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Self Support and Advice by Non Nuclear Users of Radioactive Substances

Science Report SC030166/SR



**ENVIRONMENT
AGENCY**

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This report is the result of research commissioned and funded by the Environment Agency's Science Programme.

Published by:

Environment Agency, Rio House, Waterside Drive, Aztec West,
Almondsbury, Bristol, BS32 4UD
Tel: 01454 624400 Fax: 01454 624409
www.environment-agency.gov.uk

ISBN: 1 84432 398 6

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March 2005

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Dissemination Status:

Publicly available

Keywords:

self support; radioactive substances; non nuclear

Research Contractor:

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Science Project reference:

SC030166/SR

Product Code:

SCHO0305BIVI-E-P

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Professor Mike Depledge

Head of Science

Executive Summary

Environment Agency is continually trying to improve its approach to regulation. Improvement may relate to ensuring that standards of environmental protection are met with less expenditure, or it may mean that “lighter touch” methods of regulation are used where operators can be shown to be “lower risk”. If the latter can be achieved then proportionately more regulatory effort can be directed to where environmental risks are higher.

The Environment Agency is considering how this approach could be applied to the regulation of radioactive substances in the future. Clearly, the development of a risk assessment methodology relevant to radioactive substances is one essential step. But in addition, a clear understanding of the risks involved in adopting the principle of a risk-based, self-supporting approach to regulation of radioactive substances is also important. This project was conceived to provide some insights into what might be involved in adopting this approach and to investigate the risks. It also set out to seek the views of people who would be affected by such an approach, both inside and outside the Environment Agency as to how such an approach may be constructed for the regulation of radioactive substances.

The goal of the project is to provide input into the process of developing risk-based assessment methods (RAM) for Radioactive Substances Regulation (RSR) for non-nuclear users of radioactive substances. These users are regulated by the Environment Agency under the Radioactive Substances Act 1993 (RSA93).

This report provides an overview and the findings of the work, and makes suggestions for a way forward. Overall, the study has found that:

- The Environment Agency seems to be leading in this field as there is little published work describing the implementation of risk-based, self-supporting regulatory regimes for radioactive substances.
- Those personnel within the Environment Agency who will have responsibility for delivering regulation under a risk-based, self-supporting regime are broadly supportive of the principles.
- A selected group of users of radioactive substances whose work could be regulated under a risk-based, self-supporting regime is broadly supportive of the principles.

These findings suggest that there is no reason why the Environment Agency should not proceed towards establishing a risk-based regime for RSR that enables users to demonstrate that they are able to control and minimise risk. Demonstration of this ability would require the proper application of self-supporting management arrangements. The report recommends that the Environment Agency should continue to co-operate with users in determining detailed arrangements that are acceptable to all parties.

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1. Introduction

The Environment Agency is committed to a modern regulatory approach within England and Wales, which is in line with the Government's Better Regulation Principles [Better Regulation Task Force 2000]. These state that regulation should be consistent, transparent, targeted, proportionate and accountable. The Environment Agency is also committed to adopting risk-based and outcome-focussed approaches, as outlined in its *Vision* [Environment Agency 2002]. Such an approach will allow resources to be targeted on those activities, which present highest environmental risks so that continuous improvement can be delivered despite an increasing workload. The Environment Agency has contracted RM Consultants Ltd (RMC) to provide input into the process of developing risk-based assessment methods (RAM) for Radioactive Substances Regulation (RSR) for non-nuclear users of radioactive substances. These users are regulated by the Environment Agency under the Radioactive Substances Act 1993 (RSA93).

This report provides an overview and the findings of the work, and makes suggestions for a way forward. Overall, the study has found that:

- There is little published work describing the implementation of risk-based, self-supporting regulatory regimes.
- Those personnel within the Environment Agency who will have responsibility for delivering regulation under a risk-based, self-supporting regime are broadly supportive of the Better Regulation Principles.
- A selected group of users of radioactive substances, whose work could be regulated under a risk-based, self-supporting regime is broadly supportive of the principles.

The following sections of this report describe the nature of, and methodology for, the project, its findings and the conclusions drawn. It also suggests areas for further work, and where to target work to help in moving further towards a modern regulatory framework.

