

**Legal uncertainty of safety principles such as ALARA  
as a consequence of the omission of introducing political and societal considerations  
in the legal consensus building around scientific recommendations**

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**INTRODUCTION:**

In 1999 the Committee of Ministers of the Council of Europe charged me with a comparative study<sup>1</sup> of the national regulations related to radiation protection. The idea was to compare the legislation of Ukraine with that of a few European Union member states in order to examine whether – post-Chernobyl - the Ukrainian authorities had undertaken the necessary legislative efforts to protect their population adequately against the risk of exposure to ionising radiations.

It is not my intention to come back to this study, but I want to mention some of the conclusions that encouraged me to have a closer look into the legal implementation of the optimisation principle, known as and referred to hereafter as ALARA (As Low As Reasonably Achievable).

Generally speaking, the four countries that were the subject of this study can be divided into two groups based on the ‘extra’ national context that has a significant influence on their national regulations. For the internal legal system of the three European Union countries, Belgium, France and the United Kingdom, the *supranational*<sup>2</sup> character of the European Institutions and as a consequence, the legal impact of Community law and especially of the European Directives is of great importance. Because of the direct impact of some of the Community law provisions, the traditional instruments of international law such as treaties have – within the field of competence of the European Union – become relatively less important.

Ukraine has no such regional supranational legal sources and is only bound by the traditional international law instruments (in the nuclear field, the same as for the European Union countries).

This supranational level *could* be an explanation for the fact that none of the examined European Union countries has a *real*<sup>3</sup> nuclear law, unlike Ukraine.

This same supranational level might also explain why Ukraine was the first of the four examined countries to have implemented the most recent scientific recommendations of the ICRP<sup>4</sup> (1990), whereas the European Union countries could only in 1996 agree on a new Directive (based on the same ICRP recommendations), which obliges them to adapt their national regulations by May 2000.<sup>5</sup>

The common character of the national regulations is that they are all inspired by those ‘extra’ national (supra- or inter-) instruments, which in turn are based on the scientific recommendations of the ICRP.

This explains the relative homogeneity of the nuclear regulations in general and of radiation protection in particular. The concepts, the prescribed conditions and measures as well as organised control are very similar

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<sup>1</sup> ‘Comparative study of legislation on radiation protection of the population of Ukraine, Belgium, France, United Kingdom’, Council of Europe, AP/CAT (2000)2, January 2000

<sup>2</sup> The difference between inter- and supranational lies in the fact that the latter includes a transfer of national competences to an international body, which consequently becomes invested with competences of his own.

<sup>3</sup> Meaning by ‘real’ that, though executory decrees are (necessarily) based on laws, these laws do not *deal* with nuclear matters.

<sup>4</sup> International Commission on Radiological Protection

<sup>5</sup> Looking at this aspect from a broader perspective (independent from the scope of the comparative study), this conclusion needs to be put into perspective : probably, the Ukrainian legislation would not have been adopted so fast if there had not been the Chernobyl accident and the European Union countries might not have adapted their regulations at all if there had not been the EURATOM Treaty compelling them to do so.

What strikes, is that the national provisions do not always reflect accurately the ICRP wordings, which generates discussions on the interpretation and the scope of some principles such as ALARA, but which also induces divergent even contradictory jurisprudence.

In this sense, ALARA can be considered a good example.

I will now examine the formulation of the ALARA-principle in the existing regulations and then compare the relevant jurisprudence and theory of law.<sup>6</sup>

#### *PRELIMINARY OBSERVATION:*

The most relevant ICRP recommendations are those from 1977<sup>7</sup> and 1990<sup>8</sup>.

Until 1996, the European Directives and thus the national regulations of the member states of the European Union were based on the 1977 ICRP recommendations. Since May 2000, the latest EURATOM Directive 96/29<sup>9</sup>, based on the 1999 ICRP recommendations, should have been implemented into national law.

At international level, the Nuclear Safety Convention<sup>10</sup>, the Basic Safety Standards<sup>11</sup> and thus the Ukrainian regulations have already been based on the 1990 ICRP recommendations.

It is obvious that the available jurisprudence and to a lesser extent the theory of law are based on the ‘former’ ICRP recommendations, those from 1977.

#### *NATIONAL REGULATIONS:*

ALARA is part of the **ICRP’s** recommended fundamental framework of radiation protection with two other principles: justification of a practice and limitations of doses of exposure. I’ll come back on their relationship later; the survey of the wordings hereafter is limited to those of ALARA<sup>12</sup>.

1977 Recommendations (Publication 26):

*“For the above reasons, the Commission recommends a system of dose limitation, the main features of which are as follows: (a) ...; (b) all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account; (c) ...”*

1990 Recommendations (Publication 60), the optimisation principle for Practices:

*“In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received, should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints) or the risks to individuals in the case of potential exposures (risk constraints) so as to limit the inequity to result from the inherent economic and social judgements”.*

**Nuclear Safety Convention**, article 15 imposes the principle of optimisation in compliance with dose limits, with reference to domestic legislation:

*“Each contracting Party shall take the appropriate steps to ensure that in all operational states the radiation exposure to the workers and the public caused by a nuclear installation shall be kept as low as reasonably achievable and that no individual shall be exposed to radiation doses which exceed prescribed national limits.”*

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<sup>6</sup> This paper only treats legal provisions, jurisprudence and theory of law related to practices, and does not deal with medical applications and interventions.

