

Foreword

by Jean-Christophe NIEL

ASN Director-General

One year after the adoption of a European Directive on nuclear safety, a European area for nuclear safety and radiation protection is more and more taking shape. *Contrôle* obviously had to produce an issue on such an important topic.

The French Nuclear Safety Authority (ASN) has always been very keen on pursuing an international policy in its activities. Actually, article 9 of the Nuclear Transparency and Security Act (Loi TSN), which describes the ASN prerogatives in international relations, has structured a "can-do" policy. It is confirmed by the very strong ASN involvement for many years in such international organizations as IAEA and NEA and in European forums, in the extent of relations established with the foreign safety Authorities or its involvement in the creation and operation of structures like WENRA or MDEP (Multinational Design Evaluation Programme).

Europe holds a special place in ASN international policy and we shall look at it from three complementary angles:

- Europe through bilateral relations, whereby we can discuss intense and fruitful technical cooperation with our immediate neighbours and the other European countries. It is also manifest in cross-border inspections and personnel exchanges;
- Europe through regulators networks, including WENRA (Western European Nuclear Regulators' Association), no doubt the best known, and which today has the most impressive results in terms of concrete achievements in nuclear reactor safety and waste and spent fuel management. But WENRA must not hide other multilateral European initiatives which are also continuously making progress on safety and radiation protection. These include the initiative by HERCA (Heads of European Radiological protection Competent Authorities) which has already contributed to the development and harmonization of radiation protection in Europe;
- lastly, the European Union, which has provided a legal framework for drawing up public policies on radiation protection and, more recently, nuclear safety since 1957, the year when the Treaty establishing the European Atomic Energy Community (Euratom) was signed.

These three European dimensions interact and help construct a "European area for nuclear safety and radiological protection". They can none of them replace the other, they exist side by side and each one helps developing this area. This complex, dynamic and efficient process has no international equivalent.

For many years, ASN has been very keen on building a Europe of nuclear safety and radiation protection and has supported efforts vigorously. Under its bilateral relations, of course, but also in setting up regulators networks. Everyone is well aware of the part played by the Chairman of ASN, André-Claude Lacoste, along with other European regulators, in creating WENRA in the late 1990s, the constant involvement of ASN in pursuing its work and the more recent ASN support for the setting up of HERCA.

ASN is also very much involved in such community forums as ENSREG (European Nuclear Safety Regulators' Group) and committees of experts advising the Commission on the application of the Euratom Treaty.

In this respect, in close cooperation with the French authorities and in constant dialogue with the nuclear safety Authorities of the 27 Member States and with the European Commission, it has thrown all its weight behind adopting a directive on the safety of nuclear installations in 2009.



The adoption of this directive is of prime importance, for several reasons.

Firstly, it forms part of the community legislation binding the provisions of the Convention on Nuclear Safety, something totally new, which naturally applies to all current EU Member States and which will also be mandatory for any new candidate for accession to the EU. It highlights especially the independence of safety Authorities, the duties of nuclear power plant operators and the necessary transparency of the information provided to the public.

It also has the immense value of anchoring Euratom competences on nuclear safety in a legislative act, thereby supplementing an elaborate legal framework for radiation protection.

Lastly, and possibly most importantly, it has created in Europe a consensus on the need to set up at community level a robust regulatory framework around the operation of nuclear power.

ASN believes that this consensus, which has to be preserved, must lead to rapid adoption of a directive on the safe management of radioactive waste and spent fuel, by "transposing" this time the provisions of the Joint Convention into community law. It also opens up prospects for working, still at community level, on new topics, for example relating to transparency or safety objectives of the new reactors. Under this last theme, it would be odd for the EU, the leading political "area" in the world to have made the IAEA's safety fundamentals mandatory, not to be also in the front line on the expected safety requirements for reactors which will be constructed in Europe.

ASN will also pay special attention to the Commission's future initiatives on upcoming basic standards for radiation protection or the security of radioisotope supplies in Europe.

Building this European area for nuclear safety and radiation protection is just like building Europe itself - at times it has stuttered badly, at others it has all of a sudden gained momentum. ASN will continue to apply itself to maintaining the current dynamics. ■





The European nuclear safety and radiation protection area: steps and prospects

by Guillaume Gillet, Director of ASN International Relations Department – French Nuclear Safety Authority (ASN)

The Europe of nuclear safety and radiation protection is gradually taking shape. In particular, it recently adopted a directive on the safety of nuclear installations. To coincide with this, we felt that this issue of *Contrôle* should propose an overview of the nuclear safety and radiation protection situation in Europe today and to attempt, insofar as this is possible, to imagine what the future holds.

The context of this issue is evidently one that goes beyond French borders and even goes beyond the simple political framework of the European Union, as it aims to take in European initiatives and bilateral links that are not covered by the Euratom Treaty.

ASN wanted to provide an opportunity to speak for all those who, in one way or another, took part and indeed are still taking part in building this European nuclear safety and radiation protection area. This is why this issue is open to industry, associations, trade unions, other European safety regulators and even non-European regulators, because what is happening in Europe in the field of safety and radiation protection is, for those not involved in the logic of European construction and integration, something that is complex, surprising and an object of great curiosity.

Consequently, and although the construction of this European nuclear safety and radiation protection area is by definition a “collective adventure”, the approaches by the various

stakeholders contacted and their views on such or such an episode in the history of this construction, are all slightly different. One of the main features of this issue is that it proposes a variety of viewpoints rather than a single, artificial vision of nuclear safety and radiation protection in Europe.

To conclude this foreword, we must stress ASN’s particular attachment to Europe, an attachment that led to its decision to devote an entire issue of *Contrôle* review to this topic. For ASN, Europe is no longer strictly speaking a component of its international relations policy. It has become a subject of interest and involvement in its own right.

ASN considers that Europe, in all its various dimensions – bilateral, multilateral, Community – constitutes a geographical, regulatory and political area in which it can implement its strategy and develop its activities. The community legislative impact is structural. The development of good practices, of references, of regulatory approaches and techniques that are shared Europe-wide, is a necessity. The presence of nuclear installations, sometimes a few kilometres from national borders, the mobility of materials and individuals, means that bilateral relations are essential. ASN is also aware that anything done on a European scale could be echoed internationally, in particular within international organizations such as IAEA or NEA. ASN has made Europe, one of its main priorities since the 1990s. That is why it exists at ASN such a strong European culture.



Europe and nuclear power: hope and disappointment

Nuclear energy in Europe has enjoyed a chequered history. It was almost immediately conceived as a European project, with the 1957 signature of the Treaty establishing the European Atomic energy community (Euratom), concerning which Ambassador Philippe Etienne and Frédéric Mondoloni recall the foundations and the main provisions.

In 1957, at a time when many placed the greatest hope in the peaceful applications of nuclear power, France, Germany, the Netherlands, Belgium, Luxembourg and Italy decided to combine their efforts to develop this energy source. In a text felt today to be excessively promotional by certain Member States, the founding nations of the EU laid the basis for the development of a robust nuclear sector in the fledgling Europe.

On reading the Euratom Treaty today, what is surprising is the astuteness of its authors, who built a European atomic Community which in fact contains every single attribute. It covers the issues of R&D, investments, international relations, fuel supplies, the ability – once again a collective approach – to create “joint undertakings” and so on. What is also striking, is the awareness of the risks linked to the use of nuclear power, which the Euratom designers, far from being blinded by the potential and promise of nuclear power, included in the preamble to the Treaty, in Title I, and in Chapter III devoted to “health and safety”.

A common desire to develop nuclear power, a feeling that it was even urgent to tap the benefits of this new source of energy, a solidly constructed Treaty giving significant room for “security” – which is the term used in the Euratom Treaty; all the conditions were in place to make Euratom a success and, after the European Coal and Steel Community (ECSC), a model of European integration.

However, this was not enough. Very quickly a number of Member States considered that nuclear power was so strategically important that it was incompatible with a collective development approach. At the end of the 1970s and in the 1980s, the Three Mile Island accident and the Chernobyl disaster clearly raised the question of the safety of nuclear installations and the radiological consequences of a disaster. At the same time, the EU expanded, in particular incorporating Member States who were openly opposed to nuclear power.



Signature of the Treaty of Rome on 25 March 1957: the representatives of the six Member States of the European Coal and Steel Community (ECSC) sign the treaties establishing the European Economic Community (EEC) and the European Atomic Energy Community (EAEC or Euratom)

These and many other factors explain the relative lethargy of Euratom for many years. Surprisingly, Euratom, which in fact had a far stronger legal arsenal than the European Economic Community (EEC) went in the opposite direction. Whereas the EEC, backed by new treaties, has seen its competence grow over the past 50 years, Euratom has lost its original momentum. Also from an institutional viewpoint, the Euratom Treaty has only been superficially modified. The decision-making procedures defined when Euratom only comprised 6 members, have remained the same – in most cases, measures are adopted unanimously even though the number of its members, whether in favour of or opposed to developing nuclear power, is continuing to rise. The inevitable result is, often, paralysis of the decision-making process. It was therefore perfectly natural for initiatives to appear outside a community framework that had become less effective.

The Europe of nuclear safety and radiation protection outside the Community framework

Relative community inertia

It would be overstating matters to claim that nothing major has been accomplished at community level over this long period of time. As underlined by Jean-François Lecomte, the requirements of Chapter III of the Euratom Treaty have been constantly improved and have updated the radiation protection standards for workers and the general public. They have also led to permanent monitoring of the levels of radioactivity in the atmosphere, water and soils, and the provision of data concerning radioactive releases from any new nuclear facility.

It should also be noted that through the actions of the Commission's Joint Research Centre (JRC), created by the Euratom Treaty, and thanks to the R&D Framework Programs – which it is sometimes forgotten were created to promote nuclear research – a policy of research and development was and still is being conducted on the subject of nuclear safety and radiation protection. In his contribution, Jacques Repussard also recalls the major involvement of IRSN in the Euratom R&D Framework Program and its cooperation with the JRC.

Thanks to the Euratom Treaty, the Member States were also able to respond quickly, in particular when required to create community instruments for information in emergency situations, following the Chernobyl disaster. Dominique Ristori recalls that a few months after this event, in 1987, the ECURIE system was implemented by a decision of the Council of Ministers, and is still in place today. The same year, a Council ruling set maximum radioactive contamination levels for foodstuffs and feedingstuffs. Two years later, again in response to Chernobyl, a directive on information of the public in the event of a radiological emergency was adopted.

However, if we ignore the changes to basic standards and the legislative response to Chernobyl, we are forced to admit that the community framework suffered from a degree of inertia during this period. Unlike the EEC, Euratom was lethargic and was unable to broaden its scope of action, nor even make full use of its prerogatives. Therefore, and quite surprisingly, Euratom was unable for 50 years to establish a nuclear safety framework in Europe nor one for management of radioactive waste and spent fuel, despite the fact that these are key issues for the nuclear sector.

Other nuclear safety and radiation protection channels: WENRA, bilateral and multilateral cooperation.



European Commission publication on 50 years of the Euratom Treaty

In these areas, as confirmed by André-Claude Lacoste and Jukka Laaksonen, the founder and first President and current President of WENRA respectively, the initiative lay primarily with the regulators, with the creation at the end of the 1990s of the Western European Nuclear Regulators' Association (WENRA). It is true that in 1975, a working party was set up following a Resolution from the Council of Ministers, bringing the regulators together, but this approach is in no way comparable to that of WENRA. The safety regulators came together voluntarily outside the community framework and laid the foundations for the Europe of nuclear safety, chiefly through two emblematic initiatives.

The first was to provide the Commission with an assessment of reactor safety and the organization of safety regulation in the countries aspiring to join the European Union. This was clearly a complex process, given the differences in the safety characteristics of the reactors concerned and a politically sensitive one, given the potential impact of WENRA's opinion of a "new entrant's" reactor safety on membership negotiations on the one hand, and the conditions of the country's energy supply on the other.

The report, submitted to the European Commission at the end of 2000, was indeed used by the European authorities in the EU membership negotiations which preceded the two enlargement processes of 2002 and 2006. These negotiations led to scheduling of the closure of some reactors in the candidate countries. In this respect, it is interesting to note that even though the European Union had no legal competence in the field of nuclear safety, the Commission, with the agreement of the Council of Ministers and the European Parliament, made nuclear safety a de facto criterion for admission to the EU of the new Member States.

WENRA's second major achievement is naturally its definition of safety reference levels for the existing reactors. In line with WENRA philosophy, this work to harmonise the safety standards applicable to reactors installed in Europe was initiated on a voluntary basis and it today remains the main European safety reference. The Authorities also played a very

real role in this work, because they all made a commitment to "transpose" these reference levels into their national legislations before the end of 2010, thus borrowing from community practices, but without formally integrating their work into an EU framework. This work was also done in close collaboration with the operators, who took care to consult ENISS before responding to the proposals made by WENRA, as Bernard Fourest points out in his article.

WENRA's aims and achievements should not overshadow the fact that, once again outside the Community itself, close ties have been forged in Europe between regulators, also helping to build a European safety and radiation protection area. A number of contributions to this issue cover initiatives such as ERPAN, the ALARA network, cooperation between Finland, France and Sweden on the safe management of waste, cooperation between radiation protection authorities in Scandinavia (Finland, Sweden, Norway, Denmark and Iceland), or between Luxembourg, Belgium, Germany and France with a view to harmonizing the countermeasures to be taken in response to a nuclear accident. With regard to bilateral agreements, and without even mentioning the joint Franco-German technical work on the EPR safety options, contacts have intensified and become more systematic. No doubt bolstered by the feeling of belonging to the same geographical and political entity, but without necessarily remaining strictly within the scope of the EU, a community of safety and radiation protection regulatory bodies has gradually come about in Europe.

2000 – The turning point

The Green Paper on security of energy supply

At the end of 2000, the European Commission's Green Paper entitled "Towards a European strategy for the security of energy supply", was a real wake-up call for nuclear in Europe. Ambassador Philippe Etienne recalls that the proposals made by Commissioner Loyola de Palacio and his Director-General François Lamoureux laid out the problem in fairly blunt terms; if the EU wanted to protect its competitiveness, guarantee the



security of its energy supply and combat greenhouse gas emissions, it would need to take advantage of nuclear power. They also recalled that with nearly 35% [in 2000] of its electricity production coming from nuclear power, the EU was one of the world's leading users of this technology. The Green Paper was however extremely clear; maintaining reliance on nuclear power in Europe had to be accompanied by efforts in the field of management of radioactive waste and reactor safety.

The European Commission's equation naturally elicited a strong response. Loyola de Palacio was obviously accused by the opponents of nuclear power of attempting to rehabilitate this source of energy, which was felt at the time to be losing steam. They were immediately wary of the announcements concerning safety and waste management, as they were presented as preconditions for the acceptance of nuclear power in Europe. On the other hand, the European nuclear sector was delighted by these initiatives and the attitude of the Commission, after so many years of apathy. These two visions of the Green Paper and the ambitions of the Commission were also to constitute a long-term framework for the discussions surrounding radioactive waste management and nuclear safety in Brussels and weighed heavily in the tense debate on the famous "Nuclear Package".

The failure of the "Nuclear Package"

The Commission's competence in the field of nuclear safety had been recognised by the Court of Justice of the European Communities in 2002 and, as a logical political follow-up to the Green Paper, it on that same date proposed a set of legislative texts to the Member States of the European Union, called the "Nuclear Package".

We will not go back over this famous "Package" here, nor its fate at the hands of the Member States, because many papers in this issue cover this episode. We will simply recall that the initial idea of Commissioner de Palacio, who was astonished that "the EU had issued directives on bathing waters, but nothing on nuclear installations" was extremely pertinent. But the Commission no doubt gave an over-centralised, over-interventionist flavour to these proposals, to the extent that they received very little support.

The European industrial sector was to see with a worried eye the Commission's desire to intervene on the subject of the funds ring-fenced by the electricity utilities for decommissioning of nuclear installations. Neither was the idea of creating a Joint Undertaking, as defined in the Euratom Treaty, in charge of radioactive waste R&D, greeted with any particular enthusiasm by the EU Member States, who were worried about the Commission taking charge of this sensitive issue. Finally, the approach developed by the Commission to guarantee nuclear safety in Europe also ruffled the feathers of the competent Authorities.

Perhaps, suffering from an excess of confidence following its initial involvement in safety, through the membership negotiations, or as a result of the ruling by the European Court of Justice giving it access to the legislation nuclear safety and radioactive waste management, the Commission was unable to convince the Member States, the industrial world and NGOs of the soundness of its approach. The rejection of the "Nuclear Package" in 2004 was a legislative failure that was to leave long-term traces in the minds of all those involved, and several years were needed before the nuclear safety dossier could be gradually brought back onto the community agenda.

Adoption of a directive on the safety of nuclear installations

Several articles in this issue of *Contrôle* cover in detail the preparation of this directive, its content and the negotiations to which it led, so there is no point in repeating what some, such as Andrej Stritar, Chairman of ENSREG, describe in such detail and with such humour. We will simply recall that after the failure of the "Nuclear Package", bringing the Member States back to the negotiating table to discuss a new text devoted solely to safety – to avoid reawakening painful memories of the "Package" – was a lengthy business. After the technical work done by the Working Party on Nuclear Safety (WPNS), there were of course the conclusions of the Council under German Presidency, the Conclusions of the European Council in March 2007, the creation of the European Nuclear Safety REgulators' Group (ENSREG), and so on.

These milestones are all very useful in plotting the history of this directive, but they do not fully reflect the full intensity of the discussions that went on behind the scenes, the sometimes difficult exchanges between the safety regulators within ENSREG and WENRA on whether or not such a directive was really opportune. The tipping point was without doubt September 2008, when the Commissioner for energy at the time, Andris Piebalgs, took the floor at ENSREG and declared that even if ENSREG were to oppose it, the Commission had a moral duty to present a legislative text on this topic and that it would be doing so very shortly. The determination finally shown by the Commission was to accelerate the agenda and enabled the proposed "nuclear safety of nuclear installations" directive to be placed on the agenda of the French Presidency of the EU Council. A few months later, in June 2009, it was adopted under the Czech Presidency.

It has often been said that the provisions of this directive were modest indeed, that they "simply" transcribed the IAEA safety fundamentals into community law, which was not in the end a real step forwards because the Convention on Nuclear Safety was already binding. But it was these same people who scrutinised and sometimes fiercely debated the wording of the various articles of the directive, proof that in this legal format, these provisions took on a completely new dimension.

