

U.S. Regulatory Infrastructure Findings¹

OVERVIEW

The United States has the safest, most reliable and largest operating nuclear reactor fleet in the world – and is generally acknowledged to have the “Gold Standard” in nuclear regulation.

However, new U.S. nuclear energy development is inhibited by unpredictable regulatory processes. The U.S. Nuclear Regulatory Commission (NRC) approval of the Westinghouse AP1000 design certification, as well as the Vogtle and V.C. Summer combined operating licenses (COLs) at the turn of 2012 in the face of efforts by some to delay a final decision to incorporate post-Fukushima recommendations represented an important stride forward.

Notwithstanding, the process for new reactor licensing is still unproven and unpredictable – and still challenged with respect to full accountability, transparency and surety for stakeholders.

Compounding these dynamics is the August 7, 2012 order by the Commission to impose a moratorium on “issuance of licenses dependent on the waste confidence rule – such as new reactors” until a June 8, 2012 remand by the U.S. Court of Appeals can be addressed. The Commission is to be commended for its unanimous action directing NRC staff “to develop an environmental impact statement (EIS) and revised waste confidence decision” within 24 months.

BACKGROUND

Clearly, there would be no nuclear industry without a strong, effective regulator to assure public health and safety standards are met. Mindful of incidences such as Three Mile Island and Fukushima, stringent oversight is necessary to assure public and investor confidence in nuclear generation. This necessary oversight comes at the price of high barriers of entry for new projects

¹ *This report was prepared for the Nuclear Infrastructure Council (NIC) by its advisory committee member Margaret Harding and senior fellow Cornelius Milmoie with contributions from NIC staff and members as part of a series of papers on new U.S. nuclear infrastructure building block issues. The views expressed do not necessarily reflect the views of all NIC members.*

new technologies, and new suppliers. It makes change and innovation in the nuclear industry expensive and -- more --often-than-not -- slow.

Investors accept the familiar regulatory risks in the Food and Drug Administration-regulated pharmaceutical industry and the Federal Aeronautics Administration-regulated airline industry, where safety risks are arguably greater. However, those industries have continued to have significant technology advances and regulators have continued to update both regulations and oversight process without compromising safety.

The long hiatus in new U.S. commercial nuclear construction has resulted in regulations not keeping pace with technology development. This made investors less certain about regulatory outcomes in the nuclear industry than in the airline and pharmaceutical industries.

Building a new reactor requires NRC approval of its design, construction, and operation. Investor uncertainty about the timeliness of licensing decisions is a major obstacle for reactor developers. During the 1970s and 1980s, several new reactor projects suffered extreme financial dislocation from the cumulative effects of delays in the litigation-plagued adversarial licensing process:

- capital carrying costs during prolonged delays
- increased labor costs from inflation and rework
- higher interest charges from inflation and higher perceived risk
- the cost of replacement power;
- the cost of incorporating NRC-imposed design changes for reactors already in the construction process

These unintended consequences of NRC regulation resulted in issues with state rate regulators about the prudence of reactor investment as construction and licensing costs skyrocketed.

Reactor owners were then unable to receive a reasonable return on their investment, and in some cases defaulted on the bonds and went bankrupt.

The Energy Policy Act of 1992 spawned an overhaul of the NRC's old "Part 50" two step reactor licensing process that contributed to regulatory risk. Part 50 required reactor developers to obtain a construction license and then, after billions had been invested in the construction of the reactor, apply for an operating license, with a second round of adversarial hearings. The

reformed process, “Part 52” of the NRC regulations, has features intended to prevent the delays experienced under Part 50:

- An option for developers to obtain advance approval of nuclear power plant sites through an “Early Site Permit” (ESP) process to address site-specific environmental issues.
- A generic safety review of reactor designs proposed by reactor vendors like Westinghouse, GE-Hitachi, Areva, Toshiba, and developers of small modular reactors (SMRs). The process ends with NRC approval of the vendor’s standard reactor design by issuing “Design Certification Document” (DCD) which may be used by reactor developers at any approved site.
- A combined construction/operation license (COL) authorizing construction and operation of a specific reactor design at a specific site. The license application may reference a previously approved ESP and/or DCD.

More than a decade after Part 52 became effective; only four ESPs have been approved:

- Grand Gulf, Mississippi (Entergy)
- Clinton, Illinois (Exelon)
- North Anna, Virginia (Dominion)
- Vogtle, Georgia (Southern)

Exelon has withdrawn the ESP application for its Victoria, Texas site. The filing dates are uncertain for reactors proposed by PSEG (Salem, NJ), Blue Castle (Utah), Ameren (Callaway, MO), and Duke Energy (Piketon, OH).