<sup>7</sup> Recommendations of the International Commission on Radiological Protection, ICRP Publication 26, Pergamon Press, Oxford, 1977

<sup>8</sup> Recommendations of the International Commission on Radiological Protection, ICRP Publication 60, Pergamon Press, Oxford, 1991

<sup>9</sup> Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the health protection of the general public and workers against the danger of ionising radiation. OJ L 159 of 29.6.1996

<sup>10</sup> IAEA-document, ref. GOV/INF/821-GC(41)/INF/12, adopted on 17 June 1994, entered into force on 24.10.96

<sup>11</sup> International Safety Series, n° 115, IAEA, Vienna, 1997, adopted on 12 September 1994 by UNSCEAR, NEA, ILO, FAO, WHO and PAHO

<sup>12</sup> The quoted provisions are those where ALARA is mentioned as a general principle. These are not necessarily the only provisions where ALARA can be found. Because these other provisions do not add any precision to the meaning and the formulation of ALARA, they are not mentioned here.

Directive 80/836/**Euratom**<sup>13</sup>, article 6 (Title III) lays down the three general principles:

*“(a. Justification); “b. Optimisation of protection or the ALARA principle: all exposures shall be kept as low as reasonably achievable”; (c. Maximum allowable doses)”*

Directive 96/29/**Euratom**, article 6, general principles:

*“(…) 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; …”*

Article 7, dose constraints : *“1. Dose constraints should be used, where appropriate, within the context of optimisation of radiological protection. …”*

**Ukraine**, the Law 40/95 on Utilisation of Nuclear Energy and Radiation Safety<sup>14</sup>, article 4, §3:

*“- individual dose values, the number of people exposed to radiation and the probability of exposure to any type of ionising radiation shall be the lowest practically possible, regard being had to economic and social factors;”*

**Belgium**, the General Regulations<sup>15</sup>, article 20.1.1. sets out the general principles:

(a. Justification); b. the principle of optimisation: *“all exposures shall be kept as low as is reasonably possible”*( c. compliance with dose limits).

**France**, Decree 66-450<sup>16</sup> of 20 July 1966<sup>17</sup>, article 6:

*“Exposures of persons to ionising radiation and the number of persons exposed, within the limits prescribed in the regulations, must be kept as low as possible.”*

**United Kingdom**, 1985 Ionising Radiations Regulations<sup>18</sup>, article 6 (1):

*“Every employer shall, in relation to any work with ionising radiation that he undertakes, take all necessary steps to restrict so far as reasonably practicable the extent to which his employees and other persons are exposed to ionising radiation.”*

The absence, in most texts, of “taken social and economic factors into account” is striking since these considerations seem to me fundamental parts of the ALARA principle, as recommended literally by the ICRP since 1973<sup>19</sup>. Furthermore, specific criteria and parameters for the operators to apply ALARA are lacking.

Both findings are regrettable.

As to the absence of ‘taken social and economic factors into account’, this implies that ‘reasonable’ is the only limit set on ‘as low as achievable’. It is obvious that a notion as vague as ‘reasonable’ must inevitably lead to different and divergent interpretations.

And the lack of guidance in the regulations on how to apply ALARA leads to legal uncertainty, as I will try to demonstrate hereafter.

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<sup>13</sup> Council Directive 80/836/Euratom of 15 July 1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation, OJ L 246 of 17.9.1980; amended by Council Directive 84/467/Euratom of 3 September 1984, OJ L 265 of 5.10.1984

<sup>14</sup> Adopted on 8 February 1995

<sup>15</sup> The Royal Decree of 28 February 1963 concerning General Regulations for protecting the general public and workers against the dangers of ionising radiation, M.B. of 16.05.1963

<sup>16</sup> Decree No. 66-450 of 20 July 1966 on the general principles of protection against ionising radiation, J.O. of 30.06.1966

<sup>17</sup> Also in article 3 of Decree N° 75-306 of 28 April 1975, as amended; and article 4 of Decree N° 86-1103 of 2 October 1986, as amended

<sup>18</sup> S.I. 1985, n° 1333

<sup>19</sup> Recommendations of the International Commission on Radiological Protection, ICRP Publication 22, Pergamon Press, Oxford, 1973

## **JURISPRUDENCE**

Actual jurisprudence shows that two tendencies coexist:

1. where ALARA is considered as an obligation of conduct that can not be used to determine the eventual liability of an operator;
2. where ALARA is considered to be an obligation of result, so that the operator can be held liable even when the limitation of doses have been respected.

We will try to illustrate both trends by case law from Common Law countries, Belgium and the European Court of Justice.

### **Common law countries:**

I hereafter quote the findings of Donald E. Jose<sup>20</sup> who made a clear summary of recent evolution in the U.S. and the U.K..

Most case law follows the O'Connor doctrine. According to this doctrine : “ some small doses is necessary in the operation of nuclear technology for the public good ... ALARA is a good professional philosophy of trying to achieve excellence in radiation protection by keeping doses even lower than the permissible limit but ALARA cannot serve as a clear statement of the minimum standard of care a jury applies in a lawsuit. Making ALARA the duty owed would destroy the total federal pre-emption of nuclear safety and delegate nuclear safety standards to the whim of what ever jury happens to be sitting on a case.”

