RISK BASED MODEL FOR COMPLIANCE ASSURANCE INSPECTIONS FOR THE NON-NUCLEAR SECTOR

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ABSTRACT

In 2002 The UK was appraised by an IAEA team (TranSAS-3). Three recommendations were made. Recommendation 3 was '... the DfT should evaluate the adequacy of its inspection programme ... minor consignors and consignors of mobile sources should be more fully integrated into this programme. Priorities should continue to be risk based...'

Within the UK it's a legal requirement for organisations holding RAM to be licensed. The database of holders is approximately 3000. Potentially, all these organisations transport RAM.

DfT has 3 inspectors ensuring compliance in this sector. The team will audit approximately 120 organisations annually. Nominally, organisations are inspected every 3 years. We would inspect 360 organisations or 12% of our duty holders. It is essential that prioritisation is established.

In 2008 DfT sent a questionnaire to its duty holders. Answers were used to create a risk model that used the following parameters: number of RAM items held; amount of activity (relative to package type); number of movements made annually; if the organisations QA system is registered; if the QA system covers RAM transport ; and if the organisation's aware of security requirements.

For each parameter a 'normal amount' was established and a 'normal' risk total proposed. A value above that total indicated an organisation worth visiting. It was recognised that some organisations below the cut-off should also be inspected to confirm the thresholds appropriateness.

A spreadsheet recorded information from the questionnaire and risks were calculated. Nil returns were given a default value that exceeded the 'safe' threshold. Inspectors then targeted the higher risk organisations

The inspection's output was a list of non-compliances. To validate the risk model we assigned an actual 'risk' to each inspected organisation. A numerical value was agreed at a team meeting and assigned to each category of non-compliance. We now had a hypothetical and objective risk value for each organisation. The risk model was then amended accordingly and continues to be used to guide the inspection programme and also to inform where education and dissemination of information is required.

INTRODUCTION

This paper attempts to outline the reasoning behind our risk based model for compliance assurance inspections for the non-nuclear sector. It looks at the results so far and how that data informs our

actions and shapes our policy. It also looks at improvements that can be made in the future. Two colleagues have produced papers that are relevant to this one: David Rowe will discuss paper no. 419 – 'Findings from Non Nuclear Small User Inspections in 2009/2010' and Michael Turner will discuss paper no. 91 – 'How the UK Competent Authority has developed a risk based Strategy for Carrying out Non-Nuclear Small User Inspections'. Paper 91 looks further back in our regulatory history (pre-2008) and discusses wider issues than this risk model.

HYPOTHESIS:

Currently within the UK there is no legal requirement for transporters of radioactive material (RAM) to be licensed. It is, however, a legal requirement for organisations holding RAM to be licensed by the Environment Agency (EA) in England and Wales and the Scottish Environmental Protection Agency (SEPA) in Scotland. The EA and SEPA send copies of their databases of registered holders to the DfT and, on face value; there are potentially 2,500 known duty holders who could be involved in the transport of RAM.

The GB Competent Authority (CA) for the transport of RAM is the Secretary of State (SoS) of the Department for Transport (DfT). It is the Dangerous Goods Division (DGD) of DfT that acts as CA on behalf of the SoS. The scope of this paper is restricted to the CA responsibilities for ensuring compliance with the regulatory requirements of transporting radioactive material by road and therefore the requirements of the modal regulations ADR [1], which are based upon the IAEA TS-R-1 regulations [2] and enacted in GB law by CDG 09 - Statutory Instrument number 1328:2009 [3].

Regulation 5 of CDG 09 requires that carriage can only be undertaken in accordance with ADR. Paragraph 1.7.3 of ADR discusses Quality Assurance expectations and this comes directly from paragraph [306] of TS-R-1. Chapter 1.8 of ADR concerns compliance assurance and this is analogous to paragraph [307] of TS-R-1. GB legislation requires that the CA 'spot checks' that transport within the UK complies with ADR.

The IAEA were invited to appraise the RAM transport operations of the United Kingdom in 2002. The resulting TranSAS[1] mission made three recommendations, one of which was "It is recommended that the Department for Transport (DfT) should evaluate the adequacy of its audit and inspection programme and that the necessary resources should be provided for audits and inspections. Specifically, minor consignors and consignors of mobile sources should be more fully integrated into this programme. Priorities should continue to be risk based to maximize the effectiveness of the limited resources". There followed a couple of recruitment campaigns and DGD now has 3 full-time inspectors ensuring compliance in the non-nuclear sector. The expectation is that each inspector will perform 40 audits per year i.e. the team will audit approximately 120 organisations per year. The audit frequency in our nuclear sector is that organisations are inspected every 3 years. If this period is carried into the non-nuclear sector then we would be inspecting only 360 organisations or approximately 12% of our duty holders (estimated to be 3000 i.e. 2000 known in England and Wales, 500 more in Scotland (not yet

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[1] IAEA Transport Safety Appraisal Service – TranSAS-3 – Appraisal for the United Kingdom of the Safety of the Transport of Radioactive Material.

questioned) and another estimated 500 that are unknown (including carriers)). It is essential, therefore, that some form of prioritisation is established.