2 Project Phases

The following sub-sections briefly discuss each of the major phases of the study.

2.1 Literature review

Given that the Environment Agency has no wish to 'reinvent the wheel' in terms of risk-based regulation, the first phase of this study looked for any precedents for similar regimes, as well as for existing best practice, that could be built upon further.

The principal conclusions from the literature search are that:

- Increased use of self-support is in the early stages of development in many other industries, and there is currently very little information on which to base best practice. The next major step for most industries is therefore to build a workable system of self-support. Organisations with a pro-active approach to regulatory compliance will already be working with some form of self-support and advice to ensure that any regulatory inspections do not throw up any surprises. Formalising these systems, where possible, would enable a more consistent approach to regulation throughout industry.
- There is currently no direct reference to international best practice in self-support and regulation with respect to non-nuclear use of radioactive materials, although evidence suggests that the Australian regulatory authorities have been working on self-regulation tools, and have identified good practice for schemes at a strategic level. The research did identify International Atomic Energy Agency (IAEA) methodologies which could be adapted for use in assessing the radiological hazard potential within the framework of a risk assessment methodology.
- The existing Environment Agency self-regulation scheme for Band 4

premises¹ in that has been developed and adopted in Wales allows the operator to determine 'environmental' and 'management' risk factors using a spreadsheet based on information from a questionnaire which is completed by the operator. This could be modified by including radionuclide-specific data, which take account of the possibility of internal exposures and the potential for accidents. This might then allow this scheme to be extended to Band 3 premises².

- Additional elements which could also be used to extend the Welsh scheme include self-assessment techniques identified in the Environment Agency's existing Operator Pollution Risk Appraisal (OPRA) scheme, together with the risk screening methodology developed by the Environment Agency for biota protected under the Habitats Regulations.
- The existing models of accreditation and advice used for assessing quality systems could be adapted to be applicable to small users of radioactive material, perhaps allowing for registered consultant Radiation Protection Advisors (RPAs), or similarly qualified persons, to act as independent auditing bodies.

2.2 Knowledge elicitation workshops

With the literature search establishing that there is currently no single 'off-the-shelf' model that could be adopted for risk-based regulation, workshops were held to elicit the opinions of those who would be

¹ Band 4 premises are those (defined by the RSR Charging Scheme) that have registrations under RSA93.

² Band 3 premises are those that are authorised under RSA93 (as opposed to registered)

affected by such an approach. The first workshop focused on eliciting knowledge from Environment Agency personnel, including several with direct current experience of applying radioactive substances regulation (RSR). The second sought opinions and views from a representative group of users.

As input to these workshops, consideration was given to the 'high-level' factors that affect risk. Introductory presentations highlighted the fact that risk is a function both of hazard (radioactive inventory) at any given location and of the quality of management systems implemented at that location. The basic idea presented was that reduced levels of regulatory intervention could be offered to individual users who were able to show that their premises presented a lower level of risk than that presented by another user with similar inventories and conducting similar work. This is illustrated schematically in Figure 1.

Both workshops focused attention on establishing both 'importance' – the relative level of risk associated with a given range of factors, and 'suitability' – the ease with which any of those factors could be used under a regime of increased self-support. The workshop results show good overall agreement, particularly with regard to the 'importance' of the different risk factors. The following sub-sections summarise some of the key points arising from the two workshops.

2.2.1 Environment Agency personnel

The discussion at the first workshop is only summarised here. The Environment Agency personnel concluded that there are significant perceived risks to the environment, and to the reputation of the Environment Agency, associated with a move towards increased self-support. While such movement is possible, the current situation is such that significant further work is required before this type of

regime could be safely implemented. The work identified includes:

- Defining necessary competences for the 'self-regulator' – whether this is the RPA acting as an auditor, or a group of individuals acting as 'governors';
- Clarifying minimum standards to be met in environmental hazard assessments with guidance provided on typical issues to be addressed;
- Developing guidance with regard to 'quality' and extent of management systems that all, small users will be required to put in place.