Although this doctrine is firmly established, some judges occasionally fail to follow it. As a consequence, any cancer diagnosed in a person who worked at and lived near a nuclear plant can result in a lawsuit.

As D. Jose rightly notices, people with cancer are very sympathetic plaintiffs and even though science and facts fail to prove the operator's fault, jury's verdicts are often based on emotions.

According to D. Jose, these cases have in England often been taken out of the legal system and have been processed through a formula agreed upon by the employer and the trade unions. Results so far show that the British system compensates about ten percent of the cases it processes.

D. Jose concludes correctly “if the public develops the perception that the nuclear industry is responsible for causing about ten percent of the cancers in the workforce, it may not be politically possible to continue to operate a nuclear industry.”

### **Belgian jurisprudence<sup>21</sup>:**

In Belgium, we haven't had any ALARA case until now, but it is interesting to examen the application of the precautionary principle. Only from 1999 we find explicit references to precautionary. Looking at the reasoning of the judges we'll notice the analogy in the difficulties of interpretation and application of precautionary and ALARA.

- In a suspension judgement on 25 January 1999, the Council of State dismissed as not serious the violation of the precautionary principle that had been expressly raised in the proceedings, on the basis of the following consideration: “*that a first reading of the provisions that were invoked prompts the conclusion that these provisions do not contain any enforceable rules, merely general principles in the area of general environmental policy, principles that need to be worked out further and translated into enforceable regulations, that consequently leaving aside the questions whether or not these principles have been ignored, in the current state of the proceedings there is nothing to indicate that a possible violation of these principles should, or even could, lead to the annulment of the disputed licence.*”

Yet, the Council of State has broadened the scope of the precautionary principle. This can be illustrated by two judgements concerning demands for suspension and annulment of building permits of high voltage lines that were introduced by residents of houses under such lines.

- In his judgement n° 79.893 of 22 April 1999, the Council of State still considered: “*Whereas the plaintiff sets forth general point; whereas in his foregoing summary statements, he fails to supply any elements to support his claims in this case; whereas therefore the risk of serious detriment that is difficult to rectify has not been established.*”

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<sup>20</sup> Donald E. Jose, ‘Recent Litigation Involving exposure and radiation’ in Proceedings ‘Nuclear Inter Jura 1999’, Biennal Congress Washington 1999, p. 91-98

<sup>21</sup> Larmuseau Isabelle, ‘The precautionary Principle in Belgian Jurisprudence’, European Environmental Law Review, February 2000

- In a similar case though, the Venter case, on 20 August 1999, the Council of State stated: “Whereas it emerges from the documents submitted in the proceedings that the effects of magnetic fields induced by a high-voltage line are the subject of debate in medical circles, whereas it is not up to the Council of State to settle such a debate; whereas the Council can merely note that there are elements that lead it reasonably to suspect a health risk, and even **if the relevant existing regulations are amply respected**, as the defendant points out, such a risk cannot be ruled out either; whereas for the Council of State, to be able to suspend a challenged act, the detriment need not be certain, whereas **it suffices for the risk of detriment to be plausible**, whereas this applies in the present case; whereas the risk in question poses a threat to the right to the protection of health, guaranteed by Article 23, 3rd paragraph, 2°, of the Constitution, as well as the right to the safeguarding of a healthy environment, guaranteed by 3° of the same paragraph; whereas with respect to the basic rights, the detriment of which the risk must be considered certain, is serious, whereas it is by its very nature difficult to rectify.”

Although this case is based on the constitutionally guaranteed right to safeguard a healthy environment, the precautionary principle has undoubtedly served as a guideline for this decision.

We find a more reassuring decision in the case of the Wilrijk incineration Plant<sup>22</sup>:

The President of the Tribunal of Antwerp in an interim proceeding of 2 February 1999 ordered the shutting down of the incineration plant operated in Wilrijk by ISVAG, on the grounds of the violation of the precautionary principle. The President concluded his judgement with the words: “whereas with regard to public health no compromises should be made, precisely because it is the future of the residents and their quality of life that are at stake, whereas this is a problem that concerns everyone and should not leave anyone unaffected.”

Remarkable in this case is that the President concludes that the violation of the precautionary principle is ‘evident’ without verifying the legality of the licence. This aspect is of major importance. If the licence seems to be legal, it is not or not in the first place the operator who failed but the competent authority that granted the licence.

This is also the conviction of the Court of Appeal of Antwerp that overruled the judgement of the lower court, stating:

1. that it is within the competence of the legislator to create a legal framework and up to the Executive power to execute. Judges therefore have no decision making power.
2. That the competent authority had implemented the precautionary principle through the emission norms imposed on Isvag as a licence condition.
3. Besides, **that no causal relationship can neither be proved nor presumed**.

#### **The European Court of Justice and the opinion of the Commission:** <sup>23</sup>

In the case C-376/90 CEC v. Belgium, the Commission brought proceedings against Belgium for failing to fulfill its obligations under Article 141 of the EURATOM Treaty on the grounds that it had fixed stricter limits<sup>24</sup> than those provided for in Council Directive 80/836/Euratom.