In 2008 DGD sent a questionnaire to all our duty holders to gather information. The questionnaire was deliberately short (so as not to put people off) and asked only 8 questions. The answers to 6 of these questions could easily be used to create a risk model and it was proposed that we prioritise our inspections based on the following risk model:

Risk is a function of the number of RAM items held; the amount of activity (in relation to the package type); the number of movements made per year; if the organisation has a registered QA system; if the QA system covers RAM transport ; and if the organisation is aware of the security requirements.

Parameters:
The consolidated database of duty holders more or less defines the parameters without too much further thought. Parameters available (or easily calculated) are:
1. Total RAM items held - parameter A;
2. Radionuclides held and packages used – amend to a fraction of permissible activity for the package type i.e. (2xactivity)/A2 or some other similar calculation depending on the package type – parameter B;
3. Movements (assumed total) per year (N) – for N>4 then divide number by 50; for N<4 then reciprocate number and add 1 - parameter C;
4. Registered QA system – yes =0 value; no = 1;
5. RAM transport part of QA system – yes = 0 value; no = 1;
6. Awareness of ADR 1.10 – yes = 0 value; no =2.
7. As evidence is collected then a parameter for 'industry sector' may improve the model e.g. if it is known that the oil industry are consistently non compliant them we might factor their results by 2.
8. If an organisation has High Consequence Dangerous Goods then it is suggested that they are automatically top priority for an inspection.

The 'risk', R, can be calculated as:

$$R = A/10 + 2B/A_2 + C/50 + \text{remaining fixed values}$$

Rationale - Weightings are applied to the parameters in order to make the 'nominal' value no more than 1 i.e. at numbers above 1 it is perceived that the operation becomes more of a concern.

1. (Parameter A) For A/10 to be greater than 1 then the number of RAM items must be greater than 10. It is suggested that the greater the number of items that you have then the greater is the risk of losing an item (security) or not being in control of all these items (safety);
2. (Parameter B) The weighting is such that if you had half the maximum permissible inventory for the package type then the returned value would be 1. As you approach the maximum allowable value then the returned value would approach 2. For small amounts of radioactivity in a robust package then the returned value would be between 0 and 1.
3. (Parameter C) It is suggested that an organisation should be in full control of operations if they only had 1 consignment per week. As the number of operations increases then there

might be a loss of control i.e. 100 movements per year (or 2 per week) would return a value of 2. Conversely if you perform less than one movement per quarter then operators may lose skills due to a lack of practice e.g. 1 move per year would return a value of 1+1/1=2
4. Simply 0 if you have a registered QA system and 1 if you don't;
5. Simply 0 if RAM transport is part of the QA system and 1 if you don't; and
6. Simply 0 if you are aware of ADR 1.10 and 2 if you are not.

Figure 1 shows part of the risk analysis spreadsheet (with sensitive information deleted).

It is suggested that organisations are ranked according to the value of R and that the highest 20% or any organisation that returns a score of more than 4 (whichever is higher) is targeted. NB to re-iterate these values e.g. '4' are just an initial guess. It is expected that the hypothesis will change as inspections are completed and data is collected.

Notes:
1. Due to the lack of clear information there will be many organisations that can not be ranked according to our risk model. These will have to be considered on their individual merits and a value deduced.
2. Once sufficient evidence is gathered then the model can be improved so that the correlation between what we know and what we were told matches more closely e.g. parameters can be added or removed, different weighting factors can be used, parameters can have an exponent added etc. This may result in a significant change to the rankings.
3. It is recognised that for operators that have or move 100s of packages per year then they will return a large risk value. The risk value should not be considered to be anything other than an indicator that that organisation is worth visiting.
4. There is a problem with 'nil returns' - it was suggested that in travelling between inspections, we drop in on these organisations and, depending on circumstances, conduct an inspection or leave a paper copy of the questionnaire to complete.
5. As intelligence is gathered on individual organisations then we could add another parameter to increase or decrease the lapsed time before the next inspection. For example if an organisation barely meets the required standard or there are other concerns then we could factor the R value by 1.0 to 2.0 depending on how concerned we were. Conversely of an organisation were exemplary then we might factor their score by between 0.5 and 1.0.

A value of 4 or more indicated an organisation that we would be interested in visiting. It was also recognised that a few below 4 would also need to be inspected to ensure that this threshold was appropriate.

