

The Role of the Regulatory Body in Ensuring that the ALARA Principal is Implemented in Practice

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Abstract

Regulatory authorities throughout Europe are responsible for granting authorisation (notification, registration and/or licensing), where appropriate, for practices involving the use of sources of ionising radiation. In considering whether a new authorisation should be granted the applicant is required to demonstrate to the regulatory authority that it has put in place measures to afford the highest degree of protection to members of the public, patients and workers in the context of optimisation.

The IAEA's International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (Safety Series No. 115) states that "except for medical exposure, the optimisation of the protection and safety measures associated with any particular source within a practice shall be subject to dose constraints".

In addition to the use of dose constraints there are other "tools" that regulatory authorities can use to ensure optimisation, including for example requirements on users to carry out prior risk assessments, restrict access to areas, classify workers develop radiation safety procedures, carry out dose monitoring of areas and personnel and to provide appropriate information and training to all staff. Practical experience has shown that the use of inspections by regulatory authorities is an extremely effective tool in ensuring that the ALARA principal is implemented in practice.

The 8th European ALARA Workshop (EAN) Workshop (Occupational Radiological Protection Control through Inspection and Self-assessment) considered how the regulatory process contributes to achieving ALARA for occupational exposure. In particular one of the final recommendations from the Workshop was that national authorities should promote communication between different national regulatory authorities.

As a result of this recommendation the European Radiation Protection Authorities Network (ERPAN) was created in December 2005. The purpose of this new network is to promote communication between national regulatory authorities including for example the exchange of information and experience on the process of authorisation and inspection methods employed in European countries in the non-nuclear sector. The Network aims to help improve the operational efficiency of radiation control and the ALARA principal throughout Europe while respecting the different regulatory systems that are used.

Introduction

The concept of optimisation, and the application of the ALARA principle, is central to the internationally recognised justification, optimisation, and dose limitation principles for radiological protection. It is a concept that can be applied to all activities involving a source of ionising radiation ranging from a simple application such as a dental or a cabinet X-ray unit to more complex activities such as radiotherapy or the generation of electricity in a nuclear power plant and to exposures to naturally occurring radioactive materials. In an ideal world the ALARA principle would be applied and implemented as a matter of course by all users of sources of ionising radiation (hereafter referred to as the operator). However, in practice, the existence of regulations and the enforcement of them play a considerable role in ensuring that this principle is implemented effectively [1]. The process of optimisation can not be considered as a once off activity but instead as an on-going process that continues throughout the life of a facility and in some cases beyond the date at which operations cease.

Both operators and regulators have roles to play to ensure the effectiveness of optimisation. The operator will design, propose and implement optimisation and then over the course of operation of the facility will further enhance radiological protection through optimisation based upon operational experience. In contrast the regulatory authority has a responsibility to determine whether there is an effective, appropriately supported and functioning programme and safety culture that promotes the finding of optimum solutions to manage doses for each exposure situation [2].

The Role of the Regulatory Authority

In almost all European countries the regulatory authority is responsible for the implementation of a system for the authorisation of activities involving sources of ionising radiation. The process of authorisation varies from country to country but generally involves either notification to, registration with or the holding of a licence from the regulatory authority or a combination thereof. The authorisation process may also be specific to individuals/organisations carrying out the activity, the activities being carried out, or the sources of ionising radiation being used.

One of the primary roles of the regulator is to foster a 'safety culture' amongst all users of sources of ionising radiation. This can be achieved by the promotion of a culture of continual questioning, continual review and continual improvement within each facility. This continual process should involve all the key players including for example the regulator, management and workers within the facility and radiation protection consultants.

On occasion operators may not have read all the relevant legislative and regulatory documents and may be unaware of all their requirements and responsibilities. Adherence by the operator, and its employees, to these requirements is often essential in ensuring that exposures to ionising radiation are ALARA. While in some countries the supplier of new sources of ionising radiation is required to provide information to specific operators in many cases it is only when the regulator draws the operators' attention to the relevant requirements that appropriate measures are put in place to ensure the ALARA principle.