The Belgian government argued that the dose limits are not absolute values so that the Member States are allowed to adopt stricter limits.

The Commission's reasoning in challenging the validity of stricter limits was essentially based on two arguments: (1) the general principles as elaborated by the ICRP need to be transposed into legal regulations, taken into account the social and economic context. For the Member states, the social, economic and even legal framework that they should take into account when elaborating their national regulations, is that of EURATOM! As the EURATOM Treaty requires uniform security standards<sup>25</sup>, member states are not allowed to adopt stricter norms; (2) secondly, if member states want to strengthen the radiation protection, there is no need for lower limits, this can perfectly be achieved by paying particular attention to optimisation procedures, a.o. through dose constraints at the source.

<sup>22</sup> Hof van Beroep, Antwerpen, 11 oktober 1999, Tijdschrift voor Milieurecht 2000, p.52 e.v.

<sup>23</sup> Lennartz R. ‘La protection sanitaire contre les rayonnements ionisants et la Cour de Justice des Communautés européennes, Bulletin de droit nucléaire, n° 53, juin 1994

<sup>24</sup> The Royal Decree of 28.02.1963, amended in 1987, established dose limits for apprentices and students aged between 16 and 18 intending to pursue an occupation in the course of which they would be exposed to ionising radiation or who, by reason of their studies, were obliged to use sources, at one-tenth of the annual dose limits fixed for persons exposed in the course of their occupations, rather than the three-tenths recommended in the Directive.

<sup>25</sup> Article 2b of the Euratom Treaty

The Court did not follow the Commission, ruling that all ionising radiation other than 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 keeping the exposure as low as reasonably achievable. According to Lenartz, on the one hand the Court confused the optimisation principle and the principle of individual dose limits by denying their mutual autonomy. On the other hand the Court resolutely opted for the highest possible degree of protection, at the cost of uniformity within the Community, thus sacrificing one of the instruments explicitly foreseen in the Treaty for the accomplishment of its missions!

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When examining jurisprudence, we primarily notice that there is no unanimity about the status of ALARA. Should ALARA be considered as merely a principle, a guideline or should it be applied as a real legal standard?

Secondly we observe a different approach between common law and continental countries: precedents in Common law countries show that ALARA can be used to establish the liability of the operator even in the absence of a causal relation. In continental countries so far, ALARA is invoked to justify preventive measures. But in the absence of legally defined criteria for the operators to apply ALARA, we notice that the judges are capable of jeopardizing the government's nuclear policy, this by granting preventive measures 1. as soon as damage is plausible, 2. without reference to the financial cost, thus, without considering social and economic aspects.

A third observation is that of lot of misunderstandings and confusions persist as to the relationship between ALARA and dose limits.

#### **OPINIONS OF NUCLEAR LAWYERS**

The theory of law reflects the same observations and questions.

Besides authors who are specialised in nuclear law, I will also refer to environmental lawyers who are confronted with the same problems of interpretation when applying the precautionary principle.

However ALARA became 'famous' within the framework of nuclear law; it is not only a nuclear concept. Long before ALARA was introduced in international law, it was well known and established as ALAP (As Low As Practicable) in British labour law and the Netherlands refer to ALARA in their environmental licence policy.

Grosso modo the ALARA *problematic* can be summarized in five questions:

1. Is ALARA to be considered as a principle or as a rule?
2. Should economic and social factors obligatory be taken into account?
3. Is ALARA an obligation on the authorities and/or on the operators?
4. What is the relationship between dose limits and ALARA?
5. Is ALARA to be considered as a principle of liability or prevention?

#### **I. ALARA: principle or rule?**

R. van Gestel and J. Verschuuren<sup>26</sup> rightly wonder whether ALARA should be considered as a principle or as a rule. According to the authors, a rule applies to every concrete situation and leaves little freedom for deviation. Rules are directly applicable and enforceable; whereas principles rather indicate in what way a rule should be applied, without the obligation of a specific result.

Or one can formulate this question as being one of obligation of result versus obligation of conduct.

Looking at the actual vague wordings of ALARA in all the national regulations, it can hardly be considered to be a rule.

This qualification is in line with the intention of the ICRP, stating that "*optimisation provides a basic framework of thinking*"<sup>27</sup>, "*a state of mind*".

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<sup>26</sup> R. Van Gestel and J. Verschuuren, 'ALARA: minimumregel of beginsel met aspiraties?' in Milieu en Recht, maart 2000

<sup>27</sup> ICRP Publication 60 (1991), § 8

According to J. Lochard and M.C. Boehler<sup>28</sup>, due to the rigidity of our legal system and because of the practical problems to define the obligation of the operator and of the control of its implementation, the authorities had no other choice as to opt for an “obligation de comportement”: *“La technique juridique classique du droit administratif qui se réfère au concept de “norme-règle” et qui est adaptée à la transposition du principe de limitation de doses individuelles ne répond pas exactement aux problèmes que pose la mise en oeuvre du principe d’optimisation : des obligations de prestations imposées traditionnellement par l’administration, il semble qu’il faille passer à une obligation de comportement des acteurs, où, d’une part, la difficile qualification juridique du principe d’optimisation et d’autre part, la difficulté de mettre en place un système de contrôle sur la mise en oeuvre effective du principe d’optimisation.”*

## **II. Social and economic factors?**

R. Van Gestel and J. Verschuuren also draw the attention to the question whether and if so, to what extent, economic (and social) factors should be taken into account.

