The Vital Role of Industry in Contributing to the IAEA Transport Regulations

Garry Owen

BNFL, United Kingdom

1. ABSTRACT

Industry has taken a key role in the development of radioactive transport regulation for many years.
There are two main parties that need consideration in the regulatory process:

- the 'public and worker' interest, this responsibility is represented by the regulators
- the 'industry' interest, these parties by their nature, give priority to representing their own interests.

Any amendment or review of the regulations benefits greatly from the industry perspective. The opposite ends of the 'spectrum of opinion' suggests that insufficient industry involvement may lead to uneconomic transport, whereas, insufficient Competent Authority involvement may lead to unsafe transport. These seemingly polarised views are considered and discussed, but it becomes clear that the two parties complement each other, both ensuring each remains grounded.

The basis for a regulation that compares the costs directly with the benefit in terms of reduced risk to the public or employees is at the heart of successful regulation.

This balance is fragile and sensitive and underlines the importance of a harmonised approach by both Industry and Competent Authorities.

2. INTRODUCTION

The story starts with the approval of the IAEA Statute on 23 October 1956. Within the statute, Article III Paragraph 6, authorises the Agency:

> To establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialised agencies concerned, standards of safety for protection of health and minimisation of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operation as well as to the operations making use of materials, services, equipment, facilities and information made available by the Agency or at its request or under its control or supervision; and to provide for the application of these standards, at the request of the parties, to operations under any bilateral or multilateral arrangements, or at the request of a State, to any of that State's activities in the field of atomic energy.

The IAEA then published its first set of regulations for the Safe Transport of Radioactive Materials in 1961.
This essentially was the beginning of 'universal' radioactive transport regulations.

These regulations have subsequently been adopted for all modal transport throughout the majority of the world; effectively driving the global radioactive material transport infrastructure in existence today.

The TS-R-1 system is 'science and risk' based, controlling the three main hazards:

- Criticality,
- Radiation,
- Containment

It is clear that the safety record for the transport of radioactive material in the public domain is excellent. No transport accidents have ever been reported that have resulted in severe health effects to members of the public due to the dispersal of radioactive package contents or to radiation emitted from a damaged package.

Consequently, the 'perceived' risk is many times higher than the 'real' risk, a concept that is widely recognised throughout the radioactive community by both regulator and industry alike.

3. Scope of this Assessment

To consider the current regulatory arrangements, differentiate the various roles and responsibilities. To identify the author's perceived areas of importance, strength, and weakness within the current system.

4. Key 'Ideal' Regulation Aspects

Below is a list of 'ideal' regulatory characteristics. It is key that regulations are based on these ideals.

4.1 Proportionate Regulation - To the risk

- Adopt and maintain only regulations for which the costs on society are justified by the benefits to society, and achieve objectives at lowest cost.
- *Minimum necessary regulation*: when government intervention is desirable, regulatory measures should be the minimum required, and least distorting, in achieving desired outcomes.
- *Net benefit outweighs both cost and risk arguments*: In general, proposals with the greatest net benefit to society should be selected and implemented. Cost and benefit cases must be made collectively, not one without the other.
- *Reasonable compliance cost*: the compliance burden imposed on society by regulation should be reasonable and fair compared to the expected regulatory benefit.
- *Minimal fiscal impact*: regulators should develop regulatory measures in a way that minimises the financial impact of administration and enforcement.
- *Cost benefit analysis*: regulatory proposals should be subject to a systematic review of the costs and benefit. Resources invested in cost benefit estimation should increase as the potential impact of the regulation increases.
- *Risk Assessment*: regulatory proposals should be subject to a risk assessment, which should be as detailed, as is appropriate in the circumstances.

4.2 Consistent Regulation - Predictable, so that people know where they stand;

- *International Compatibility*: where appropriate, regulatory measures or standards should be compatible with relevant international or internationally accepted standards or practices, in order to maximise the benefits of trade.
- Regulatory Obligations, standards and sanctions should be designed in such a way they can be imposed impartially and consistently.
- Regulation should be consistent.
- People in like situations should be treated in a similar manner, similarly, people in disparate positions may be treated differently.
- Reliance should be able to be placed on processes and procedures of the regulatory system: a regulatory system is regarded as fair or equitable when individuals agree on the rules of that system, and any outcome of the system is considered just.

