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Mr. Yukiya Amano, Director General
International Atomic Energy Agency
Wagramer Strasse 5
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Dear Director General Amano::

I am writing in my capacity as Chairman of the International Nuclear Safety Group ("INSAG"). Our terms of reference state that INSAG should provide "recommendations and opinion on current emerging safety issues" to the IAEA and others. During my term as Chairman, I have customarily sought to fulfill this obligation not only through the various INSAG reports, but also with an annual letter. My past letters are available on the INSAG website at http://goto.iaea.org/insag. This correspondence constitutes this year's installment of the annual letter.

As you are aware, there are now 450 power reactors in 31 nations that serve to provide about 11 percent of the world's electrical energy. Moreover, some 57 reactors are under construction and many more are contemplated, some in countries that do not currently benefit from nuclear energy. Nearly all of these reactors are water-cooled reactors[1] and, no doubt, most of the reactors to be built over the next decade or two will also be water-cooled reactors. Nonetheless, there is great interest in the pursuit of advanced reactors that do not use water as a coolant and moderator. These reactors use gas, molten salt, or liquid metals.[2] Advocates for these reactors believe that they may offer greater safety and security, improved economics, greater thermal efficiency (perhaps including the production of high-temperature process

[1] Most are light water reactors, but some countries have also deployed pressurized heavy water reactors.

[2] Some of these reactors, but not all, are small modular reactors ("SMRs"). There are also SMRs under development that use water as a coolant and some of these reactors have novel features, such as passive safety systems, that present some of the regulatory challenges that confront applicants for advanced reactors using other coolants. Of course, reactors using other coolants can present a wide variety of additional challenges. Several new-entrant countries are considering SMRs.

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heat), better fuel utilization, more benign and reduced mass of spent fuel, or a greater opportunity for burning stockpiles of plutonium.[3]

At this point, it is uncertain whether the promises of the advanced reactors will be realized. But, given the interest, it is necessary to prepare a regulatory infrastructure that can accommodate advanced and innovative designs effectively and efficiently. This task presents both procedural and substantive challenges. This letter is to alert the IAEA that more needs to be done in this area and to provide a broad overview of the nature of these challenges and some of the means to address them.

I. Procedural Innovation

Although the regulatory process can vary from country to country, most existing reactors were licensed using a two-step process. The first step is the issuance of a construction permit. Many issues, including in particular the adequacy of a site and environmental concerns, are addressed at this stage. Although a preliminary review of the design typically occurs at this early stage, the detailed review required for the issuance of an operating license typically occurs only during and after construction. This two-step process can be fully satisfactory for licensing a reactor that is identical (or at least substantially similar) to a plant that has already been licensed. In that case, there is precedent to guide the designer on compliance with regulatory obligations and the previous regulatory approval provides a measure of certainty as to the acceptability of the design. But the process presents a challenge to those who would pursue a novel design.

The two-step process can present unacceptable financial risks for those pursuing a novel design because the final determination of whether a given design can be licensed is resolved only after the construction is complete and an operating license is pursued. At that stage considerable funds have been invested. Moreover, the approach involves a licensing process that involves a particular utility at an identified site, not the determination of the general suitability of a design by a vendor. (Of course, vendors will advance designs that they anticipate are suitable for a range of sites.)

The United States sought to resolve this dilemma by establishing an alternative approach (reflected in 10 CFR Part 52) by which a vendor could pursue a design certification by the Nuclear Regulatory Commission ("NRC"). This certification can be issued long before there is a commitment to actually construct the design and is independent of any specification of a particular site. Because the design certification precedes any safety-related construction (absent authorization), there is less danger of regulatory determinations during or after construction that challenge the suitability of

[3] New fuels are also being developed for water reactors that offer the prospect of improved safety.

the design.[4] Of course, a subsequent decision to construct the reactor requires that the design must be compatible with the risks presented by the particular site (earthquake, wind, flooding risk, etc.).

Although design certification provides some early certainty as to the adequacy of a design, the US experience has shown that the cost of design certification can approach a billion dollars because of the necessity for submission of a well developed design for NRC review, along with all the necessary test data. Design certification thus involves a formidable front-loaded investment. Moreover, once a design certification is issued, any changes in the safety features may necessitate a new regulatory process for approval of the modifications. Thus, design certification may serve to "freeze" the design prematurely.