This would also fail to do justice to the broad scope of the directive, which in particular covers the independence of the regulator, its powers of sanction, the duties of the operators, the information of the public, plus the obligation of self-evaluation and peer review of the safety systems of the Member States. It is true that this directive is a subtle compromise between the need to avoid rubbing up certain delegations the wrong way after the failure of the "Nuclear Package" and the search for credible content. But one need simply read the article by Philippe Jamet to see that IAEA itself considered this directive to be a major step forward. It would be to forget, finally, that with this directive, nuclear safety is now well and truly a competence of Euratom and that it is a fully-fledged component of Community legislation, binding on the future Member States of the EU.

Finally, one of the great virtues of this directive and its preparation was to put an end of the tensions and misunderstandings created by the debate surrounding the "Nuclear Package". As some of the protagonists underline in this issue, the links created within WENRA were of great help in maintaining the dialogue between regulators during the debates at ENSREG and the Council of Ministers. One must also applaud the work of the European Commission, and particularly of Dominique Ristori, who was able to create an atmosphere of trust among all the stakeholders and thus pave

the way in the best possible conditions for the debates to take place in the Council of Ministers. Finally, and as pointed out by the FORATOM contributors, European industry – through the European Nuclear Energy Forum – also committed itself heavily to this dossier and, albeit not without its own motives of course, provided real support for a regulatory text on safety.

What now for this European nuclear safety and radiation protection area?

With the adoption of the directive on the safety of nuclear installations, the Europe of nuclear safety and radiation protection has entered a new phase, characterised by the parallel and complementary implementation of the two methods which have so far allowed progress to be achieved in Europe: the community method, which has been given a new lease of life with the adoption of the directive; and the “informal” method, combining the work done by Regulator clubs and networks, with bilateral relations.

Community outlook

If we look first of all at the community method, the calm perceptible after adoption of the directive should encourage the European Commission to complete its implementation of a regulatory framework for the utilisation of nuclear power.

The initial exchanges concerning a possible directive on the management of radioactive waste and spent fuel are already taking place in a peaceful atmosphere, indicating that the negotiations will take place in a constructive climate. Probably in 2011, the Council of Ministers should begin discussions around a revised directive on radiation protection basic standards, taking account of the progress achieved since directive 96/29/Euratom.

The Commission is also interested in the security of supply of radioisotopes, which is directly linked to the safety of nuclear installations, with the aim being to avoid at all costs having to arbitrate between patient health and the radiological protection of the public. It is also examining the subject of nuclear civil liability, because it must be said that the international system in place is not satisfactory. The Commission also recently raised the issue of joint certification of reactors in Europe, implicitly inviting the safety regulators to “share” their certification work.

There is thus no shortage of possible initiatives and, on all these topics, ASN and the Authorities in charge of nuclear safety and radiation protection in Europe will have to adopt a stance. However, ASN considers that two subjects that fall within the remit of the community require particular attention.

The first concerns the “safety” directive. Although it has been adopted, it will above all require correct transposition and application. The Commission, tasked with monitoring implementation of this transposition, will be playing a major role as of 2011, the cut-off date for incorporation of the requirements of the directive into the legal corpus of the Member States.

The second concerns the level of safety that Europe must set for new reactors. As of the accession phase for the new Member States in 2000, the Commission, with the support of the Council of Ministers, set a de facto acceptable safety level for reactors situated in Europe. With the “safety” directive, it became the world’s first “political zone” to make the IAEA safety fundamentals binding. The next, coherent step would, on the basis of the technical work done by WENRA, be to set safety objectives for new reactors.

“Informal method” outlook

As we have seen, the informal work carried out in Europe has made a substantial contribution to building the European nuclear safety and radiation protection area. This trend will have to be confirmed. It will continue to be tangible in bilateral relations of course, the value and usefulness of which are described in his article by Gerald Hennenhöfer.

Initiatives are also appearing in the various clubs and networks.

This is the case within WENRA, which is continuing its work on reference levels for the safe management of radioactive waste and spent fuel. WENRA also recently produced a report on the safety objectives for new reactors, a subject of prime importance at a time when a number of Member States are announcing ambitious construction programmes. WENRA thus proposes examining the safety of research reactors.

WENRA, the regulators club, is clearly continuing to adopt a stance on the technical priorities on which there is consensus among its members. The creation of ENSREG has taken nothing away from the value of this association, which must continue to play its role: attempt to harmonise nuclear safety practices in Europe, hatch ideas which can then be taken up by the European Union, and prod the Commission when they feel it opportune to take an initiative on such or such a subject.

Attention should also be given to the work being done by the Heads of European Radiological protection Competent Authorities (HERCA) association, which is a sort of radiation protection equivalent of WENRA. Its Chairman, Ole Harbitz, presents its creation and its ambitions in this issue of *Contrôle* review.

What is remarkable about this initiative, is that together with the European Commission, it proposes investigating areas of radiation protection which are currently not covered by community legislation. From this viewpoint, HERCA is the result of an opposite approach to that adopted for nuclear safety. Whereas WENRA was created owing to a clear absence of EU competence in the field of safety, HERCA came about even though this community competence exists. This shows that the European nuclear safety and radiation protection area is not simply the result of a transition from informal work towards the community method, but that the work of the clubs and networks can exist and demonstrate their legitimacy even when the Commission enjoys legislative competence. On reading the contributions from Ann McGarry of the Irish RPII, that of Maria Neira of the WHO or that of Guy Frija for the European Society of Radiology, significant progress is still to be accomplished in the field of radiation protection. This is the task that HERCA has set itself.

Conclusion

As we have seen, the creation of a European nuclear safety and radiation protection area has not been a smooth and peaceful enterprise over these past fifty years. The very concept of a “hub” was not even premeditated and is above all the result of the aggregation over time of initiatives by the competent European Authorities and of nuclear safety and radiation provisions, based on the requirements of the Euratom Treaty.

This “area” now exists. Its foundations are both the legal framework of Euratom and the “informal method” of working which grew spontaneously and freely outside the confines of the community.



The architecture of this hub would now appear to be stabilised, with on the one side the community framework, enabling the European Commission, with the benefit of advice from expert groups such as ENSREG or the Article 31 Committee, to produce legislative instruments; and on the other, “informal” networks of regulators working on safety (WENRA) or radiation protection (HERCA, ALARA, learned societies). In this landscape, one must not forget the operators, grouped within ENISS, or represented on the European Nuclear Energy Forum (ENEF), who also play a role in the construction of this area. Even if not everything is perfect – and in this issue both the CGT trade union and Greenpeace point out what they feel its inadequacies to be – it must be admitted that the European area looks to have a promising future.

Europe therefore holds a strong hand for consolidation of this area, first of all by strengthening the regulatory framework, with a directive expected on management of radioactive waste and spent fuel. On the basis of the WENRA report, it should also turn its attention to safety objectives for new reactors, given that nuclear reactor construction programmes are once again under way in Europe.

In the field of radiation protection, overhaul of the basic standards will take place in 2011, but the highly active European radiation protection networks are also expected to make progress, for example in harmonizing management of radiological emergencies, or the dosimetric passport.

This European nuclear safety and radiation protection area will also have to concern itself with its place on the international stage, ensuring that it is considered a major player on these two topics, with enough weight to influence the outcome of the main debates.

In his article, Jean-Paul Joulia recalls that with the Instrument for Nuclear Safety Cooperation (INSC), Europe is already present on the world stage, for example in helping countries set up a safety infrastructure. José Manuel Barroso, Chairman of the Commission, in March 2010 in Paris announced a “European initiative to raise international safety and security standards and make them legally binding worldwide”. This is a worthy aim, but we are waiting to find out what the exact content might be.

As shown in the articles by Gregory Jaczko and Philippe Jamet, changes in Europe attract interest from outside our borders. They therefore have to be explained and maximum benefit must be derived from this “area of influence” that is today being built in Europe, in the field of safety and radiation protection. In this respect, the first European Conference on Nuclear Safety, to be held in June 2011 in Brussels, will be a key step in communicating about European achievements on this subject. ■



Free comments on European construction in nuclear safety and radiation protection

Interview¹ with André-Claude Lacoste²,
Chairman of the French Nuclear Safety Authority (ASN)

Contrôle: Mr Lacoste, you were a driving force in the establishment of WENRA³ in 1999, were a founding member, and have also served as its president. Can you throw some light for us on what motivated your initiative and tell us about the main milestones of this process?

There you approach the problem of the regulation of nuclear safety in a certain number of countries in Europe and around the world. I think that the history of nuclear safety has been very marked by a national or even nationalistic character, since the first developments in nuclear energy were in the military field. The first nuclear countries were the countries that possessed nuclear weapons, which gave the subject a very national connotation. In the field of civil nuclear energy there were policy elements shared at world level, for example to draw the maximum feedback from the Three Mile Island accident or from the Chernobyl disaster, but the national view was predominant.

The IAEA was exercising a degree of coordination and initiatives were taken in the 90s by the NEA's which endeavoured to bring together regularly a certain number of heads of nuclear safety Authorities. But there was room to hold a genuine debate among regulators.

I therefore decided to launch a first initiative with a few counterparts whom I knew well personally. I wanted us to explore the possibility of working together. The first meeting was organized in November 1995 in Toledo by the Head of the Spanish safety Authority at that time, Juan-Manuel Kindelan. Things were accelerated after this first exploration by the prospect of the enlargement of the European Union. Some Eastern European countries were knocking on the door of the EU, some of them were nuclear countries, and there was nothing to allow the Union to make a judgement on nuclear

safety in these countries. The European Union had neither mandate nor competency to do so.

So a number of my colleagues and myself set ourselves a somewhat crazy challenge: that of collectively, we the 10 heads of safety Authorities in Western Europe (the heads of the Authorities of the nine nuclear countries of the European Union, and our Swiss colleague), making an overall judgement on the seven candidate countries, without being sure beforehand of being consistent between ourselves.

The work was carried out by the various safety Authorities with technical support from their respective TSOs⁴. It was done in two phases, with two consecutive reports in March 1999 and October 2000; each covered on the one hand the state of safety of the power reactors and on the other hand the state of the organization of regulation in each of the seven candidate countries. The task was demanding and the discussions were sometimes extremely difficult, as we did not have all the necessary information.

In fact we showed a degree of decency, a degree of reserve in our judgements which sometimes prevented us from saying everything we thought. For example, we refrained from discussing a really fundamental topic, that of the corruption in certain countries, although this practice could have direct consequences on safety.

Nevertheless, we expressed clear opinions that were taken up by the European Commission which, on our recommendations, obliged certain candidate countries to definitely shut down their nuclear power plants. This led to the definitely shut down of two nuclear units in Lithuania, four units in Bulgaria and two units in Slovakia. In practice the discussions were somewhat complicated regarding Bulgaria and Slovakia, as their reactors

1. Interview conducted by Pascale Luchez (ASN).

2. André-Claude Lacoste has been Chairman of ASN since it was established as an independent administrative authority by the 2006 Act on transparency and nuclear security, after occupying the posts of Director of nuclear installation safety (DSIN) from 1993 to 2002, then Director-general of nuclear safety and radiation protection (DGSNR) from 2002 to 2006.

André-Claude Lacoste is a founding member and former President of WENRA (Western European Nuclear Regulators' Association). He is a founding member and former President of INRA (International Nuclear Regulators' Association). He is

President of the Commission on Safety Standards (CSS), which has an overview role in the establishment of the nuclear safety standards of the International Atomic Energy Agency (IAEA). He is the Chairman of the Policy Group of the MDEP (Multinational Design Evaluation Program) initiative, which pools the work of safety Authorities and which is tasked with assessing the safety of new reactors.

3. WENRA (Western European Nuclear Regulators' Association): association of the heads of 17 nuclear regulatory Authorities in the countries of Western Europe.

4. TSO (Technical Safety Organizations): bodies providing technical and scientific support on nuclear safety.



"This is typical of the determination of WENRA to show that only third-generation reactors, EPR and equivalents, should be built from now on."

were much less problematic than the Lithuanian reactors, which were the same type as that of Chernobyl.

Contrôle: At the end of this initial exploration phase, what topics did you decide to work on and what results were obtained?

Once WENRA was established, we returned to a logical order with the determination to formalise what we shared on the safety of existing reactors, to formulate reference levels in terms of safety and to do the same for waste management. On this second point, as the topic is more difficult, the work is progressing but still ongoing.

In contrast, things have progressed well on the first point, that of establishing reference levels for existing power reactors. There has been a very substantial investment by the safety Authorities, and clearly ASN has played a major role, in particular by working in the ad hoc group and then chairing it, which is the case at present for Oliver Gupta, ASN Deputy Director-General. In a few years we have established 300 reference levels, which we have made public on our website and also at a conference in Brussels early in 2006. We asked for comments from the stakeholders. We have incorporated these comments, in particular those of European nuclear plant operators, which actually set up in 2005 a structure for the occasion, ENISS⁵.

We then decided to formally adopt these levels, i.e. the heads of safety Authorities decided to apply these safety levels in their respective countries by the end of 2010. That is what we are doing at the moment in France with the draft BNI order, which is going through the consultation process and is motivated very extensively by the determination to transpose these reference levels into the French law. In using the word "transpose", I am deliberately using a strong expression, since it is the term used for transposing a European directive.

The work continues and other topics have just been launched. Discussions are under way on research reactors, and we have

the project of defining the safety objectives for the new power reactors, objectives which closely resemble those that ASN and its German counterpart have defined for the EPR. This is typical of the determination of WENRA to show that only third-generation reactors, EPR and equivalents, should be built from now on.

That is for the technical history of WENRA. In the meantime there has been a major event, with the expansion of the membership from 10 to 17 Authorities, joined by our colleagues from Eastern Europe. We considered changing the name of the association for the occasion, but the spokesperson for the Eastern European Authorities, our Czech colleague Dana Drabova, clearly indicated to us that they did not wish to change the name and wanted to keep it as it was, because it was now a known 'trademark,' and above all that the new WENRA members felt themselves to be completely Western Europeans.

One of the challenges facing us at the moment is the appropriate inclusion of the heads of radiation protection or safety Authorities from non-nuclear countries such as Denmark, Ireland and Austria – which we are trying to do, with some success in fact – and association and then inclusion of our colleagues from the three nuclear countries in Europe that do not yet take part in our work, Russia, Armenia and Ukraine. We have recently taken a first step, as our Russian and Ukrainian counterparts have accepted to participate in our work from now on with the status of associate members.

This work between peers is not very formalised: the decisions are taken by consensus; we have absolutely no legal status. Nevertheless we have managed to achieve recognition and are now cited among the organizations that count when speaking of nuclear safety around the world.

Contrôle: WENRA is an informal and yet recognised structure. How is this recognition, which in the end has been acquired quite rapidly, perceived by French and European institutions?

There is a near-miraculous aspect. I do not know in detail how it happened in each of the other countries, but what I do know is that at the time when WENRA was established, in France ASN was not yet independent of the government and reported to relevant ministries. I informed them of the initiatives that we took and, after each meeting, I drew up a report, but no obstacles or objections were ever raised by the ministers to advancing the work of WENRA. It seems to have been the same for my colleagues; in any case, we have never heard anything within WENRA about any difficulty, or censorship or interference.

It might be considered that our results have been convincing because we objectively filled a gap. In fact the European Union understood very rapidly the whole value of our approach and the need to invest in nuclear safety, but initially it did so excessively. Starting from the fact that success had been achieved by work between peers, without upsetting the countries, the European Commission wanted to straight away draft highly-constraining European directives tending to give enormous power to Brussels. This resulted in the so-called 'Nuclear Package.' The project was badly received by all the stakeholders. An opportunity was missed and a number of years have been lost through the desire to move too quickly, without taking account of sensitivities.

There was thus extremely firm resistance and the Commission had to withdraw its drafts. In the end progress on the draft

5. ENISS: European Nuclear Installations Safety Standards.



directive was resumed only when the initiative was retaken by WENRA, when we said to ourselves, and I strongly pushed for this, that the time had come to continue the bottom-up approach that we had taken and to give our work a 'political umbrella.'

Contrôle: How did the work on preparation of this 'political umbrella' proceed? What was the linkage between the work of WENRA and that of ENSREG? Was a merger of the two entities considered?

The first work that we got down to was the directive on nuclear safety. Contact was made with Dominique Ristori, Deputy Director-General of the Directorate general for transport and energy. The EU understood that the only chance it had of succeeding was by making use of WENRA. The Commission then established a body, ENSREG⁶, which brings together the heads of safety Authorities, meeting in a different context, since

in that framework they are appointed by their respective governments. They are the same persons, but the atmosphere isn't the same. In WENRA I have never asked anyone to give me official instructions. For ENSREG, the government can give me instructions, since it appoints me.

In fact this directive was pushed through very quickly, as it was adopted on 25 June 2009. It is a directive of general scope which restates a number of major nuclear safety principles. One of the most powerful instruments that is set up is the introduction of a system of peer reviews to which the countries regularly subject themselves. The work of WENRA now has a political cover.

Since then a second directive, on the issue of nuclear waste, has been in preparation and should be discussed in the near future.

At the stage where we are now, WENRA has covered a path that I consider highly interesting. We were capable of making a judgement on nuclear safety in the East, we have produced technical documents on safety, we are currently producing technical documents on waste, and we have contributed to producing the political cover that is needed. One of the very surprising things, when one thinks about it, is to see how this

6. European Nuclear Safety REGulators Group (high-level European Union group on nuclear safety and waste management – formerly HLG).





“Because it was now a known ‘trademark,’ and above all that the new WENRA members felt themselves to be completely Western Europeans.”

first European Directive has generated relatively few debates, in contrast to the previous setback.

A merger of WENRA and ENSREG has never been considered, since the conditions under which my colleagues and myself take part in the work are not at all the same. At WENRA we define our work; at ENSREG, on sensitive topics, there may be inter-ministry preparatory meetings to define France’s position, which is very different. It is essential that the Authorities express their independence. We have discussed this issue and concluded that the two bodies had to be maintained: one more political, ENSREG, and one more technical, WENRA.