4.3 Targeted Regulation - Focused on the problem, with minimal side effects

- Regulation should be carefully designed to achieve the desired outcome.
- *Direct approaches to problem*: In general, adopting a direct approach aimed at the root cause of an identified problem will ensure that a more effective and efficient outcome is achieved, compared to an indirect response.

- *Problem adequately defined*: Identifying the nature and extent of the problem is a key step in the process of evaluating the need for government action. Properly done, problem definition will itself suggest potential solutions and eliminate others clearly not suitable.
- *Clear identification of the objective of the regulation*: the objective should be clearly specified against the problem.

4.4 Accountable Regulation - To Government, to users and the public;

- *Regulatory Review*: Review regulations systematically to ensure they continue to meet their intended objectives efficiently and effectively.
- *Public Consultation*: this should occur as widely as possible, given the circumstances, in the policy development process. A well designed and implemented consultation programme can contribute to better quality regulations, identification of more effective alternatives, lower costs to business and administration, ensure better compliance, and promote faster regulatory responses to changing conditions.

4.5 Transparent Regulation - open, simple and user friendly;

- *Flexibility of regulation and standards*: regulatory measures should be capable of revision to enable them to be adjusted and updated as circumstances change.
- Performance-based requirements that specify outcomes rather than inputs should be used, unless prescriptive requirements are unavoidable.
- Regulatory processes and requirements should be as understandable and accessible as practicable to both the decision-makers and those affected by regulation.
- Make things as simple as possible.
- *Plain language drafting*: where possible, regulatory text should be drafted in plain language to improve clarity and simplicity, reduce uncertainly, and to enable those affected to better understand the implications of regulatory measures.

5. PERCEIVED VIEWS OF INDUSTRY

Industry appears content with the long-term success of the regulations
There is great confidence within industry, that the original concepts utilised in the transport regulations of a 'science and risk' based approach is extremely robust.
Both industry and regulator welcome the success that this safety system has enjoyed.

Industry asserts that there is too much variation in interpretation between countries;
Complex, unclear regulations lead to different interpretations by both users and competent authorities. We have several historical examples such as dual UN numbering and certificate numbering systems.

Industry strives for stability of regulations
We are beginning to see signs of the 'harmonic' movement of proposals and regulation. During one cycle the proposals are brought in, the next thing, a proposal is received to withdraw the same requirement from the regulations.
This could be an indication that the review process is failing in some respect. The original proposal may offer;
- little 'real' value
- increase complexity
- add unforeseen side effects

Industry strives for simplification
Industry would encourage case studies, step-by-step guidelines, and plain English explanations.
It hunger's for clear, accessible and easy to understand guidelines on how to comply with government regulation. Ideally this information should be available from a single source.

The author considers that, the information provided in the schedules was extremely useful at the working level, this information has been withdrawn from the text of TS-R-1 due to the difficulties through time constraints of updating the regulatory text whilst also updating the schedules.
As the regulations begin to feel more complex, industry should be given access to information, which is easy to understand at the working level; failure to make clear information available will result in compliance issues through purely a lack of understanding.

Lack of stakeholder understanding
Industry can easily be demoralised by regulatory changes that seem to offer no obvious benefit, in terms of added value or reduced risk.
Implementing high quality regulation, even if it costs more, is welcomed by industry, as they will receive added risk benefit, protecting their livelihoods.

6. PERCEIVED FOCUS OF REGULATORS

Its clear that regulator's need to deal with a number of complex interfaces.
Regulators have many stakeholders to consider, all of which can be greatly affected by their activities.

Safety focused
A clear responsibility of regulators is to ensure radioactive material is transported safely in the public domain.

Political focus
Regulators are responsible to provide effective 'High Quality' regulation to their governments to ratify into legal documents.