Although the answer might seem obvious, this question can hardly surprise, given the vague legal formulation of ALARA. As we have seen, jurisprudence indicates that judges, based on the actual vague wordings of ALARA, can give absolute priority to public health without even considering the financial implications (economic) nor the eventual transfer of risks to other industries or other groups of citizens (social).

‘Reasonable’ is thus the only limit set on ‘as low as achievable’ without any indication on how to interpret this.

Corten<sup>29</sup>, who analysed the role of ‘reasonable’ in international law, notices that in its technical function, ‘reasonable’ is introduced in order to make law more flexible, which is in se in contradiction with the essentially static character of legal texts. In judicial discourses, ‘reasonably’ is often deliberately introduced in order *“to mask persistent contradictions regarding the meaning of a rule, behind a formula which leaves open the possibility of divergent interpretations. ... If the use of reasonably suggest any form of agreement, it is an agreement on the lack of agreement.”* According to the International Court of Justice: *“what is reasonable and equitable in any given case must depend on its circumstances.”*

This is all the more true for decisions concerning nuclear matters which depend above all on considerations of social acceptability of risks as argued by J. Locher and M.C. Boehler: *“Dans l’obligation d’accepter les doses maximales non pas comme une garantie de sécurité absolue mais plutôt comme le point de rencontre entre l’exigence de sauvegarder la santé et celle de permettre l’épanouissement du progrès scientifique et économique, le problème de la protection se déplace du domaine de la science vers celui du champ de l’acceptabilité sociale.”*

Or as Katia Boustany<sup>30</sup> says: *“... la norme technique n’apparaît plus – tant s’en faut – d’une exactitude absolue ou rigoureuse, malgré la précision scientifique de sa formulation; sa pertinence devient susceptible de contestation, puisqu’elle résulte de compromis entre les milieux de la science, de l’industrie, des pouvoirs publics et éventuellement, d’autres groupes économiques ou sociaux.”*

According to the intention of the ICRP there is no doubt about the importance of social and economic factors in determining the lowest achievable exposure.

It is regrettable to notice that it took until 1996 before these factors were incorporated in a European Directive, so it took more or less until 2000 before being transcribed in national regulations.

Nevertheless, the question remains whether these considerations should be made in the light of the situation of the affected operator, or the nuclear sector, or the complete industry.

Therefore, it is all the more regrettable that there is no better dialogue between the subjects of law (the specialists in the field) and the regulators (cfr. infra).

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<sup>28</sup> Lochard Jacques and Marie-Claude Boehler, ‘Les bases éthiques et juridiques du principe d’optimisation de la radioprotection’, Bulletin de Droit Nucléaire, n° 52

<sup>29</sup> Corten Olivier, ‘The notion of ‘reasonable’ in international law: legal discourse, reason and contradictions’ in International and Comparative Law Quarterly, July 1999

<sup>30</sup> Boustany Katia, ‘La normativité nucléaire : quelques réflexions’, Bulletin de Droit Nucléaire, n° 51

### III. ALARA, an obligation on the authorities and/or on the operators ?

Regarding the precautionary principle, a lot of lawyers contest the idea that it can be seen as an obligation of the operators.

The same question could arise concerning ALARA but the ICRP gave an unequivocal answer in its 1990 recommendations: “ According to the Commission, it intends his report to be of help to regulatory and advisory agencies at all levels (national, regional and international) by providing guidance on the fundamental principles on which appropriate radiological protection can be based. ... In addition, the Commission hopes that the report will be of help to management bodies with responsibilities for radiological protection in their own operations, to the professional staff whom they use as their advisors, and to individuals such as radiologists, who have to make decisions about the use of ionising radiation. ... ”

And further: “As to the implementation of its recommendations, the Commissions states that practical responsibilities fall on the designers and operators of equipment and installations who obtain their guidance partly 1) from professional advisors and publications such as those of the Commission and international organisations and partly 2) from regulatory and functions aimed at helping the operating managements to meet their responsibilities and at ensuring that a suitable standard of protection is maintained .”<sup>31</sup>

Although this seems very clear, practice shows that the authorities don't seem to feel too much concerned. The nuclear industry made significant efforts to implement ALARA, the result thereof is reflected in abundant literature providing manuals, guidelines, recommendations, and suggestions ... on how achieve optimisation. This research is realised both at national and international level<sup>32</sup>: ALARA committees, ALARA programmes, ALARA procedures, ALARA networks ... I think the private sector invested a lot for the application of ALARA, whereas the public sector limited its efforts to COPYING ONLY HALF of the ALARA principle as recommended by the ICRP.

The authorities not only missed a chance to add a legal dimension to a purely scientific recommendation, it is the poor constructed legal provision that is responsible for the actual confusion.

