

Remarks of Commissioner Stephen G. Burns
Reformed and Reforming: Adapting the Regulatory Process to Meet New Challenges
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I've titled my remarks today *Reformed and Reforming: Adapting the Regulatory Process to Meet New Challenges*. The theme expands upon an article that I recently published in the OECD Nuclear Energy Agency's *Nuclear Law Bulletin* which was specific to the licensing of advanced reactors. However, in reflecting on what I would speak to you all about here today, I wanted to expand on the premise of my article to cover the topic more broadly.

I first joined the NRC 40 years ago, fresh out of law school. It has struck me over the course of my 40 years in this field that there is often a central conundrum in regulation, and we continue to be challenged by that conundrum today. Let me elaborate. There is often broad agreement that the level of safety or security established by certain regulations, license conditions, or other legally binding instruments is, in the judgment of technical experts, too conservative, based on outdated information, or imposes an unnecessary regulatory burden. The regulation says you must have a 12-inch diameter widget, but professional expertise tells us that an 8-inch diameter widget will suffice. What to do? Both the regulator and the regulated seem equally frustrated, asking "why do we spend so much time trying to resolve issues of little safety significance?"

Part of the cause may be what some refer to as "paralysis by analysis" or "processitis," where we may get so caught up in following a particular way of doing things that we lose sight of the bigger picture. Or we can't seem to reach the point of satisfaction in analyzing a problem, and thus the process becomes paralyzing.

I have seen this over and over again through my career, without any lasting solution proposed or implemented. If you were hoping that I would come to you today with such a solution – or a "destination," so to speak – you will be sorely disappointed. Like my past remarks, I intend to focus on the journey of nuclear regulation, not necessarily the destination. My intention is to give you perhaps a new lens through which to think about some of our current challenges.

I will offer three current examples where this tension is playing itself out as we speak: digital instrumentation and control, accident tolerant fuels, and the licensing framework for advanced reactors. In my view, these are concrete examples where we have struggled to find reasonable solutions, in large part because we feel inextricably tied to our regulatory structure and we have been slow to acknowledge some of the difficulties in adapting that structure. However, in some respects, I would argue we are seeing some success in overcoming this dilemma. Before I begin, and certainly before I begin looking toward the future, I'd like to tell you a story about how past is often prologue.

Back in November 1971, I was an 18-year-old college freshman from Virginia, settling into academic life in upstate New York. If you remember your freshman year, you know there are a lot of adjustments to make, and most students are focused on dealing with new teachers, a new campus, and new friends. And so I was. But I was also determined to cast my vote in the first election for which I was eligible, right after the 26th amendment to the Constitution gave 18 year olds the right to vote, and so I went to the university registrar's office to fill out my absentee ballot.

I intended to vote a straight Republican ticket to support that party's push under Governor Linwood Holton to shed Virginia's legacy of segregation, but I accidentally selected two candidates on my ballot for the House of Delegates for whom I did not intend to vote. I carefully crossed out those names and wrote in "do not desire to vote for these two" on the ballot. All good as far as I was concerned. Unfortunately, others thought otherwise and my "defaced" ballot was rejected, which, unbelievably enough, led to a tie for that house seat. As an aside – yes, every vote does count. In the case of a tie, according to Virginia law, the winner is left to chance and literally drawn from a hat, well, in this case, a silver cup. By the way, my candidate won. It's a fun story, recently recounted by the *Washington Post*.

But why is it relevant now? Fast forward to late 2017. Forty-six years after my voting snafu, Virginia faced exactly the same unlikely predicament involving a disputed ballot, a tied race and a tie-breaking lucky draw to settle a state House race.

The *Washington Post* re-told this story for the same reason I am recalling it now. We often think that what we're facing today – in politics, in industries, in academia, in regulatory space – is completely novel, something never seen before. And it's just not true. There is an NRC press release with the headline "Nuclear Regulatory Commission Directs Staff to Take Experimental Steps to Improve Licensing Process." Nothing particularly surprising there. But note -- the press release is dated October 20, 1978, two months after I began my career at the NRC.

And here's something else that might sound familiar. Both the *New York Times* and the *Washington Post* ran front page stories: "President Offers Plan to Reform Federal Agencies." Which President, you ask? It was President John F. Kennedy and the stories ran on April 14, 1961. (I also note that the headline for that day was Cosmonaut Yuri Gagarin's successful orbit of Earth). Undoubtedly, we could find similar stories under more recent Presidents from Reagan to Obama.

I do not mean to be dismissive of the underlying premise that regulatory reform and effectiveness demand our attention. It clearly does. But, certainly from a regulator's perspective, neither the evolution of technology nor the institution of major regulatory reform initiatives is new or novel. Every administration in the modern era has engaged in some regulatory reform initiative. And while some of the technology and processes behind advanced reactors, accident tolerant fuels, or digital I&C might be new or novel, the challenge of appropriately regulating new technology is not.