Just four DCDs have been approved: GE’s ABWR, and three Westinghouse designs, the AP600, the AP1000, and the System 80). DCDs for GE-Hitachi’s ESBWR, Areva’s U.S. EPR, and Mitsubishi’s U.S. APWR are grinding through the approval process. No applications have been filed for the heralded SMRs.

No COL applications were filed, until DOE launched the “Nuclear Power 2010” program with the goal of building at least one new reactor by 2010. After that program was launched, and Congress passed nuclear development incentives in the Energy Policy Act of 2006, eighteen COL Part 52 applications were filed. Thus far, Southern’s Vogtle plant and SCANA’s Summer plant have been the only COL applications approved.

DISCUSSION

Understanding why provides some insight into the issues facing the energy industry in the nuclear regulatory regime.

DCD Certification Approval Delays

Before any COL can be approved, the DCD must make it through a detailed NRC review, oversight by the Advisory Committee on Reactor Safeguards (ACRS), and finally an exhaustive rulemaking process that includes a lengthy public comment period. Of the four designs with approved DCDs only two, the AP1000 and the ABWR, were of active interest to U.S. customers. Both required significant revisions from original DCD to meet customer requirements. Westinghouse submitted the AP1000 DCD revision in May 2007 and received final approval in late 2011. This date is about two years later than the original committed schedule.

Since 2005, vendors have sought certification of new designs: (the GE-Hitachi ESBWR, the Areva EPR and Mitsubishi's US APWR). ABWR DCD renewals have been requested by Toshiba and GE-Hitachi. But no reviews are scheduled. The Toshiba DCD for the South Texas project was approved in January 2012. In early 2011, the NRC staff issued the Final Safety Evaluation Reports (FSERs) for the ESBWR, AP1000 (rev). However, the pace of the DCD approval process continues to be very slow. The EPR and APWR DCD submittals have been delayed by 18-24 months beyond the original commitment dates. The NRC has docketed the ABWR renewal applications, but no review date has been set.

The NRC review of the ESBWR design took more than five years before the staff FSER was issued. The NRC initially estimated the FSER would take not more than two years. The causes of these delays may be debatable, but that is not the point. The point is that the amount of time (and cost) to complete the FSER was considerably longer than anticipated.

It is also unclear how many resources are being put into these efforts. The NRC has stated that a key driver in meeting its commitment dates is a utility with a stated interest in building the design in question. However, many utilities are reasonably reluctant to make a commitment to an unapproved design, thus setting up a "chicken-or-the-egg" dilemma for reactor vendors.

COL Application Delays

The NRC has expressed frustration in COLA's which reference unapproved designs that necessarily delay the staff's ability to review the COLA. However, the NRC does not have a reason for prioritizing review of DCD applications that lack active customer involvement, usually expressed by a COL application referencing the design. This has placed the utilities, reactor vendors, rate regulators, and investors in the difficult position of putting significant resources at risk in the licensing process with limited and costly options to mitigate that risk. This appears to be looming as a significant concern for SMR developers.

Delay in DCD review and approval has been a significant contributor to delays in COL processing and in some cases has contributed to applicant decisions to suspend work on some applications. If the NRC is unable to predict a licensing schedule, neither can investors or anyone else interested in nuclear development.

Additionally, the long cycle for DCD and COL review and approval can make designs outdated before they complete the process. The AP1000 required modifications almost immediately upon approval. The NRC has stated that the ABWR will require significant modifications not just for proprietary systems, but to comply with new regulatory requirements in regulation as well as technology developments.

Finally, reactor developers have been submitting COL applications without reference to an ESP, which has meant that the Site environmental reviews occur during the COL process. This has put additional burdens on the NRC staff and has slowed the process as well.

All these factors have contributed to significant delays in COL approvals to date.

Causes of Unpredictability

Several factors seem to be destabilizing the licensing process. State officials do formally intervene in NRC proceedings, and often seek judicial review of NRC decisions they don't like. Officials with little technical expertise frequently call on the NRC to take some action they think will make reactors safer.

External events

The industry and the NRC have a strong record of learning from events analyses of changing circumstances and new information. After significant events like TMI the 9/11 attacks, the tsunami at Fukushima, the Virginia earthquake, and the Court rejection of the Waste Confidence Determination update. The NRC practice has been to stop or slow work on new licenses or technology and deploy resources to address the issue of the day and make changes to existing reactors and licensing requirements to accommodate the lessons learned from the latest event. These changes made it difficult to move new designs through the process in any kind of predictable fashion, especially when the changes are not subject to rigorous cost-benefit analysis.

