-constrained world. [3]

Moving these technologies forward will require a cost-effective and predictable licensing pathway for small pre-revenue companies to get first-of-a-kind reactor designs developed. At present, there is no simple way for companies to get federal approval for pre-commercial, small modular (SMR) and non-light water reactor designs. [4] And while there have been small steps toward this goal—for instance, the DOE-NRC NuScale pilot project to license their first-of-a-kind small reactor [5] —more needs to be done within the NRC to prepare for even more innovative reactor designs.

The current licensing process, with timelines of up to a decade, is specifically calibrated to regulate light water reactor (LWR) technology built by well-financed utilities that can come to the NRC with a completed design. [6] This process has proven to be very safe, with 0.03 industrial safety accidents per 200,000 worker-hours in 2014 [7] (lower than the financial sector!). [8] But because the process is so focused, it has left vestigial regulatory features that, if left unchanged, would stall the development of advanced nuclear reactors.

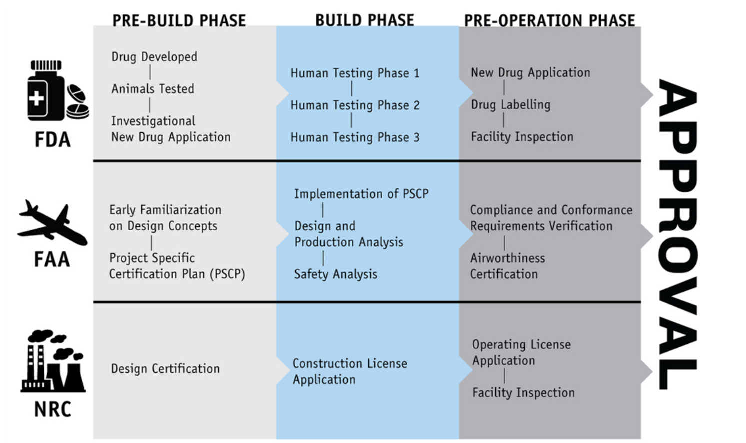
The full spectrum of the differences between current LWRs and next generation reactors is beyond the scope of this paper. But for starters, many of the safety requirements of the current generation of reactors would not be applicable to advanced reactor designs. [9] For example, many non-LWR nuclear reactors would operate at normal atmospheric pressure, making massive containment structures potentially unnecessary. Many also include passive safety features that use natural forces of physics, such as gravity, convection, and conduction to allow safe shutdown and self-cooling, with no operator action, no AC or DC power, and no external water required to meet safety functions. [10] Many non-LWR designs also have the ability to reuse spent fuel, which reduces the need for the construction of as many waste storage and disposal facilities. [11]

This leads to the classic chicken and egg conundrum: it is difficult for the NRC to develop a relevant regulatory framework without substantial hands-on experience with new types of reactors, but companies are unable to build an operational demonstration reactor without first getting approval from the NRC, which could require them to include billions of dollars in systems that may not be needed. [12]

The potential of advanced nuclear technologies to provide safe, reliable and clean energy is evident, but the structural issues in the licensing process are a barrier to rapid nuclear innovation in the United States. The NRC is aware of these issues and is willing to reexamine their processes. But currently, as other research has found, the NRC licensing process for advanced nuclear reactors costs **too much** [13] , is **too opaque** [14] , and will take **too long**. [15] How can the NRC properly evaluate safety, in keeping with its core mandate, while also enabling innovation? The answer can be found in other licensing and regulatory regimes that routinely deal with public safety and innovation.

Taking a Page from the FDA and FAA Playbooks

We've identified two regulatory agencies that routinely manage the tension between innovation and safety regulation: the Federal Drug Agency (FDA) and the Federal Aviation Administration (FAA). While neither of these processes are perfect, both use a phased approach that is orderly and conclusive. A comparison of these licensing approval processes is outlined below:



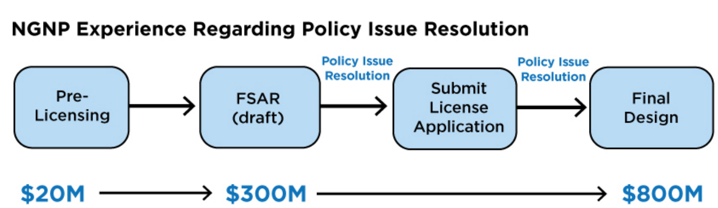
Rather than having a few large hurdles like the NRC's static "point-in time" licensing approach, the FDA and FAA each has a multiphase process with several smaller hurdles. This enables companies to make less risky investments as they pass each step of the process, encourages companies that run into problems to "fail fast" or fix the problem, and enables the regulator to learn as it goes.