The regulatory conundrum I mentioned at the outset manifests itself in any number of ways: prescriptive versus performance-based regulation; deterministic versus risk-informed thinking; compliance-based versus safety-focused regulation. Whatever you call it, they all share similar characteristic; the NRC has put in place a legally binding mechanism, or an interpretation of such, be it a regulation, an order, a license, or guidance that contains a requirement or guideline that is challenged by some as being too conservative, unnecessary, or outdated and as such an unnecessary hindrance to innovation, improvement, or progress. The basic tension in these expressions underlies much of what I have in the past referred to as the "regulatory craft".

At its very heart, this tension underlies a fundamental notion of our form of government, which is based on law and not the whim of individuals. This conflict between the so-called rule of law vs. the rule of man dates as far back as the beginning of democracy.

Although many of us have heard or used the expressions "rule of law" and "rule of man," how those terms are precisely defined is somewhat difficult to come by and varies based upon

context. I would offer that collective societal recognition of the supremacy of law, even those laws that we as individuals might not agree with, is essential to our system of government. The supremacy of law is based on society's acknowledgment that laws were enacted through an agreed-upon legislative process (such as that defined in the U.S. Constitution) through which the people of this nation have had some opportunity (usually through the political process) to voice their views.

On the other hand, what can be at times antithetical to the rule of law is the so-called rule of man. In the context of our discussion today I'm referring to situations in which individuals or groups reject laws for their own reasons, or, alternatively, the government entity charged with implementing the laws arbitrarily chooses not to apply laws. When parts of a society – be it the government or the public – choose not to follow its laws, this is essentially a breach of the “social contract” posited by the philosopher Jean-Jacques Rousseau.

We, as regulators, go through complex legal processes involving significant public input to adopt regulations or to issue licenses. Regulatory decisions can manifest themselves in the application of expert engineering or professional judgment, or even simply “common sense.” The requirements reflected in regulations or licenses are, therefore, in a real sense the “law of the land,” and choosing to arbitrarily ignore them comes with consequences.

But at times, we may come up against some rule or regulation that just doesn't make any sense. As Plato noted, a failure by rulemakers to acknowledge and take action when a rule has ceased to achieve its intended purpose is “like a stubborn, stupid person who refuses to allow the slightest deviation from or questioning of his own rules, even if the situation has in fact changed and it turns out to be better for someone to contravene these rules.” (Plato, *Statesman* 294b–c)

In other words, sometimes simply asserting that “this is the way it's always been done” is just not good enough. In fact, it may even be counter-productive to optimizing regulatory effectiveness. Thus, a natural tension exists between the societal need for predictable rules and the need for flexibility to apply common sense or acknowledge new information when needed. This is the heart of the regulatory conundrum of which I speak today.

The imperative of addressing this regulatory conundrum increases during times when resources are limited and when agencies often face increased political pressure to rationalize or reset their practices. This can manifest itself in general government-wide reform efforts initiated by almost every administration in the modern era. There is also constant pressure on the regulator to be more risk informed, efficient, and predictable.

The NRC has been notably proactive over the last few years when it comes to taking a hard look at itself. Examples are, of course, Project Aim, the reassessment of our budget requests and staffing levels, reforms to the rulemaking process, and the initiation of a retrospective review of regulations.

In my view, the NRC's statutory mandate under the Atomic Energy Act to provide reasonable assurance of adequate protection gives the agency significant flexibility to adjust itself over time to account for the regulatory conundrum I have discussed. “Reasonable assurance of adequate protection” is not a static concept. It should be fluid and adaptable to the current state-of-the-art in science and technology, and reflect the current security environment. What was deemed necessary for reasonable assurance in 1954 surely is not the same as it is in 2018.

Compliance with the NRC's regulations, for example, has long been understood to ensure adequate protection, but there are often times when the regulations are deemed not enough or too much. After the 2011 accident at Fukushima Dai-ichi, for instance, the NRC determined that the level of protection for U.S. nuclear power plants was not sufficient, and accordingly, NRC took action to increase those standards. Both expert judgment and common sense dictated that be the case, but in acknowledgement of the importance of the rule of law, changes were made to existing standards through established and transparent processes.

On the other hand, the NRC at times must acknowledge when its existing standards of safety may be higher than necessary to achieve adequate protection. An example is requirements for decommissioning power reactors. From a technical and safety perspective, we understand that these facilities do not need to be regulated to the same standards as operating facilities, yet our rules as currently written do not distinguish between the two. Recognizing this, NRC has granted exemptions under its regulations to adjust the level of regulation necessary to achieve adequate protection and is also engaged in a rulemaking to codify this judgment. But again, we do so through a public, formalized process consistent with the rule of law.