The pursuit of the commercial deployment of a new reactor technology can involve a multi-billion dollar investment that is made over many years. In general, investments in advanced technologies in other fields are typically made in stages or graduated steps in which increasing levels of investment are made at each stage as risks are retired. Some of the risks associated with the pursuit of an advanced reactor technology are technical: an idea for a new approach may not work out on further detailed scrutiny. Another risk arises from the market: namely, the risk that a new design may prove unattractive to potential purchasers. Yet another risk is regulatory in nature: the regulator may find a new technical approach to be unacceptable or might impose requirements that increase costs prohibitively.

This latter risk is believed to be particularly inimical to investment in a novel technology because the regulatory risk may be difficult for an applicant to assess. As a result, there are proposals for the implementation of a staged regulatory process in which regulatory issues are resolved in a stepwise fashion in a way that is compatible with a staged series of investments.[5] That is, regulatory issues would be resolved in increments that accommodate ever-growing tranches of investment as regulatory risk is reduced.

Many countries have processes that allow a vendor to engage with the regulator to obtain some early guidance on particular points. Both Canada and the U.K. have regulatory processes that allow early resolution of many licensing issues and they are cited as models that are compatible with investment needs.[6] That is, both the Canadian Nuclear Safety Commission and the UK Office of Nuclear Regulation provide reasonably comprehensive feedback to an applicant about a design at early

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[4] Some regulatory risk will always remain. Experience or experimental data may ultimately reveal safety challenges that require modification of the design.

[5] See, e.g., Ashley E. Finan, Nuclear Innovation Alliance, "Enabling Nuclear Innovation: Strategies for Advanced Reactor Licensing" (April 2016) (http://www.nuclearinnovationalliance.org/#!advanced-reactor-licensing/xqkhn).

[6] See id.

stages. Similarly, the NRC has stated that it can apply existing review processes to advanced reactors to allow early determination of critical issues.[7] These regulators, as well as some others, seek to accommodate a vendor's need for early determinations of compliance with regulatory requirements as the design of a reactor is refined.

When and if the world turns to advanced reactors, there will be growing need to adjust regulatory processes to accommodate the vendors' legitimate needs for early regulatory guidance. A staged review should be applied comprehensively in order to facilitate efficient licensing.

II. Substantive Regulatory Innovation

There are very mature regulatory requirements for the licensing of water-cooled reactors, but these requirements may be inappropriate for many advanced reactors.

The first commercial reactors were licensed in the 1960s, a time when knowledge was limited. Licensing focused on assuring that the reactors could survive certain design basis events, such as a large-break loss-of-coolant accident, by establishing both the need and specifications for safety systems. The intention was to select a suite of Design Basis Accidents ("DBAs") that encompassed many of the possible events that, absent safety systems, could disrupt operations and result in core melt or radioactive releases. As the utilities and regulators gained greater experience, as well as a better understanding of the gaps in licensing, the regulatory system evolved to add a broader suite of circumstances and requirements than were originally contemplated. In the early years, regulators applied deterministic analytical techniques and imposed requirements that were frequently based on judgment; probabilistic techniques were not adequately developed at the time the basic regulatory structure was established.

Beginning in the early 1990s, the nuclear industry began to utilize Probabilistic Risk Assessments ("PRAs") to assess and manage nuclear risks. These PRAs treated the plant as an integrated system and enabled utilities and designers to identify accident sequences and assess their frequencies. PRAs had a profound impact on the understanding of reactor safety. For example, the PRAs identified the risk significance of human errors and of accidents not previously considered, such as anticipated transients without scram and station blackout (the accident experienced by the Fukushima Daiichi plant). Moreover, they revealed the risk significance of more frequent events (such as small-break loss-of-coolant accidents). The result is that the current regulatory structure consists of deterministic requirements with an overlay of

[7] NRC, "A Regulatory Review Roadmap For Non-Light Water Reactors " (2017) (https://www.nrc.gov/docs/ML1731/ML17312B567.pdf)

probabilistic elements; this framework provides an extensive and complicated set of requirements that are prescriptive in some regulatory systems.[8]

Because most of the commercial nuclear units were water cooled, the regulatory requirements were tailored to the risks these reactors presented. Many regulators provided prescriptive requirements that provided a large measure of assurance and predictability to vendors and utilities of how regulatory requirements could be satisfied in licensing. But the approach may be ill-suited to some advanced reactors.