The Environment Agency already adopts a graded approach to granting permissions to operators – ranging from simple registrations to complex permits with attached conditions. The first workshop suggested that a similarly graded approach will also be needed for defining the competences, and the quality and extent of management arrangements, that are required by small users. The work also suggested that it would be useful to include, within the Environment Agency's published guidance, details of the process it uses for assessing and determining applications for registrations and discharge authorisations. This could be achieved by adopting an approach similar to that used by the HSE in its Safety Assessment Principles for Nuclear Power Stations [HSE 1992] to assist users in understanding the requirements of the Environment Agency.

2.2.2 Users

The discussion from the second workshop (involving the "user community") is summarised here. There were no direct objections from users either to the principle of increased self-support or to the principle of the Environment Agency applying its resources proportionately according to the risk at a given site. The report does, however, stress the need for regulators to describe a clear set of minimum standards and to adopt a flexible approach in

assessing the suitability of arrangements in place.

The lack of user objection to the principles underpinning the self-support approach can only be seen as positive. The workshop report recommends that this initial positive reception should be built upon further, in the process of deriving firm proposals, for implementation of a risk-based self-advice approach to the regulation of radioactive substances.

Key features to be considered in establishing a risk-based approach to regulation, and encouraging users to become more self-supporting will be:

- Deriving and adopting minimum competence criteria for environmental risk management practice. This should be both at a collective (or corporate) level and for those 'qualified experts' responsible either for implementing those practices or for auditing compliance by others;
- Flexibility in enabling users to derive their own systems and practices such that their individual needs are met;
- A transparent risk evaluation process used by the regulator to determine the level of scrutiny appropriate for any given site. This must not undermine the ability to take any such enforcement action as may later become appropriate or to vary the level of scrutiny applied to any given user at any time (for example if their level of assessed risk changes).

The second workshop also revealed that company management support for environmental issues is key to ensuring environmental policy. The experience of regulators is that only if senior management is fully engaged and understands their statutory duties does compliance become "core business". However, in some situations at present the only leverage for action is provided by the Environment Agency. This is an issue that will have to be overcome if increased self-

support is to be delivered effectively within a risk-based regulatory regime.

2.3 Other considerations

In addition to the main conclusions outlined above, general discussions, both between RMC and the Environment Agency, and within the workshops, have raised a number of additional issues:

- Whatever arrangements are ultimately put in place to enable risk-based regulation, the duty of the Environment Agency in assuring legal compliance will not change. At all stages the Environment Agency must be able to satisfy itself that the law is complied with and, in the event of an incident resulting in adverse publicity or prosecution, protect itself against possible criticism of its approach;
- To some extent, the Environment Agency already takes a risk-based approach to initial permits under RSA93 and other regulations. This existing approach gives rise to a range of permits – from simple registrations, through 'standard' permits, to bespoke permits for complex or unique sites. The level of effort involved in enabling these permissions varies according to the level of inherent hazard;
- To some extent, Environment Agency inspectors currently apply a degree of risk-based evaluation in their routine work. They often apportion time according to the level of concern they have about a site, spending more time on those sites that they perceive to present the greater levels of threat to the environment. It is recognised, however, that such *ad hoc* risk ranking is neither auditable nor likely to be consistent without clearly defined and applied minimum standards.
- There is a concern amongst regulators that the current charging regime under RSA93 presents little, if any, incentive for users to invest in measures that will

reduce the level of scrutiny they receive from the Environment Agency. There is a perception that the charges passed on to users by the Environment Agency at the time of the research barely cover costs, and are indeed so low that any alternative would be viewed as likely to be relatively poor value for money to cost-aware managers in regulated premises.

- Implementing the European Community's (EC) High Activity Sealed Sources (HASS) Directive offers the Environment Agency an opportunity to amend certain aspects of RSA93 so that a risk-based approach to regulation is enshrined in law. Similarly, any recommendations made by the ongoing Hampton Review of Regulatory Inspection and Enforcement may influence the approach taken by the Environment Agency.

