The optimisation approach of ALARA in nuclear practice: an early application of the Precautionary Principle. Scientific uncertainty versus legal uncertainty

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Abstract The late health effects of exposure to low doses of ionising radiation are subject to scientific controversy: one view finds threats of high cancer incidence exaggerated, while the other view thinks the effects are underestimated. Both views have good scientific arguments in favour of them. Since the nuclear field, both industry and medicine have had to deal with this controversy for many decades. One can argue that the optimisation approach to keep the effective doses as low as reasonably achievable, taking economic and social factors into account (ALARA), is a precautionary approach. However, because of these stochastic effects, no scientific proof can be provided. This paper explores how ALARA and the Precautionary Principle are influential in the legal field and in particular in tort law, because liability should be a strong incentive for safer behaviour.

This so-called “deterrence effect” of liability seems to evaporate in today’s technical and highly complex society, in particular when dealing with the late health effects of low doses of ionising radiation.

Two main issues will be dealt with in the paper:
1. How are the health risks attributable to “low doses” of radiation regulated in nuclear law and what lessons can be learned from the field of radiation protection?
2. What does ALARA have to inform the discussion of the Precautionary Principle and vice-versa, in particular, as far as legal sanctions and liability are concerned?

It will be shown that the Precautionary Principle has not yet been sufficiently implemented into nuclear law.

Keywords ALARA; liability; low doses; Precautionary Principle; risk regulation; scientific uncertainty

Introduction

This paper deals with regulation of those risks for which scientific uncertainty exists and the legal sanctions attributed to such regulation. The last decade is characterised by an evolution to more techno-scientific regulation, giving rise to discussions on how to formulate and monitor the rules for optimisation of safety.

These new challenges can be illustrated by the difficulties in interpretation of the ALARA principle, which has first been formulated by the ICRP (International Commission on Radiological Protection), and means that doses have to be kept as low as reasonably achievable, taking social and economic factors into account. ALARA clearly has an Anglo-Saxon origin. The UK regulators, since 1842 and the passage of the factory laws introducing the term “Best Practice,” have held the belief that regulation should be as
flexible as possible. In 1974, following the Health and Safety at Work Act, the “As Low As Reasonably Practicable (ALARP)” test became the UK standard (Bouder, 2004, p 39). The terminology used by ICRP can however be confusing because it also seems to refer to the “reasonably practicable” qualification in common law negligence actions and to the measuring of the duty of care. In contrast, the ICRP defines ALARA as “a judgemental decision-making process based on quantitative and qualitative approaches to select the appropriate protection solution.” As such, it is a risk management procedure which is applicable to a group of people or at a workplace, and it is not meant to be a measurement (in tort law) of the duty of care in an individual liability case.

Techno-science regulation is often based on a so-called “regulatory mix” of Command and Control Regulation, Economic Instruments, Self-Regulation and Voluntarism. Within the category of Command and Control belong Performance Standards, which are outcome-focused, and Process Standards, such as ALARA, which address procedures and parameters for achieving a desired result. These are mostly used in respect of hazards that do not lend themselves to easy measurement (Gunningham and Sinclaire, 1999, pp. 49–76).

Also the legal qualification of “prevention” and “precaution” often leads to confusion. While the notion of prevention is used when scientific certainty exists about the harmful consequences of a product or activity and one tries to avoid these effects, the notion of precaution is used in cases where no scientific certainty exists. The Precautionary Principle and ALARA have a common denominator: they are general rules for decision makers on risk assessment and risk management under scientific uncertainty.

The addressees of the principles differ however. The ALARA principle is clearly addressed both to the regulators (and control bodies) and to the nuclear operators and hospitals (radiotherapy, nuclear medicine and imaging), written down in law and in regulation (i.e., the operating licensing process). The Precautionary Principle in its formulation in law deals mostly with prior regulation and decisions by authorities on high risk industrial activities.

We can examine the similarities and differences of both principles in the particular field of ionising radiation, and in particular when dealing with so-called “low doses.”

When speaking about low and high doses of radiation, only for doses higher than 100 mSv received at the adult age, stochastic effects such as cancer and genetic damage are considered by UN Peer review as significant (Slama and Spira, 2004).

From epidemiological results are derived scientific thresholds for stochastic and deterministic effects. In particular the uncertainty about a dose threshold for stochastic effects and the area of low doses are the subject of this paper. In contrast, deterministic damages are those for which physical evidence can be obtained. Scientific thresholds above which these effects occur can easily be established. The low doses are generally positioned below 100 mSv.

Outline
In the next section we will present the three elements constituting the Basic Safety Standards embedded in nuclear law: Justification, ALARA and dose-limits. In the second section we will consider the question whether violation of the ALARA and the Precautionary Principle are a legal basis for liability. At the end we formulate our conclusions.

The three basic safety standards in nuclear law
Inspired by the scientific work of the International Commission on Radiation Protection (ICRP), the European Directives and national laws have introduced the triple system of
the Basic Safety Standards in nuclear law: Justification, Optimisation (ALARA) and dose-limits\(^3\).