There are many "tools", or regulatory requirements, that the regulatory authority has at its disposal to ensure that all activities involving authorised activities are optimised. The requirements are usually set out in legislation and provide the regulatory authority a legal basis for demanding that operators adhere to them. Some of these regulatory requirements are detailed in the follow section.

Optimisation Tools available to the Regulatory Authority

Guidance and Advice

One of the primary functions of a regulatory authority is to provide accurate and timely information and advice on the protection of individuals and the environment against the hazards arising from ionising radiation to a variety of organisations including for example government departments, ministers and members of the public. In addition the regulator will often develop specific guidance for operators which describes both minimal acceptable standards and commonly accepted levels of good practice. Operators will then be expected to meet and, more ideally, exceed these standards. It is through this process that the regulator can set appropriate standards and benchmarks for ALARA throughout all sectors

Education and training is universally recognised as being one of the cornerstones of good radiation protection. In addition to providing guidance and advice the regulator will often run training courses. Some regulatory authorities in addition to running their own courses will be responsible for the recognition and approval of training courses run by third parties.

Dose Constraints

The IAEA's Basic Safety Standards [3] states that "*except for medical exposure, the optimisation of the protection and safety measures associated with any particular source within a practice shall be subject to dose constraints*". In addition, Article 7 of Council Directive 96/29/Euratom (BSS) [4] states that "*dose constraints should be used, where appropriate, within the context of optimization of radiological protection.*" Both of these Standards explicitly recognise that dose constraints are a fundamental component of the optimisation process. Moreover, given that they are usually used during the design phase of any new facility they require the optimisation process to begin long before any source of ionising radiation is acquired by the operator.

The responsibility is on the operator to demonstrate to the regulatory authority that the design dose constraints are appropriate and will be met to ensure that the facility will be designed to provide the necessary protection to workers and members of the public.

Risk Assessments

Article 17 of the BSS requires operators to carry out an evaluation to identify the nature and magnitude of the radiological risk to exposed workers prior to commencing an activity involving a source of ionising radiation and to implement a process of optimisation to ensure radiation protection in all working conditions. This requirement to undertake a risk assessment is further expanded in some countries to include consideration of reasonably foreseeable risks to members of the public, as well as to workers. It is through this process of identifying the risks involved in the activities and consideration of appropriate measures to ensure that these risks are not realised that real measures are introduced to effect the ALARA principle even before the activity begins.

In some countries the regulatory authority may take this process a step further and require the undertaking to carry out a Best Practicable Means (BPM) assessment prior to commencing a new practice and to repeat this assessment on an annual basis. This is particularly relevant in the case of an authorised activity in which radioactivity may be released, albeit in a controlled

manner, into the environment e.g. patient excreta from an iodine ablation treatment facility in a hospital or a university research department. In effect, the regulator is forcing the operator of the facility to critically review its operational procedures on a regular basis. This requires the undertaking to regularly ask itself whether it is doing enough to ensure that all doses to individuals, and the environment, are as low as reasonably achievable. In considering this question it should be noted that a regulator's requirement in one area e.g. to reduce doses to the public may have consequences to doses in other sectors e.g. the environment. Weighing up the pros and cons of both sides of the fence will generally involve on-going discussion between the operator and the regulator.

Most radiation protection professionals see the requirements for risk assessment, specific to the operator's activities, to have been one of the major driving forces in significantly reducing employee and public radiation doses over the last 15 - 20 years.

Dose Monitoring

All operators engaged in activities involving a source of ionising radiation where it is reasonably foreseeable, either in routine or accident situations, that workers may receive significant radiation doses are required to provide individual dose monitoring to these workers. Unfortunately some operators may see this requirement as an un-necessary additional (financial) burden especially when past experience has shown that their employees have never received a recordable dose on their personal dosimeters. In addressing these types of issues it is useful for the regulatory authority to point out to the operators and/or its workers the many reasons why dose monitoring should be undertaken including the fact that;

- i) it provides reassurance to the worker, employer and regulator that the operator is effectively managing radiation exposures and keeping them ALARA;
- ii) it is often a legal or regulatory requirement;
- iii) dose monitoring can sometimes identify poor or changing working practices and processes;
- iv) dose monitoring can sometimes indicate deficiencies in shielding;
- v) dose monitoring can sometimes indicate defective/malfunctioning equipment;
and
- vi) dose monitoring provides a legal record of any doses, if any, received by the wearer.