Yet another example where the regulatory conundrum comes up is the inspection process. You can imagine a situation – and I assure you it's not imaginary – in which an NRC inspector makes a finding that a licensee is not in compliance with a regulation or a provision of its license. Both the inspector and the licensee may even agree that the licensee is not in compliance, and may even also agree that the non-compliance has marginal safety significance. What is the inspector to do? Ignore the issue? Not document her findings because, in her expert judgment, the issue is not safety significant? In other words, should that inspector apply her personal discretion to decide unilaterally that the license provision makes no sense and doesn't need to be adhered to?

Some might say, of course, that this is just common sense and to initiate a regulatory process to deal with a trivial issue is a waste of resources and time. But again, the license is "law," and if we all truly have respect for the rule of law, then out of principle should we allow this to occur? If the situation were different, and the licensee disagreed with the inspector on both the interpretation of the license and its safety significance, would we all be comfortable with allowing the inspector to exercise her judgment? I would suggest that we would not.

What is my point? Every day, we confront this regulatory conundrum, be it in regulations, licenses, inspection findings, regulatory interpretations, or issuance of exemptions, but we have to be extraordinarily careful in making snap judgments based on particular facts or circumstances that either our regulations or regulatory interpretations are infallible, or that "bad" requirements can simply be ignored. The integrity of our system depends on principled adherence to the process, even when it makes little sense to anyone. That said, the NRC as the regulator can and should be more flexible when it comes to finding ways to deal with this so-called conundrum. As Ralph Waldo Emerson commented, "A foolish consistency is the hobgoblin of little minds, adored by little statesmen and philosophers and divines." I said that this conundrum – this tension - challenges us every day. I'll mention a few examples that will be familiar to many here.

First, take digital instrumentation and control. I can think of no better example that demonstrates the difficulty of overcoming regulatory controls that do not appear to align with technological advances. In this case, NRC safety criteria do not readily address how typical regulatory concerns manifest themselves in digital systems. And while we all agree that digital systems have the potential to improve safety and operational performance when compared to existing analog systems, we have been unable to overcome the hurdles of the existing

regulatory process to license them, even as other industries with similar low risk tolerances (such as defense, aerospace) have succeeded.

The irony is that, in a legitimate effort to ensure that plants are safe, the NRC may be imposing regulatory obstacles that prevent the implementation of safety improvements through digital upgrades.

The NRC and the industry continue to discuss these issues frequently, and, in fact, are meeting again this week. In addition the NRC's Executive Director for Operation's recently created Transformation Team has targeted this subject as one area to explore for future transformation, hoping to improve our ability to enable the safe and secure use of new digital technologies.

Another example is the industry's pursuit of accident tolerant fuels. Several fuel vendors, in coordination with the Department of Energy (DOE), have announced plans to develop and seek approval for various fuel designs with enhanced accident tolerance.

The first testbed for these efforts involve licensees that have reached agreements with fuel vendors to load lead test assemblies at their plants. Lead test assemblies are an important first step in the licensing of new fuel designs because they can provide data about the performance of the new fuel in a reactor environment as well as provide materials for subsequent research and testing. Even though lead test assemblies have been installed at many plants in the past, the agency and the industry have been challenged to agree on the appropriate licensing path forward for those plants planning to load lead test assemblies in the near future.

This is a practical example of the tension between adherence to the established regulatory regime and allowing adaptation or flexibility to address new innovations. The past NRC practice has been to largely require NRC approval of exemptions to our ECCS requirements and often license amendments before lead test assemblies could be loaded at an operating plant. This is despite the fact that, in most cases, the safety significance of loading these lead test assemblies in these quantities is extremely low. I would note, however, that upon closer examination of the existing requirements it appears that exemptions and license amendments may not always be required.

I think it's fair to say that with both digital I&C and with accident tolerant fuels, the NRC is struggling with the process. Some in the agency may appear to be reluctant to let go of existing regulatory requirements even when some expert judgment or perhaps even common sense seem to dictate those regulations do not squarely address the exact problem or are too heavy-handed given the level of risk. It seems that we struggle to be flexible and honestly acknowledge the level of risk. Rather, many are finding it easier to steadfastly cling to what is known, proven, and deterministic.