As an example, if our Russian or Ukrainian colleagues were to be invited to ENSREG, that would be a political issue. We decided to invite them to WENRA, which is a technical issue. If things continue, sooner or later we will want Americans to participate as observers in WENRA. We have a vision of the world where we are in the process of forming a European area of nuclear safety and radiation protection, but this area exists alongside other areas. There are no doubt three areas in the world: the European area, the American area and the Asian area. Each of these areas only has meaning with respect to the others.

***Contrôle:* After WENRA and nuclear safety, you wanted to extend your work to radiation protection, with the establishment in 2007 of a second body, HERCA⁷, in which you have also been a driving force. Could you give us an outline of how that took shape?**

There were triggering elements for HERCA as for WENRA. For HERCA the trigger was the observation that, despite the existence of European directives on radiation protection, there was no harmonization between the countries on practical problems. Among the irritating topics on which no progress was being made was the harmonization of protection measures for the population to be taken after a nuclear accident: the reference levels to initiate protective actions, the conditions of distribution of iodine tablets were not harmonized. For example, in emergency response exercises, if an incident is projected to occur at the Chooz power plant, the population protection measures that would be taken would not be the same in France and Belgium, although it is a French power plant located in an enclave with three of its sides bordering Belgian territory. Other topics include the manner in which patients with thyroid disorders are treated by injection of radionuclides. In some countries these patients are supposed to stay in hospital until their radioactivity decays, while in others they are released rapidly.

In liaison with the appropriate units of the European Commission, which has responsibility for application of the directives, we have followed the same process as for WENRA, that is, make contact with certain colleagues and look at whether they were willing to participate. We decided to take a broad approach, as on this matter there is no distinction between nuclear and non-nuclear countries. We therefore targeted all the EU member countries, but also non-members

7. HERCA (Heads of European Radiological protection Competent Authorities): meeting of the heads of European radiation protection regulatory authorities. ASN organized a first meeting in Paris on 29 May 2007. Most of the EU Member States are represented at these meetings.

such as Norway and Iceland, which means that we are nearing 30 members.

This is also a French initiative: the first meetings were held at ASN. Then my Norwegian colleague became Chairman.

For the moment HERCA is in the startup phase. It is not easy, because there is an extremely large number of us and the levels of participation are very varied. One of the reasons why WENRA works well is that the heads of the safety Authorities themselves attend the two meetings per year and only rarely delegate representatives. This is not yet the case for radiation protection. The participants may be from very different levels in the hierarchy, and there comes a time when we need positions to be taken by the heads rather than expert discussions.

Moreover, the topics that we deal with are complex and sometimes difficult. Some are for the long term, such as the European dosimetric passport: the aim is to have traceability of the doses received by nuclear workers who might work alternately in several countries. This concerns only a small number of persons; nevertheless the topic is important and must be dealt with.

More generally, we are also facing another difficulty in the medical field. Here again the context varies enormously from one country to another, and the status and the responsibilities of the various Authorities in charge of medical radiation protection are extremely varied. Some Authorities do not have responsibility for radiation protection in the medical sector, others deal only with the workers and not the patients. This is a topic on which it might be hoped that international dialogue will lead to harmonise the responsibilities and the practices of the Authorities.

We are thus at the beginning of a process that can only be longer and more complicated than that for WENRA. We are all aware of this state of affairs and talked about it at our last meeting in Oslo at the end of June 2010. We are also discussing the resources that we give ourselves in order to make HERCA more visible. This requires a policy of communication on the initial results of our work, the organization of seminars, meetings in Brussels and elsewhere, etc. These steps must be taken even before producing major results.

In conclusion, we are still only at the beginning of what will be a long process. But it is of absolute importance, in the area of radiation protection as in that of nuclear safety, that we make progress towards harmonization of measures to ensure a high level of protection of European citizens. It is this harmonization the aim of the European construction in nuclear safety and radiation protection.

Contrôle: We have been able to observe your strong personal commitment in favour of European construction in nuclear safety and radiation protection. How have you shared this vision within ASN?

As you have noted, I am a strong believer in the virtues of international cooperation and in harmonization based on best international norms, standards and practices. I have invested a lot in this topic for a long time, devoting at least 25% of my time to it. It was a completely deliberate choice on my part, but I have always taken care not to allow this aspect to develop into a sort of purely personal hobby. I have always been determined to involve ASN officials and staff, and not only to develop an international relations department at ASN. I have

"... I am a strong believer in the virtues of international cooperation and in harmonization based on best international norms, standards and practices."

wanted to incorporate this concern into the day-to-day way of working of the departments.

In this regard, it seems to me that a good indicator of the level of international involvement of an Authority is to ask, when a topic is being dealt with: is this a strictly national topic or does it concern the others? Have other Authorities dealt with it and, if so, how can I draw inspiration from their experience? This is not a natural reflex, so it is all the more important to acquire it.

The approach that we advocate at ASN is the contrary of the isolationism that is too often a natural tendency. We want to exchange, share. At the moment, in fact, we are studying a third field of competence, complementing those that we cover already [nuclear safety and radiation protection], that of security. If we are given responsibility for this topic, as we have proposed to the government, we shall have to look for information outside.

Contrôle: As we draw near the end of this overview of the involvement of the safety Authorities in the European construction in nuclear safety and radiation protection, can you give us your vision of what it should be in its accomplished form?

My vision of the future is that the development of European cooperation must enable the spread of a European vision of things. This will be in fact one of the aims of the European conference on nuclear safety that ENSREG is organizing in June 2011 in Brussels in liaison with the European Commission. We are going to have the directives that are needed. Subsequently, the question that will have to be asked is: how far should we go? At one extreme it could be imagined that an integrated European safety Authority will be necessary. Personally I do not believe that there will be such an Authority in the full meaning of the term, because it could not take difficult national decisions. I cannot easily see how it could take positions on closing one or another medical facility or power plant in a



“My vision of the future is that the development of European cooperation must enable the spread of a European vision of things.”

country such as France. And anyway, I am not sure that it would be the best way to improve the situation.

What will be more effective, on the other hand, will be to maintain the national responsibility of each State and make sure that each State has an efficient and effective Authority. These Authorities will have to share a given policy, based on the need for continuous improvement in nuclear safety, conduct peer reviews regularly, develop staff exchanges, and develop joint or shared inspections, all supported by competent TSOs which will remain limited in number.

I thus have a vision of a network of national Authorities able to benefit from the expertise of a network of TSOs.

An evolution in this direction is under way in the area of nuclear safety, through the effect of the work of WENRA. Eventually a similar evolution could take place in the area of radiation protection through the effect of the work of HERCA. These developments will take time: that is yet another reason for declaring clearly from now on the objective pursued and making the effort to reach it: the objective is the harmonization of measures to ensure a high level of protection of European citizens. ■

INSTITUTIONAL CONTEXT AND REGULATORY FRAMEWORK

The Euratom legal framework in health protection and nuclear safety

by **Frédéric Mondoloni**, French representative at the AIEA Board of Governors, Director of the Strategy and External Relations Directorate of the CEA

Nuclear energy is without question enjoying renewed interest internationally, prompted by several factors. Some facilities are reaching their end-of-life and may be renewed, price volatility and depleted fossil energies are included in the reference scenarios and combating climate change and necessary restriction of CO₂ emissions have become major international environmental concerns. To many people, nuclear energy is thus one solution to tomorrow's energy challenges.

However, detractors of this energy source highlight the need for safer nuclear facilities and the question of radioactive waste management.

The European Commission understood clearly that it could not afford not to be involved in discussions on future energy issues and the associated investments. The Commission was aware of the advantages of nuclear energy given its concern also for the competitiveness of the European industry in an increasingly-globalised world. At the same time, it also set out to develop a full regulatory framework for radiological protection, nuclear safety and management of radioactive waste and spent fuel, based on the Euratom Treaty.

Since 1957, the European Atomic Energy Community has step by step built up a genuine, robust and recognised legal framework covering radiological protection as well as safety aspects, controlling waste transfers and handling emergencies. The adoption of a nuclear safety directive in 2009 supplemented this major regulatory framework.

European experience in these areas can also serve as a model for a good number of countries wishing to use nuclear energy and encourage them to develop a real safety culture that is a must when developing a responsible programme for the peaceful use of nuclear energy.

Since 1957, Euratom law has provided an efficient legislative foundation for the protection of man and the environment from ionising radiation

From the start the Euratom Treaty laid the foundations of a progressive European initiative for health protection against the effects of radioactivity. The provisions of Chapter 3 of the Treaty include both obligations for the Member States and Commission-led inspections.

Articles 30 to 33 require European standards for radiological protection to be laid down and updated based on work by a group of experts. These "basic standards" define the maximum permissible exposure levels and the principles governing the monitoring of these exposures.

Under Articles 35 and 36, Member States must establish facilities to monitor the level of radioactivity in the environment and compliance with radiological protection standards. The

Commission can verify that these facilities are functioning correctly during specific inspections, following which it produces a report for publication on its Internet site.

Lastly, Article 37 requires Member States to submit plans for radioactive effluent discharges from nuclear facilities to the Commission for its opinion. The plans are thus checked that they do not represent a radioactive risk for the territory of another Member State. The Euratom Technical Committee (*Comité technique Euratom* – ETC), charged with managing these obligations in France, thus made nine submissions to the European Commission in 2009 alone. The Commission then publishes its opinion in the European Union's Official Journal under this procedure, which is frequently poorly understood.

In addition to these articles, numerous directives supplement the law derived from the Euratom Treaty on topics as diverse as transmitting information in case of radiological emergency, the control of sealed sources or radiological protection in medical area.

There is therefore a real community base in health and environmental protection and its utility has been notably recognised by the Court of Justice in a judgement of 27 October 2009 on a matter disputed by Austria and the Czech Republic (*Land Oberösterreich v CEZ as - C-115/08*). The Court had to give an opinion of the recognition under Austrian law of an authorisation issued by the Czech Authorities for the operation of the Temelin power plant. The Court considered that this authorisation should be dealt with in the same way as an authorisation issued by the Austrian Authorities, otherwise it risked showing differential treatment, given that the Euratom Treaty and Directive 96/29 are striving to ensure health protection for the population against hazards from ionising radiation.

New impetus is now being given to the supervision of civil nuclear energy to support its development

European Commission action remained shackled for many years by the very letter of the Euratom Treaty, which, it must be recognised, has several gaps in terms of the current situation and challenges. Given that it has hardly been modified since being written in 1957, the Treaty does not refer expressly to nuclear safety, radioactive waste management and environmental protection - today's fundamentally essential topics. To rectify this, the Court of Justice has rendered several rulings clarifying community competencies on these subjects. Having ruled that Chapter III of the Euratom Treaty allocated sufficiently extensive competencies to protect the environment against radioactivity, in 2002 it confirmed the existence of Euratom Community competencies in terms of nuclear safety, thereby opening the door to European regulations in this sector.



Thus, under the French presidency of the Council of the European Union in the second half of 2008, the Commission presented a draft directive on nuclear safety. Consensus had proved impossible to reach a few years earlier, in 2002, on the "Nuclear Package" which focused mainly on two proposed directives, one on nuclear safety and the other on radioactive waste management. Many people felt that the adoption of the text in June 2009 marked the start of a changing role for the Euratom Community in supervising and supporting the development of nuclear energy in Europe.

This text made the European Union the first major regional player to grant a binding legal status to major international principles on nuclear safety like those established by the International Atomic Energy Agency (IAEA) and those resulting from the Convention on Nuclear Safety. This directive clarifies the responsibilities of all those involved whilst also aiming to boost the independence of competent national Authorities.

The adoption of this directive is a significant step in setting up a common legal framework and solid safety culture in Europe. It showcases a positive message to European public opinion, thereby boosting its confidence in nuclear energy, and internationally. In relation to the rest of the world, the directive supplements the image of technological excellence in nuclear operations, by including the idea of exemplary European regulations for nuclear safety.

To continue the trend carved by this initial success, the European Commission is planning to submit a proposed directive on radioactive waste and spent fuel management to the Council within the next few months.

The bases of the European model for nuclear energy supervision, to which the Commission makes occasional

reference, are currently being drawn at high speed, to the point of wondering whether the Commission is not seeking to push its initiatives further forwards. Beyond a fairly general framework on nuclear safety and radioactive waste management, it may be possible for the Commission to look subsequently to a harmonization of real safety standards in the European Union. It is also starting to think about nuclear civil liability which is already supervised under several international conventions. In addition, the Commission quotes reactor certification more and more frequently as a subject potentially justifying a coordinated community approach.

The European Union is seeking to promote a European regulatory model internationally in addition to its technological expertise in nuclear energy

The guidelines laid down by the European Commission for several recent initiatives confirm its desire to play a role in supporting responsible development of nuclear energy, at both European and international level.

The community safety assistance mechanism in third-party countries is important in this respect. This assistance initiated in 2007 as the Nuclear Safety Cooperation Instrument (NSCI) is not just taking over from the TACIS programme by offering assistance to Ukraine, Russia and Armenia, but also extends to the rest of the world.

The recent cooperation instituted by this instrument with Jordan, Egypt, Brazil, Vietnam and China is a clear illustration of the Commission's willingness to support, in the safety area, the countries starting up or relaunching a civil nuclear energy programme. Europe can provide these countries with the benefit of its experience via the Member States, by offering to train professionals, for example. In this context, France is called on to promote its expertise for the benefit of strengthened cooperation with the beneficiary countries. At the same time, the States receiving assistance must commit to ambitious nuclear safety/steps and report on progress made.

The INSC, like all Euratom Community actions affecting both third-party countries and nuclear safety issues, is implemented in coordination with the initiatives and frameworks provided for by the IAEA. Remember also that the Euratom Community is nowadays party to the principal Conventions placed under the auspices of the IAEA, including the Convention on Nuclear Safety, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

It is important to have the European commitment recognised internationally and to improve communication in this respect. This communication is conveyed by the European Commission and also by the Member States. The recent international conference on access to civil nuclear energy held in Paris on 8-9 March 2010, initiated by the President of the Republic and organized by France together with IAEA and the Organization for Economic Co-operation and Development (OECD/NEA), is a further example of a "can do" and structured approach to convey these messages. The wide audience (65 countries) has been a vehicle for promoting forceful messages on the support methods for a civil nuclear power plant programme in a world energy landscape undergoing total restructuring, by considering the safety requirement as an absolute must.



European flags in front of the Berlaymont building – Seat of the European Commission in Brussels

In synergy with the international principles developed by IAEA, Europe is thus seeking to export its principles on supervising the operation of nuclear energy. This effort is even clearer when reading the increasing number of international agreements between the Euratom Community and third-party States in the peaceful use of nuclear energy (Argentina, Australia, Canada, United States, Japan, Kazakhstan and soon Russia and South Africa), which include increasingly exacting clauses on nuclear safety.

Lastly, the proposed European conference on nuclear safety run by the European Nuclear Safety Regulators' Group (ENSREG) should help broadcast the European approach to these questions. ENSREG has been closely involved in preparing and now implementing the nuclear safety directive and discussions on a proposal for a waste management directive.

The organization of the European Conference on Nuclear Safety in Brussels on 28-29 June 2010 will be an opportunity to proclaim a specifically-European message on nuclear safety on the international stage.

The important role of the European Nuclear Energy Forum also deserves a mention. This contributes to discussions on the conditions of use for nuclear energy, including for safety issues. The main stakeholders interested in nuclear energy can state their views in this forum and participate in working groups.

These initiatives to broadcast European values in nuclear safety which are identified and expressed better and better within the Euratom Community are very pleasing. It is however important to bear in mind that a community approach to nuclear safety is of necessity restricted by the principle of subsidiarity, by the first competency of Member States, and national Authorities within them, and by the responsibility of operators on these questions.

Towards “controlled harmonization”?

Harmonizing Member States' legislation may result in a general improvement in safety, health and environmental protection and encourage fairer competitive conditions in the European energy market. This is nevertheless an exercise where the boundaries must be defined with caution, bearing in mind the need to ensure the existing equilibrium from a safety point of view and also the competitiveness of the European nuclear industry, in a highly-competitive international context.

The Commission may well seek to develop the European safety framework that it intends to promote internationally. Although the recent directive on the subject attempts to render the major principles in organizing and supervising nuclear safety binding by restating the national responsibility of Member States, it cannot be excluded that discussions on establishing more technical standards, possibly inspired by the work of WENRA (Western European Nuclear Regulators' Association), one day produce a follow-up to this initial text. As ENSREG underlined in its principles laid down in November 2008, it is essential to remain flexible to avoid casting doubt on the various national safety systems which have been perfected over time and proved their worth, as destabilisation could be dangerous. Similarly, the increase in community recommendations on health protection and environmental protection must be implemented responsibly.

In my view, the Euratom Community should avoid two major pitfalls: needless duplication of controls already applied by Member States and the temptation to appear as an all-powerful



Cooling towers of a nuclear power plant

institutional player despite the competencies attributed to it by the Euratom Treaty not being without limits.

It is advisable at this stage to avoid a European body seeking to play a nuclear safety controller role in the Member States. Certain practices developed by the European Commission can sometimes seem excessive in this respect.

For example, Article 37 of the Euratom Treaty requires Member States to submit plans for radioactive effluent discharges from nuclear facilities to it for an opinion, to check that neighbouring States are not likely to be affected by radioactivity - which is both necessary and useful.

Unfortunately, this procedure, currently affecting not only the radioactive effluent discharge plans but also waste management and accident situations, has expanded enormously over time and does not really submit to the letter of the Treaty; both the European Commission and the contributing experts find it difficult to apply. This situation means that it takes far longer to study the files, thereby delaying the national decision-making process. It is therefore important to avoid creating new obligations resulting in excessive administrative burdens weighing on the national administration and the operators when the ultimate benefit is not clearly demonstrated - to find a perfect balance between the actual needs for information and the imposed constraints.

The second risk I can see lies in the Commission's proactive behaviour in areas not directly within its remit. It is important to define a balance in themes as sensitive as nuclear security and non-proliferation between the role of Member States, of other international organizations like IAEA and of the Commission. The Commission must not line up systematically



with regulations but rather support or sustain the Member States and IAEA which have the legal competencies on the subjects.

The implementation and development of community law in terms of safety, health and environmental protection are monitored carefully by the French Authorities

In this context, France must manage without fail to encourage the formulation of a European nuclear energy policy guaranteeing the development and competitiveness of the European nuclear industry at the best safety level.