In cases where high doses are recorded on personal dosimeters an investigation into the cause of the dose usually results in corrective action to ensure that a similar occurrence cannot happen again.

Inspection

To assess compliance with legislative and regulatory requirements regulatory authorities routinely undertake inspections of authorised facilities. These inspections will usually be undertaken as part of a planned inspection programme but they may also be carried out

following an incident or in cases where a concern may be brought to the attention of the regulator by a member of the public or even an employee of the facility.

In devising a programme of routine inspections the regulator has to optimise the resources available to it. In deciding the number and nature of planned inspections consideration must be given to the nature of the activities carried out, the inherent risks involved in the activity and the time since the last inspection as well as previous experiences with individual operators.

While one of the primary objectives of any inspection is to audit the facility against regulatory and legislative requirements it provides the inspector, and hence the regulator, an opportunity to assess first hand how effectively radiation protection is being implemented in practice. This can be further assessed if the inspectors are offered an opportunity to speak with the workers who carry out the authorised activities. It is important that regulators continually remind operators of their responsibilities with respect to radiation protection and that the ultimate responsibility for ALARA rests with them rather than individual managers, workers, or radiation protection consultants. This can often be achieved through the regulator's insistence that the senior management of a facility should be present and actively involved in the inspection process.

Inspections also provide an opportunity for the inspector to provide some recommendations and advice to the operator on suggested improvements that could be undertaken to further improve the radiation protection structures in place. However inspectors have to be ever mindful of the fine lines between being an enforcer, providing advice on suggested improvements, and engaging in consultancy services to the operator.

Of particular relevance to ALARA, inspectors often observe procedures and protocols that have made a real improvement in radiation safety. This information is routinely brought to the attention of other users on future inspections and in the development of guidance referred to above.

Enforcement and Prosecution

There will be times when an operator does not comply with the requirements of the regulatory authority. In these cases the regulatory authority may have no choice but to take enforcement action against the operator. The enforcement actions vary from country to country but will generally include some of the following:

- i) issuing a formal direction to the operator requiring it to comply with the requirements of the regulator and/or legislation;
- ii) issuing an enforcement notice which prohibits the use of a particular item of equipment or process;
- iii) revocation of an authorisation;
- iv) the imposition of fines; and
- v) prosecution in a court of law.

While enforcement is usually undertaken as a last course of action by the regulatory authority there can be no doubt about its effectiveness as an optimisation tool. Operators who have been the subject of an enforcement action will, in general, put in place corrective measures to ensure

that a reoccurrence will not take place in the future. However, regulatory authorities need to consider how this can be used as an optimisation tool. While the operator in question will no doubt address the non-compliance that led to the enforcement action the regulatory authority can use this to its advantage. By bringing it to the attention of other operators, though for example newsletters, press releases etc., the regulatory authority can remind other operators that it has enforcement powers available to it and that it does exercise these powers when required.

The European Radiation Protection Authorities Network

In September 2004 the 8th European ALARA Network Workshop was held in Uppsala, Sweden. This workshop, entitled *Occupational Radiological Protection Control through Inspection and Self-assessment* brought together many stakeholders throughout Europe to assess how regulatory authorisation and inspection, together with internal controls (peer reviews, self assessment etc) contribute to achieving ALARA for occupational exposure. Participants in the workshop included representatives from regulatory authorities, trade unions and utilities in the medical and industrial sector. The workshop provided a forum both for reviewing existing inspection and self-assessment practices in Europe and for developing a set of recommendations as to how radiation protection could be further improved into the future.

At the end of the workshop a series of recommendations were developed. Recommendation number seven addressed the issue of communication between Regulatory Authorities. In particular it is recommended that *“National Authorities should promote communication between different National Regulatory Authorities including the exchange of information on the licensing and inspection methods employed in different countries. Joint inspections, i.e. involving two or more Regulatory Bodies from different countries, should also be encouraged as a means of sharing information and experience. The creation of a network of contacts through which such information can be exchanged, is also recommended.”*

The final set of recommendations arising from the workshop were discussed at a meeting of the EAN’s Steering Group in December 2004. In order to progress recommendation number seven the Steering Group decided to establish a new sub-network in order to facilitate communication between regulators. Recognising the work of other regulatory authority networks it recommended that this new sub-network should focus primarily on areas such as inspection and authorisation processes in the non nuclear/fuel cycle sector, rather than higher level policy making areas, and should involve participation from inspectors or managers of inspection teams across Europe.