3 Project Findings

3.1 Comparing Environment Agency and user opinions

Table 1 indicates that both Environment Agency personnel and users are in broad agreement regarding the key factors that influence risk. This finding provides valuable insight for those seeking to establish a generic risk evaluation tool which can be used either as an initial screening model for new sites or for reviewing the risk profile at existing sites. Both Environment Agency personnel and users agreed that such a tool would be required to support the Environment Agency's decision-making process when assessing the level of risk at any specific premises regulated under RSA93.

In terms of increasing self-support as a means of risk management, there were further areas of broad agreement between the two groups. These include identifying areas where existing practice is seen as beneficial, as well as those where further work is needed to establish a more standardised approach. The following sub-sections summarise some of the more significant areas of agreement and outline where further work is required.

3.1.1 Areas of agreement

In terms of managing risk at any given location all workshop participants agreed that the role of the 'suitably qualified expert' (usually the RPA) was pivotal both in assuring compliance with the legislation and in promoting best practice. Equally, they generally agreed that those sites presenting the lowest risk were those where the RPA held a position within the local management chain and could 'get things done'. It also emerged that a strong and supportive relationship with the Environment Agency site inspector could

be an important contributor to lower risk sites, citing instances where Environment Agency visits had proved essential in assisting the RPA to get the necessary work completed. It was clearly felt that reduced Environment Agency presence at such sites could further reduce the RPA's ability to implement necessary controls, thus increasing the environmental risk posed by the operations. This effect must be kept in mind in further developments of a risk-based self-advice system, if some environmental protection benefits from visits from Environment Agency staff are not to be lost.

On a separate, but linked, topic, several participants expressed concern that the responsible person named on the site permission or authorisation did not always have the necessary authority to deliver compliance with the conditions attached. Both workshops suggested that there should be increased standardisation in the role that should be held by the nominated person under the permission or authorisation. At present, this could be a Chief Officer, a middle manager or a "Radiation Safety Officer" with limited authority. In most cases this would need to be the local senior executive. Environment Agency personnel suggested that the named individual would, *in extremis*, be the person they would 'expect to see in court'; user RPAs agreed with this as a starting point.

Given the key role of the 'suitably qualified experts', it is clear that more thought needs to be given to agreeing the degree of competence required of them if a more formal approach towards self-support is to be adopted. Generally, RPAs fill this role. RPAs are professionally qualified in radiation protection and safety, but often have no equivalent formal qualification in environmental matters. Both Environment Agency personnel and users agreed a need to work together to determine what

competences are required if RPAs are to continue to fulfil this role under an increasingly self-supporting regime. The Environment Agency proposed the concept of a Radioactive Waste Advisor (RWA) as a professionally qualified individual who could hold the role; users accepted the principle and agreed that contact with accrediting bodies such as the Society for Radiation Protection may be a useful step towards achieving minimum standards.

On a similar theme, there was also clear agreement on the need for greater consistency in regulatory interpretation across users within same industry sector. Both workshops cited examples of regional differences, and of changes in expectations arising from a change of inspector at a given site. The Environment Agency will need, as part of a move towards reduced intervention and increased self-support, both to clarify the guidance and standards issued to users and to improve consistency in application and interpretation among its own personnel.

3.1.2 Areas for further work

While the workshops revealed broad agreement with the principles of risk-based regulation and increased levels of self-support, the Environment Agency workshop highlighted a number of areas where further work is necessary if such a shift is to occur.

Traditionally the Environment Agency has equated high hazard to high risk. While useful as a starting point, this approach is now recognised as overly simplistic. Whatever model is ultimately derived for risk evaluation (and monitoring) due recognition must be given to the benefits gained from high quality physical and managerial safeguards. At least one member of the Environment Agency expressed the opinion that the variability in risk across sites with comparable hazard (illustrated in Figure 1) was not sufficiently widely appreciated across the Environment

Agency. Development of the risk assessment models to become more realistic (reflecting a mixture of risk factors and not simply hazard) will enable the Environment Agency to target its resources in a more auditable manner in the future.

Bearing in mind concerns over variability in interpretation – by different inspectors and across different industry sectors – of what is required from permitted premises under RSA93, Environment Agency personnel accepted that improved standards and guidance material must be made available. It was noted that a uniformly high standard would be needed in all areas before the Environment Agency could begin to reduce its overall level of regulatory scrutiny.