Public focused;
The public perception of the radioactive community is generally poor, through lack of knowledge and misinformation we are often considered to be secretive and unsafe.
Regulators are often at the front line of questioning when responding to concerned members of government agitated by public concern.

Industry focused
The regulators also have a duty to those who they regulate. They must interact with industry to ensure that continued safe economic transport is maintained without unjustified barriers for the overall benefit of society. These benefits being seen in power generation, reduced environmental impact and also in the field of medical products.

7. COST OF COMPLIANCE

What are compliance costs?
Compliance costs are the resource, hardware, administrative and paper work costs that businesses incur when meeting an obligation imposed by regulation.
Administrative burdens include all associated compliance costs, such as equipment purchases, retooling, recurrent production costs, buying in specialist services, staff training and monitoring compliance.
The cost of identifying and understanding the regulatory environment also forms part of the cost of compliance.
The key cost areas are often experienced in terms of time and money, including the cost of accessing expertise.
Regulation creates compliance costs in terms of resources, energy, money and time.
Costs of complying were increased by such factors as:

- The degree and pace of change
- The complexity of regulation.

The degree and pace of change
The frequency of legislative change has a significant impact on compliance costs. Each alteration or amendment meant more time had to be spent understanding what was required and then responding and putting new systems in place. It is important that changes are not simply adhoc, but strategically planned changes.
The regulatory process need identify the key areas where unnecessary and excessive compliance costs occur

- Prioritise areas for action, and
- Provide workable and practical solutions

Complexity of Regulation
It is very easy for the regulations to become more and more complicated. Regulatory experts from both industry and competent authority can become so embroiled in their speciality that they lose sight of the overall intent of the regulation.
Regulation that is comprehensive, complex, and covering infinite scenarios is useless, if it is also impracticable, unworkable and regularly misunderstood.

Why is compliance cost reduction important?
Industry clearly acknowledges that regulation is necessary and vital for their continued operation. Industry sees the cost of compliance as an essential part of doing business, being a responsible employer and a good member of the community.
It is clear from my investigation that compliance costs are not always foremost in regulatory proposal or change, the evidence is clear when examining 'Proposals for Change' many omit to delve into predicted costs or real overall benefit. This situation has the potential to impact on the 'quality' of new legislation developed under the existing processes and frameworks. Under the current system it is possible to create regulation imposing unnecessary and excessive compliance costs throughout industry.

Is there a solution?
To ensure that compliance costs associated with all new legislation are reduced to the lowest possible levels, the predicted costs/risks and overall benefits need to be developed early in the process by the 'Proposer' of the change or new regulation. This consideration could take the form of a brief 'Regulatory Impact Statement'.

Regulatory Impact Statement
The 'Regulatory Impact Statement' (RIS) or 'Regulatory Impact Assessment' (RIA) documents are often developed after the revised regulations have been drafted for incorporation into the modal regulations.
The RIS is typically a milestone in the regulatory process for many international and national regulations including ADR, RID, CFR and the UK Regulations. At this stage in the process, where the regulations are being considered for incorporation into law, the usefulness of the RIS is negligible, due to the enormous cost of 'not complying, if everyone else goes ahead'.
For this reason the RIS is often ineffective and fails to have an impact on the overall 'quality' of regulation.
The importance of incorporating RIS at an early stage within the IAEA process is therefore key.