As J. Lochard and M.C. Boehler notice : “*Le droit de la radioprotection s'est, pour certains, trop conformé à la réalité scientifique et technique, alors qu'il aurait dû se situer à un niveau minimum d'abstraction et cultiver davantage l'artificiel, en ce sens que le droit implique une intention, 'un projet de l'homme sur la réalité brute'. Le principe d'optimisation donne peut-être l'occasion au juriste d'exercer sa fonction qui est celle d'imprimer un sens à la réalité et d'amorcer un retour vers une règle générale. Le droit de la radioprotection doit tenter d'échapper aux prescriptions d'ordre technique, à la simple "mise en normes" en intégrant des principes généraux tels que la justification de l'activité, la limitation des doses individuelles et surtout l'optimisation de la protection qui, par ses considérations d'ordre économique, politique et social, oriente aussi l'action réglementaire vers l'édification d'un consensus social sur les choix technologiques impliquant l'utilisation des rayonnements ionisants ... Si l'on introduit ce principe dans la législation, on estime donc nécessaire de définir des données suffisamment claires car faute de normes ou moyens concrets, l'application pratique est en fait dans le vague et c'est finalement le juge qui décide et qui s'érige donc en législateur.*” !

Besides, the ICRP itself suggested an enumeration of measures<sup>33</sup> to be taken by the authorities in order to contribute to the implementation of ALARA by the operators:

#### 7.4. General responsibilities of the competent authorities:

(170) Competent authorities may wish to impose general requirements for optimisation of radiological protection to be carried under all circumstances ranging from major designs to individual dose control in the workplace. **In order to assist with implementing these general requirements, the competent authority should specify the general criteria needed to implement the optimisation procedures.** It must be remembered however that the final responsibility for radiological protection remains with the operating management.

<sup>31</sup> Publication 60 (1991), § 227

<sup>32</sup> See C. Lefaure, 'How to apply optimisation in radiation protection', Refresher Course Document, IRPA – International Congress on Radiation Protection, Vienna, April 14-19, 1996, Centre d'Etude sur l'évaluation de la protection dans le domaine nucléaire (CEPN), and P. Govaerts, 'Op zoek naar het redelijke, opportuniteiten en beperkingen van de toepassingen van het ALARA-principe'

<sup>33</sup> Recommendations of the International Commission on Radiological Protection, ICRP Publication 55, Pergamon Press, Oxford, 1988



(171) The specific way in, which the competent authorities can assist, are by:

1. **encouraging** the development of decision-aiding techniques suitable for optimisation assessments and recommending their use,
2. **establishing** relevant criteria, such as the value of unit collective dose, for performing optimisation assessments,
3. **recommending** the relevant factors to be taken into account in optimisation studies of different types,
4. **guiding** designers and managers on how to apply the requirement on a case by case basis,
5. **encouraging** the provision of information suitable to determine relevant biological protection parameters and models for use in optimisation studies,
6. **making or commissioning** generic assessments in order to establish optimised design parameters and recommending standards that can be deemed to be optimised,
7. **assuring** the comprehensiveness and quality of implementation of radiological protection optimisation in design, operation and maintenance **BY SUITABLE ENFORCEMENT REGULATIONS AND BY AUDITING THE PERFORMANCE ACTIVITIES.**

I think that it is not sufficient to impose ALARA conditions in the licence, because Belgian jurisprudence shows that even without verifying the legal validity of the licence, or even if the relevant existing regulations are respected, the judge can order preventive measures and thus prejudice economic activities.

Objective criteria and parameters should therefore be determined for the complete nuclear industry and incorporated into the regulations. Only then, the judges, as “bouche de la loi”, will have some tools to evaluate the operators ALARA policy.

From a democratic point of view, the best guaranty towards legal certainty (for the operators as well as for the population) is accomplished by law, because of the parliamentary debate.

*“Dans le processus conduisant à l’adoption d’une norme juridique,  
l’incertitude n’introduit pas seulement un facteur de complexité supplémentaire,  
elle impose d’en modifier radicalement la méthode :  
le législateur est ici voué à s’adjoindre la participation du public.”*

Rémond-Gouilloud.

But even in the absence of a law, a priori defined criteria and parameters of what is socially acceptable, of what is reasonably achievable should be determined by the authorities.

This reasoning is not only valuable for the sake of a correct implementation of ALARA but also of the justification principle which is defined as: “no practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes.” According to the intention of the ICRP justification of a practice “requires there to be more advantages than disadvantages, it does not require the benefit to be the greatest obtainable”.<sup>34</sup>

This implies that a certain risk margin is accepted – besides, as it is the case for any other industrial activity.

This also implies that an extensive interpretation of the ALARA principle by the judges, in the given legal context, might deny the justification principle and in turn jeopardize the governmental nuclear, industrial and energy policy.

So in order to avoid that extensive application, it is the responsibility of the authorities to make the evaluation of what is economically and socially reasonable to achieve, and to give – in function of the result of that evaluation – guidance to the operators by determining objective legal a priori defined criteria and parameters.

#### **IV. Relationship limitation of doses and ALARA.**

The dissenting opinions of the European Commission on the one hand and the member states and the European Court of Justice on the other hand already showed that no unanimity about their mutual relationship exists.