One particular concern raised by Environment Agency personnel related to the timing of registration/authorisation applications and variations to existing permits. It was observed that applications are sometimes made at too late a stage for the Environment Agency to influence operational control measures to reduce risk. Similarly, the Environment Agency sometimes receives advice from users only when there is a need to amend the numerical limits associated with the particular registration/authorisation, and not when changes are made to a site's inventory, design or management arrangements. These are all relevant to assessment of risk. Prior to any further move to self-support, it will be necessary to provide users with better guidance on when a change in practice at a site requires that the Environment Agency should be informed.

Under a regime of increased self-support, the Environment Agency will probably be called upon more frequently to comment upon whether or not a proposal at a given site represents good practice (or at least meets the minimum standard required). Environment Agency personnel suggest that meeting this demand will require improvement in current mechanisms for

recording and promoting best practice in a given sector.

In summary, work is required to define the competences required of the 'suitably qualified expert' and, ideally, establish a means of having those individuals professionally accredited. In addition, improved guidance, for regulators and the regulated is required, and improved communication between the regulators and the regulated will also be pre-requisite to an effective risk-based self-support scheme for regulating radioactive substances.

3.2 Additional background information

As the project has proceeded, informal discussions between RMC and the Environment Agency have highlighted additional issues for consideration. Based on experience elsewhere, RMC has in some cases been able to draw parallels between the Environment Agency's aspirations and practice and those of other bodies. These 'other issues' are discussed below.

For several years the HSE has also been seeking to take a risk-based approach to regulatory decision making and to make that approach as transparent as is practicable to those outside the HSE. The HSE document, *Reducing Risk Protecting People* (R2P2) [HSE 2001], summarises this approach and provides a useful accepted benchmark for initial decision making. However, R2P2 relates primarily to decision making in response to an application for permission to conduct some activity, rather than to regular monitoring. It does not give any indication as to how the HSE would vary its regulation of any range of activities based on risk.

Within the British nuclear industry, the HSE has had a long history of allowing nuclear site licence holders a large degree of autonomy and self-support. This self-support is delivered through a

standardised set of licence conditions covering most aspects of safety and risk management. Licensees are required, by law, to assess all changes to their activities, categorise them according to their impact on risk and provide information directly to the HSE whenever those changes breach agreed criteria. Equally, one of the licence conditions requires that the site must establish a Nuclear Safety Committee (NSC) to provide advice and guidance on a range of matters affecting risk. Such NSCs are generally comprised of senior experts in the relevant aspects of the licensee's business, and always include some level of independent membership. The nuclear site licences offer a possible model for self-support by small users of radioactive substances.

Again within the British nuclear industry, the HSE has published detailed guidance on their basis for evaluating safety at a given site. The Safety Assessment Principles for Nuclear Plants [HSE 1992] also offers an approach to establishing required standards, which could be adopted by the Environment Agency to provide guidance to users on how they expect to see risk evaluated.

The EC HASS Directive is due to be transposed into UK Law within the next two years. This directive is intended to increase the security of sealed sources of radioactivity, making them less likely to be 'lost', and hence reducing the risk associated with such sources. Ongoing work to implement the directive gives the Environment Agency an opportunity to consider what additional legislative measures, if any, they might propose to Government to enable a more risk-based approach to RSR.

The Hampton Review of Regulatory Inspection and Enforcement was commissioned by Budget 2004. Its remit is to look at the inspection and enforcement of regulations, with a view to streamlining the inspection system without adversely affecting regulatory outcomes. It is looking

at all interactions between businesses and regulators – from form filling, through inspection, to enforcement – and plans to report at the time of Budget 2005. The Environment Agency is outside the review's scope, although the Environment Agency itself recognises the importance of the review and its potential implications for environmental regulation.

It is clear that in seeking changes to current practice the Environment Agency

could risk some loss of reputation if occasionally something goes wrong, resulting in environmental harm, or potential for harm. The fact that increased self-support might be perceived as a 'slackening' in the regulation of radioactive materials should be recognised and addressed. Similarly the possibility that changes in legislation might be perceived as a remedy to existing shortcomings in regulation should also be managed.