In contrast, I offer the example of the NRC's work on advanced reactors. Despite some early criticism that the NRC has been slow to act and the existing regulatory structure made it difficult for new entrants to get involved in the field, I would argue that the NRC has designed a strategy that is extremely flexible and forward-looking. In simplest terms, the conundrum is represented by the fact that the NRC's current technical standards applicable to plant licensing have been drawn largely from experiences with light water reactor technology. It has been argued that these standards are overly conservative, not risk informed, or simply inapplicable to some advanced nuclear technologies. The appropriateness of current regulatory standards and the need to make changes to address advanced reactor technologies is an important issue -- and one that may well warrant regulatory changes in the long term. But, at least in the near term,

case-by-case assessments of the particular relevance of generic technical standards and requirements to the technology being put forward in an application will be necessary. Let me discuss some examples, however, where the NRC has proactively tried to address the limitations in its framework. Beginning in 2010, for instance, the NRC staff began work on re-looking at a number of policy, licensing, and technical issues that might warrant further Commission engagement as the staff prepared for reviews of SMR designs. Generally, those issues included accident source terms, site suitability, emergency planning, security and safeguards requirements; and the application of defense-in depth. I believe the NRC is making real progress on these issues.

Also, in 2013, the NRC and DOE initiated a joint effort to address the licensing framework for advanced non-LWR technologies that ultimately led to the 2017 issuance of a draft regulatory guide addressing general design criteria. In late 2016, the NRC issued a vision and strategy statement and developed implementation action plans to address actions to achieve its objectives.

The NRC has also looked for experience with staged approaches to licensing used by other federal agencies, including the Federal Aviation Administration and the Food and Drug Administration and within the international community, such as Canada's Vendor Design Review and the United Kingdom's Generic Design Assessment

The NRC staff also recently issued its Regulatory Review Roadmap in December 2017. The roadmap illustrates how a staged approach can align with the current licensing process. Looking further down the road, efforts to update the NRC's framework to be more technology-neutral and inclusive, risk-informed and performance-based are also underway.

I purposely used in the title of my *Nuclear Law Bulletin* article and for these remarks the phrase "reformed and reforming." Although that phrase is generally used in an ecclesiastical context (and for those of you who marked the 500th anniversary of the Protestant Reformation this past October, you will know what I mean), the phrase underscores my view of the historic and ongoing approach the NRC has taken to meet the challenges put before it. The NRC continues to examine itself, its processes and approaches, to adapt them when necessary, and to reflect in good faith on experience gained and then reform yet again when needed to meet new challenges.

In order to come up with practical and implementable solutions to our current challenges, we must first and foremost acknowledge the reality that we exist in a system of laws and that those laws have meaning. We can't take short cuts simply for the sake of expediency or because the rules or the processes for changing the rules seem inconvenient in the moment. A principled and consistent acknowledgment of the rule of law is essential to the integrity of our system.

But that said, the rules should not be seen as infallible, unbending, or unchangeable. Rules that no longer serve their intended purpose or that are, because of advancements in technology or operating experience, determined to be overly conservative, can and should be changed. The NRC should make realistic acknowledgments of risk and always keep in mind its statutory mandate of reasonable assurance of adequate protection.

This notion of being "risk-informed" can apply equally to our processes as well. I mentioned the terms "processitis" or "paralysis by analysis" earlier, and it seems at times that we can all get stuck on processes and not solutions. Adjusting our standards or processes to keep up with the times cannot move at the glacial pace that it sometimes seems to take. When I started at the

agency 40 years ago, rulemakings, for example, took on average of 2 years, but now the average is closer to 4 years – this despite major technological changes that should make the process more efficient and capable of being responsive.

Blind adherence to a process simply for its own sake does not advance nuclear safety and does not reflect well on the NRC as an efficient and effective regulator. At times it can also cause us to lose the forest for the trees. No doubt the trees are important, but the forest, like nuclear safety, is the bigger picture, and we cannot lose our focus on that. To do this, we must be honest with ourselves and be able to assess if our processes are truly furthering the mission of safety, and we must be willing to reassess whether there is not a better or more innovative way to ensure that.

The reformation of the NRC is not a destination; it's a journey. We will never be able to say "mission accomplished" in trying to reach some of these ideals, nor should we. Much like the technology we regulate, we as the regulator should be constantly evolving and reforming.

I'll leave you with a quote from Thomas Jefferson. If you've ever visited the Jefferson Memorial in the Tidal Basin, I'm sure you've seen four passages from Jefferson's writing inscribed on the walls. The quote on the Southeast Portico seems apropos: "I am not an advocate for frequent changes in laws and constitutions, but laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths discovered and manners and opinions change, with the change of circumstances, institutions must advance also to keep pace with the times. We might as well require a man to wear still the coat which fitted him when a boy as a civilized society to remain ever under the regimen of their barbarous ancestors."

Jefferson's words align with my view of why the NRC must continue to examine itself, its processes and approaches, to adapt them when necessary, and to reflect in good faith on experience gained and then reform yet again when needed to meet new challenges.

Propellente reformata, semper reformanda: the agency is reformed, and is always being reformed.

Thank you and I'd be pleased to take your questions.