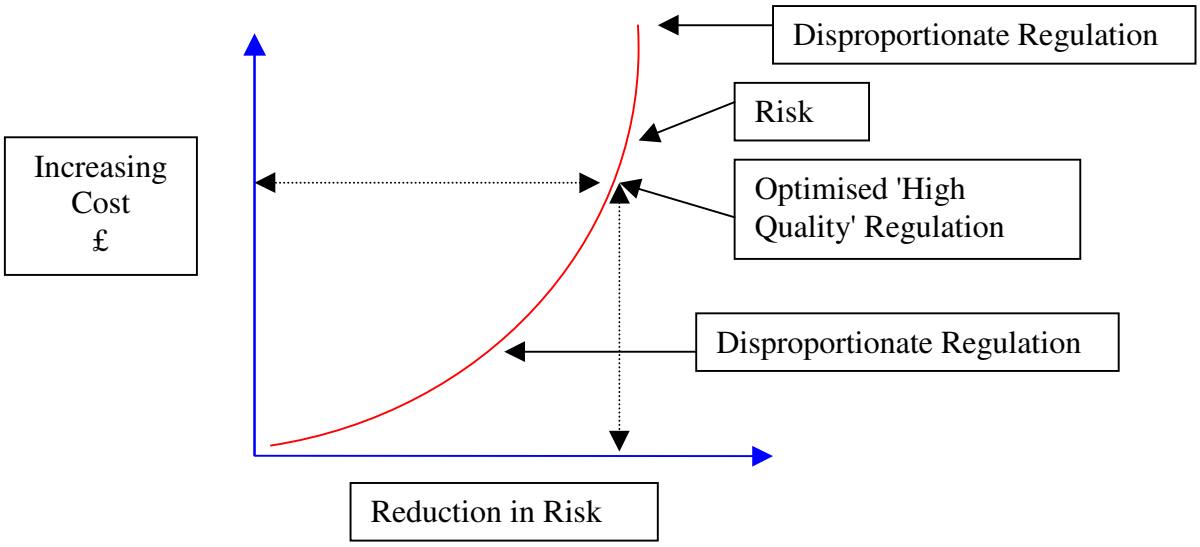
8. REDUCING RISK - GOOD GUY, BAD GUY?

Is a reduction in risk a good or bad concept?
The answer is both, as the misuse of a 'reduction in risk' remains the biggest single threat to the continued commercial transport of radioactive materials. Reducing risk initially seems a warm, friendly concept, which feels the right way to go forward with. However, reducing risk without further qualification is a concept readily sold to the uneasy and can ultimately lead to 'uneconomic' and 'disproportionate' transport costs which adds negligible 'real' risk benefit.
For example, consider this extreme 'disproportionate' proposal, imagine applying Type B mechanical test criteria across all types of package?
Risk would be reduced, but cost would be huge and overall benefit would be negligible.

Cost Vs Risk
To demonstrate this the graph below shows a typical example of the cost and risk in determining optimum regulation. It is assumed that, through perceptions, spending additional sums on safety will provide for an exponentially growing increase in benefit; whereas the reality is a point is reached where spending money provides a diminishing return in terms of increased benefit.

In the example, a balanced approach may effectively reduce risk to a small, insignificant and acceptable level whilst also optimising spending, thus any further changes to the regulations would not bring any true benefit to society.

Although in reality it is difficult to measure risk, whether real or perceived, the theoretical issue as described above is the lynchpin ensuring 'high quality' regulation during any proposed changes to the transport regulations.



It is important to find a balanced approach between obtaining an increase in benefit whilst systematically demonstrating it is worthy of the true economic costs of implementing the said proposal. This is the challenge faced by the IAEA Review Panel, regulators, and industry alike.

9. LEGISLATION QUALITY ISSUES

Its key that all stakeholders are provided with an early opportunity to have input into the regulatory development process.
Industry is keen to play a role in discovering:

- areas of duplication within the regulations
- unintended consequences, and
- unnecessary and unforeseen compliance costs

Good quality legislation is indicative in the following ways

- Simple and easy to understand
- Does not conflict with other regulatory requirements
- Clearly sets out its intent or purpose
- Is regularly reviewed to keep it up to date and relevant
- Imposes only unavoidable compliance costs.

10. DOES SIZE OF BUSINESS MATTER?

Businesses with less than 100 employees must be considered in the regulatory process.
The compliance cost burden induces greater costs on small to medium size businesses. They cannot benefit from the economies of scale to offset the costs.
They often need to hire and rely on outside experts, often at significant costs.
The ratio of staff required to achieve compliance is disproportionately higher than for larger businesses.
The overall impact on the business through prohibition is also disproportionate than for larger enterprises.
Compliance tasks can starve a small business from undertaking its core 'income generating' activities.