Every new nuclear practice has to be justified, i.e. the benefits have to outweigh the possible detriments. The application of this principle in practice has already been considered by the UK High Court (Leigh, 2003, pp. 43–51). In this case the decision by the Secretary of State for Environment, Food and Rural Affairs and the Secretary of State for Health by which the MOX plant of BNFL in Sellafield, UK, was licensed for operation, was challenged by Greenpeace and Friends of the Earth, as being not “justified in advance.” It was thereby established that Justification is a legal duty on the Authorities on the moment they have to decide on a building or operating license.

The second Basic Safety Standard is optimisation, or the so-called ALARA Principle. The ALARA principle requires the nuclear operators and hospitals to organise safety management which limits the radiation risk as low as reasonably achievable, taking social and economic factors into account. This is a utilitarian approach which still requires dose limits for the individual protection, being the third Basic Safety Standard.

The dose limits are legal thresholds for protection of the workers and the general public (20 mSv for nuclear workers and 1 mSv for the members of the public per year, under normal circumstances). Dose limits for specific deterministic effects are set at 500 mGy/organ and 150 mGy for the lens of the eye, for workers (and at 1/10 for the public).

In a Judgement of the European Court of Justice\(^4\), it was ruled that Belgium was allowed to set, for apprentices and students aged between 16 and 18 years, stricter dose limits than those which were prescribed in the Directive 80/836.

Following consideration of this Judgement, the Recommendations of the ICRP were accepted as the legal basis for the interpretation of the EU Directives, and even Recommendations which were published after the said Directives. Moreover the Court gave a clear preference to the optimisation duty, over the dose limits. According to the Court dose limits are not absolute values but are published “merely for guidance.” The Court derives its opinion from ICRP Publications which show that “all ionizing radiation, in excess of natural background radiation, involves dangers for human health and that, whilst it is accepted for economic and social reasons, such acceptance merely represents a balance between its advantages and disadvantages.”

It follows that the dose limits fixed by the ICRP are not absolute values but are published merely for guidance and that the principle underlying them is that of the optimization of protection.


Article 6:
1. Member States shall ensure that all new classes or types of practice resulting in exposure to ionising radiation are justified in advance of being first adopted or first approved by their economic, social or other benefits in relation to the health detriment they may cause.
2. Existing classes or types of practice may be reviewed as to justification whenever new and important evidence about their efficacy or consequences is acquired.
3. In addition each Member State shall ensure that:
   a. in the context of optimisation all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account;
   b. without prejudice to Article 12, the sum of the doses from all relevant practices shall not exceed the dose limits laid down in this Title for exposed workers, apprentices and students and members of the public.

\(^4\) ECJ, 25 November 1992 (Case C-376/90), ECR 1992, I-06153
With this example we can show how in nuclear law techno-scientific guidelines (or soft law) are entering the legal system through jurisprudence. It also shows the dangers of interpretation involved. Indeed this position of ICRP on the dose limits is not discussed with a larger public than experts, while these recommendations are put in operation through EU Directives and national laws without such a prior evaluation of advantages and disadvantages as proposed by ICRP. From the context of the commented judgment of the European Court, it follows that the dose limits in national legislation can only be stricter than these prescribed by EU directives. Moreover, these considerations of the Court were only decisive on regulation policy and should not be used in liability cases. It seems that the Court has made a mixture of the ideas behind optimisation and those behind dose limits. The first is meant to protect a group of people (because the focus is on the collective dose), the second is meant to protect individuals within the group (distribution of the risk among the group members).

ALARA and the precautionary principle as a legal ground for liability?

As opposed to the dose limits, which in our view set forth an obligation to achieve a result, the optimisation principle creates typically an obligation of optimal care. For liability cases, both can be at stake. But legal rules also deal with the clarity and security of law for all legal subjects, the risk-takers included. In case of unlimited burdens of claims, industry but also medicine would be made impossible.

Because of the justification process, nuclear operators can argue that the residual risk, the risk not covered by the dose limits, is not the responsibility of the licensed operator.

This has been accepted in the US under what is called “the O’Connor Doctrine”:

In a highly technical field such as this, although a plaintiff should be provided a very high level of protection from excessive exposure from radiation, a defendant public utility should also be provided with some clear statement regarding how it may limit a worker’s dose without exposing the worker to injury or itself to liability.

In the US, this doctrine is firmly established so that the duty owed to a plaintiff (the standard of care) is not based on ALARA but on the dose limits set forth in the law and the operating licence. Such guarantee could better protect potential victims, while a liability claim is easier to prove, but it also entails legal security for the risk-taker. It is of course necessary that dose limits are set at low levels limiting risk to a degree of tolerability and acceptability.

In the nuclear sector, the “three-tier system” of justification, ALARA, and dose limits should offer a protection to victims which already incorporates the precautionary approach through the justification process and the dose limits. Indeed, the dose limits are already by a factor of 10 lower than the doses at which stochastic damage has been scientifically shown. But this techno-scientific way of setting thresholds in the law dates back to scientific and legal positivism. Before the Precautionary Principle was incorporated in the legal system, it was common practice that regulation was based on science, as if it were objective and true (“value-free”).