Responsible mainly for defining and defending national nuclear interests, the General Secretariat for European Affairs (*Secrétariat général aux affaires européennes* - SGAE), the Permanent Representation of France in Brussels (RP) and the CTE form a suitable three-way association for monitoring nuclear files, based on the competencies of all players involved.

The CTE supports the SGAE. It must ensure compliance by our country with the obligations laid down by the Euratom Treaty and help in the national coordination to define French positions. It is also responsible in its own right for monitoring the application of international checks on nuclear materials carried out in France by the European Commission and IAEA.

As CTE is a Prime Ministerial department, administered by the Atomic and Alternative Energies Commission - CEA (International Relations Division), I can only be pleased that France has a department with both legal and technical expertise covering all topics of the Euratom Treaty. The assistance it receives in its everyday work from French experts is of course essential and necessary, especially in radiological protection and nuclear safety given the likelihood of an exercise to revise the directive on basic standards and that a draft directive on radioactive waste and spent fuel management is currently being prepared. The consistency of this system and its perfect coordination with all those involved will be our strength in the pending debates. ■

INSTITUTIONAL CONTEXT AND REGULATORY FRAMEWORK

European Commission action aimed at constructing a european regulatory framework

by Dominique Ristori, Deputy Director-General, Directorate General for Energy – European Commission

The challenges of climate change and of promoting low carbon economies should encourage the development of renewable energies and, for many Member States, offer a new lease of life for nuclear power. It is hardly surprising that the goal of gradual decarbonisation of electricity production in Europe is leading to a closer European interest both in renewable energies and in nuclear power.

The European Union (EU) is one of the regions in the world in which civil nuclear power is most extensively developed. At present, 143 nuclear power plants in operation in 14 EU Member States produce about one third of the EU's electricity. Nuclear power accounts for two-thirds of zero-carbon emissions electricity in the EU and, by 2020, almost two thirds of the EU's electricity could come from carbon-free sources, such as nuclear power and renewable energies.

A number of Member States have plans to build new nuclear power plants (NPP) or extend the lifetime of plants already in operation, in order to meet rising electricity demand, improve security of supply and combat climate change.

Nuclear power is thus one option capable of meeting today's European energy policy challenges, in other words providing clean and reliable energy while at the same time ensuring the supply of energy at competitive and affordable prices.

Given the current context of renewed development of nuclear energy in Europe and indeed worldwide, the responsible use of civil nuclear energy clearly has to be guaranteed.

The EU has a two-fold role in the civil nuclear field:

- On the one hand, within its borders, and in the interests of all Member States, to develop the most advanced legal framework meeting the most stringent safety, security and non-proliferation standards.
- On the other, to take or support initiatives worldwide, aimed at ensuring that these high standards are met internationally.

For more than 50 years, the Euratom Treaty has acted as the legal framework for the development of nuclear power, in particular with regard to investments, radiation protection, safety, nuclear liabilities, research and international relations. A number of highly tangible measures have thus been taken, particularly in the fields of radiation protection and nuclear safety.

Radiation protection

The EU has extensive competence in the field of radiation protection. Chapter III "Health Protection" of the Euratom Treaty gives the Community a key role in laying down basic standards for the health protection (of workers and the population) against the hazards of ionising radiation.

The first basic standards issued in 1959 set limit values (for dose and activity concentration). From the outset, the standards were established on the basis of international recommendations from the International Commission of Radiological Protection (ICRP), ensuring that they were consistent with the basic standards issued by the International Atomic Energy Agency (IAEA). The Euratom basic standards are based on the work of the independent experts group established pursuant to Article 31 of the Euratom Treaty. The experts issue an opinion on all legislative proposals built around this Article. Their field of competence covers the actual basic standards, but also other directives, regulations and recommendations.

While the subject of the Euratom Treaty is the development of nuclear power, health protection standards must apply regardless of the source of radiation. Further to the successive recommendations from the ICRP, the scope of the basic standards was extended to other fields through a number of updates, in particular medical applications (1984) and naturally occurring radiation (1996).

Other texts were added: a Commission Recommendation¹ on radon in the home (1990), regulations concerning the maximum allowable levels of radioactivity in foodstuffs in the event of a nuclear accident² (following regulations adopted under the EC Treaty setting the conditions for the import of foodstuffs contaminated by the Chernobyl accident). Subsequent to this accident in 1986, a directive on information of the public in the event of a radiological emergency (1989)³ and a Council decision concerning the early exchange of information between the Commission and the Member States (1987)⁴ were adopted.

The Community has thus acquired vast experience in the field of radiation protection and the Commission's significant role in the development of standards is undisputed. Correct transposition of community texts into national legislation, verified in accordance with the highly specific requirements of Article 33 of the Euratom Treaty, to a very large extent ensured the harmonization, and in some case the uniformity of national legislation provisions and good radiation protection practices in Europe (Switzerland and

1. 90/143/Euratom: Commission Recommendation of 21 February 1990 on the protection of the public against indoor exposure to radon.

2. 87/3954/Euratom: Council Regulation of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency.

3. 89/618/Euratom: Council Directive of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency.

4. 87/600/Euratom: Council Decision of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency.





European Commission in Brussels. The Berlaymont building.

Norway for example draw extensively on the Euratom standards). It is essential that this role be maintained if public confidence in health protection is to be retained. Although a 1992 decision of the Court of Justice introduced the concept of “minimum standards”, thus enabling the Member States to introduce more restrictive requirements, the States did not as a rule consider it necessary to take up this option.

The latest recommendations from the ICRP⁵ led to a further revision of the basic standards in 1996⁶, as well as of the directive on medical applications⁷. Coherent management of the health risk was introduced for all exposure situations (existing, planned and emergency situations) and for all categories of exposed individuals (workers, members of the public and patients). This enabled greater emphasis to be placed on to protection against naturally occurring radiation. It was also an excellent opportunity to consolidate into a single text all Euratom radiation protection directives⁸. This revision and overhaul work was considerable and is currently on the point of being completed. The Group of Experts issued its opinion on the revised and consolidated draft directive on 24 February 2010⁹, which enabled the Commission’s proposal to be finalised. If this proposal is adopted by the Council, the user of the basic standards will then find all the Community requirements in a single document. Reading and interpretation of the texts will thus be made easier. After more than 50 years, Community legislation will finally have basic standards covering all of the many aspects of radiation protection.

5. ICRP Publication 103, the Annals of the ICRP, Volume 37, Nos. 2-4, Elsevier, 2007.

6. 96/29/Euratom: Council Directive of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.

7. 97/43/Euratom: Council Directive of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, and repealing directive 84/466/EURATOM.

The scope of the new basic standards will be further expanded by incorporating the provisions of the recommendations on radon in the home and by for the first time introducing construction material controls on the basis of a reference level of 1 mSv per year. The technical procedures for classification of materials will be covered in CEN standards for construction products.

In accordance with the ICRP recommendations, environmental protection is introduced in addition to human protection with regard to environmental exposure routes. Incorporation of this aspect into a Euratom directive should ensure a coherent approach between the two aspects of environmental radioactivity management.

Even if only a very few modifications were made to the medical directive, the overhaul enabled a clearer distinction to be made between medical exposure and imaging for non-medical purposes, in particular the growing use of security checks. The overhaul also allowed the introduction of measures to prevent accidental medical exposure (or exposure running contrary to the intended medical result). The new basic standards will thus be a key element in the implementation of the Communication on medical applications, in particular nuclear medicine, to be presented by the Commission this year.

Nuclear safety

Chapter III of the Euratom Treaty had only been used to deal with radiation protection of workers and the general public until the Court of Justice of the European Communities (CJEC), in

8. Those already mentioned as well as directive 2003/122/EURATOM on the control of high activity sealed radioactive sources (2003) and directive 902/64/EURATOM on outside workers (1990).

9. http://ec.europa.eu/energy/nuclear/radiation_protection/doc/art31/2010_02_24_opinion_on_bss.pdf

case 29/99¹⁰, recognised that “it is not appropriate, in order to define the Community’s competencies, to draw an artificial distinction between the protection of the health of the general public and the safety of sources of ionising radiation”. On the basis of this ruling, nuclear safety thus became an absolute priority for the EU.

A Community-wide approach to nuclear safety is a key element in developing a sustainable safety system at a national level and in meeting the safety challenges posed by the renewed interest in nuclear energy both within the Community and around the world.

The nuclear issue is also attracting the interest of the public, who are demanding information and wanting to make their opinions heard on the subject. European citizens need to be reassured about the safety of the nuclear facilities around Europe. According to various opinion polls, this is their primary concern. Within the context of the expanded EU, it therefore became necessary to adopt a common approach in order to guarantee the highest level of safety by establishing strict rules applicable to the safety of nuclear facilities throughout the EU.

The development of such a common approach was made considerably easier by the European Commission’s 2007 decision, with the full support of the Council, to create the European high-level group on nuclear safety and waste management (subsequently renamed ENSREG – European Nuclear Safety Regulator Group), with the aim of defining a common vision and reinforcing joint approaches in the fields of nuclear safety and the management of radioactive waste in Europe. ENSREG comprises the heads of the national regulators of all the Member States, responsible for regulation or for nuclear safety, including those which do not use nuclear power to produce electricity. The French nuclear safety Authority (Autorité de sûreté nucléaire – ASN) is an active participant, through its Chairman, Mr André-Claude Lacoste.

The adoption by the Council on 25 June 2009 of the directive on nuclear safety¹¹, with the support of the 27 Member States and a vast majority of the European Parliament, is a key step towards the creation of said common legal framework and a robust nuclear safety culture in Europe. The EU is therefore the first leading regional player to give binding legal force to the main international nuclear safety standards, that is the IAEA’s Basic Safety Principles and the obligations arising from the Convention on nuclear safety. The directive also strengthens the independence and resources of the competent national regulatory bodies.

The directive in particular obliges the Member States to implement and continuously improve their national nuclear safety requirements. The directive strengthens the role and independence of the national regulatory bodies, confirming the responsibility of the licensees for nuclear safety. The Member States are required to encourage a high level of transparency in their regulatory actions and to guarantee that independent safety assessments are regularly carried out.

The EU is the first leading regional nuclear player to establish a binding legal framework in the field of nuclear safety. Europe could therefore become an example to be followed by the rest

of the world given the current renewed interest in nuclear power.

It is now up to the Member States to ensure that these obligations are correctly and rapidly transposed into national legislation within the time-frame stipulated by the directive, in other words by 22 July 2011.

The Commission is aware that cooperation with the national Authorities needs to be developed very early on in the process if this objective is to be met in full. A seminar on the transposition of the directive was therefore held on 7 May 2010 in Luxembourg. Collaboration with the competent Authorities of the Member States also extends to the review of various legislation projects transposing the directive into national law, which have to be notified to the Commission pursuant to Article 33 of the Euratom Treaty.

Similarly, ENSREG, thanks to its high-level expertise, had already contributed to the preparation of the nuclear safety directive and will provide its support for the efficient and uniform implementation of the directive. Concrete examples concern the proposal of a standardised structure for the reports to be sent by the Member States to the Commission, a common methodology for periodic self-assessment by the Member States and a system for coordinating the international reviews required by the directive. The Group will thus facilitate consultation of and cooperation by the national regulatory bodies and will thus contribute to achieving the Community’s nuclear safety goals.

A fundamental principle of nuclear safety, which is also underlined by the directive, is that only truly independent regulators can guarantee the safe operation of nuclear installations within the EU. This is why, in the directive transposition and implementation process, the Commission will rely on the expertise of national regulators and, in this context, will encourage permanent dialogue at a European level in order to ensure that continuous improvement in nuclear safety is promoted.

In the light of its role of regulating a fleet of nuclear power plants that is the largest and most diversified in the EU, and its daily commitment to nuclear safety and radiation protection, ASN plays an essential role in developing a common European approach to nuclear safety and radiation protection. ■

10. CJEC ruling of 10 December 2002, Commission of European Communities against the council of the European Union, Case C-29/99.

11. 2009/71/Euratom: Council Directive of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations.



INSTITUTIONAL CONTEXT AND REGULATORY FRAMEWORK

France's contribution to the construction of a European regulatory framework for nuclear safety

by Philippe Étienne, France's Permanent representative to the European Union

At the beginning of the process to build Europe, the Euratom Treaty enshrined a two-fold ambition on the part of the founding States. On the one hand, that of uniting together to create the conditions for development of a European nuclear industry and, on the other, to establish "safety conditions" which would protect workers and the general public from the harmful effects of ionising radiation.

As a pioneer in the development of a nuclear industry in Europe, France's expertise meant that it was able to play an active and positive role in the emergence of a robust European regulatory framework for nuclear safety and radiation protection.

In a half century of cooperation, and as European integration progressed, legislation derived from the Euratom Treaty laid down basic standards for radiation protection (Article 31 of the Euratom Treaty). The legislation adopted in this way in particular concerned transport, the shipment of radioactive waste and spent fuels, and a common system for managing emergency situations.

This willingness to regulate NPP operation was extended internationally by the Community's active contribution to international safety and radiation protection arrangements (primarily the IAEA Conventions) but also by the conclusion of framework agreements with third-party States (United States, Russia, Australia, etc.) and through community instruments concerning nuclear safety. These were all opportunities for Europe and France to promote a high level of safety.

The upsurge in interest in nuclear power around the world and in Europe has motivated the European Commission, with the support of France, to propose new initiatives to provide Europe with a true regulatory safety framework. This aim, which was given form in the "Nuclear Package" from Commissioner Loyola de Palacio (2003), laid the foundations for a European-wide debate on the conditions for the use of nuclear power, the resulting responsibilities and the need to harmonise a certain number of practices.

Given the considerable differences of opinion, it proved impossible to adopt the package, so the process of debate continued with the ad hoc working party on nuclear safety (WPNS) whose report led to the conclusions of the European Council in March 2007 and those of the Council in May 2007. The European Council decided to create a high level group (HLG), which has subsequently become the ENSREG group of national safety regulators, and to set up an open European Nuclear Energy Forum (ENEF) which was to launch the idea of a binding nuclear safety instrument.

The directive on the safety of nuclear installations, adopted under the Czech Presidency in June 2009, was first of all the fruit of lengthy debate between regulators outside the confines of the community (within WENRA - Western European Nuclear Regulators' Association) and within ENSREG. The first legislative debates began under the French Presidency, which also saw through the adoption of Council conclusions aimed at maintaining expertise in the nuclear sector, criteria for granting nuclear safety assistance to third-party countries and a resolution on the management of waste and spent fuel.

Through its undertakings to the Council, France made a continuous contribution to the establishment of a true European nuclear regulatory framework that is both binding and effective.

This undertaking by the French Authorities will continue with the future Council review of a legislative text on radioactive waste and spent fuel management policy promised by the Commission before the end of the year.

Nuclear safety and radiation protection: a priority for France

The French nuclear industry, which covers the entire cycle, is the result of political and industrial choices. Today, more than ever, its aims are to meet the needs and challenges of security of supply and of a low-carbon yet competitive economy. However, one must not lose sight of the fact that this industry also owes its success to the past and ongoing close and constant attention by our institutions to the subject of radiation protection and safety standards. This is thanks to a strict and rigorously enforced regulatory framework.

This legislative framework was recently supplemented and strengthened by the 13 June 2006 Act on Transparency and Security in the Nuclear field (TSN). Together with the Public Health Code, the TSN Act organizes a clear distribution of roles with regard to the oversight of nuclear operations in France and defined the prerogatives of the French Nuclear Safety Authority (ASN), which now enjoys independent administrative authority status.

With this Act, France has established an ambitious benchmark for the Brussels debates on the creation of a Community nuclear safety framework, given form by the "safety" directive. Although the Euratom Treaty contains explicit provisions concerning health protection (basic radiation protection standards)², it was only with ruling C-29/99³ in 2002, that the Court of Justice of the European

1. Euratom Treaty, 1957, 4th sentence: "Anxious to create the conditions of safety necessary to eliminate hazards to the life and health of the public, [...]"

2. Title II, chapter 3, art. 30 and following, Treaty establishing the European Atomic Energy Community (Euratom).

3. CJEC, ruling of 10 December 2002 in case C-29/99 Commission versus Council

Communities clearly established shared Community competence in the field of nuclear safety. This is founded on Chapter III of the Euratom Treaty, devoted to protection of the public and the environment against radiological risks and nuclear contamination. As this is a shared competence, it must be borne in mind that uniform Community standards can in no way replace more stringent national measures, such as those which in particular exist in France.

It was therefore with the help of jurisprudence favourable to the emergence of derived nuclear safety legislation that France's Permanent Representation to Brussels, together with ASN, the Ministry for Ecology, Energy, Sustainable Development and the Sea (MEEDDM), the Ministry for Foreign and European Affairs (MAEE), the General Secretariat for European Affairs (SGAE) and the EURATOM Technical Committee, was able to defend the Commission's efforts to establish a Community framework based on the International Convention on Nuclear Safety⁴. It should be noted that, unlike the IAEA Convention, the directive is binding.

From the "Nuclear Package" in 2003 to the Council Conclusions of May 2007: a slow but necessary process

In its 2000 Green Paper entitled "Towards a European strategy for the security of energy supply", the Commission was already endorsing the idea of using nuclear power within a Community regulatory framework for nuclear safety and the management of radioactive waste and spent fuel.

Nuclear power was identified in it as a preferential source of energy because of its low carbon emissions and ability to offer security of energy supplies, provided that at the same time, a regulatory framework was created to ensure the safety of the installations and good management of radioactive waste.

This "nuclear safety" part was to be proposed in the "Nuclear Package" from Commissioner Loyola de Palacio in 2003, once Community competence had been recognised in this field by the Court of Justice in Luxembourg in 2002⁵.

In the past, the French Nuclear Safety Authority (ASN) had already worked towards improved nuclear safety in Europe, within WENRA (Western European Nuclear Regulators' Association) and had contributed to establishing reference levels for the safety of existing reactors. However, and despite the importance of this technical work, there was still no legal definition of nuclear safety in Community law.

Despite their reservations concerning the scope of these proposals, the French Authorities in 2003 offered their support for the "Nuclear Package" from Commissioner Loyola de Palacio and his Director General, François Lamoureux.

France was convinced by the Commissioner's argument which stated that it was "absurd to have a directive on bathing water and nothing on nuclear safety", and was in favour of creating a community legal framework able to guarantee a high level of safety both in Europe and worldwide.