The reason is that many of the requirements in the existing regulatory system are not necessarily appropriate or relevant for advanced reactors using coolants other than water. Such reactors may present entirely different risks and, indeed, some of the requirements make no sense in application to these designs. For example, requirements for emergency core cooling in water-cooled reactors result from the behavior associated with rapid depressurization of high-pressure water and are inapplicable to reactors operating at or near atmospheric pressure, such as those cooled by liquid metal or molten salt. Moreover, there are accident sequences associated with some advanced reactors, such as those involving sodium fires, that are not part of the regulatory framework for water reactors.

Because the state of knowledge regarding the operation of nuclear power plants has advanced considerably over the years, there is now an opportunity to use new understandings and methods as the foundation for a revised regulatory system and thereby avoid the serious challenges that would attend an effort to adapt regulatory requirements developed for water-cooled reactors to reactors of very different types.

One of the serious challenges in applying the existing regulatory requirements to advanced reactors arises from the uncertainty that is associated with identifying appropriate Licensing Basis Events ("LBEs")[9] and developing the associated requirements to meet them (such as defining the DBAs and the requirements that must be satisfied by systems, structures, and components). This situation can be addressed through the development of a process to define the critical regulatory elements in licensing through a blend of deterministic and probabilistic inputs. That is, the licensing process should be fully risk-informed. The process might best be founded on a technology-inclusive methodology for the identification of a set of LBEs appropriate to a given reactor technology using both deterministic and

[8] Learning from PRAs continues today. The Fukushima Daiichi accident revealed the necessity for PRAs to include multi-unit risks – that is, the impact of an event at one reactor on others. There is a major effort underway to expand PRAs to accommodate multi-unit risk.

[9] LBEs are defined broadly to include all the events that could affect the safety aspects of the design. They cover a comprehensive spectrum of events ranging from normal operations to rare, off-normal events.

probabilistic methods to define the risk-significant accident sequences.[10] A previous INSAG report, A Framework for an Integrated Risk Informed Decision Making Process (INSAG-25, 2011), should be applied to the challenge of developing the substantive requirements to be satisfied in the licensing of advanced reactors.

Defense in depth ("DID") must remain a central principle in licensing. DID is aimed at providing necessary assurance that the plant has a robust safety capability, but DID requirements are customarily determined by application of a large measure of judgment. By examining event sequences using deterministic and probabilistic safety evaluations across the whole spectrum of LBEs, a systematic assessment of DID might be accomplished, clarifying the balance of prevention and mitigation and identifying important DID elements covering design, manufacturing, construction, testing, and operational activities. This is a challenging task that will require time to accomplish, but the aim of the analysis should be to define the scope of the DID requirements in a logical and reproducible fashion.

Of course, an additional challenge in the regulation of advanced reactors arises from the simple fact that we have less experience with them; knowledge of the physical phenomena that affect safety is more limited for advanced reactors than for current water reactors. This reality should be accommodated in defining the LBEs and indeed, the analysis discussed here can help in determining the appropriate focus of research efforts bearing on advanced reactors. Experimental data will be necessary and should be shared among interested countries. Moreover, the construction of prototypes can be helpful in this regard and perhaps both vendors and regulators should consider ways to facilitate the use of prototypes built in one country to support licensing and safety regulation in other countries.

In short, there are opportunities to use the significant advances in knowledge that have developed over the years in the determination of the licensing and safety requirements for advanced reactors. We need a modernized approach that ensures adequate protection of the public and the environment and that facilitates innovation.

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As this is written, the prospect that advanced reactor designs will replace current technology is uncertain. But if the contemplated benefits of advanced designs are to be realized, the licensing system should be modernized. This letter has sought to identify the general nature of the procedural and technical reforms that are appropriate. The IAEA staff is pursuing some of the matters discussed in this letter,

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[10] This effort is underway in the United States through the Licensing Modernization Project. See NRC, "Non-Light Water Reactor Implementation Action Plan – Progress Summary and Future Plans," Enc. 1 at 14-16 (SECY 18-0011) (2018) (https://www.nrc.gov/docs/ML1733/ML17334B184.pdf)

but there is hard work to be undertaken in introducing reforms. INSAG will explore the matter further with IAEA staff at an upcoming meeting.

As always, please feel free to contact me if INSAG can offer assistance on this or other matters.

Best regards.

Best regards,

Richard A. Meserve

cc: INSAG members
Juan Carlos Lentijo