In case such laws have been made without going through a democratic process (i.e., just transferring the ICRP Recommendations into European and national law) it is highly questionable if such dose limits represent the legal threshold under which the risk has been accepted by society (the public).

Because of the lack of democratic acceptance of such thresholds, the dose limits are giving a double message: a message of risk, since there seems to be a clear need to limit

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exposure, and a false message of safety because the citizen is assured that this level of radiation is harmless.

If the Precautionary Principle is not prescriptive enough to involve liability and the possibilities of defence for the industry are well-established, what is then its influence on the "state of the art and the industry" and the evolving standard of care?

The licensing authority has an important legal duty to examine the risks at first instance. Also during the licensed exploitation there might be changes of circumstances that necessitate the authority to withdraw a licence. In nuclear (safety) law, article 6.2 of the EU Council Directive 96/29 Euratom clearly stipulates that justification is an ongoing process: "Existing classes or types of practice may be reviewed as to justification whenever new and important evidence about their efficacy or consequences is acquired."

To our knowledge, justification as a recurring review, including the necessity of safety measures, has not yet been applied and the possibility for third parties to claim a new justification procedure remains unclear. In our view, it is therefore clear that given the fact that risks also evolve and the regulatory systems in nuclear law do not give enough strength to a recurring appraisal of benefits and costs, the optimisation duty of ALARA comes automatically to the forefront, as the general duty of care applicable in the nuclear sector, which is also applicable in individual (liability) cases.

As ALARA as a legal duty is also directed to the regulatory and control bodies, it is in our opinion unacceptable that when Justification is only a rather passive confirmation of a licence proposal for nuclear activities at high risk without implication of the stakeholders, ALARA is not further defined as to what "best practices" it is orientated towards.

Of course a formal system can be contradictory to the goal expressed by IRCP: "it is important not to let a formal approach to optimisation detract from the basic principles of doing what is reasonable to improve protection." However, at least there should be transparency on the control measures and the possible sanctions.

As a comparison with another domain one can refer to the IPPC Directive (Integrated Pollution Prevention and Control Directive) 96/61/EC. In the framework of this IPPC Directive an Information Exchange Forum (IEF) has been created and a permanent IPPC Bureau in Sevilla, Spain. In this IPPC Bureau, the EU country experts decide on the so-called BREFs, being BAT (Best Available Techniques) reference documents, such as "Waste Treatments", "Treatment of Metals and Plastics," etc. In total, since 2003 already 18 BREFS have been agreed upon.

Conclusions

The combination in a risk management system of the duty of Justification, an optimisation duty (ALARA) and legal thresholds (Dose Limits) seems to combine the advantages of different kinds of risk regulation ("regulatory mix").

The dose limits are not taking into account the requirement of a democratic process to come to a sound regulatory and justification process. This is one of the main objections to the classical risk assessments and the techno-scientific regulation. Since the Precautionary Principle has been introduced into our legal system, it should be a stimulus for nuclear law to come to a more democratic way of regulating nuclear risks, including the possible long-term effects of low doses, which cannot be measured today. The Precautionary Principle has been put into operation through other legal prescriptions than the

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Precautionary Principle alone, as for product safety, cleaner production techniques and the environmental impact assessment (Fischer, 2002).

The Precautionary Principle is gradually expanding into more specific regulation while the principle itself remains a general standard which is flexible enough to deal with the evolving risks. The Precautionary Principle is, in essence, an ethical principle which promotes a better use of public participation in risk regulation, where the purely cost/benefit analysis has failed. The main cause for this failure is the perception of the (nuclear) risk, which cannot be measured that way.

As for the optimisation principles, such as ALARA and BAT, the legal system is not yet adapted to these new regulation techniques based on legal standards and self-regulation, which are derived from Soft Law. It necessitates a shift in paradigm, from positivism to reflexivity and more procedural regulation, so that stakeholders are more included in the decision making process.

Nuclear law as a whole seems reluctant to apply the Precautionary Principle in nuclear safety and radiation protection because only in the dose limits a risk factor has been discounted for, but without confronting these limits with a public debate. It is regrettable that the Justification process is not further developed in such a way that the stakeholders are involved in the balancing of benefits and potential harm of a new nuclear practice or a new major risk, occurring during the licensed operation. What remains is a “horizontal” precautionary approach, which is embedded in ALARA. The legal duty of risk management under scientific uncertainty is already formulated in ALARA in the field of radioprotection. It is, however, doubtful if this approach gives enough protection by lack of control mechanisms and benchmarking of the safest practices.

References


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8Ost (1999). Le temps du droit. Ed. Odile Jacob, Paris, pp. 310-331, as cited in Deblonde and Warrant (2000). Science and Precaution in Interactive Risk Evaluation: Theoretical framework (Flemish and French), see http://extranet.ufsia.ac.be/MTT/STEM/docs/352.pdf. “Très nombreux sont en effet les auteurs qui considèrent qu’en temps où l’indécidable fait sens, il n’est plus de rationalité que procédurale et de légitimité que négociée” (a great deal of scholars are considering that since today’s society has to deal with the impossibility to decide, there is no other rationality than the one which is procedural and no other legitimacy than the one which is reflexive).