This highly ambitious package proposed a series of new and related measures in areas as sensitive as radioactive waste management or the provisioning of the decommissioning funds.



European Commission green paper published in 2000

The "Nuclear Package" was no doubt over-ambitious and gave excessive powers to the Commission. It led to a dead-end. Its failure ushered in a period of consultation and discussion in order to determine what were the best instruments, the priorities and the degree of Community intervention in this field. This lengthy work was inaugurated by the creation of a group of experts within the WPNS, tasked with assessing and making concrete proposals for safety, waste management and the decommissioning funds. The MEEDDM, ASN and the Permanent Representation actively contributed to this work.

The WPNS final report, ratified in 2006 by the Council of Ministers, recommended the creation of a high level group (HLG which subsequently became ENSREG) to deal with these questions in an appropriate and specific way.

On the basis of this report, the Council of Ministers in May 2007, under the German Presidency, adopted the Conclusions which created this high level group (HLG then ENSREG) to develop "strategies for the safe management of all types of spent fuel and radioactive waste" and urged "each EU Member State to establish and keep updated a national programme for the safe management of radioactive waste and spent fuel that includes all radioactive waste under its jurisdiction and covers all stages of management". In its conclusions, the European Council of March 2007 had already asked the Commission to create this high level group as rapidly as possible.

As of the start of the work by the high level group, France was present through ASN and its Chairman, André-Claude Lacoste, and the General Directorate for Energy and Climate (DGEC) at the Ministry for Ecology, Energy, Sustainable Development and

4. Convention on nuclear safety adopted 17 June 1994.

5. CJEC, ruling of 10 December 2002 in case C-29/99 Commission versus Council.



the Sea. It also obtained the Presidency of the “waste” sub-group.

The European Council of March 2007 also recommended setting up the European Nuclear Energy Forum (ENEF), an open platform for all nuclear stakeholders, including representatives of civil society, in order to promote a constructive and transparent dialogue on the risks and opportunities of this energy source. The ENEF, in which French industrial firms, CEA and also the ANCLI (national association of NPP local information committees) are active, made a significant contribution to the debate outside Community circles and thus helped prepare the “safety” directive. Recently, on the issue of maintaining expertise levels, the Forum oversaw the launch of the ENELA academy, an initiative bringing together industrial firms, including AREVA, for training of future managers in the nuclear sector.

The French Presidency of the Council of the European Union, 2nd half of 2008

The Presidency of the Council in the second half of 2008 was an opportunity for the French Authorities to table a certain number of initiatives and support the efforts of the Commission, so that at the end of its Presidency the “safety” directive proposal could be presented.

The Presidency grasped the opportunity it was given to consolidate safety conditions and send a strong signal from the Council to the Commission, but also to our international partners, in favour of a more complete regime.

The Council thus obtained:

• Conclusions on the criteria for granting assistance to third-party countries with regard to nuclear safety

While underlining the positive contribution of the instrument for nuclear safety cooperation (INSC) or the stability instrument (“nuclear safety” part), the aim was to invite the Commission, when providing assistance, to meet a certain number of criteria so that the upsurge in interest in nuclear power around the world was given “responsible oversight” as advocated by France.

• A Resolution on the management of radioactive waste and spent fuel

A graduated approach was used to obtain unanimous adoption of this resolution on such a sensitive subject. ENSREG was

asked to present its work to the Working Party on atomic questions; various reports were produced, leading to a text which in particular underlines the need for each Member State to set up a national waste and spent fuel management plan. This resolution also aimed to pave the way for a directive proposal.

• Presentation of the directive on the “safety of nuclear installations” directive (adopted under the Czech Presidency)

France worked with the Council and the Commission to dust off this directive proposal, which was finally tabled on 26 November 2008. The French Presidency “cleaned up” the text, identifying the main difficulties and proposing some initial answers.

The “safety” directive

Following the discussion initiated under the French Presidency, this text was adopted on 25 June 2009 by the Council under the Czech Presidency. The relatively short period of negotiation (about 7 months) for a text which had in the past aroused such strong feelings, is down to a number of factors.

Firstly, attitudes had changed and the debate had been enhanced by informal discussions and recommendations from various groups created after the 2003 nuclear package had been placed on ice (ENSREG, ENEF, etc.).

Secondly, the Commission had opted for an approach felt by some to be more reasonable and disconnected from the other linked measures in the 2003 “package”. At issue therefore was just a single text on nuclear safety.

Although some initially regretted the fact that the proposals were less wide-ranging than in 2003, the final text enabled the delegations to reach an agreement preserving the essential substance and the binding nature of the requirements.

It is important to remember that the main benefit of the “safety” directive is that it creates a European framework and incorporates the provisions of the IAEA’s nuclear safety Convention into Community law. The “fundamental principles” as incorporated in the directive become an integral part of Community law and oblige each Member State to establish a national regulatory framework for this field.

The scope of the directive excludes waste or spent fuel storage facilities outside installations in service. However, the definition of the installations concerned is broader than that defined by IAEA in its Convention on Nuclear Safety.

The major principles mentioned in the directive include the requirement for the independence of the safety regulator, the availability – both for the regulator and the licensee – of adequate financial and human resources, and the importance granted to the issues of competence and training. This latter point was actively supported by France, in line with the previous resolution on the same subject adopted under the French Presidency. Finally, the question of assessment and constant improvement of nuclear safety will be the subject of a peer review, in accordance with the wishes of the French Authorities.

This directive was relatively warmly welcomed by the stakeholders in the nuclear sector and represents a first step towards the more complete regulatory framework the European Union aims to create. The problem of waste management is the next one being targeted by a Community text and should incorporate the safety of waste and spent fuel management aspects.



Meeting at the Council of the European Union

Towards a directive on the management of waste and spent fuel

The Commission is preparing a draft text on the management of waste and spent fuel, which should be presented to the Council in autumn of 2010. The goal is to require that the Member States set up a national waste management plan and to regulate some of the corresponding procedures.

This goal is in line with the expectations of the citizens of Europe, as indicated by the Eurobarometer surveys of 2008 and 2010, but also with the guidelines issued by ENSREG and the ENEF Forum, both of which contributed to the debate by carrying out in-depth work on a text concerning radioactive waste and spent fuel.

As we mentioned to the European Commission, the French Authorities will give a favourable welcome to such a project: the management of radioactive waste concerns all Member States and it is therefore important that each one of them implement measures to ensure responsible and sustainable management.

The resolution of 16 December 2008 adopted by the French Presidency already supported the creation of a national waste and spent fuel management plan and we are continuing to defend this position.

In order to complete the safety framework set up by the 2009 directive, which only partially covers waste storage facilities, it would be interesting to have some of the safety principles of the IAEA Joint Convention on the safety of spent fuel management and on the safety of radioactive waste management transcribed into the text of the future directive.

It will also be important to define the notion of "radioactive waste" which could be inclusive, while preserving elements already covered by the existing regulations.

The directive must also be a guideline tool for the Member States that are less advanced in this field. Solutions which are the subject of international consensus and which contribute to safe and sustainable waste management could be mentioned, such as deep geological disposal.



French Presidency of the Council of the European Union – joint research and atomic questions group – Aix-en-Provence, 4-5 September 2008

It would seem to be clear that in addition to the safety culture developed by the regulations resulting from the work done by the Euratom Community, a true European nuclear safety regulatory framework is being created. Its foundations can be traced back to the technical work launched at the end of the 1990s by WENRA, and it became anchored in Community law thanks to the adoption of the "safety" directive. Its logical continuation will be the proposed text for the management of waste and spent fuel.

This Community framework has the advantage of being binding and will be part of the full range of Community texts that will have to be accepted by any new Member State. The Community's external influence and its export of this "enhanced" safety culture are also perceptible through agreements with third-party States or nuclear safety cooperation instruments. Europe and France, as a major nuclear player, have an obligation to act in an exemplary fashion, to be demanding and to be active on subjects as sensitive as these. Their credibility depends on it. ■



INSTITUTIONAL CONTEXT AND REGULATORY FRAMEWORK

The European approach to nuclear safety: justification and limits

by **Claude Birraux**, member of Parliament for Haute-Savoie, Chairman of the French Parliamentary Office for the evaluation of scientific and technological options

Every year, pursuant to Article 7 of the TSN Act of 13 June 2006, the French Parliamentary Office for the evaluation of scientific and technological options (OPECST) receives a copy of the annual activity report from the French nuclear safety Authority (ASN). The Office evaluates this document at a public hearing open to the press, which is also an opportunity to make this report public, a mark of respect by ASN to Parliament in general and the OPECST in particular. Every year, the Chairman, André-Claude Lacoste describes ASN's involvement in multilateral and bilateral international cooperation in the field of nuclear safety.

The European aspect of this international cooperative effort is naturally a special one, owing to the close ties France has forged with its neighbours throughout its nuclear history. Pictures of the Solvay conferences, attended by the founding figures of nuclear science, show Marie Curie, Maurice de Broglie and Paul Langevin alongside Albert Einstein, Max Planck and Ernest Rutherford in 1911; Marie Curie and Paul Langevin were once again by the side of Albert Einstein and Max Planck, but also Niels Bohr, Erwin Schrödinger, Werner Heisenberg, Wolfgang Pauli, Paul Dirac and William Bragg in 1927. That year, the American Arthur Compton was the odd man out in this assembly of European scientific giants.

The European nuclear science community today remains a closely knit one, through numerous research staff exchanges between the major national science establishments: Commissariat à l'énergie atomique, Max Planck Institute, Centre d'étude de l'énergie nucléaire, Niels Bohr Institute, and so on. Furthermore, the CERN, whose official name is the "European Organization for Nuclear Research", became a hub for fundamental nuclear physics in Europe in the post-war period.

Yet this same level of intensity cannot be found in European cooperation on the subject of safety. The fact that there is constant progress cannot be disputed, but it is taking place at a far slower rate than the progress made in international cooperation around the world.

A very gradual process

There are several possible explanations for this.

The first is linked to the relatively recent nature of the practical structuring of nuclear safety monitoring, which only assumed its full importance with the expansion of the nuclear power generating industries in the 1960s. Nuclear safety, which aims to prevent harmful effects on individuals and the environment from the use of radioactive sources only has any meaning when applied to the operation of installations that are actually in service. Particular European awareness of nuclear safety was therefore only possible once the safety issue had achieved a



Participants in the 1st Solvay conference in 1911 in Brussels

sufficiently high profile on the national agenda to enable it to become a subject of international cooperation. Even in France, it was only the 13 June 2006 Act that finally provided a robust and uniform legal basis for the entire safety regulation system, which hitherto had relied on a scattered body of regulatory standards and a tenuous legislative framework.

This observation is not incompatible with the fact that the international standardization body for safety conditions, the ICRP (*International Commission on Radiological Protection*) was founded a long time ago, in 1928. However, from cooperation on standards to cooperation on regulation there was quite naturally the time lapse which normally occurs between release of fundamental scientific data and its practical medical or industrial implementation on a vast scale, a lapse which can frequently span several decades.

Another hypothesis that could explain the belated appearance of European cooperation in the field of safety, within the broader context of international cooperation, could be the fact that nuclear safety is basically more global than regional. In economic theory terms, it could be considered an international public good. At a time of information globalisation, any nuclear accident immediately strikes a blow at the credibility of the use of nuclear power worldwide, rather than simply in the part of the world where the accident actually happened. The accidents at Three Mile Island in 1979 and Chernobyl in 1986 immediately became global, rather than simply American or Soviet events.

This observation justifies the fact that the international cooperative effort on safety first of all looked to achieve progress at a global level, with the focus on European cooperation only coming at a later stage.

Finally, a last explanation for the belated arrival of European cooperation could be quite simply a lack of political



André-Claude Lacoste, Chairman of ASN, and Claude Birraux, Chairman of OPECST, at the presentation of the 2009 ASN report – April 2010

synchronisation between the countries concerned: the accidents at Three Mile Island and Chernobyl led to a moratorium on nuclear programs in Sweden, Spain, Austria and Italy. Germany opted to abandon nuclear power following the general election of 1998, at a time when safety cooperation was taking shape internationally. For its part, the United Kingdom ignored nuclear power as long as it was able to count on its hydrocarbon resources from the North Sea. The progress of European cooperation was for a long time hampered by a lack of partners.

The upsurge of interest in nuclear power, linked to the rising awareness of climate change issues and dwindling fossil fuel resources, has led to greater synchronisation in European approaches to nuclear safety.

Enhanced European cooperation is now well under way and the best symbol of this is the creation by the European Commission in 2007 of ENSREG (European Nuclear Safety Regulators' Group), whose initial work concerned the preparation of a safety directive, adopted on 25 June 2009.

Cooperation does not mean integration

In the field of European cooperation on safety, the process was therefore different from that in most other fields: whereas enhanced European cooperation was usually a means of opening up the member countries to a broader cooperative mechanism, as was typically the case with discussions on obstacles to international trade, the efforts towards European coordination in the field of nuclear safety in fact piggybacked an international cooperative movement that was already well under way.

Euratom was indeed created at the same time as the International Atomic Energy Agency (1957) and the OECD's Nuclear Energy Agency (1958), but it was dedicated to coordinating research, with no focus on safety, unlike the other two international structures. As for INRA (*International Nuclear Regulatory Association*), it preceded by about ten years

the appearance of ENSREG, which could be considered its European equivalent.

Since 10 December 2002, the European harmonization effort has benefited from the legal backing of a ruling of the Court of Justice of the European Communities, which recognised the principle of Community competence in the field of nuclear safety.

Although one should be pleased with the progress achieved in European cooperation on safety, this does not mean one should necessarily go as far as centralising the regulation of safety in a Community agency, relieving the national Authorities of their responsibility. A change such as this would have the drawback of weakening the oversight of safety in two ways: by geographically distancing the regulator from the regulated party and by giving the regulator a legal arsenal that is probably less powerful than that currently in force in the strictest countries, because this centralised arsenal would necessarily be the result of a European compromise.

Furthermore, the rigidity entailed by a compromise procedure would weaken the very substance of the safety approach, which is a living process benefiting from the constant contributions from research and permanently drawing strength from comparison between the analyses conducted by the regulatory Authority, its technical support organization (IRSN in France) and the licensees regulated.

Conversely, European discussions, even just for adaptations, are often lengthy operations and I remember a visit to the Czech Republic in 1992 during which my contacts explained to me that they themselves had to take the initiative of convening in Brussels the leading sponsors of the PHARE program in order to obtain answers to the questions raised by its implementation.

The harmonization effort must function as an additional guarantee of the effectiveness of national safety provisions and in no case lead to a decline in the situations gradually achieved in countries where the regulatory structures have become stronger with each passing decade.



An essential investment for ASN

There is no surprise that ASN plays an important role in international and European cooperation, because in the same way as any French independent administrative Authority in charge of a technical field [such as the ARCEP for electronic communications and postal activities] it has a duty to represent France in multilateral discussions. Article 9 of the TSN act states that ASN *"sends the Government its proposals to define the French position in international negotiations in the fields of its competence. It participates, on request by the Government, in the French representation in the bodies of international organizations and of the European Communities competent in these fields"*.

For ASN, over and above the constraints inherent in this task, particularly in terms of technical resources mobilised, active cooperation has two-fold benefits.

First of all, and this is only to be expected, multilateral but above all bilateral cooperative contacts, contribute to improving the performance of the Authority in its day to day activities, because they offer an opportunity to garner information about operating experience feedback and good practices.

In this respect, ASN has already developed staff exchange programs with the nuclear safety and radiation protection regulators of Belgium, China, Finland, Germany, Hungary, Japan, Spain, Switzerland, the United Kingdom and the United States. All continents are concerned by these exchanges, but for reasons of proximity, the primary focus is logically Europe. These can take the form of joint inspections, short missions targeted on a specific topic, or long secondments to a foreign safety regulator. These exchanges forge human ties which subsequently facilitate institutional cooperation.

But the other benefit to be gained from greater international and European cooperation is to consolidate the legitimacy of the national authority. The role of a safety regulator is to impose binding measures which are rarely easy to implement by those concerned, either because they disrupt their organization or because they entail extra costs. The entire weight of a robust and legitimate state is required to make these measures truly binding; but technical controversy often remains a possibility when safety rules are issued to deal with events which by definition are of extremely low probability, because the entire safety approach is built around preventing the worst from happening.

This is why incorporating the national safety regulator into a network of international and European counterparts confers greater credibility on the technical quality of its decisions. Close cooperation with other safety regulators, in particular by means of staff exchanges, in fact acts as an implicit guarantee of increased harmonization of the safety criteria adopted, such that in similar circumstances, identical decisions would probably have been made in the other countries agreeing to take part in this international cooperation.

The new initiative whereby several national safety regulators concerned by the same subject publicly issue a joint recommendation, such as that issued by the French, Finnish and British Authorities concerning the EPR instrumentation and control system in November 2009, is a direct illustration of the potential extra impact of this joint approach.

Legitimacy: an essential factor in authority

Consolidation of legitimacy is of fundamental importance for an independent administrative authority and therefore the emphasis placed on international and European cooperation has the same symbolic significance for the nuclear safety regulator as being placed under the direct control of Parliament, via the Parliamentary office for the evaluation of scientific and technological options. On the one hand, there is an opportunity to draw on the expertise of an international professional community and on the other to build on the trust granted to duly elected representatives.

This is why the Chairman André-Claude Lacoste's statements concerning international and European cooperation at the annual presentation of the ASN report to OPECST, is such an important moment and one that it so warmly appreciated by the representatives of the two houses of Parliament in OPECST: it reflects the vigilant attention the safety regulator rightly pays to the institutional relations that underpin its position: sharing of experience with its counterparts, but also a relationship with Parliament based on respect and trust. ■

INSTITUTIONAL CONTEXT AND REGULATORY FRAMEWORK

A licensee's viewpoint of Europe and nuclear safety

by **Bernard Fourest**, Director of international relations with safety regulators – Nuclear Engineering Division (EDF)

In the 1950s, one could have thought that the first civil applications of atomic energy would be international. The “Atom for peace” speech by President Eisenhower, which opened up American nuclear technology to the free world, the creation of the International Atomic Energy Agency and, in Europe, the signing of the Euratom Treaty, which along with the coal and steel treaty was one of the foundation stones for the construction of Europe, should have enabled the development of widespread international cooperation. It didn't happen and for the next thirty years nuclear power was a purely national affair with a strong nationalistic flavour. The countries which borrowed water reactor technology from the United States adapted it to their national situations and even if the principles and basic concepts of nuclear safety were common to all the countries concerned, they rapidly began to implement them differently.

