



REGULATION OF THE TRANSPORT OF RADIOACTIVE MATERIALS

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ABSTRACT

There are many ways to regulate the safe transport of radioactive materials. This paper reviews the range of approaches that can be used from a coercive regime to embedding regulators with operators. The pros and cons of the differing approaches are discussed. It is argued that one of the best arrangements is collaborative regulation which requires a considerable amount of trust and confidence from both operators and regulators.

INTRODUCTION

Within the UK the transport of radioactive materials is regulated through the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (1). These regulations were introduced into GB to comply with the requirements of Euratom Directives 94/55/CE and 96/49/CE (2). These Directives give regulatory force within Europe to the ADR/RID (3) requirements for road and rail. ADR/RID applies to the road and rail transport of radioactive materials and for sea and air transport the IMDG (4) and IATA (5) codes apply respectively. All these modal requirements come from the UN Transport of Dangerous: Goods Model Regulations (6). The UN Model Regulations are derived from the IAEA Regulations for the Safe Transport of Radioactive Materials (7).

The IAEA Regulations places responsibilities on a Competent Authority, for any purpose in connection with those regulations. In many Member States, the Competent Authority is the regulator who is responsible for ensuring that the regulations are met in practice. The IAEA has also produced a series of documents dealing with the responsibilities and operation of regulatory bodies for nuclear and radioactive material safety. Within the UK there are UK guides that apply to all regulators, not just those involved with nuclear or radioactive materials. These guides provide a range of advice that all UK regulatory bodies are expected to follow.

This paper examines the different activities that the competent Authority/Regulatory Body for the transport of radioactive material is required to undertake and the overall approach that can be taken by that body to ensure that these requirements are met in practice.



FUNCTIONS OF A REGULATORY BODY

BASIC FUNCTIONS

The basic functions of a regulatory body are:

- develop and enact a set of appropriate, comprehensive and sound regulations
- verify compliance with such regulations
- in the event of a departure from licensing conditions, malpractice or wrongdoing by those persons/organizations under regulatory oversight, to enforce the established regulations by imposing the appropriate corrective measures.

For the transport of radioactive materials within the UK there are two main regulatory activities undertaken by the Competent Authority, assessment of packages and inspection/audit of duty holders to ensure that they are manufacturing and transporting packages in compliance with the regulations.

GENERAL REGULATORY BODY REQUIREMENTS

In March 2005 a UK report was issued Reducing administrative burdens: Effective inspection and enforcement (8) that considered the scope for reducing administrative burdens by promoting more efficient approaches to regulatory inspection and enforcement, without compromising regulatory standards or outcomes. This report was accepted and enforced within the UK through The Regulators' Compliance Code (9) and is a central part of the UK Government's better regulation agenda. Its aim is to embed a risk-based, proportionate and targeted approach to regulatory inspection and enforcement among the regulators it applies to. The general principles of this approach are:

- Regulators should recognise that a key element of their activity will be to allow, or even encourage, economic progress and only to intervene when there is a clear case for protection.
- Regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources in the areas that need them most.
- Regulators should provide authoritative, accessible advice easily and cheaply.
- No inspection should take place without a reason.
- Businesses should not have to give unnecessary information or give the same piece of information twice.
- The few businesses that persistently break regulations should be identified quickly and face proportionate and meaningful sanctions.
- Regulators should be accountable for the efficiency and effectiveness of their activities, while remaining independent in the decisions they take.



PRACTICAL PROBLEMS

Given this framework of general requirements the UK Competent Authority has to meet them and ensure that the requirements of the transport regulations are also met.

In the UK holders of radioactive materials are required to be registered with the Environment Agency (EA). Currently there approximately 2500 duty holders registered with the EA. A survey by the Department for Transport of these registrants has shown that about 750 duty holders are significant transporters of radioactive material and this represents the total number of registrants that need to inspected/audited for compliance with the regulations. If the Competent Authority wanted to inspect/audit all these registrants every 2-3 years then the overall inspection programme would be large and suffer from not being targeted at the most significant risks. The UK therefore has adopted a proportionate approach to inspection and regulation that has the following key steps:

- Identify Duty Holders Holding Radioactive Material
- Send duty holder questionnaire
- Prioritise inspection programme using risk model
- Carry out desk top based audits
- Carry out inspections
- Identify themes and trends
- Feedback findings to stakeholders and make changes to inspection programme

The prioritisation process in step 3 takes account of the radioactive materials being transported, the number of transport operations, previous inspection reports, incidents and accidents and other relevant regulatory information, including the responses to the duty holder questionnaires. On average, this approach means that duty holders will be visited by an inspector once every ten years. However this is only an overall average and the time period between visits is quite variable. For very infrequent transporters of small quantities of radioactive material, paper assessments of compliance are considered proportionate, whereas for frequent transporters of large quantities of radioactive materials relatively frequent inspections are undertaken.

REGULATORY INTERACTION

As well as dealing with the inspection/assessment programmes the actual regulatory approach undertaken when visits are undertaken is important. There is a wide spectrum of how regulators can interact with duty holders. This spectrum of interactions can range from a coercive approach of regulatory enforcement to one where regulators are embedded into the duty holders team. Although classifying these approaches implies that they are mutually exclusive it is more likely that differing approaches would be needed at different times, with different operators, under different



circumstances. In discussing these approaches I have tried to identify the key characteristics of the approaches, their strengths and weaknesses and under what circumstances it is more appropriate to use that approach.