As an example, ABWR renewal submittals from both GE-Hitachi and Toshiba have been received by the NRC in late 2010 and were docketed in early 2011 prior to events at Fukushima, despite the fact that the NRC felt that design changes would be required that were not included in the applications. More than 18 months later, a letter requesting a response to 26 items related to Fukushima and events in the US that have not yet been incorporated into requirements for the operating fleet was sent to the applicants.

Workforce management

Licensing unpredictability is driven by human resource issues and NRC licensing management procedures. The wave of design certifications and COL applications in 2007-9 stretched the limited pool of experienced engineers and project managers as the NRC and industry hired staff to manage the significant increase in work load needed to support the licensing process. The NRC hired new staffers who were relatively inexperienced in the nuclear industry. Also, there are reports that conflict of interest concerns make the NRC reluctant to hire experienced people from industry, even retirees, for high level positions. Lack of people experienced in actual reactor operating and design practices limits NRC efficiency and reduces predictability in the review process. Inexperienced reviewers make Requests for Additional Information (RAIs) to obtain background information they need to develop the technical knowledge to render a valid assessment of the assigned work. These unexpected “Teach Me” RAIs caused extra work for applicants delaying their responses to safety-related RAIs. In some cases, reviewers have demanded explanations why designs do not comply with standards that are not applicable to the technology under review. Applicants have been required to modify DCDs to reflect these

demands. On at least one occasion, the issue escalated all the way to the ACRS before outside experts were able to make the issue clear to the NRC reviewer and the inappropriate requirement eliminated.

The long license cycle and overlapping review scope has caused previously closed issues to be re-opened. When applicants point out that RAI questions have been asked and answered, the typical response has been that the new reviewer doesn't understand or accept the prior reviewer's analysis. While it is recognized that errors and/or differences of opinion occur, the applicant should not see these "Zombie" RAIs. Such issues should have been handled internally. Such "Zombie" RAIs raise a knowledge transfer concern that the NRC is not adequately documenting the review process internally such that others can read and understand a reviewer's decision. If information beyond the original RAI is required, the issues should be clearly understood and communicated to the applicant. These "Zombie" RAIs cost the applicant and the NRC time and money.

There have been reported cases where the NRC's Difference of Professional Opinion (DPO) process has caused delays or unintended consequences. The DPO process was strengthened after lessons learned from the Davis Besse incidents and is intended to protect NRC employees who raise concerns about safety determinations. This is a sound concept and can improve safety. However, employees who threaten to invoke the DPO process to force NRC management to make inappropriate and excessive demands on an applicant disrupt an already thorough process. On the other hand, senior NRC management should not automatically sanction a manager if a formal DPO comes from a member of his team. Punishing the manager may induce managers to avoid the DPO process by compromising with reviewers who raise groundless concerns.

A large number of RAIs required in the review of license applications indicates insufficient review during the docketing process. The NRC can reasonably expect that the information in the license application is sufficient for its review. It is troubling that a supposedly complete submittal might require hundreds of RAIs to garner enough information to support a licensing decision. It would be prudent for the NRC to focus resources during the docketing review to determine that all information required for review is available in the application. Inadequate submittals should not be docketed and the applicant should be provided with a clear explanation of the docketing decision.

The NRC has observed that revisions to the DCDs sometimes contained significant design changes from the prior versions. Such changes are frustrating both for the applicant and for the NRC, which may have to reconsider parts of the submittal that had been at or near completion. In some cases such issues may have been avoided if a more diligent pre-docketing review had uncovered inadequate documentation.

Finally, NRC press releases or leaders have criticized applicants regarding normal review issues and characterize applicants as unresponsive or applications as being of poor quality. These comments may engender a lack of confidence in the process in both the public and investors and do not promote safety. Such comments create an adversarial relationship between the NRC and the applicant and work to undermine cooperation and lengthen the review by discouraging honest exchange between applicant and reviewer.

Looming challenges

The NRC faces a number of challenging assignments that are crucial to new DCD and COL applications:

- Completion of pending reactor DCD and COL application proceedings.
- Uncertainties about spent nuclear fuel management and the outcome of the Waste Confidence
- DCD applications for SMRs, next generation gas reactors, and fast reactors

CONCLUSIONS

A rigorous NRC licensing process, even one that takes a long time, is not necessarily an issue for nuclear developers and investors. It can be managed. Effective NRC regulatory oversight is beneficial. It increases public confidence in the industry. The issue for nuclear developers, investors and reactor vendors is an unpredictable process that does not increase public confidence or safety in the industry. Uncertainty about the length and outcome of the process is a problem. An unpredictable process that has no cost or schedule discipline is unmanageable and makes nuclear a less attractive option for the electric power industry.

