The Regulatory Challenges Of Licensing Innovation In The UK Nuclear Industry And How These May Be Resolved

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SUMMARY

- This paper identifies regulatory challenges facing innovators in the UK nuclear industry.
- The UK nuclear safety regulator (Office for Nuclear Regulation - ONR) cannot accept lower safety standards, so operators must explore alternative approaches in their safety cases to justify their designs and/or processes.
- ONR funded a research report [1] looking at how innovation is regulated and safety demonstrated in other 'high risk' industries. Using some of these approaches as well as the authors' experiences, a variety of approaches are proposed to overcome the regulatory challenges facing innovators.

1. INTRODUCTION

1.1 History

Nuclear power generation will play a key role as the UK drives towards net zero carbon emissions by 2050. Early in the UK nuclear industry, there was no Nuclear Installations Act and many innovative reactor designs were built when there was no need to licence.

The Nuclear Installations Act set up the Nuclear Installations Inspectorate (NII), now ONR, but initially only new civil power reactors and nuclear chemical facilities were licensed, with existing United Kingdom Atomic Energy Authority (UKAEA) reactors not requiring licensing until the 1980s.

NII's Safety Assessment Principles (SAPs) were in their infancy – in fact, there were separate SAPs for reactors and chemical plants. The basis for proportionate regulation, Tolerability of Risk and Reducing Risks Protecting People, had not been published. Similarly, the concept of Technical Assessment Guides (TAGs) and Technical Inspection Guides (TIGs) only began in the 1990s.

ONR is unusual compared to nuclear regulators in other countries because of the many different types of nuclear facilities that it currently regulates, i.e. reactors, waste storage facilities, waste treatment facilities, fuel manufacturing facilities, some Ministry of Defence (MoD) establishments, and, in the future, possibly disposal sites. This led to the UK's renowned non-prescriptive, goal setting regulatory regime. It would be very time consuming and inordinately expensive to set out prescriptive regulations for the broad range of facilities that ONR regulates. This goal setting approach has served its purpose over decades of the UK nuclear industry helping to establish ONR as one of the foremost nuclear regulators despite purportedly having less inspectors per licensed site than others.

This non-prescriptive regulatory regime lets the operator decide how to demonstrate the safety of its facility at its specific location. The safety case and the operator's competence are assessed by ONR in deciding to grant a license. The SAPs and TAGs indicate the factors that ONR considers, but these are guidelines with no legal basis and hence are non-mandatory. For some designs achieving compliance with all the factors identified would be impossible or unnecessary.

1.2 Innovation – The Problem

The problem facing innovation in the nuclear (or any other) industry is there can never be as much supporting evidence as exists for current designs. Hence any requirement for RGP must favour the past.

Innovative designs are likely to have an absence of:

- Specific Codes and Standards;
- Relevant Good Practice (RGP) and;
- Operating Experience (OPEX).

The absence of RGP and OPEX is a true Catch-22: to obtain a licence, RGP and OPEX are usually required, but to obtain RGP and OPEX you need a licence. Similarly, the lack of Material Test Reactors (MTRs) means that obtaining test data to fully validate models and materials may be impossible or at least challenging and costly, especially replicating the exact temperatures and neutron flux spectra of radical innovative designs.

Nevertheless, at least one of the SMRs in the recent UK Government (BEIS) competition received ONR "significant comments" that "there were no relevant OPEX, relevant test/experimental data or evidence of RGP." These valid comments result in vendors/operators of innovative reactor designs facing the Catch-22 situation described above.

Despite ONR being "a facilitating regulator", i.e. according to the UK Regulators' Code it "should carry out its' activities in a way that supports those they regulate to comply and grow", ONR cannot sanction reduced safety requirements. Therefore, how can vendors/operators overcome this deficiency in relevant data, and can lessons be learnt from other high-risk industries?

1.3 Aviation

Despite aeronautical models, flight simulators, and numerous wind tunnel experiments, ultimately somebody (the test pilot) has to sit in a new plane, take off and (hopefully) land safely. Everything possible is done before a flight to ensure that the design will work as expected. The maiden flight involves a minimal number of people on board and very straightforward operation involving a short flight over relatively unpopulated areas. The test flights then progress in complexity to further examine the flight characteristics of the plane to demonstrate that it is safe to obtain an airworthiness certificate.