We have identified three features of a phased, risk-informed regulatory process that Congress and the NRC should consider for licensing advanced reactors:

1. Reducing Costs of Licensing Process

The costs associated with building any first-of-a-kind reactor are likely to be substantial. What does not need to be prohibitively expensive is the cost of licensing. At present, the NRC is legally required to recover its costs through fees charged to applicants. [16] This is challenging enough for large, experienced investor-owned utilities that can recover costs from ratepayers. But for advanced nuclear companies that are still in the process of constructing demonstration reactors, the high cost of licensing could prove insurmountable.

Under the current structure, advanced nuclear developers will first have to pay the NRC $268 per hour to consult with them in the pre-application phase. [17] And because the NRC has not had the opportunity to gain thorough knowledge about how these innovative reactor designs operate, they need plenty of consultations. [18] This was demonstrated by the Next Generation Nuclear Plant (NGNP) project, which was a Department of Energy (DOE) project led by the Idaho National Lab (INL). With the DOE acting as a surrogate applicant, the NGNP project engaged the NRC in a pre-licensing process to address technical and policy issues with the reactor design. In this process, the leaders of the NGNP project convened approximately 25 NRC public meetings and responded to approximately 500 requests for information. This resulted in $20 million in pre-licensing fees alone. [19] Below is the entire projected cost of the development process:



By comparison, the FDA and FAA fee procurement method is phase-oriented, which results in more affordable licensing costs. For example, the FDA has fixed fees that correspond to different application types and stages, i.e. an application requiring clinical data costs $2,374,200, regardless of any other factors. [20] This fixed fee model could have an advantage over the NRC model because it reduces the variability of fee costs, giving both investors and developers a more concrete idea of the level of funds they need to raise. So while it is not out of the ordinary for licensing processes to have costs associated with the risk and task of regulating, the costs should not present insurmountable hurdles for first-movers.

A fixed fee model also could be offset further with government funds. For example, the costs associated with FAA oversight are paid for through the aviation fuel tax. [21] For the NRC, a similar process might involve the DOE passing through funds to create a dedicated advanced nuclear budget, which could include a specific pool of money to fund NRC staff time. [22] Furthermore, advanced nuclear developers could receive DOE funding support, which could act as a type of "store credit" for developers to use in the National Lab testing facilities. [23]

It is important to note that the changes we suggest here only apply to first-of-a-kind demonstration reactors and are separate from the user fee-funded work done by NRC for existing generation reactors. Moreover, once advanced demonstration reactors are built and their operational and safety characteristics are established, developers could return to the pre-established user fee model. But by modifying the NRC licensing fee model for demonstration reactors using lessons from the FDA and FAA, nuclear entrepreneurs would have a much easier time generating the funds needed to develop functioning designs even before the marketability of these new reactors can be confirmed. [24]

2. Leveraging Knowledge from the Private Sector

Advanced nuclear investors lack a signal that the NRC will create a viable path towards commercialization. This is related to the NRC's mandate not to promote the nuclear industry, which consequently distances developers from the licensing process. This separation from the industry strengthens the ability of the regulatory body to avoid industry influence and ensure safety. At the same time, the need to combat climate change and ensure energy reliability creates a ***national interest*** in getting advanced nuclear reactors developed and deployed. Congress should take the national interest into account and provide the structure and funding needed to help the NRC improve their engagement with advanced nuclear designs. To engage effectively, the NRC will need to leverage the knowledge of advanced nuclear developers to better understand the technical aspects of innovative reactor designs, in order to provide a safer path to commercialization.

The NRC itself has recognized these issues. Commissioner Stephen Burns notes that "the NRC's current regulatory framework is focused on light-water reactors," resulting in "knowledge gaps" for both NRC staff and prospective applicants. [25] But even with this recognition, budget constraints limit information exchange between the NRC and advanced nuclear developers, leaving the NRC unequipped with the necessary technical knowledge. [26] The Rand Corporation states that this "is tantamount to a demand that companies invest tens of millions of dollars developing advanced plant designs based on no more than an educated guess about what the ultimate regulatory requirements will be." [27] Developing a way to build staff expertise is essential to close knowledge gaps and stimulate developer and investor confidence.