The late 1980s revealed the limits of these purely national strategies: the Chernobyl accident, which clearly showed that no country could remain indifferent to what was happening beyond its borders, the cost of construction and of installation licensing processes that were everywhere different, allied with a significant fall in the price of oil, thereby affecting the competitiveness of nuclear energy, led to the closure of nuclear programs in a large number of countries, in any case in the United States and Europe. Practically the only exception was France, where a strategy of standardisation in the design, construction and operation of a single model developed by a single manufacturer, Framatome, in a series of incremental plant designs, an overall architect and single operator, EDF, ensured the success of the French nuclear programme, in terms of both safety and economic competitiveness.

The lessons learned from the first phase of nuclear development

Lessons were rapidly learned, first of all by those closest to events, in other words a number of European industrial firms: Framatome forged an alliance with Siemens and they were soon joined by the German electricity utilities and EDF for the development of a European reactor, the EPR, which was to benefit from the lessons learned from the first reactor generations, in particular with regard to safety. This first initiative was followed by the creation of the EUR (European Utility Requirements) organization, bringing together the leading European electricity utilities, including EDF, who together drafted joint specifications for the new light water reactors to be built in Europe. These specifications comprise many safety requirements concerning the strictly nuclear part of the installation, but also its energy production part, connection to the grid and availability and operability. These specifications are regularly updated and today constitute the most complete basis for the harmonization of safety in Europe and the standardisation of future European reactors. They have already been used and are currently being applied by several utilities to underpin their calls for bids. The main reactor



“Atoms for peace” speech by United States President Dwight Eisenhower to the United Nations General Assembly – December 1953

manufacturers around the world, interested in the European market, are seeking in increasing numbers to have the models they propose analysed to ensure conformity with the EUR.

Standardisation means greater safety

Standardisation of reactor models means greater safety, drawing on design and operating experience throughout the life of an installation: design, construction, commissioning tests, operation, decommissioning. The databases rapidly built up from a large number of identical reactors constitute a firm foundation for improved safety.

The design of new models can incorporate the latest technologies, benefitting from experience from operation of the reactors in service. During construction, replication of the same model enables quality to be improved, by using proven methods and techniques. During the operating phase, operating experience feedback allows continuous safety improvements, which can be deployed uniformly and therefore effectively on several installations.

There is of course the risk of a generic defect affecting the entire fleet of standardised reactors, but the probability of early detection of this defect is far greater if several reactors of the same model are built and operated at the same time. Resolution of the problem detected can be organized and implemented far more quickly and effectively.

Standardisation at an international level is also of interest to the safety regulators. It enables them to share their views of



a given problem, to compare their approaches, to go further in their analyses and in the end, to achieve a higher level of safety.

Although within a given country the decision to opt for standardisation lies solely with the industrial firms involved, at an international level it cannot happen without harmonized safety rules.

Globalisation of the nuclear industry demands harmonization of safety

Today's nuclear market is a global one. By comparison with previous decades, only a small number of manufacturers are left, and their legitimate aim is no longer to serve a national or regional market, but a global one. Deploying the same model in different countries is a pre-condition for the competitiveness of nuclear power and its ability to meet the challenges of providing mankind with energy, while preserving the environment.

Furthermore electricity utilities are no longer national entities working within well-protected borders and they now operate internationally. Deregulation of the electricity markets also entails common rules for nuclear safety, to ensure a level playing field for all.

International harmonization of safety rules is therefore a necessary part of this move towards globalisation. A situation in which nuclear safety becomes an issue in international competition, whether on the part of the manufacturers or the operators, would be totally unacceptable, both for industry and for politicians and public opinion. The prospect of a "low cost because low safety" nuclear industry is inconceivable.

Construction of a European safety area: first steps in the right direction

Several articles in this issue of *Contrôle* magazine describe the progress made in the last ten years towards the construction of a European nuclear safety and radiation protection area: the work done by WENRA to establish Reference Levels for reactors in operation and waste and spent fuel storage facilities, more recent safety target proposals for future reactors in Europe; and the initiatives by the European Commission to create exchange forums on the one hand for the safety regulators (ENSREG) and on the other for all stakeholders (ENEF). The first tangible result of these initiatives was the adoption of a European directive on nuclear safety. How do the European nuclear operators, and in particular EDF, the largest, see these initial results?

Like most of the other European nuclear licensees, EDF warmly welcomed these initiatives. EDF played a very active role in the creation and subsequent operation of specific industrial bodies to respond to these initiatives, whether the ENISS (European Nuclear Installation Safety Standards) or ENEF (European Nuclear Energy Forum) working parties. One must first of all underline the highly positive and constructive nature of the dialogue which has ensued between industry and European safety regulators. This type of dialogue between international organizations should be able to act as a model for international exchanges of the same type, on a broader scale. With regard to its technical content, WENRA's final version of the Reference Levels for the reactors in operation, which takes account of some of the remarks submitted by industry, can be considered a satisfactory balance between the viewpoints of the 17 regulatory Authorities making up WENRA and the European nuclear operators. The public commitment by the safety

regulators to bring their national regulations into line with the WENRA reference levels before the end of 2010 should lead to initial harmonization of safety rules in Europe for the installations in operation, provided that transposition into the national requirements does not exceed these reference levels, unless specifically justified.

Furthermore, a European nuclear safety directive has come into being. EDF was also heavily involved in the debate surrounding its preparation. In political terms, this is a major step forward, clearly showing public opinion - which is still divided in its view of the nuclear issue - that Europe is dealing with matters essential to their safety. Industrialists insisted that this directive leave technical considerations to one side and focus on incorporating IAEA's fundamental safety principles, stating the operators' responsibility for safety and the need for independent safety regulators. The Commission's plans for a nuclear waste directive are also welcomed. In the eyes of public opinion, the final fate of this waste is a major issue for the nuclear industry. It is essential that for Member States which have opted for nuclear power, Europe require them to ignore short-term considerations and undertake a rigorous process to define a long-term solution for this waste, as has been undertaken in France, Sweden and Finland.

The WENRA website recently published draft safety objectives for the new reactors. EDF fully supports the aims of this undertaking, which could be a key factor in harmonizing safety rules in Europe and thus allow the construction of standardised reactors in different European countries. However, owing to a lack of agreement among European safety regulators, these objectives remain essentially qualitative and are subject to a wide variety of interpretations. Although the principle of continuous safety improvement is unanimously accepted in Europe, greater recognition must be given to the fact that safety depends as much on the quality of construction, operation and the steps taken to enhance the safety culture and personnel training, as on design measures alone. The aim of improving safety as of the design of the new reactors is a legitimate one and it is clear that progress is possible and indeed under way. However, once a high level of safety has been achieved, one cannot search indefinitely for improvements without weighing the safety gains still possible against the costs involved. The fear is that by constantly demanding even greater technical safety, regardless of the high level already reached or of the economic consequences, Europe could isolate itself and create an obstacle to greater internationalisation of safety rules, ultimately opening the door to a two-speed safety process in which there would be countries wealthy enough to acquire reactors complying with the most demanding safety standards, and the rest of the world.

WENRA should rely more on the work done by the operators within EUR which, as mentioned early, is the most complete basis yet for safety harmonization in Europe.

Furthermore, there is also a risk that this work by WENRA on safety objectives for the new reactors to be built in Europe might just be achieved too late. Within the next few years, several European operators are getting ready to issue tenders. As they currently stand, these safety objectives are too vague to enable either the manufacturers wishing to propose their models, or the future licensees who will be operating them, to make a correctly informed choice with sufficient guarantees that these choices will then be authorised by their safety regulators.

What outlook for the future?

The harmonization of safety in Europe has taken its first steps, but how can we go further?

It is highly probable that in the end, safety will remain a national responsibility, corresponding to the industrial reality: safety is mainly an issue during construction and operation and the regulation of safety must remain a local activity as close as possible to the actual grassroots level, in order to understand the local context and culture of the operators as clearly as possible and to allow a quick and effective response whenever necessary. However, the same does not apply to certification of the design of reactor models. One cannot but wonder whether the ongoing and virtually simultaneous analysis of a particular European reactor model (EPR) by three different safety Authorities, each with its own history and its own national particularities, inevitably leading to modifications to the original model for safety gains that it will be hard to justify and quantify, is really the best way of guaranteeing safety, of effectively using the resources of the industrial contractors and safety regulators concerned, and of winning public confidence?

The aeronautical industry, admittedly after a lengthy and difficult process, managed to overcome this obstacle with the Chicago convention, which agreed on mutual recognition of the certification of aircraft models. Each national Authority in the end retains responsibility for certifying the airworthiness of each aircraft registered on its national territory. In Europe, this certification is the role of a European body comprising the national civil aviation Authorities.

This example is one that is recommended by the World Nuclear Association's CORDEL group in its recent report on the subject, a report which received support from the highest levels of many industrial contractors and operators, including EDF. So is this goal really that far away? Do we not already have enough safety analysis expertise to create the nucleus of an international reactor model safety assessment centre? Will the European Commission one day broker inter-governmental agreements recognising the certifications issued by such a centre? What is clear is that the energy and environmental protection objectives Europe is setting for itself do not allow the luxury of a 30-year wait for progress. ■



INSTITUTIONAL CONTEXT AND REGULATORY FRAMEWORK

ENSREG: how European Nuclear Regulators are striving for continuous improvements

by Andrej Stritar, Chairman of ENSREG¹, Director of Slovenian Nuclear Safety Administration

I can start by going half a century in the past, when Euratom Treaty was passed. It represents one of the oldest European binding agreements. However, at the time of the creation of Euratom, the nuclear safety was not very high on the agenda, so it is only marginally addressed by the treaty.

Decades have passed, civilian nuclear programmes were developing in a number of European countries and there was a period of a rapid increase of the number of operating nuclear power plants. But then also some accidents have happened and nuclear power gradually switched from the positive to the negative attitude in the minds of ordinary people. Nuclear safety moved very high on the list of society interest and concerns. Nuclear community has been working on common standards and harmonization of nuclear safety in different international organizations. The most important is the International Atomic Energy Agency (IAEA), whose standards became the major reference for all countries. Another important step towards harmonization of requirements was the adoption of the Nuclear Safety Convention and later the Joint Convention on Radioactive Waste Management and Spent Fuel Management. All Member States of EU with nuclear power plants are signatories to these two Conventions and are therefore obliged to follow the basic safety principles set there.

Legally binding frameworks, necessary for assurance of nuclear safety, were built in each country separately. Although all were based on internationally adopted standards and Conventions, they developed into different directions. In Europe we have countries with big civilian nuclear programmes, countries with programmes of the medium size, small nuclear countries, two nuclear weapon states, countries using nuclear technologies of former Eastern Block, one country with cancelled nuclear programme and one country with Canadian heavy water technology. Adding also different power plant concepts (PWR², BWR³, PHWR⁴, AGR⁵, GCR⁶, WWER⁷, RBMK⁸ and even fast reactors), one could understand easier, why legal frameworks for nuclear safety have developed into different directions. It would be very hard and unfair to judge which national legal system is better or worse. They are simply different, they are all based on the same internationally recognised basic safety principles and standards, and we could

say that each of them is properly providing framework for assuring safe operation of nuclear facilities.

Desire for common legal framework

Towards the end of the nineties ideas were emerging asking for the establishment of some legally binding common EU instruments for assuring nuclear safety. The European Commission was the main driving force. There were different explanations for those desires ranging from plain statement "Since there are directives for so minor things like the shape of cucumbers or size of condoms, why don't we have the common directive for such an important issue like nuclear safety?" to much more serious statements about the need to assure public with harmonized and good approach in the whole European union.

In parallel with purely political desires to harmonise nuclear safety in EU, European nuclear regulatory bodies have in 1999 created a working network named WENRA. Through a voluntary process they have to a large extent harmonized nuclear safety requirements. For the operating reactors they were summarized in so called *Reference Levels*, which each country promised to introduce in its own legal system by the end of 2010.

In 2002 the Commission launched two draft directives, one about nuclear safety another about radioactive waste management. At that time I was fresh as the nuclear regulator and also as public administrator. I started as director of Slovenian Nuclear Safety Administration in the autumn of 2002. In addition my country, Slovenia, was not yet member of the EU, but was included in discussions about those directives as it was clear that once we become full members (which happened on 1st May 2004), they would become mandatory also for us. So, the developments around those proposals were one of my first practical exercises in understanding how EU is functioning.

Very soon after launch of the two proposals EU Member States divided into two groups. One group was clearly supporting the Commission and directives, another group was strongly against. From that period is the anecdote about creation of Slovenian position. One day the instruction came from Brussels through our Government that Slovenia has to either support or be against those drafts, in other words to join one or another

1. ENSREG is an acronym of European Nuclear Safety Regulators Group. It is an advisory body to the institutions of European Union (UE) in the areas of nuclear safety and radioactive waste and spent nuclear fuel management. EU Member States have mostly nominated top nuclear regulators into that High Level Group. In addition to 27 country representatives, the European Commission is also a full member. Detailed and formal description of ENSREG activities could be found in the first *Report of the European Nuclear Safety Regulators' Group, July 2009* [available from http://ec.europa.eu/energy/nuclear/ensreg/doc/2009_ensreg_report.pdf]. In this paper I am trying to more personally describe how we have created it and how it is working.

2. PWR – pressurised water reactor
3. BWR – boiling water reactor
4. PHWR – pressurised heavy water reactor
5. RBMK – reactor bolshoy moshchnosti kanalniy
6. AGR – advanced gas cooled reactor
7. GCR – gas cooled reactor
8. WWER – water water energy reactor

group of countries. I have gathered in my office senior staff members of our administration and we were discussing quite some time all pros and cons. There was nothing in those two drafts that would, if becoming mandatory, cause any substantial change in our legal framework and/or our daily practices. We have recognised that countries are divided more because of some political reasons than because some technical issues. Finally we decided to be against directives primarily because we did not see real benefit in getting another layer of legislation above us. In next hour or two one of our staff members prepared wider written explanation of our decision. Once it was ready, I made the final call to the minister for environment, to whom I reported. After I explained to him our reasoning, stressing that either decision would not make big problems for us, but that we have opted to be against, he replied: "Oh, Mr. Stritar, why don't we go along with the Commission's proposal? Let them not be angry with us! We may need their support some day." Since I did not have arguments against that political decision, we have just slightly reworded the explanation and changed our position. From then on Slovenia was supporting both draft directives.

However, that attempt of the Commission failed. The majority of countries were against and the formal adoption procedure was eventually stopped after almost two years. As I see it now the main reason was the fear of member countries that the Commission was getting to much power and gradually taking over the legal framework and even inspection system to the EU level. Also the way how the Commission launched the proposal contributed to its failure. There were not enough preparations and discussions before the announcement. The way how Member States were almost being forced to adopt those drafts was counterproductive.

After failure of that attempt ideas for harmonization of nuclear safety did not disappear. It was a wise decision to make a break of a year or two and continue after some rethinking. The Working Party on Nuclear Safety was established by the Council of the European Union in 2004 and asked to prepare proposals how to proceed. The group was lead by Mr. Erik Jende from Sweden. In their final report in December 2006 they have summarized the situation in Europe, proposed number of actions and as a general recommendation advised to establish "a standing EU working infrastructure, such as a working group of experts on nuclear safety and regulation..." The Council of EU and the European Commission followed that advice and have established on 17th July 2007 the so called High Level Group on nuclear safety and radioactive waste management. The institutional framework of so called "High Level Group" already existed. Such groups were advisory bodies to the institutions of EU without power to make formal decisions, but producing highly respectful advices and opinions to European institutions.

First year of the High Level Group on nuclear safety and radwaste management

Between July and October 2007 Member States have nominated one member and one deputy member per country into the newly established group, at that time referred to by High Level group (HLG). Most members were and still are heads of nuclear regulatory bodies. We met for the first time on 12nd October 2007 in a big, impressive meeting room in the Berlaymont building in Brussels. The Commissioner for Energy Mr. Piebalgs welcomed us personally. He pointed out that nuclear safety should not be seen any longer from solely

national perspectives. The Commission, but also the European Parliament, considers that there is a need to have binding nuclear safety legislation within EU. But, he also said, that the HLG should be free to decide about the priorities of its work. At that point and also never in the next year were we explicitly asked to prepare the draft of any kind of nuclear safety directive. But somehow most of us felt that this was expected from us.

That first meeting was extremely difficult. In 2007 I already understood much better the working of European Union, but I was once again shocked with the fact, that the main misunderstanding in the Union in the nuclear safety field was between Member States and the European Commission. Most of the time in the morning was devoted to the discussion about the relationship between the Commission and the HLG i.e. Member States. The HLG was indeed established by a Commission's Decision, but based on previous proposal and invitation by the Council of EU. We were spending time elaborating why we should be reporting to the Council and not to the Commission, while the Commission was claiming the opposite priority. The discussion of the type "What was first, chicken or egg?" seemed to me more or less a loss of time. We were not able to elect the chairman of the group in the morning, as nobody prepared the scene before the meeting, there were no candidates proposed and there was even no agreement about the way how to elect him or her. So the morning session was chaired by the Commission, which made majority of members uncomfortable.

Soon before the lunch break I asked for the floor and appealed to everybody to stop loosing time with fruitless discussions and start talking about some concrete and more important issues. I also said that we should take the

chairmanship of the meeting from the Commission into our hands and by that become really an independent advisory body. During the lunch break, which had to be two hours long because of interpreters, Mr. Jende from Sweden asked me if I would agree to take over the interim chairmanship of that meeting. I was really surprised, as I did not expect anything like that. But I was also honoured and agreed. Mr. Jende probably had enough consultations during the lunch break that his formal proposal after the lunch was not a surprise to anybody and I was indeed elected by the consensus as an interim chairman until the next meeting.

Running the afternoon of that first meeting was not much easier than the morning. However, at the end we had managed to agree on the principle of reaching conclusions under consensus. It was decided to prepare Rules of Procedure for the next meeting. Most importantly we have initiated discussions about the priorities of our activities and already shaped three main areas: 1. nuclear safety, 2. radwaste management and 3. transparency.