4 Conclusions and Recommendations

4.1 Study conclusions

The study concludes that:

- Risk-based regulation of activities under RSA93 is both desirable and may initially be achieved through formalising existing practices applied by individual Environment Agency inspectors;
- Users of radioactive substances are receptive to the principle of self-support as a risk-reduction measure that offers the potential for them to operate with reduced regulatory involvement;
- The Environment Agency needs to review its own practices, standards and guidance to enable a consistent approach to RSR across industry sectors;
- The role of the (existing) RPAs in assuring compliance with the RSA93 is critical. It would be beneficial to agree minimum competence criteria for persons holding this position. It might also be beneficial to establish a formal qualification which covers the additional responsibilities associated with waste management and environmental protection enshrined within RSA93;
- Ongoing legislative developments, at both national and European level, offer the Environment Agency a possible opportunity to bid for amendments to RSA93 to enable greater self-support in the future.

4.2 Recommendations for future development

The Environment Agency is already investigating the possibility of formal risk assessment 'tools' for use both by its inspectors and by users of radioactive

substances. The present study outlines the views of the Environment Agency and users of radioactive substances on what factors influence risk, and recommends that these factors should be considered in the development of those tools.

Given that charges made by the Environment Agency for regulation under RSA93 are very low, there is little incentive for users to seek to earn autonomy that would result in them having less regulatory intervention. It is recommended that:

- The Environment Agency reviews its charging arrangements to reflect, more directly, the costs incurred in regulation;
- The Environment Agency continues to engage with users in determining a framework within which increased self-support can be delivered. Such engagement could, and should, include defining minimum competences needed by 'suitably qualified experts' to comply with the requirements of the legislation;
- The Environment Agency considers how a system of accreditation of "suitably qualified experts" might be established
- The Environment Agency continues to review its standards and expectations with respect to RSA93 compliance. The output from that review should, as a minimum, include internal guidance enabling greater consistency between inspectors. Ideally, the output will also include increased publicly available information that enables users to understand the requirements more easily.

Table 1: Review of factors perceived to affect risk levels

Issue	Description	Importance			Suitability		
		H	M	L	H	M	L
1. Administration							
Adequacy of administration	Inadequate due to confusion over requirement or objectives	B				I	U
Lines of communication	Unclear lines of authority or responsibility within organisation	B			I		
Lack of co-operation	Objection to or lack of co-operation on a particular aspect of requirement	B					U
Financial constraints	Excessive or unforeseen or financial liabilities cause problems		B				B
Delays	Delays in making submissions or changes to registration/authorisation	B			B		
	Delay in making annual return	U			U		
Record errors	Inadequate records lead to errors or omissions	B			B		
Apathy	Apathy, lack of interest			I			I
Housekeeping	Well-kept site?				U		
Culture		B					B
Safety issue				I			I
Review and internal audit	How well carried out, how often, how thorough		U		B		
2. Organisational							
Organisational problems	Instability in organisation	B					B
Working practices	Complex or changes in working practice cause problems	I				I	U
Resourcing	Unavailability of the right personnel	I				I	
Conflicting priorities	Conflicting priorities within organisation		B				B
Communication/supervision	Poor communication, supervision	B					B
Logistics problems	Logistical problems or restrictions cause problems tracking sources	I	U		U		
Site services	Problems with site services lead to safety issue	U		I		U	I
Waste disposal	Difficulty disposing of wastes	U	I		U		I
Training	Inadequate resources or training, eg with regard to the competent person	B			U	I	
Management systems							
Professional advice	Quality and availability	B			U		I
3. External Factors							
Third party issues	Problems co-ordinating with third parties – contractors, suppliers	B					B
Public interface	Interfaces with the public or public liabilities lead to unforeseen complications – casual or invited site visitors.			B			B