The benefits of information exchange can be seen in the phased licensing processes of the FDA and FAA. For instance, the regulator can provide feedback on a drug or an aircraft at each stage of development, providing a signal to developers and investors that a technology is meeting or failing criteria. [28] These regulatory agencies also leverage knowledge from the private sector in other ways. The FDA emphasizes scientific partnerships with outside parties, including industry and academia, with its "Technology Transfer Program." This initiative establishes collaborative research agreements that facilitate knowledge sharing between FDA researchers and industry, academics, and nonprofits to ensure the full use of the results of FDA's investment in research and development. [29] Meanwhile, the FAA undertakes a different approach through its delegated system for certification, where developers are preapproved to take on some of the burden for ensuring quality control. [30] The FAA has final oversight, but aims to utilize the knowledge, expertise and resources of the developers by delegating safety testing. [31]

The NRC has taken steps to increase engagement with advanced nuclear applicants and potential applicants. For example, the NRC-DOE Workshop on Advanced Non-Light Water Reactors in September 2015 was an essential starting point for engagement. [32] And plans for more workshops are forthcoming. However, there needs to be a codified process in place so that industry can provide needed technical knowledge to NRC regulators, and the NRC must have a larger budget to act on the information they receive in order to build a necessary skill-set. [33] Improved information exchange could also help developers identify "key questions" that the NRC would like them to address in introductory discussions, thereby hastening the pre-licensing process. [34] In order to build knowledge and spur confidence, industry must be a partner rather than a passive observer.

3. Streamlining Demonstration Reactors to Better Assess Risks

Developers are moving from "paper reactors"—that is, designs on computer hard drives—to testing materials and building prototype or demonstration reactors. However, this transition runs up against an NRC licensing pathway process that attempts to evaluate risk based on preliminary schematics. This is unwise for both the developer and the regulator. For the developer, it significantly slows down testing, which is a challenge because developers seeking phases of investor funding can't wait years to find out if a technology is viable. It also makes the NRC's task that much more difficult, since there are few points of reference for novel reactor designs. [35] Instead of expending resources to evaluate "paper reactors," a more effective way to evaluate risk could be to test the materials and safety in action, through the construction of demonstration reactors.

This type of model can be identified in the FDA and FAA licensing process, where companies can develop a new drug or aircraft as soon as the design is approved, or even prior to approval. Once products are developed, these regulatory agencies can gather the necessary information to accurately assess risks before commercialization. For example, an aircraft has to go through flight tests before the design is approved, which means that the aircraft must already be built because the only definitive way to test risks of flight is to have it fly. [36] Similarly, in the FDA drug approval process, there are different phases of testing with different levels of risk attached. For instance, initially only twenty to eighty participants are exposed to a new drug, then hundreds, then thousands— this process makes sure that there is less and less risk as the product gets closer to market. [37] In both of these processes, the only way to accurately access risks in a timely manner is to determine the safety of a design in practice. This applies just as much to innovative nuclear technologies as it does to aircrafts and medicine.

To accurately assess risks, the NRC must be able to evaluate designs in practice. And while the NRC itself may not be able to fast-track the licensing of demonstration reactors, this lesson can be applied through the establishment of a DOE sponsored private-public partnership for a test-bed center in a low risk environment. [38] The recent White House announcement of the Gateway for Accelerated Innovation in Nuclear (GAIN) marked an important step down that path. GAIN aims to improve access to testing facilities in the National Labs. Through a test bed at the Labs or elsewhere, the NRC would be able to evaluate safety requirements for new reactor models and develop a relevant regulatory framework that accurately reflects safety concerns. This framework could take the form of a spectrum of licensing requirements that takes into account the varying safety features of advanced concepts. [39]

Conclusion

The NRC has done a great job regulating large LWRs for the past 40 years. But the agency, like the industry, stands at a crossroads. To regulate for innovation, the NRC needs a 21st century licensing pathway. While this pathway shouldn't provide shortcuts or less stringency, it should adapt to the changing face of nuclear technology in the United States. To move these technologies forward, advanced nuclear developers need a well-defined, affordable, and predictable licensing process. Congress and the NRC should examine elements of the FDA and FAA phased, risk-informed model—with modifications—to improve the nuclear licensing approach for first-of-a-kind reactors. This involves modifying the licensing fee structure, making the private sector a partner in development, and getting reactors online to evaluate risk.

This doesn't mean that there aren't other challenges when it comes to building innovative nuclear reactors. It is still necessary for nuclear developers to prove the safety of their designs and to bear these costs. They need to set up thorough simulations and undergo rigorous component testing to optimize design, minimize risk, and validate processes before construction. [40] However, the regulatory process should not work against advanced nuclear companies or create unreasonable obstacles. The NRC's job is to ensure the public is properly protected from any possible health or safety impact, and to do so it must prepare to license and regulate innovative, zero-emissions nuclear reactors. This is made even more urgent by the retirements of existing nuclear reactors over the next 25 years. [41] Cost effective and timely development of advanced nuclear technology is vital if we are to address climate change and engender a low-carbon energy future. [42]

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