The months between first and second meeting in January 2008 were the busiest for me as a chairman. Among other things I had to organize the preparation of Rules of Procedure from scratch and to coordinate the elaboration of a detailed list of work priorities to be adopted at the next meeting. The second meeting was again very dynamic, but we had managed to adopt Rules of Procedure, I was elected as a Chairman for two years, Mr. Mike Weightman, UK, and Ms. Ann McGarry, IR, were elected as Vicechairpersons and we agreed about establishment of three working groups and their Chairs, dealing with:





ENSREG website, www.ensreg.eu

1. Improvements of nuclear safety arrangement (chair: Mr. Weightman, UK)
2. Improvements in the decommissioning, radioactive waste management and spent fuel arrangements (chair: Mr. Vincent, FR).
3. Improvements in transparency arrangements (chair: Ms. McGarry, IR).

Somehow we were beginning to function as a coherent group, looking for synergies. The latent conflict between the Commission and Member States was not in forefront anymore, for which I must give the considerable credit to the representatives of the Commission. Although the Commission was a full member of HLG/ENSREG, Mr. Ristori, who was its representative, and Mr. Garribba, who acted as the secretary of the group, let other members work without any undue pressure.

Later in the year we defined a detailed working programme for each of the working groups. In the area of nuclear safety we decided to introduce a structured approach for systematic use of lessons learned from the Convention on Nuclear Safety reviewing process and to encourage each Member States to intensify the use of IAEA reviewing processes. In the area of spent fuel and radioactive waste management we agreed to propose common principles and to strengthen cooperation by using the review process for the Joint Convention on Radioactive Waste and Spent Fuel management. To improve the transparency of nuclear safety issues in EU, the website www.ensreg.eu was created, where all relevant information is available to general public. During the year we also invented our current name ENSREG.

To have or not to have a Nuclear Safety directive

As I have already written, members of ENSREG were never directly asked to prepare the text for the potential Nuclear Safety directive, but during 2008 we all somehow felt that we should say something about that. So the main discussions at our meetings in 2008 were about pros and cons of such legally binding document. We had members, that were strongly against the directive and there were others that supported it. The opponents didn't want to give too much power to the Commission and would like to remain more or less free in their

countries in setting standards for nuclear safety, while supporters claimed that common safety requirements do make sense and that they would protect from potential deterioration in individual countries.

It was very hard for me as a chairman to run meetings when such strong division of opinions was present and we had to work with the consensus. But we somehow managed to proceed by long and patient formal and informal consultations. We have produced a document with an elaborated analysis of pros and cons, however, also it did not give an obvious clue that would convince either side and enable us to reach the consensus.

In the mean time the Commission made a political decision to go forward with the proposal for the Nuclear Safety directive. Their representatives have informed me about that decision during the IAEA General Conference in Vienna in September 2008. Somehow I felt that it was a crucial point for ENSREG. Our next meeting was scheduled for 15th October and the directive was not on the Agenda. We were still discussing about pros and cons. Before the meeting I have alerted our Vice-Chairs and Chairs of our working groups. My feeling was that at that point we had to follow the political will, or we would become a marginal group and the decisions about nuclear safety in EU would be made without us, national nuclear regulators.

The meeting of 15th October 2008 was another very hard meeting. Commissioner Piebalgs came once again to address us. He clearly said that the Commission wanted to have that directive before the end of its mandate that is by the end of the next year. He said that they could not wait for our pro and cons report anymore. We were told that the draft text was already prepared, but that they nevertheless want to have some input from us before they release it. We were given one week time to send individual comments before that document is released to inter-institutional procedure in the Commission.

Members of ENSREG were very upset with such an approach! It was putting under question our existence and time spent for all the consultations we had in the past year. During the meeting we were nevertheless able to agree on 10 basic principles, that the directive should be based upon and asked the Commission to take them into account in the directive. We could not, however, discuss the text of the draft, which was put on our tables during the meeting. We also clearly said that in one week time the Commission could not get any opinion from us as a group.

Our reaction at the meeting and also our individual comments after the meeting made Commission rethink their moves. Few days later I was informed that the Commission is reconsidering the text. They were working on the inclusion of our 10 principles into it. They asked us to meet once again three weeks later and discuss the text they submitted to us before that meeting. We agreed and ENSREG met on 7th November 2008 at the extremely successful meeting! All the members were very constructive, we had an efficient general debate and we were able to go through the text article by article. The Commission listened to us and later followed all our comments. The draft of the Nuclear Safety directive was launched about a month later. It was constructively discussed under the French and Czech Presidencies in the Atomic Question Group and finally passed at the end of June 2009.

What has ENSREG achieved, where is it now and where does it go?

After a dynamic first year and tedious experience of passing the Nuclear Safety Directive, my feeling is that ENSREG has now

positioned itself fruitfully into the complex EU institutional space. People, responsible for nuclear safety regulation in EU, now know each other very well and are learning from each other with the desire for continuous improvement. As in any human endeavour, the communication between people is crucial for the success. It is very important that we meet several times per year and have opportunity to feel each other and thereby better understand other's opinions. Very important is also that European Commission is now considering ENSREG as a respectful partner, whose opinion is crucial before taking any decision. For example, the process of creation of the directive, regulating radioactive waste and spent fuel management, is now proceeding completely differently, to my view much more efficient. The commission formally asked ENSREG to advice about the content of such a directive, ENSREG has provided the proposal of the text of the draft and the Commission is now expected to start the formal legal process. Since the Commission's draft will be based on the proposal from ENSREG, i.e. national nuclear regulators, one can not expect any difficulties in passing it through Council of EU. I am confident that we can have a new directive in several months.

I believe that in next years ENSREG will remain a useful advisory body to European institutions. Although there are desires to completely harmonise nuclear regulatory systems in EU countries by making them identical or even to create a big, supra-national nuclear regulator, I think that something like that can not be achieved in a foreseeable future. Europe is too complex, historical and cultural differences are too big. Maybe we will get some more EU common legal requirements, but I doubt that they will get much deeper into technical details. I also think that the final responsibility for nuclear safety must remain in the hands of people living near to the nuclear installations. The operators must remain prime responsible. But also their regulators must live close, that is the licensing, review and assessment, inspection and enforcement should remain national responsibility. ■



INSTITUTIONAL CONTEXT AND REGULATORY FRAMEWORK

Action by the European Commission to promote nuclear safety outside the territory of the European Union

by Jean-Paul Joulia, Head of Nuclear Safety Unit, AIDCO Directorate General, European Commission

The TACIS programme to improve nuclear safety in Central and Eastern Europe and the former USSR has now entered its final phase. A new programme – the Instrument for Nuclear Safety Cooperation (INSC) – has been launched and its aim is to promote nuclear safety in all third-party countries. Support for improvement of the regulatory framework and the effectiveness of the bodies in charge of nuclear safety is a key element. Within the European Commission, the “Europe, Southern Mediterranean, Middle East and Neighbourhood policy” Directorate, belonging to the AIDCO General Directorate, is tasked with implementation.

Improving Nuclear Safety in the former USSR was a major objective of the European Commission

Before 26 April 1986 and the accident in the Chernobyl nuclear power plant in Ukraine, the Soviet nuclear industry was not a source of concern for the Western world. Only the military nuclear threat was a real preoccupation for our countries. Very little information was actually available regarding the situation of the nuclear power plants beyond the iron curtain. Reactor design, construction reliability, quality of operation and maintenance, the existence of a safety regulator capable of guaranteeing compliance with safety rules were all to a large extent unknowns. On 26 April 1986, the Chernobyl accident turned the glare of the media spotlight on nuclear safety in that part of the world. The nuclear industry is only slowly recovering from the damage to its image among the general public. Chernobyl made all our countries aware of the fact that nuclear safety does not stop at the borders of the State in which the accident occurred. With the fall of the Soviet empire, the West (G7, OECD, European Community, IAEA) launched action programmes to assess needs, offer emergency intervention and remedy the major shortcomings. The European Union designed and implemented the nuclear safety parts of the assistance programmes, which carried funding worth several billion euros. It mobilised its industry, its nuclear safety regulators and their specialist technical support organizations (TSO) in assisting the accession candidate countries through the PHARE Programme (*Poland and Hungary Assistance for Reconstruction of Economy*) and the countries of the Commonwealth of Independent States (CIS) through the TACIS Programme (*Technical Assistance to the Commonwealth of Independent States*).

In recent years, several States have joined the Union. The PHARE and TACIS programmes came to an end in 2006. A new programme – the Instrument for Nuclear Safety Cooperation (INSC) – covering the period 2007-2013 has been launched. It is thanks to the experience acquired with TACIS that the Commission and its partners are able to operate outside the geographical scope of the community action carried out so far.

The TACIS programme, a major financial effort

The TACIS programme was launched by the European Community in 1991. Its aim was to support structural reform in the countries of the CIS (justice reforms, modernisation of the administrations, assistance for security and customs services, human rights, etc.), including improving nuclear safety.

From 1991 to 2006, about 1,300 million euros were allocated to projects concerning nuclear safety, for interventions in a variety of sectors:

- support for nuclear operators;
- support for regulators and their TSO (technical support organizations);
- waste and decommissioning;
- emergency plans;
- accounting of materials and combating illicit trafficking.

Some of these funds (€ 226 million) has financed projects carried out at Chernobyl through the fund managed by the European Bank for Reconstruction and Development (EBRD). The rest of the budgets was distributed among the various intervention sectors, as illustrated in the following diagram.

Two countries benefited from most of the aid: the Russian Federation (about € 400 million) and Ukraine (€ 500 million, including Chernobyl) with the other beneficiary countries sharing smaller budgets.

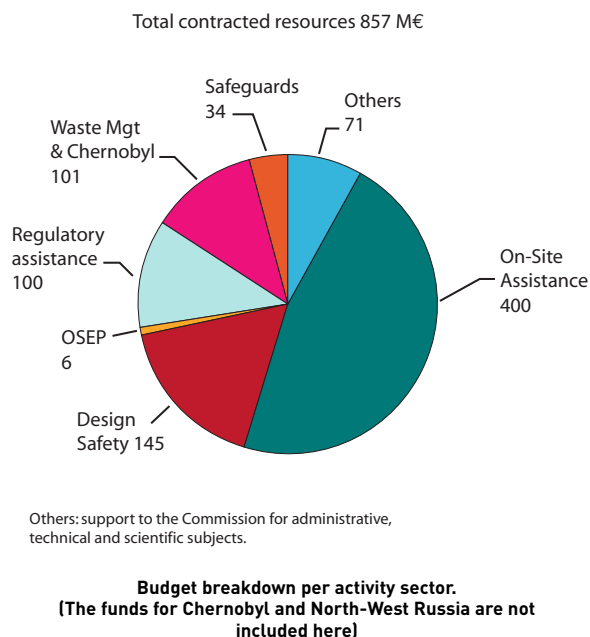
This effort by the European Union, implemented by the European Commission, was based on international work, especially IAEA studies, conducted towards the mid-1990s¹ to assess the condition of the Soviet designed nuclear reactors and the assistance needs.

So far, significant results

Evaluating the impact of such a vast programme, run over a period of nearly 15 years, is a difficult task. The nuclear safety component of TACIS was regularly assessed by the Court of Auditors of the European Union in 1997, 2000 and 2005. These assessments highlighted teething troubles and a management system that was sometimes ill-adapted to the circumstances and the degree of urgency. The 2005 report also showed that the Commission had managed to transform these difficult beginnings into an undeniable success.

The Commission also mandated several independent experts to appraise the results of TACIS. A compilation of these

1. Final Report of the Programme on the Safety of WWER and RBMK Nuclear Power Plants – IAEA February 1999, IAEA-EBP – WWER – 15.



sectorial assessments was submitted to the Commission in 2010 and will soon be made available to the public². They show that the TACIS programme has had a major impact on nuclear safety in the beneficiary countries, in particular the operators and regulators.

The Commission, together with IAEA, also financed an in-depth study on the safety of nuclear power plants in Ukraine³, finalised in 2009. This study concludes that the nuclear power plants and the Ukrainian regulator are in compliance with most of IAEA's safety requirements with regard to design, operation, waste management, decommissioning of installations and the inspection and regulatory capacity of the regulator.

The TACIS programme played a significant role in this safety improvement of the Ukrainian power plants. Comparable results would probably be obtained with the power plants in the Russian Federation. Unfortunately, it has not yet been possible to carry out a similar study.

As for Chernobyl, and apart from the preliminary design studies for projects aimed at remedying the consequences of the accident, the Commission supported specific projects for the future decommissioning of units 1 to 3, shut down in 2000. This is the case with the solid waste processing project, for which the installation was inaugurated in 2009, and the disposal site within the exclusion zone.

The European Commission is Ukraine's major partner in its efforts to remediate the consequences of the Chernobyl accident. More than 400 million euros have been allocated to this, to which must be added support for research projects under the Union's successive framework R&D programmes. This includes the contributions to the "Chernobyl Shelter Fund" and the "Nuclear Safety Account", for the construction of a new containment above the damaged unit 4 and the construction of liquid radioactive waste processing and spent fuel interim storage installations.

2. The Tacis nuclear safety review report; P. Haig, N. Kelly, MJF Leroy, B. Roche and J. Vrijen; Itatrend February 2010; contract 2009/172-067.

3. EC-IAEA-Ukraine Joint Project: Safety evaluation of Ukrainian Nuclear Power Plants; Final Project Report, IAEA-EC Agreement No: 2007/145268; Department of Nuclear Safety and Security, IAEA, Vienna, Austria February 2010.

Considerable financial resources (€ 77 million) have been allocated to projects directly managed by the Commission, in particular the construction of solid waste disposal and treatment installations, with a view to decommissioning of units 1 to 3.

In the field of nuclear waste, which has taken on major importance in recent years, the Commission's actions have been particularly significant. The TACIS Programme is a major contributor to the nuclear aspect of the Northern Dimension Environmental Partnership dealing with North-West Russia, the aim of which is to deal with problems posed by the decommissioning of the Soviet North-West nuclear fleet. Projects have also allowed preliminary studies to be carried out to resolve the problem posed by the "Lepse", a nuclear-powered ice-breaker on which nuclear waste is stored in Murmansk. Finally, the programme supported the development of a strategy for nuclear waste processing in Russia with an essential contribution from the leading specialist entities in the European Union.

Development of a regulatory framework for safety and strengthening the safety regulators

From the outset, the European Commission targeted some of its nuclear safety improvement programmes on the safety regulators of the beneficiary countries and their technical support organizations (TSO). This approach, which complemented the action taken on nuclear installations, proved to be crucial: the safety of nuclear installations cannot be guaranteed in the long-term without rigorous regulation of these installations by a robust and competent safety regulator.

On the one hand, the European Commission focused on helping the beneficiary countries to consolidate or rebuild a regulatory framework for nuclear safety. On the other, the programme offered support for industrial projects to improve installations safety, with parallel assistance to the safety regulator and its TSO with regard to the nuclear safety aspects of its licensing of these projects.

The safety regulators and their technical support organizations (TSO) in the beneficiary countries were reinforced by training, management improvement, regulatory text development and licensing actions. With regard to this latter aspect, cooperation focused on the regulatory aspects, but even more on implementation of a culture of dialogue between the safety regulator and the licensee, a working method hitherto little used in the former Soviet republics.

The European Commission calls on the safety regulators in the Member States, including the ASN, and their TSOs to provide their counterparts in the beneficiary country with their knowledge of the regulatory framework in their country of origin as well as their own experience of its development. This participation by the safety regulators of the Union makes a significant contribution to the success of the projects, because the beneficiary cooperates with a similar organization, sometimes faced with comparable difficulties.

To define and implement the activities related to this policy, the services of the European Union naturally enough relied on the safety regulators of the Member States, including ASN, themselves backed up in this work by their TSOs. In order to facilitate coordination between the various national safety regulators, the Commission set up a study and advisory group, comprising representatives of the national safety regulators, the RAMG (*Regulatory Assistance Management Group*), which



meets twice a year to provide the Commission with its opinion on projects concerning the regulation sector, and their impact, and to identify the requirements specific to a beneficiary country, in order to orient the work and coordinate it with the other international organizations.

The INSC programme, expanded cooperation

The new INSC programme enjoys broader geographical coverage in order to address the renewed interest in the nuclear industry in the mid-2000s, while continuing its action in favour of the countries of the former USSR. Owing to energy policy demands, many countries have decided to opt for electricity production from nuclear power. In close cooperation with the Member States of the European Union and with IAEA, the European Commission supported projects with a number of countries able to meet the programme criteria, in other words, those who have or are in the process of signing IAEA's major nuclear safety treaties, in particular the Convention on Nuclear Safety.

This geographical extension of the programme, in particular for the newcomers to nuclear power, focuses mainly on cooperation with the safety regulators, assistance to the regulators themselves and their TSOs. In certain countries with which cooperation has been initiated, work had to be started on setting up a safety regulator.

The enclosed map shows the geographical distribution of countries in which discussions are underway or programmes already scheduled.

To date, however, support for non-CIS countries, although regularly scaled up, still accounts for only a minority share of the funds allocated. Collaboration between the services of the Commission and IAEA are developing. The Commission supports the Agency with general projects to promote nuclear safety culture.

The European Commission's mandate is to offer support to countries turning to the production of electricity from nuclear power. The project consists first of all in helping the beneficiary

to define and prioritise the action required in terms of regulation, organization, human resources, training, etc.

The fundamental role of the safety regulator is to ensure the safety of nuclear installations, and to do so it must define a series of requirements with which the licensee is required to comply. This essential role of the safety regulator was perfectly integrated into the regulations of the INSC programme, which clearly states that promoting a true safety culture must involve continuous support for the regulatory Authorities and technical support organizations, with reinforcement of the regulatory framework, especially in the field of licensing.