11. THE REGULATOR / INDUSTRY RATIO

The user base is relatively small compared to many other classes of dangerous goods, for example, the transport of radioactive materials accounts for less than 1% of all dangerous goods transported through the UK each year. Additionally, within this small user base specialisation often occurs. Individuals' become expert in one particular field within RAM transport, but often fail to understand or fully appreciate the issues involved in other radioactive transport methods. Hence, industry support within the various fields can be extremely limited. To make this situation even more difficult, the gap between 'front' and 'back' end materials can also often cause further difficulties.
To summarise, the radioactive transport industry is limited in resource with many specialising in only one particular area. This makes for considerable difficulties for internal support within industry for areas affected by new regulation or regulatory change.
This situation has become easier since the advent of World Nuclear Transport Institute, an organisation that is keen to improve the communication of issues affecting industry. Only using this co-ordinated approach can the true, positive or negative value of proposed regulatory changes be recognised and responded to.

12. DISCUSSION

Sometimes it is difficult for the nuclear industry to focus on 'cost' as key criteria. 'safety' criteria often overshadow all others. However in order to provide good quality policy and regulation it's vital to ensure regulation is tested against benefit and cost.
Regulation that avoids this test is in danger of being disproportionate, de-motivating and open to compliance concerns.

The 'perceived' risk by the public is many times higher than the 'real' risk, which in view of the safety record could be considered almost negligible.
Some would argue that Radioactive material carries an 'unhealthy' high political profile, as demonstrated by the European contamination issues and this could easily detract from a 'science' based approach of optimising regulation, to a 'politically' based approach of reducing perceived risk.

As extreme weather conditions become more frequent and the impact of global warming continues to be discussed, it is extremely important that the safe transport of radioactive material remains a commercial commodity.
The real risks need be put in perspective, questioning and challenging the many 'damaging' myths surrounding radioactive material and its transport.

Reducing risk is easily carried out, can be extremely costly and can also have a negligible safety benefit, clearly this situation needs to be avoided by ensuring that due process can take its course.

Regulatory Impact Assessments add value to the regulatory process and can deliver better quality and lighter touch regulation.

Clearly isolating 'risk' and using it to persuade and convince continues to threaten continued economic transport. It also impacts on the overall quality of regulation, as stakeholders take issue with changes to the regulations, they will begin to try and reverse the process, resulting in 'harmonic' proposals.

The clever part, is clearly demonstrating risk reduction whilst maintaining maximum cost benefit. All stakeholders support this approach, as it benefits them all.

13. CONCLUSIONS

- Regulations have stood the test of time; we need take stock and look towards clarity, stability and simplification of regulation.
- Industry must raise its game and strive to recognise its own, important responsibilities in the regulatory process.
- We should aim for regulatory 'Ideals' improving the quality of regulation.

- A regulatory process that isolates either 'regulator' or 'industry' is destined to fail to deliver 'quality' regulation.
- It is imperative that the cost/benefit of new or regulatory change is dealt with at the IAEA Review Panel stage.
- We already have a strong base of effective regulation, proposed changes or new regulations must be measured against net benefit, considering both cost and risk in tandem.

14. RECOMMENDATIONS

- The author proposes that the regulatory form ' FORM FOR SUBMITTING PROPOSAL FOR CHANGE' is modified to adequately consider 'regulatory impact'.
  An amended form would help prompt the proposer to consider cost, risk, and compliance issues, ensuring the 'overall benefit' remains worthwhile.
  If the cost/risk criteria were impacted significantly, then some further justification would be required to demonstrate that the overall benefit is also significant.
  This extra consideration would lead to fewer, but 'higher' quality proposals, with improved stakeholder ownership.

- In the interests of clarity of regulation, the author proposes that it be considered whether Technical Authors competent in 'Global English' could attend Review Panel working groups. Ensuring regulatory text is constructed, to attain 'universal' understanding, remains targeted and minimises any unwanted effects.

15. REFERENCES

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