COERCIVE REGIME

This approach is characterised as being: compliance with regulations is paramount and duty holders must comply with the regulations. Instances where non compliance are found demand regulatory action, although it is not always through the courts.

This approach places high demands on any inspection programme as it is important to visit all consignors and ensure that they are complying with the regulations as any regulatory action taken is dependent on the non compliance being discovered.

This approach is very rigid and little discretion is given to the inspectors, invariably there are rigid sets of rules that are followed.

This approach has the advantage that that rules and compliance requirements are very clear as are the outcomes. It is very easy to show the independence of the regulator as they are following a process that is independent of the duty holders involved.

This approach tends to be used where there may be a lack of trust between the regulator and the regulated. It is relatively straightforward to administer and can use fairly inexperienced regulators as significant judgement is not needed or wanted. It is best used in transient environments where interactions do not need to be developed over time.

BALANCED REGULATORY APPROACH

This approach is characterised as being: compliance with regulations is very important but the inspector's judgement can be used for minor infringements and every infringement found does not automatically result in regulatory action. A stronger reliance is placed on a proportionate regulatory response.

In this approach less reliance is placed on the inspection programme and more reliance is placed on the judgement of the inspectors. This requires more experienced inspectors to be used as their judgement has to be used to tailor the proportionate response.

There is still significant reliance on an inspection programme and in order to demonstrate independence of the regulator the inspector must maintain a distance from the regulated. Regulatory action is still regarded as a reasonable response to non conformances.

This approach is more flexible than the coercive regime and allows the inspector to respond more dynamic business conditions.

This balanced approach is likely to be the main approach adopted by Competent Authorities as it allows discretion on behalf of the competent authority. It allows the regulators some flexibility



when major business changes occur that may have temporary impacts on compliance or problems following an incident. It does not require a deep understanding of the business being regulated.

COLLABORATIVE REGULATION

This approach is characterised as being: the regulator and regulated working closely together to achieve compliance. It requires the regulator and regulated to have a good understanding of each others viewpoint and requirements and to take them into account to achieve compliance. Both groups try to ensure that there are 'no surprises' from changes to the duty holders business or from regulatory changes. This requires the duty holders to make the regulators aware of their planned work programmes so that the regulators can tailor their programmes. Stakeholder meetings are regarded as being very important. Regulatory action is seen by both parties as an action of last resort and is seen as a failure for both parties. It is reserved for significant issues only.

The inspection process is seen as part of the regulator's familiarisation of the work programme as well as reassurance that compliance exists in the workplace.

This approach requires considerable trust between the two groups and relies on using experienced and trusted inspectors who have sufficient experience to identify when the situation has become unacceptable. This approach is more likely to occur with the larger or well established duty holders as they will have longer term plans and it allows trust to be built up. It is resource intensive for the regulators as they need to understand more about the business of the transporter to allow the trust to develop between the two parties.

EMBEDDED REGULATORS

This approach is characterised as being: the regulators become part of the team whose focus is to achieve the overall objectives. All members of the team are responsible for achieving the objectives, including the regulators. In this approach it is important that everyone operates from the same office to maximise interactions, although both groups do not need to spend all their time in the same office. However, when the regulator is on the site they will work from the team's office. The aim is for a seamless operation with a one team approach to achieving objectives. With such a focussed approach regulatory action will be very unlikely as the whole team focuses on the main objective.

This approach is appropriate for singular situations such as emergencies or where intolerable risks may exist and there is extreme importance in resolving the main issue.

The main disadvantages of this approach are that it is resource intensive as the regulators will spend a significant proportion of their time in the team offices and regulatory independence is at significant risk as the main focus of the objectives could cause a loss of objectivity on regulatory compliance. It is also difficult to inspire public confidence in the regulatory process as the regulators are seen to be more focussed on business objectives than the protection of the public.



This approach requires very experienced inspectors who know when the regulatory process or they are being compromised.

UK COMPETENT AUTHORITY

Within the UK the balanced regulatory approach is mainly used for the regulation of the safe transport of radioactive materials. This allows the inspectors to exercise their judgement when inspecting and auditing duty holders but requires them to follow a formal process to decide whether regulatory action is needed. This formal process is the Enforcement Management Model (9) used by the Nuclear Installations Inspectorate (and other regulators) of the Health and Safety Executive. This allows the competent authority to show it has a consistent and independent process to decide on whether any regulatory action is proportionate to the breach of regulations.

More recently, for some major operators, where a longer term relationship is required, a more collaborative approach has been used. Although this is more resource intensive it allows a longer term strategic approach to be built up. This ensures that the regulators are more aware of the duty holders longer term programmes and these can be better balanced against the resource requirements of other work programmes. Although this work is beneficial it is has the risk that as it is more resource intensive the resources used on this particular duty holders work are disproportionate. Also this approach becomes more challenging if ever any regulatory action is required.

CONCLUSIONS

In order for the UK Competent Authority to meet all the general requirements for regulators as well as the regulatory requirements from the transport of radioactive materials regulations we have adopted a risk based inspection and audit approach. This allows a targeted programme for higher risk transport operations.

For the regulatory interactions with duty holders the UK competent authority has adopted a balanced regulatory approach with a collaborative approach for some of the major duty holders and transporters of radioactive material. This approach gives a good balance between effective and independent regulation of the transport of radioactive materials and the need for scarce resources of very experienced inspectors.

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