This progressive commissioning of the plane is one route whereby the nuclear industry can introduce innovation, i.e. by developing staged commissioning processes that would usually involve increased risk, but actually, decrease the risk by benefitting from the confidence provided from preceding stages in the commissioning process. This approach is already adopted for nuclear treatment plant where staged commissioning typically involves inactive operation before active material is introduced. This commissioning process becomes an important part of the safety case.

The aircraft industry has cautionary tales regarding innovation. Not all safety issues manifest themselves immediately. The initial Comet planes introduced rectangular windows without understanding the stress concentrations created in the corners. These stress concentrations caused fatigue cracks that eventually reached a critical size causing the fuselage to catastrophically fail and loss of all on board. Ageing effects cannot typically be justified by staged commissioning and other measures are required.

Another cautionary tale relates to the recent Boeing 737-MAX crashes where the innovation to the automatic pilot was introduced. Although the prime cause of the accident was the vulnerability of the new design to a single failure and allegedly, testing was not carried out thoroughly, Boeing also believed that pilots could rectify the fault if it arose. However, pilots had not all been trained in the procedures when the innovation was installed which would presumably have indicated Boeing was mistaken. Although the need to avoid the single failure criterion is well recognised, it is also important that any innovation should be thoroughly tested to include fault conditions (not always possible during commissioning), and operators need to be fully trained in changes resulting from the innovation.

With respect to ageing, assurance can often be gained by in-service inspection or even destructive examination of a "first of a kind" (FOAK) reactors' components, e.g. early post-irradiation examination of fuel pins or inspection following early defuelling - SMRs being smaller, makes this approach more economically feasible. Indeed, MoD cut a whole Vulcan bomber into pieces examining for any signs of deterioration before extending its life. Because of the compact nature of SMRs defuelling, thorough inspection and subsequent refuelling could be economically feasible, especially considering that in the case of SMRs this exercise could be a precursor for tens of further reactors. At least one SMR is actively considering this approach.

1.4 Medical

A good example of medical industry innovation is the Covid pandemic. The science excelled in developing vaccines that the available models showed would work. However, nothing was guaranteed, and eventually, several live humans had to be vaccinated. Similarly, new surgical procedures e.g. heart transplants need to have their first human "guinea pig", the risk being minimised as much as possible by prior testing and modelling. But why is this risk acceptable? In the case of the first heart transplant it was presumably because the patient would be terminally ill if not operated on, i.e. the risk of operating, whilst still clearly high, was less than that of not operating. Similarly in the Covid example, the overall benefit and risk of adopting the vaccine compared favourably with the risk to the population of not having it.

The nuclear industry is in a different position. Existing reactors do not pose unacceptable risks and therefore there is no reason (other than to further improve safety) to drive innovation from a risk reduction perspective. However, those vendors/operators of new designs clearly have reasons for their innovations, e.g. innovations resulting in greater safety, significant cost savings (bearing in mind the need to meet the ALARP principle), reducing radioactive waste, or assisting in other areas such as reducing the plutonium stockpile. The onus remains on the vendor/operator to demonstrate safety and as already stated, staged commissioning can help. Ageing can be ameliorated by in-service inspection, potentially destructive decommissioning of a FOAK reactor or even the use of surveillance specimens such as those in Pressurised Water Reactor (PWR) pressure vessels to confirm embrittlement rates.

Regulators will seek as much validation of safety-related models as possible. Innovative chemical plant designs licensed by ONR include MOX and THORP where there was heavy reliance upon laboratory modelling, and for MOX, a prototypic demonstration plant. The Canadian Safety Regulator Chief Inspector [2] has cited the need for a prototype reactor, followed by a FOAK, and then further fleet reactors when justifying new reactor designs. This is consistent with the concept of preceding actions reducing what would normally be a staged increase in risk – BUT the prototype reactor still has to be shown to be adequately safe to be licensed before being used to validate models. The economics of constructing a reactor predominantly to produce data could be problematic.

ONR's deliberations (especially following the MOX experience) require that it must have some confidence that not only is the design safe, but that it will work. If this is not ensured then the country is potentially left with a heavily contaminated facility needing to be decommissioned, the radioactive waste managed, and with significant resultant dose accruals to workers performing these tasks. A reactor design successfully showing no harm in the event of an accident, and being amenable to decommissioning, is still unlikely to be accepted if it cannot also prove to be reliable and guarantee overall benefit.