Approval of the Vogtle and Summer COLs was a positive step, but new reactor development faces significant regulatory risk. Schedule and cost uncertainty create a vicious cycle. Without patient investors, it is difficult for reactor vendors to develop and license new designs. Without licensed reactor designs, developers are unable to make firm cost and schedule estimates for new reactor construction. Without firm cost and schedule estimates or government protection against regulatory delays, investors require an increased return on their investment. We have already seen this increase in the estimated cost of new reactors. Regulatory uncertainty is a particular challenge for SMR developers.

Actions that would improve the efficiency and predictability of the NRC process include:

1. Complete the current roster of new LWR designs. To improve confidence in the industry and the NRC licensing process, the NRC should outline a comprehensive schedule going forward with target dates for approvals. The following actions would accelerate priority applications:
 - Project Managers (PMs) should curb “Teach Me” and “Zombie” RAIs. As a part of this effort, the performance of PMs across the commission should be reviewed to ensure consistency of process.
 - Procedures for decisions on issues where safety is not affected should be reviewed and streamlined.
 - Mandatory hearings should be conducted concurrently with the review process as areas are ready for hearing rather than waiting for all hearings on all issues at the end of the process.
 - Complete the reviews of the pending DCDs and establish firm schedules for completing active COLs and ESPs.
2. To create a sustainable, predictable process to license safe and cost-effective nuclear power plants, the NRC and industry should consider a joint task force or other vehicle to develop lessons learned from the AP1000 and ESBWR DCDs and the Vogtle and Summer COLs.
 - Implement these lessons in the NRCs Standard Review Plan (NUREG-0800), Regulatory Guide (RG) 1.206, and all supporting RGs and other documents that inform DCD, reference COLAs, and subsequent COLA reviews with a goal of improving on schedule predictability and efficiency. Reliable NRC process milestone predictions will give

confidence to applicants, investors and the public that schedule and cost targets will be met, and project licenses will not be delayed by opponents who manipulate the process. A part of this reform should include more concurrent development of SERs by beginning development of SER after first round of RAIs is completed.

- Industry should also implement lessons learned in their submittal processes to improve quality of submissions and help the NRC perform reviews more efficiently.
 - The NRC pre-docketing review of DCD and COL applications needs to be more thorough. By spending more time early in the process identifying weaknesses or inadequate documentation, the NRC and the applicant will be better able to manage the process and predict more accurately the amount of time and resources required to complete the licensing process. This may require a longer docketing and acceptance period for such applications. Before docketing, the applicant should have the burden of proving the application contains the information needed to make a final safety decision. If the NRC staff is not convinced the application is ripe, it should not be docketed. After docketing, however, the burden should shift and the NRC staff must prove that a response to each RAI is needed to make a licensing decision.
 - A fundamental review of the licensing process and licensing fee structure needs to be undertaken. Application of current policies stifle innovative reactor designs like SMRs by making license process costs, and costs of complying with large LWR standards so high that investment in SMR development is not economic.
 - The NRC should develop a clear guideline for incorporating new information into the licensing process. Any changes proposed after an application has been docketed should be considered similarly to changes required of the operating reactors. At a minimum, there should be a cost benefit analysis reflecting the increased costs of design changes.
 - Similarly the applicants should promptly notify the NRC when design changes are required after docketing and work to minimize such changes.
3. Some reforms may require Congressional action to align the NRC with the best practices of other regulatory agencies like the FDA and FAA.

- Congress should streamline the extended appeal process, mandatory hearing process, and other adjudicatory procedures to be more in line with those of other agencies like the FDA and FAA. These agencies protect public safety with more efficient processes.
- Congress should require the NRC to perform a cost-benefit analysis for all regulations and standards for small and advanced reactors. The NRC performs cost benefit justifications before it requires operating reactors to back-fit to conform to a new regulatory standard (“the back-fit rule”). However the NRC can make new regulations applicable to future plant designs without making much of a case for their benefit. In many cases, these changes significantly increase cost of construction and operation and contribute almost nothing to the safety of the public and plant workers. The NRC must be prudent to avoid requiring high cost, low-benefit changes to address lessons learned from the Fukushima incident.

The NRC and the industry should be encouraged with the collective work done to complete the DCD for AP1000 and to bring first-in-kind COLs to fruition after a decades-long hiatus of since the last new construction permit was approved. However continuous improvement in processes must continue to assure safe nuclear energy is available to provide reliable, affordable, clean and secure energy for a competitive U.S. economy.