Issue	Description	Importance			Suitability		
4. Quantities							
Number of sources	How many separate sources are kept on the premises?	I	U		B		
Type of source	What type(s) of source are they and what is the nature of the source (solid, powder, liquid or gas) and its radioactivity beta or gamma)?	B			B		
Strength of source	What are the isotopes involved and what is the activity of the source – radiological source strength?	B			B		
New acquisitions	Are additional sources to be obtained (new or borrowed) in the foreseeable future?	U	I		I	U	
5. Storage							
Number of stores	How many different storage locations are there? Are the source(s) always stored in the same location?	U	I		B		
Location	Location of premises and where on the premises are source(s) stored	U	I		B		
Containment	Nature of storage containment, primary (eg container and seals) and secondary (eg locked cabinet or room)	U	I		U	I	
Conditions	Under what environmental conditions are source(s) stored – temperature, pressure and humidity? Is the storage area vented?	U	I		B		
Security	How many people have access to the sources? What measures are in place to prevent unauthorised access?	B			I	U	
Change of storage arrangements	Is the storage location likely to change in the foreseeable future? Are the storage conditions described above likely to change in the foreseeable future?		I	U	I		U
6. Usage							
Normal use	Itemise the normal usage of the source(s) and how often they are used for each				B	U	I
Abnormal use	Are there any further uses (eg loan to third parties) of the source(s) not listed above that are rarely or infrequently undertaken? If so what are they and how often do they occur?	B					B
Abuse	What measures are in place to prevent the source from being used for reasons or functions other than those for which it is intended?	I		U		I	U
Damage	Do you have a procedure for handling a source (or its container) that is damaged or where its integrity is compromised?	B			U		
Contamination detection and clean up	What provision is made for the use of personal detection badges and decontamination facilities following spillage or exposure to radiation?	B			U	I	
Personal protection equipment	Is appropriate handling equipment and protective clothing provided?	U		I	U		I
New build		B					B
Disused sources	Are appropriate measures in place?	U	I		U		I
Changes	Are all changes/experiments properly considered and pre-authorized?	B				I	U

Issue	Description	Importance			Suitability		
Limits	Division between departments or distribution across time	B			B		
7. Transportation							
To/from	What are the normal locations for source(s), where are they moved from and to and how often? Do they ever leave the premises?						
Transport conditions	Under what conditions are source(s) transported?	U	I		U		I
Protection	What measures are in place to prevent damage or inappropriate actions to source(s) while in transit?						
Third party use	Is the source ever used by third parties?	U		I	U		I
	What arrangements are in place to ensure its proper and safe usage by third parties?		I				I
	What checks are made on return of a source from third party use?		I			I	
8. Disposal							
Approved disposal route	Do you have an approved disposal route for source(s)?	U	I		U		I
Procedures	Do you have procedures in place for the safe removal and disposal of source(s)?	B			B		
Records	Do you maintain records of sources that have been sent for disposal?	B			B		
Recent disposals	Have you disposed of any source(s) since the last report? Are you expecting to dispose of source(s) in the foreseeable future?		I		I		
9. Records							
Recording consistency	How are records of the source maintained – eg paper, electronically?	B			B		
Records content	Is the following information recorded about the source (see below):	B			B		
Labelling of source	Is the source correctly labelled – Word “Radioactive”, “Trefoil”, date of receipt, name and activity of each radioactive element?	B			U	I	
Labelling of container		U	I		U		I
Signs and symbols	Are the areas where the source is normally used and stored correctly signed and labelled?	U	I		B		
10. Competence							
Roles and responsibilities	Name the individuals responsible for the sources and describe their roles and responsibilities.	B			B		
Competent person	Who is the competent person for the source?	B			B		
Training	What training has the competent person received?	B			U	I	
11. Procedures							
Bookings and delivery procedure	Are there recognised procedures for the notification of use with the competent person? Are records of source movements with dates for its delivery and return to store maintained?	U			U		

Issue	Description	Importance			Suitability		
Emergency planning	Are emergency procedures in place for all reasonably foreseeable accidents?	B			U	I	
Lost sources	Are there recognised procedures and training in place for: - the notification of loss of control of sources; - the recovery of sources over which control has been lost?	B			B		
Exposure to fire	Are there recognised procedures and training in place for: - the notification of exposure of sources to fire; - their removal or protection when exposed to the threat of fire; - clean-up following exposure to fire?	B			U		I
Damaged sources	Are there recognised procedures and training in place for: - identifying whether a source has been damaged (flood or incident); - the recovery of sources to a safe state pending disposal or re-use?	B			B		