The spreadsheet was used to record information from the returned questionnaire (NB only about 50% of questionnaires were returned within 6 months).

For each organisation a risk was calculated according to the above equation and the spreadsheet was ordered according to the highest risks. Nil returns were given a default value of 6 to ensure that they exceeded the 'safe' threshold.

Inspectors were then able to contact 2 or 3 organisations in close proximity that exceeded the 'safe' threshold and perform compliance inspections in that region.

The output of these inspections was a list of non-compliances – typically 10 per organisation. This data was recorded on another spreadsheet – the 'non-compliance register' shown in Figure 2. In order to validate (or modify) the risk model it was necessary to assign an actual 'risk' to each inspected organisation. This was done during a team meeting and a numerical value was agreed on and assigned to each category of non-compliance e.g. 'radiation monitors out of calibration' was assigned a high factor as this was deemed very safety critical whereas the omission of eye-rinsing liquid was assigned a low factor as this was deemed irrelevant to RAM transport (but its omission could be symptomatic of more serious short-comings).

We now had a hypothetical risk value for each organisation and also a more objective value.

Results at April 2010 (after 3 months)

26 organisations had been inspected and their non-compliances recorded on a spreadsheet. At that time non-compliances were evenly weighted so their 'real' risk was simply the sum of the non-compliances. When the hypothetical risk was compared to the 'real' risk then there is not a great deal of correlation. In short just over half showed reasonable to good correlation and just under a half showed poor correlation – we might as well have tossed a coin!

Recommendations:
   (a) good information has come out of the inspections so far (see later paper (419) by my colleague David Rowe). That information will be disseminated and used to educate our duty holders and focus attention to areas that require guidance material;

   (b) the sample was relatively small so we need to continue and periodically review the situation to inform our inspection programme; and

   (c) Carriers/couriers have been identified as an unknown quantity. Carriers do not need to be registered with the EA or SEPA and so, generally, have been under the radar! This sector therefore was targeted to obtain metrics of their performance.

Results at End September 2010 (after 9 months)
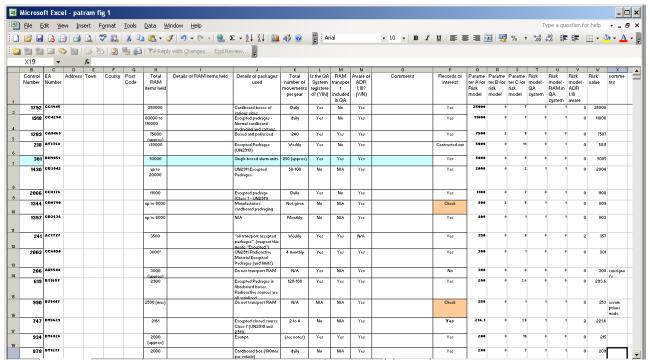
To be advised in my presentation at Patram 2010.

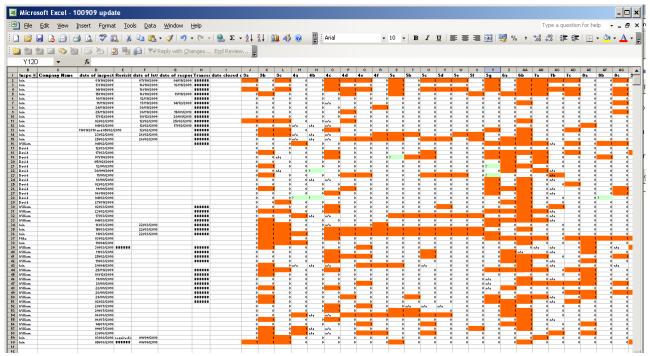**Figure 1. Risk assessment spreadsheet (sensitive info removed).**

Figure 2. Non-Compliance Register (sensitive info removed).

CONCLUSIONS

It is a very difficult task to work out who are duty holders are at any point in time. Organisations may not be registered, may change their names or may enter or exit the market on a regular basis!

Conducting inspections is the best way to gather intelligence on that organization plus any carriers that it may use. Anecdotal information on competitors is also gratefully received!

Finite inspection resources means that inspections must be prioritised. This has been done using a risk model based on an industry questionnaire. The act of validating our risk model is ongoing at the time of writing but, come October, we will have amended our risk model to accurately reflect what we have found and so maximized the effectiveness of our limited resources for future inspections.

Reminder: The views are those of the author and do not constitute official UK Competent Authority policy

ACKNOWLEDGMENTS

REFERENCES

1. ADR – The European Agreement Concerning the International Carriage of Dangerous Goods by Road 2009.
2. TS-R-1 – The IAEA Regulations for the Safe Transport of Radioactive Material 2009.
3. SI 1328:2009 – The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009.