1.5 Software Validation

The complexity of modern software is such that much of it can no longer be verified in the traditional sense. ONR requires a "validation report" for all new software but it is acknowledged that some "smart" sensors and "off the shelf" components cannot be validated in the "traditional" manner. In these complex cases, confidence is sometimes achieved by a mixture of quality assurance and proven reliability of the software upon which the new software is based. This is a clear example of where the ONR TAG wanting all models to be validated cannot be fully complied within the traditional sense, but safety is still acceptably achieved through other means by which progressive commissioning again usually plays a big part. Amusement park rides are a good example of this form of validation where previous software plays a major part in justifying the validity of the new software which is too complex to verify in the normal manner.

1.6 Automobile

Another way of justifying safety is removing the hazard, e.g. use of unleaded petrol in cars. Of course, this is difficult to achieve in a reactor where the radioactivity in the core represents most of the hazard. However, innovative reactors that segregate the hazard and prevent single (or combined) failures that impact upon more than one of the segregated hazards could assist in improved safety. Gated fuel cooling ponds or waste/disposal facilities involving segregated cells, or the Geological Disposal Facility (GDF) concept of multiple segregated containers could also offer benefits, as could multiple co-joined SMRs.

Another way to improve safety is by reducing the risk, e.g. by the introduction of dual-circuit brakes to prevent overall brake failure thereby minimising the effects of a single failure. Alternatively, the latest tyres that do not instantly deflate when punctured are an example of where the risk cannot be removed, but the impact of the risk can be. Similarly, reactor risk of hydrogen explosions can be avoided by not using water as a coolant, e.g. gas, sodium, or molten salt, but these have their hazards, for example, sodium fires.

Another alleged benefit being explored in the automobile industry is driverless cars. This is because one of the main risks with cars is that drivers can make mistakes, despite supposedly being capable as shown by being licensed. The same innovative approach may be proposed in the nuclear industry, i.e. less reliance upon operators, e.g. to ensure that the reactor is warmed up within the appropriate temperature and pressure parameters in PWRs and to take the correct remedial action in the event of potential problems being identified. At least two SMR designs are being proposed where there is either no operator or the role of the operator is little more than that of a monitor. Nevertheless, how many of us will feel comfortable in our first ride in a driverless car especially if we had no way of overriding the "system" and stopping the car?

1.7 Model Validation

Fully validating innovative models (possibly involving novel approaches such as digital twinning) can be onerous, so another approach represents designs where the safety significance of the model is less. For example, models demonstrating core behaviour become less significant if the core is shown to be damage tolerant. Models involving heat transfer also become less important from a safety perspective if the reactor can be shown to be tolerant to temperature extremes. There is a strong case for classifying models according to their safety significance in the same way that safety-related components need to be classified. This classification could then determine the extent of validation required.

1.8 Relevant Good Practice

Reactor designs would have a reduced reliance on RGP if safety is adequately demonstrated by alternative means, e.g. modelling, staged commissioning, and inherent safety (damage-tolerant). Indeed, the requirement for RGP should only be a requirement if the practice is relevant to the situation being justified, e.g. the need to avoid fuel melting should clearly not apply to reactor designs involving liquid fuels. Vented fuel pins could be safer than sealed fuel pins if the risk posed by pressurised pins failing is greater than the loss of containment that the pins normally provide. RGP dictated that putting safety equipment at a low level was safest to withstand seismic events. However, Fukushima proved that this RGP should not apply in coastal areas where an accompanying tsunami could occur.

1.9 Other Considerations

An alternative way in which innovation can improve safety, assuming that the hazard will always be present in some form and operator interaction has been minimised, is by addressing risks. In conventional reactor designs, this can be by:

- removing the potential for missiles
- minimising the potential for radiation spread by avoiding significant pressurisation using damage-tolerant containments guaranteeing no radiation release
- ensuring fully compatible materials
- reducing the number of required safety components
- conversely having several independent shutdown safety systems
- ensuring full inspectability of safety components subject to ageing
- minimising potential for core damage or damage-tolerant cores ensuring designs produce minimal radioactive waste and waste is compatible with treatment and/or disposal concepts.

One reason for innovation could simply be the cost to make nuclear power more affordable. This is potentially an even more difficult concept to convince regulators, especially where innovation relates to changes to existing designs. Regulators would need to be convinced that any cost savings:

- do not result in any reduction in safety, and/or
- that any safety reduction results both in acceptable safety AND that the increased cost of reverting to the old design is grossly disproportionate to the resultant increased safety.