Key:

I: Ranking assigned by Environment Agency personnel (inspectors)

U: Ranking assigned by users

B: Ranking assigned by both Environment Agency personnel (inspectors) and users

H: High risk

M: Medium risk

L: Low risk

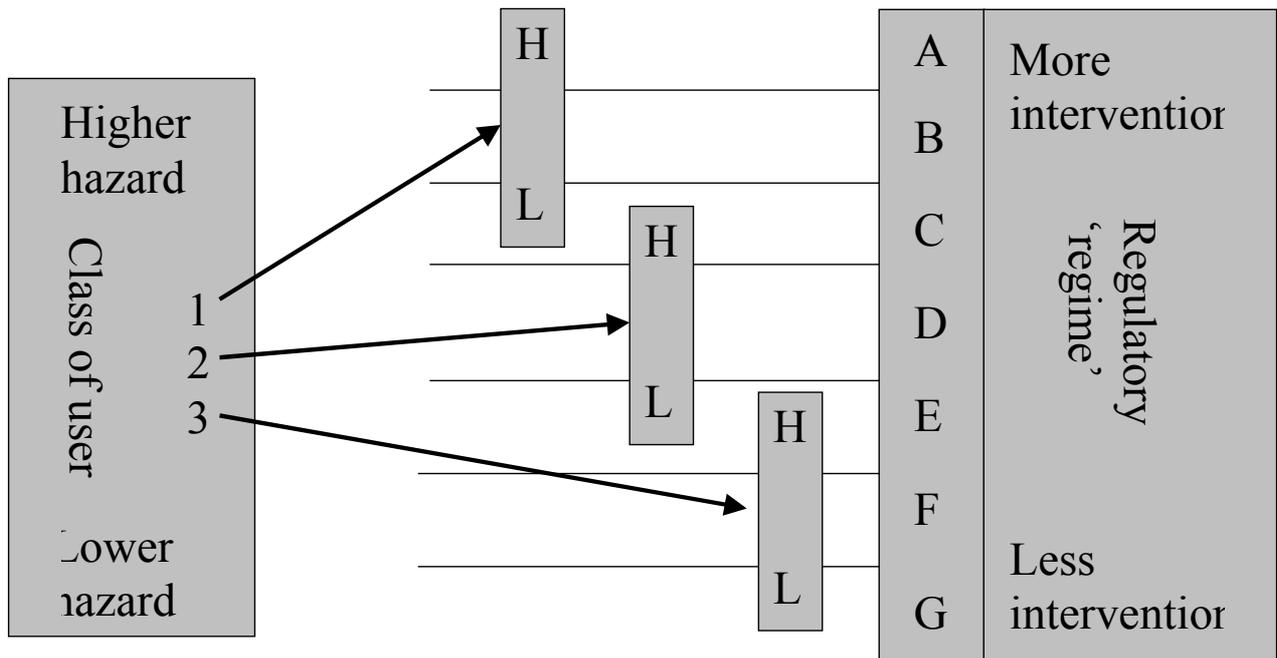


Figure 1: Relationship between regulatory effort to risk for different classes of user

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List of abbreviations

EC	European Community
HASS	High Activity Sealed Sources
HSE	Health & Safety Executive
IAEA	International Atomic Energy Agency
NSC	Nuclear Safety Committee
OPRA	Operator Pollution Risk Appraisal
RA	Risk-Based Assessment Methods
RMC	RM Consultants Ltd
RPAs	Radiation Protection Advisors
RSA93	Radioactive Substances Act 1993
RSR	radioactive substances regulation
RWA	Radioactive Waste Advisor
SAPs	Safety Assessment Principles

We welcome views from our users, stakeholders and the public, including comments about the content and presentation of this report. If you are happy with our service, please tell us about it. It helps us to identify good practice and rewards our staff. If you are unhappy with our service, please let us know how we can improve it.