In France, the President of a company operating ionising radiation emitting machinery was convicted in June 1993 for unintentional battery and assault. Although the dose limits were considerably exceeded, the judge based its decision on the non-respect of the optimisation principle arguing that the President had not done the best he could by keeping exposure as low as readily possible below the dose limits instead of considering that he had not achieved “a minimum”, namely respecting the dose limits.

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<sup>34</sup> Publication 55 (1988), § 29

The confusion can partly be explained by the historical evolution of the knowledge of radiation protection. Until 1955, based on the certainty of the existence of deterministic effects, the key issue of radiation protection as recommended by the ICRP was the respect of dose limitations. The uncertainty caused by the discovery of the stochastic effects led to the introduction and the development of the optimisation principle.

According to the ICRP, *‘the primary aim of radiological protection is to provide an appropriate standard of protection for man without unduly limiting the beneficial practices giving rise to radiation exposure’*<sup>35</sup>.

Three general principles were developed and a hierarchy between them was established :

1. Justification of a practice : which determines decisions concerning the adoption and continuation of a practice;
2. Optimisation of protection;
3. Individual dose and risk limits.

The ICRP now considers optimisation with its source-related approach (opposed to the limitation of doses which is based on an individual-related approach) as the central element of the framework of radiation protection., once a practice is authorised. Limitation of doses is nevertheless indispensable: *“dose limits are needed as part of the control of occupational exposure both to impose a limit on the choice of the dose constraints (to cover the occasional case where the same individual is employed on several tasks each with its own constraint) and to provide a protection against errors of judgement in the application of optimisation”*<sup>36</sup>.

Let me illustrate this in the light of the differing opinions of the European Commission and the European Court of Justice.<sup>37</sup>

As the main target is risk avoidance by keeping exposure as low as reasonably achievable, from an operational point of view, this can be realised by imposing limits, even stricter than those recommended by the ICRP. This is the opinion of the Belgian government, approved by the European Court.

I prefer –because of the hierarchy the ICRP established -the reasoning of the Commission though, stating that the same result can be achieved by insisting on optimisation through dose constraints.

There is *no need* for stricter limits if optimisation works. Optimisation is *“the more appropriate course of action”* (cfr. infra), dose limits are then some kind of a safeguard (in case of exposure to several sources and in case optimisation should have failed).

So authorising stricter limits as the Court approves :

1. denies the hierarchy between ALARA and dose limits,
2. creates confusion on what is acceptable by introducing mandatory limits in the area of stochastic effects (cfr. infra);
3. (denies the political context of EURATOM that requires uniform security standards).

The Commission, itself recognises that many misconceptions have arisen.<sup>38</sup> : *“In practice, several misconceptions have arisen about the definition and function of dose limits. In the first place, the dose limit is widely but erroneously, regarded as a line of demarcation between “safe” and “dangerous”. Secondly, it is also widely and also erroneously, seen as the most simple and effective way of keeping exposures low and forcing improvements. Thirdly, it is commonly seen as the sole measure, strengthened by the incorporation of dose limits into regulatory instruments. Causing a dose limit to be exceeded then becomes an infraction of the rules and sometimes a statutory offence. Against this background, it is not surprising that managements, regulatory agencies and governments all improperly set out to apply dose limits whenever possible, even when the sources are partly, or even totally, beyond their control, and when the optimisation of protection is the more appropriate course of action.”*

Even if dose limits cannot be regarded as demarcation line between safe and dangerous, we should bear in mind that dose limits *do* indicate the borderline between unacceptable and ‘not-unacceptable’ (tolerable and acceptable).

Indeed, deterministic effects are those effects where the severity of the effect is directly proportional to the size of the dose. The dose limits correspond to the presumed threshold. This is a scientific approach based on statistical material.

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<sup>35</sup> Publication 60 (1991), § 99

<sup>36</sup> Publication 60 (1991), § 147

<sup>37</sup> in the case C-376/90 CEC v. Belgium, cfr. supra

<sup>38</sup> Publication 60 (1991), § 124

The legal approach should then be one of rejecting what is unacceptable and accepting what is 'not-unacceptable', namely by encouraging to improve what is tolerable.

The legal result is then the result of 'political' considerations, political in the sense of reflecting in a democracy, intellectual choices that are based on scientific findings but which take into account considerations of cultural, economic, social, ethical ... nature.

#### V. **Responsibility/liability or prevention or ... optimisation.**

The distinction between dose limits and ALARA is also important to estimate the responsibility and the liability of the operator.

Cfr. Lefaure<sup>39</sup>: "*respecting a limit guarantees that an individual will not only suffer none of the pathologies known to be caused by high doses, but, in addition, that the probability of his eventually developing radio-induced cancer is not socially unacceptable.*"

When exceeding dose limits, it is *possible* to prove that damage (cancer) has been caused (deterministic effect) by the fault (non respect of dose limitation) of the operator.

This proof can impossibly be given in the field of optimisation because of the very nature of stochastic effects where *in se* no certainty exists about the effect, only a presumption of increase of probability. Therefore, even in the case of a certified fault of the operator, the eventuality of holding an operator liable in civil law (compensation) or even the criminal law offence of involuntary battery and assault should by definition be excluded because of the impossibility to demonstrate a causal relationship between the damage occurred and the fault.