On the 21st June 2006 the first meeting of the newly created European Radiation Protection Authorities Network (ERPAN) took place at the headquarters of Autorite de Surete Nucleaire (ASN) in Paris. Representatives of regulatory authorities from 12 European countries participated in the meeting at which the Terms of Reference for the operation of the network were agreed. These are provided in Appendix I.

It is universally accepted that good communication links between regulatory organisations is key to providing a harmonious system of control for any regulated practice. This is especially important within individual countries but the concept could equally be applied across neighbouring countries as well. One of the important functions of this new network is to create a network of individuals, and not organisations, facing similar situations on a day-to-day basis. By aiming to ensure that participation in the network is by people involved in, or managing programmes of, inspections it is hoped that the network will be able to deal with practical issues rather than getting tied up in high level/policy deliberations.

The network also recognises that applications involving sources of ionising radiation are generally similar across Europe and that the regulation and subsequent inspection of these activities should be largely based on similar criteria. Radiation protection is not a problem faced by individual countries but can instead be considered as a global issue. The network sees merit in sharing inspection experiences and advocates the idea of inspectors from one country participating as observers on inspections carried out in other countries. While it is unable to provide financial support towards any of these opportunities it is worth considering that this sharing of experiences is a fundamental part of on-the-job training for inspectors and be financially resourced as part of a training and development budget.

The network is open to all regulatory authorities throughout Europe. Regulatory Authorities wishing to nominate someone to the network should contact one of the authors for further information.

References

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2. W Weiss, Optimisation of Protection – Broadening the Process, EAN Newsletter Issue 17, 2005
3. International basic safety standards for protection against ionizing radiation and for the safety of radiation sources. — Vienna : International Atomic Energy Agency, 1996. (Safety series, ISSN 0074-1892 ; 115. Safety standards)
4. Council Directive 96/29/Euratom **OJ** L159 29th June 1996

Appendix I

Terms of Reference of the European Radiation Protection Authorities Network (ERPAN)

Purpose

The ERPAN aims to promote communication between national regulatory authorities including the exchange of information, requirements and experiences on the process of authorisation and inspection methods employed in European countries in order to promote the ALARA principal. It also aims to help improve the operational efficiency of radiation control across Europe while recognising the different regulatory systems within the various countries.

Collaboration with the European ALARA network (EAN)

On an annual basis the network will update and inform the European ALARA network of its work and through the EAN's newsletter and web site.

Scope of the network

The network will cover all radiation protection topics relevant to European radiation protection authorities relating mainly to non-nuclear users of ionising radiation such as research, education, medical and industrial application as well as NORM.

The following topics may for instance be addressed:

- Inspection and investigation practices, joint inspections
- Training requirements for inspectors
- Process of authorisation (notification, registration, licensing)
- Reporting system from users to regulators
- Regulatory communication with users
- Intervention issues
- Communication on radiological events
- Environmental impacts arising from the uses of ionising radiations

Membership of the network and nomination

All European radiation protection regulatory authorities should be encouraged to participate in the network. Representatives should be nominated by the appropriate regulatory authority within each country. Regulatory authorities should ensure some continuity in their representation.

Duration of the membership

Participation by the representatives of regulatory authorities is entirely voluntary.

Roles and responsibilities of the representatives

To express the views of the regulatory authority they represent, to contribute to debate, to prepare for meetings, to undertake specific tasks as required and disseminate information within their own country.

Process for nomination of a chairperson, a deputy and a secretary

The chairperson, its deputy and secretary are elected every two years. These elections take place during meetings of the ERPAN.

Financial consideration

Each participant will cover their own travel and subsistence expenses.

Venue and frequency of the meetings

The network will meet approximately once a year at a convenient location. The date and venue for each meeting will usually be chosen to coincide with an European ALARA network meeting or workshop.