The recent example of the Flamanville RPV, where the forging was produced using an innovative approach, resulted in inferior material being a cautionary tale from the nuclear industry.

2. DISCUSSION

There has been little true innovation in reactor design over decades, just the evolution of existing designs. The UK's non-prescriptive regulatory regime lends itself to vendors/operators wanting to license innovative designs in the UK. However, insistence upon OPEX, representative experimental data, RGP, and fully validated models are unlikely to be achievable for truly innovative reactor designs.

Recognising that ONR must ensure adequate safety and cannot "sacrifice" its safety requirements for the sake of permitting innovation, both regulators and vendors/operators need to explore different approaches to achieving their mutual objective of safe nuclear power, whilst still facilitating the growth of the industry by allowing novel approaches that not only meet safety targets but can potentially be lower cost in the long term. In the case of the regulators, a more open-minded approach that does not insist upon adherence to existing practices is needed, and an understanding that many current Technical Assessment Guides were developed around existing designs and may not be applicable to innovative new designs. Similarly, the vendors/operators should obviously be confident that their designs are safe and consequently be prepared to argue their safety cases. In doing so, a range of approaches derived both from existing nuclear safety cases and innovation in other industries will need to be developed to persuade the regulator of the safety of their designs:

- Minimising or segregating the hazard: for most designs, this will not be achievable as even an SMR would contain sufficient hazard to warrant full regulatory scrutiny. It is unlikely that any core could be designed so that only a small hazard could be affected by any fault, e.g. a CANDU pressure tube or the Windscale piles are possible rare examples of where any fault may be limited to one tube/channel without damaging the core as a whole.
- Designing the reactor such that many of the existing risks prevailing in current reactors no longer exist, e.g. the avoidance of potential hydrogen explosions.
- Demonstrating that even where risks still exist, their impact on overall safety is minimised, e.g. by demonstrating that loss of core integrity does not lead to radioactive release.
- Having a staged commissioning process relying on each previous stage of the commissioning process to partially justify the next step and the possible adoption of a prototype philosophy.
- Making provision to demonstrate that ageing is not an issue by inspection, the use of surveillance specimens, or premature destructive testing.
- Minimising the need for operator interaction.
- Ensuring any radioactive waste produced is minimised and compatible with treatment, storage, and disposal methods.
- Designing to facilitate effective decommissioning.
- Any cost savings not resulting in safety improvements can be justified on ALARP grounds.

3. CONCLUSIONS

Under the terms of the Regulators' Code, ONR has to support the nuclear industry to grow whilst obviously maintaining its existing safety standards. However, there has been little true innovation within the industry for many years. The resurgence of the nuclear industry is likely to give rise to a number of new innovations that may challenge both ONR's current approach to ensuring safety and how vendors/operators justify the safety of their facilities. This is especially true in the absence of appropriate Codes and Standards, RGP, and available suitable material test reactors. Other potentially high-risk industries have successfully been allowed to innovate and their approach can be useful in some instances to justify innovation in the nuclear industry. In conclusion:

1. There may be lessons to be learnt for the nuclear industry from other industries in respect of the introduction of innovative designs to safety-critical applications.
2. A requirement for RGP, relevant OPEX, and fully validated models will not be achievable for many radical reactor innovations.
3. Regulators cannot reduce their safety requirements for the sake of encouraging innovation, but regulators should be open-minded to assessing safety cases that do not comprise RGP and OPEX including the degree to which some models are validated.
4. Potential designers and operators must be imaginative in how they justify the safety of their innovations. Experience from other high-risk industries might be useful in indicating helpful strategies.

REFERENCES

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ACRONYMS

ALARP	As Low as Reasonably Practicable
BEIS	Department for Business, Energy and Industrial Strategy
CANDU	Canadian Deuterium Uranium
FOAK	First of a Kind
GDF	Geological Disposal Facility
MoD	Ministry of Defence
MOX	Metal Oxide fuel
MTR	Material Test Reactor
NII	Nuclear Installations Inspectorate
ONR	Office for Nuclear Regulation
OPEX	Operating Experience
RGP	Relevant Good Practice
SAP	Safety Assessment Principle
SMR	Small Modular Reactor
TAG	Technical Assessment Guide
TIG	Technical Inspection Guide
THORP	Thermal Oxide Reprocessing Plant
UK	United Kingdom
UKAEA	United Kingdom Atomic Energy Authority

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