But even in the absence of the proof of a causal relationship fault-damage, the operator can be found "guilty" of not having adopted the correct behaviour. As J. Lochard and M.C. Boehler notice : "*Le principe d'optimisation est un comportement tendant vers un but envisagé que l'exploitant ne promet pas d'atteindre. Toute obligation est orientée vers une finalité ce qui ne veut pas dire que l'exploitant soit tenu de réaliser cette fin. Il n'est donc pas responsable s'il ne la réalise pas. En effet, en se proposant d'agir avec diligence, l'exploitant n'encourra la charge de la responsabilité que si son attitude est fautive, la faute pouvant être une erreur de conduite quand il y a contradiction manifeste entre les actes et le comportement promis ou une négligence.*"

Or as Lefaure stresses: "*In theory, the ALARA principle corresponds mainly to a "state of mind" and could be applied without any regulatory control. However, as in practice, it necessarily involves calling behavioural patterns into question, the presence of a system of regulations, and particularly the will to apply it, play an important role.*"

The evaluation should thus be one of conduct and not of a specific result: did the operator organise the necessary structures, programmes, tools, training, etc. in order to achieve an adequate implementation of ALARA? As argued before, it is in the first place the responsibility of the authorities to impose these conditions.

It is this evaluation of 'performance' and the sanctioning of not-sufficient-performance that is new and therefore difficult to introduce in our legal system.

Classical preventive measures might not be sufficient, besides, is it still correct to speak of 'preventive measures' as prevention deals with risks that are foreseeable whereas optimisation deals with risks that are not even certain to occur?

Anyway, several options are available, such as:

- Establishment of dose constraints by the authorities. (by doing so it is important to stress the difference with dose limits (see supra) and to make sure that dose constraints are not seen as thé ALARA tool, it can only be one amongst others...)
- Encouragement/obligation for the operators to introduce management tools: programmes, committees, evaluations,...
- Introduction by the authorities of performance indicators<sup>40</sup>(cfr. horticulture in the Netherlands)
- Establishment of investigation levels<sup>41</sup> that once exceeded can lead to consultation procedures with the competent authorities.

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<sup>39</sup> C. Lefaure, 'How to apply optimisation in radiation protection', ibidem

<sup>40</sup> For the horticulture sector in the Netherlands, a basic set of prescriptions of conduct has been elaborated; leaving a margin that enables the operators to establish some priorities. Every possible measure corresponds with a certain value and it is the total result that is evaluated by the authorities—See R. van Gestel and J. Verschuuren.

In 'guiding' the operators, the competent authorities can either prohibit certain practices or methods, or adopt a more positive approach by encouraging or imposing others.

The authorities also have a choice of sanction. Unlike the French word sanction, the English word includes both the encouraging (reward) as well as the repressive aspect (punishment). So in the field of optimisation, I feel that the authorities have three options: (1) granting incentives, rewards for those operators with a good functioning ALARA approach, with an 'ALARA mentality', (2) consultation procedures when some investigation levels are reached; and (3) classical methods of administrative sanctions (e.g. fines.).

I don't think that all this will induce fundamental changes for most operators' methods of working, at least not for those who invested seriously and who succeeded in creating an 'ALARA mentality'. On the contrary, for those operators, these legal changes can mean recognition of their efforts.

From a legal point of view, the fundamental change will consist of more legal certainty for both the operators and the population and more clarity about the consequences of the non-respect of ALARA (consultation procedures and/or administrative sanctions) and the dose limits (responsibility, in case civil liability of the operator).

I don't think that we can excuse our self by saying that we have no legal tools.

We're confronted with a new approach wherefore our established legal system had no *immediate* answer. As we see with the precautionary issue, this is not limited to ALARA and not exclusively nuclear.

We have this wonderful challenge to innovate and to find a legal solution that reflects a 'reasonable' or let me say a 'right', in the sense of 'equitable', balance between human and environmental rights and economic interest.

#### SUMMARY

The optimisation principle as recommended by the ICRP includes an obligation for the competent authorities as well as for the operators.

The private sector undertook considerable efforts to implement ALARA, whereas from a legal point of view the wordings of the principle are too vague to make it a workable instrument.

Both current interpretations of ALARA, as a legal principle, give no satisfaction: either priority is given to the dose limits, which reduces ALARA to a moral obligation without any consequences in case of non-respect; or absolute priority is given to ALARA, which can lead to the liability of the operator even when the dose limits have been respected. In the latter interpretation the dose limits have lost their meaning.

The only correct interpretation is to evaluate both principles within their own scope, and therefore the legal context should be clarified:

- Whether dose limits have been respected or not can easily be verified, non-respect should be sanctioned, damage –if proved- should be compensated.
- Whether ALARA has been respected or not can only be controlled if evaluation criteria have been a priori determined – probably new repressive and/or rewarding sanctions should be foreseen.

25.10.2000

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<sup>41</sup> Publication 60, § 239 : "A high proportion of operations can be conducted in such a way that the standard of protection is set by the process of constrained optimisation and not by the dose limits. Mandatory dose constraints, applicable to selected classes of operation, then provide a useful regulatory tool. Alternatively, the regulatory agency might establish investigation levels for classes of operation. Exceeding an investigation level would require an investigation to be made on the optimisation programme of the operator or the designer."