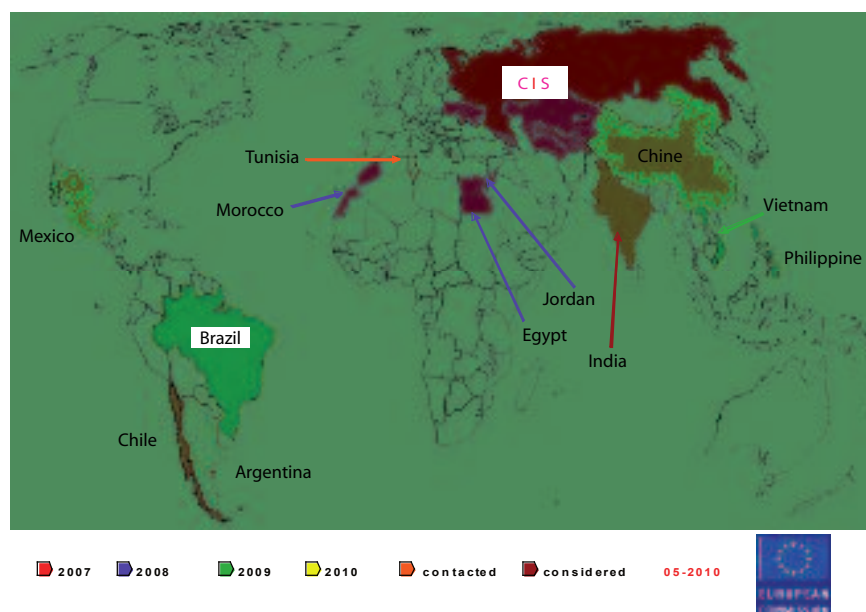
The European Commission now ensures that the projects to improve nuclear safety take account of the requirements of Directive 2009/71/EURATOM of 25 June 2009 establishing a community framework for the nuclear safety of nuclear installations. The new projects will encourage harmonization of regulatory frameworks beyond the borders of the Union.

Alongside support for the regulators, the programme emphasised major problems such as the rehabilitation of contaminated sites in central Asia, or the efforts made concerning research reactors. Finally, these new activities are carried out concurrently with those concerning nuclear safety under the terms of the stability Instrument (the fight against the risks of proliferation of agents that can be used in manufacture, illicit trafficking of radioactive and radiological materials and materials accounting).

The key objective of the community programme is to support the implementation of effective nuclear safety, but it must be done without promoting recourse to nuclear power, a decision which remains within the remit of the energy policy of each country addressing the European Union for access to the capacity available in the Member States.

Outlook

There is still considerable potential for cooperation with the safety regulators in the beneficiary countries. First of all, geographical coverage could be extended even further,



Countries in which the INSC nuclear safety programme is operational. The colours represent the project programming years.



General view of the Khmelnytsky nuclear power plant, Ukraine

depending on the new needs expressed. There must also be a change in the form of cooperation with countries such as Ukraine, where the beneficiary has acquired a degree of maturity. For countries opting to go down the nuclear road, it is essential to help them, so that the safety regulators can acquire experience, solidity and know-how and provide the population with a guarantee of effective independence. For those countries revitalising their nuclear industries, good practices must be exchanged. With regard to the means deployed, training and tutoring will be strengthened. Specific projects will be devoted to this in order to obtain a coherent, more effective and more visible approach.

Support for the completion of projects in Chernobyl will of course remain a major priority with regard to commissioning and dealing with the risks involved in containment of the unit

damaged in the 1986 accident. The development of waste management strategies is becoming increasingly important, with regard to both regulation and processing.

It must be underlined that for the populations, the development of a real and effective safety culture must go hand in hand with implementing oversight of the accounting of nuclear materials in such a way as to enhance the fight against illicit trafficking.

Priority will in the short term remain focused on the countries close to the European Union, but community action will be expanded through the legislative and regulatory framework it has created. Through the wealth of experience that has been acquired by its specialists, the European Union offers a unique opportunity for many countries to make progress towards optimising their nuclear power safety culture. ■



INSTITUTIONAL CONTEXT AND REGULATORY FRAMEWORK

Europe's contribution to implementation of a radiation protection system

by Jean-François Lecomte, Head of monitoring of international organizations with competence for radiation protection — Institute for Radiological protection and Nuclear Safety (IRSN)

What is commonly referred to as a radiation protection system is a range of scientific considerations, principles and rules, the aim of which is to contribute to an appropriate level of protection of individuals and the environment against the harmful effects of exposure to ionising radiation, without excessively limiting desirable human activities which can be associated with such exposure [see ICRP Publication 103]. This system is essentially based on an international consensus. The European level only concerns the Member States of the Union but it is crucial that it constitute the final, legally binding step prior to the definition of national regulations. The European radiation protection system (the Euratom Treaty and its derived legislation) is presented below, not from the legal perspective but from a contextual viewpoint. Research activities are not discussed here.

An international system

The radiation protection rules in force in France (Public Health and Labour Codes) are to a large extent the transposition of European directives. These directives drafted under the Euratom Treaty are themselves the result of an international process which established a consensus on the health effects of exposure to ionising radiation, then the principles governing responsible management of the radiological risk and then the resulting radiation protection standards.

More precisely, the international consensus covers values and units, basic concepts [source, dose, effects, etc.], the weighting factors for radiation and biological tissues, the dose-effect relationship (in particular the no threshold linear hypothesis for low doses), the nominal risk coefficient, the general protection principles (justification of actions, optimisation of protection, limitation of doses) and the methods for managing various exposure situations (deliberate or inadvertent) and exposure categories (exposure of workers, the public, patients).

A whole chain of international organizations

This process, which is specific to radiation protection, involves numerous organizations, whether scientific or regulatory, general or specialist, governmental or not. They are mainly as follows.

Upstream, the role of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) is to estimate the worldwide exposure of the population from natural or artificial sources of ionising radiation and to assess the consequences of this exposure for human health.

The International Commission on Radiological Protection (ICRP), which is a non-governmental organization, in its turn assesses the radiological risk and issues recommendations on

how to manage it. This organization in particular establishes the principles of radiation protection. Its recommendations are based on current scientific and technical knowledge, but also on social, economic and other considerations. They are sent out to the States and to international organizations which contribute to drafting international or regional radiation protection standards.

The International Atomic Energy Agency (IAEA), which is a UN agency, thus publishes and regularly revises recommendations which constitute standards for protection against ionising radiation and for radioactive source safety. The purpose is to provide help for States with limited resources to devote to developing technical rules and international harmonization of radiological protection and safety standards. The IAEA "basic standards" take account of the ICRP's recommendations. They are produced in collaboration with other agencies, such as the World Health Organization (WHO), the International Labour Organization (ILO), the United Nations Food and Agriculture Organization (FAO) and the OECD's Nuclear Energy Agency (NEA).

At the European level, the European Atomic Energy community (known as Euratom) has since 1959 issued its own basic standards for the health protection of the general public and workers against the harmful effects of ionising radiation. These basic standards are the subject of a directive prepared in line with international standards, but unlike them, those of Euratom are legally binding because they have to be transposed by the Member States into their national legislation.

So in short, this international process is a way of ensuring a minimum amount of uniformity for radiation protection rules worldwide, but without preventing specific national variations.

The construction of Europe

The ICRP is very much a senior citizen, created in 1928, but the UN and European institutions date from the 1950s. The organizations are cooperating today as best they can, but each piece of the puzzle was created independently of the others. In Europe, after the creation of the European Coal and Steel Community (ECSC, 1951) and the failure of the Defence Community in 1953, the Euratom Treaty signed in 1957 gave a formal framework to the Europe of nuclear power. It was to a certain extent a gamble on a new and promising form of energy, which the first Member States believed would be the basis for common economic development (the treaty instituting the European Economic Community was signed at the same time).

The Euratom Treaty

Nuclear industrial development differed widely among the various Member States and the pro-nuclear orientation of the

Treaty even triggered a degree of reticence among the new arrivals. However, everyone had to be brought on-board and the trade-off was that certain parts of the treaty were left dormant. The chapter dealing with health protection, which was one of the keystones of Community competence in the field of radiation protection, remained active. Its main requirements concern the production of uniform basic standards (articles 30 to 33), the permanent monitoring of radioactivity in the environment (Articles 35 and 36) and the obligation to submit plans for the release of radioactive effluents to the Commission for its opinion (Article 37).

Apart from the power struggles between community institutions and the temptation for some to use radiation protection constraints as a way to hinder the nuclear activities of others, application of the corresponding chapter of the Euratom Treaty raised no insurmountable obstacles. In order to avoid opening Pandora's box, the Euratom Treaty has remained unchanged since its signature even if it is somewhat obsolete. Commission communications have clarified and updated application of the most important articles. In the 1990s, the Commission made an effort to organize and plan its actions for implementation of the Treaty (in particular concerning the verification visits as stipulated in Article 35).

The two most controversial aspects were the applicability of the Treaty to military matters and the application of Article 34 on particularly dangerous experiments. The first point, never settled, opposes the Member States possessing atomic weapons and the Commission plus the other Member States. The resumption of French nuclear weapons testing in the Pacific in 1995 was a particularly tense time. The second point is also more political than technical: no Member State wishes to admit that it is conducting particularly dangerous nuclear experiments (the Superphenix case led to heated discussions between France and the Commission).

Basic standards

The basic standards are defined in the Treaty as being the maximum allowable doses or exposure levels (the optimisation principle had not yet been defined in the 1950s). They are the origin of derived legislation which was fleshed out and clarified over the years, in the form of directives, regulations and recommendations. The first directive on radiation protection basic standards dates from 1959. It was updated several times and that currently in force, dating from 1996, is itself currently under revision.

Before 1996, the main chapters of the directive concerned the scope of application (with the notification and authorisation regime), dose limitation for controllable exposure (including optimisation of protection and, as of 1980, justification of activities) and operational protection of workers and the general public; there was virtually nothing concerning emergency situations.

The 1996 version was a turning point, and not just because the dose limits were lowered. It ushered in a true modern radiation protection system. The general principles are clearly defined, with concrete measures for implementation. It set up differentiated management for practices (human activities liable to increase exposure) and interventions (human activities intended to prevent or mitigate exposure).

That is not all, and the directive now explicitly covers naturally occurring sources of radiation, with specific requirements. Among the situations requiring intervention, a distinction is now



3rd ten-yearly outage at Fessenheim, the various participants (EDF, ASN, IRSN) pass through the inspection portal to ensure that they carry no contamination before exiting the controlled zone

made with regard to radiological emergencies, with requirements concerning preparedness and response, and to long-term exposure (resulting from a radiological emergency or from a past or legacy practice).

At the same time, operational protection requirements were strengthened, in particular those concerning workers. This change accompanied the development of a radiation protection culture within the installations (mainly in the nuclear sector). The 1996 directive was transposed into the French Public Health and Labour Codes in the early 2000s.

With the benefit of hindsight, it must be said that the 1996 directive, which was consistent with ICRP Publication 60 (1991) and coherent with IAEA's Basic Safety Standards (BSS 115, 1996), set up a two-speed system: highly restrictive for practices and on the contrary extremely flexible for situations requiring intervention. This observation caused the ICRP to modify its recommendations with Publication 103 (2007), which in turn inspired the latest version of the Euratom directive currently being drafted.

The other texts

For many years, the directive establishing the basic standards was enough. Radiation protection law derived from Euratom then became more substantial, occasionally in the wake of events that had occurred.

Medical applications of ionising radiation go back a long way. In 1984, following a revision of the basic standards, a specific directive was adopted for radiological protection of individuals undergoing medical examinations and treatment. Practitioners were unfamiliar with it and it was rarely applied. Hence its replacement by another directive in 1997, supplementing the new version of the basic standards and stressing the implementation of the justification and optimisation principles (dose limits do not apply to patient exposure). Since then, making medical staff aware of the need for greater vigilance has been a daily battle for the Authorities, together with the experts and professional associations.

The Chernobyl accident in 1986 triggered the adoption of regulations on the maximum allowable contamination of foodstuffs. One concerns the conditions for the import of agricultural produce from a third-party country following an accident; to be precise, it was not adopted pursuant to the Euratom Treaty but to the EEC Treaty. The other, based on Euratom, requires triggering of measures in the event of



another accident, wherever it happens. After adoption in 1987, they have changed since then, but still do not refer to the same numerical values, which would make it hard to implement the second regulation after years of applying the first one. This is one significant weakness of the Community system.

The Chernobyl accident also triggered a 1989 directive regulating information of the public about health protection measures applicable and what to do in the event of a radiological emergency. Another directive adopted in response to an event is that of 1992 concerning the surveillance and monitoring of transfers of radioactive waste (updated in 2006), following the "Transnuklear affair" at the end of the 1980s (radioactive waste illegally transported from a German nuclear power plant to a Belgian disposal facility).

The purpose of the 1990 directive concerning operational protection of outside workers exposed to a risk of ionising radiation during their intervention in a controlled zone was to reinforce the protection of staff more exposed than others owing to their work and who were harder to monitor owing to their status (subcontracted workers, sometimes on very short contract) and their mobility. The Member States integrated the directive's requirements into their general rules for worker's protection. This can only be a good thing but it is not really in the spirit of the directive which aimed to implement a special system to protect this most vulnerable category of workers.

In 1993, the creation of the single intra-community Market meant that there was a risk of France having to give up the radioactive source monitoring system that it had been using for a long time (including transfer licenses), as it was seen as a barrier to trade rather than a radiation protection rule. In response, France convinced its partners of the usefulness of regulation of the transfer of radioactive materials (1993); it also originated the 2003 directive on the monitoring of high-level radioactive sources and orphan sources. As a result of this initiative, the most dangerous sources are monitored from fabrication to disposal. At the same time, IAEA adopted a code of conduct for this issue.

This legal arsenal is considerable. Each new community text, regardless of its origin, demands a review of French regulations and practices. For directives, an interministerial transposition committee is generally set up. The operators try to anticipate the new rules, but integration of them is not always trouble-free.

The French attitude

The Commission is the depositary of the treaties and for a long time gave the Member States considerable latitude with implementation of Euratom. Then, following the Chernobyl accident, it adopted a more interventionist attitude. As a major and strongly independent nuclear country, France considered the Commission's new approach to be intrusive and unjustified, hence its sometimes less than cooperative approach ("the whole treaty but nothing but the treaty"). One consequence of this tendency to cultivate the principle of subsidiarity to the extreme was an introspective attitude and a failure to anticipate international change. For example, France unsuccessfully attempted to avoid and then delay integration of the dose limit reductions in the international and European standards following the ICRP's Publication 60.

In recent years however, the virtues of an – albeit relative – international consensus on such a sensitive subject, became increasingly apparent and the attitude of the stakeholders

changed. In addition to Europe itself, France focused on participation in international organizations and plays an active part in their work. Industry created international associations. HERCA, the Heads of European Radiological protection Competent Authorities was created at the initiative of ASN. Strangely enough, these are the technical support organizations, which have always been present on the international stage, which are today the least well organized collectively (there is a European association for nuclear safety but not for radiation protection). For its part, civil society, the fourth stakeholder, remains to a large extent outside the circle, a situation which cannot be allowed to last. Each stakeholder has a role to play. This more constructive attitude is also more effective: France as a partner is now listened to more closely.

The near future

Revision of the basic standards is under way. The Commission should be submitting a proposed directive in early 2011. The two objectives of the process are to update the radiation protection system and merge into a single text those provisions today scattered among a variety of directives. The most significant advances are the introduction of a graduated approach to implementation of the regulatory system according to the magnitude of the risk, the application of stricter requirements to natural sources of radiation, the greater importance given to questions of education, training and information, harmonization of the notion of qualified expert with recognition of the corresponding status within the Union, development of measures for managing radiological emergencies and, finally, the beginnings of a specific environmental protection system (rather than one linked solely to human protection). The future directive will also monitor changes with respect to ICRP Publication 103, in particular harmonization of the management of exposure situations, no matter what they are (planned, emergency, or existing) allied with reinforcement of the optimisation principle.

These changes are all designed to ensure greater protection. Without making any assumptions as to the final result, a number of challenges still need to be met. Merging the directives into one text makes for greater rationalisation but does entail a loss of visibility of certain sensitive issues (outside workers, sources). The desire to strengthen requirements concerning natural sources of radiation is unanimous, but bringing the regulations in this sector into line with those of the nuclear industry is not self-evident: the radiation protection culture is considerably different. Along the same lines, the awareness by the medical profession of the importance of closer control of exposure in this sector is still very much a work in progress; here again, regulations cannot do everything. With regard to radon, the challenge in France is not so much to align with the recent reassessment of the estimated risk, but more to implement an effective means of controlling radon in dwellings.

Concerning the functioning of the system, efforts are still needed with regard to improved assimilation of regulatory tools linked to the optimisation principle (dose constraints, reference levels). The interface between security (prevention of malevolent acts) and safety (incorporating radiation protection) will need to become more than just wishful thinking, if one is to avoid establishing standards and practices that are contradictory. In France, incorporating the French figure PCR (person with competence for radiation protection) into the future Community system for qualified experts will also be an issue.



IRSN visit to the EPR construction site at Olkiluoto in Finland. Workers, cranes and reactor building with the containment dome designed to withstand an aircraft crash

The priority given in recent years to harmonizing the application of exemption and release concepts is debatable. The time spent on defining the lower end of the regulatory scale is time not spent on thinking about ways of reducing the highest levels of exposure. Furthermore, the profusion of numerical values (dose or concentration) related to these concepts gives the mistaken impression that the differences have real meaning and that their use in the field is well controlled. This tendency to let radiation protection be based on numbers (rather than on good judgement) is not in agreement with the ICRP's message and could in fact prove counterproductive.

For the longer term

Given the increasing number of ionising radiation sources, the rise in medical exposures and the upsurge in interest in nuclear programmes, disseminating a radiation protection culture within civil society and among the professionals is a crucial issue. Much remains to be done, but France has taken an initiative in this direction within IRPA (International Radiation Protection Association).

Establishing environmental protection rules not directly linked to human protection, in line with the message from the ICRP, and their integration into a global system, will take time. This process needs to be supported by building on French experience and know-how.

Application of the justification principle should give rise to regulatory developments, probably involving more explicit procedures. There is now a demand for particular uses of radiation (for security purposes). The current debate will need to look at all uses (nuclear, consumer goods, etc.) and involve civil society.

The vast pluralistic review exercise conducted in France on the post-accidental phase, under the aegis of ASN (CODIRPA) should enable our country to become a driving force for change to international doctrine in this area. The issue is in fact almost more psychological than regulatory: minds must be prepared for the hypothesis of a radiological accident with long-term consequences, even if everything is done elsewhere to prevent it happening.

Finally, even though the radiation protection system is all the more robust because of its simplicity (even if the rules are increasingly detailed), it is crucial – both in France and worldwide – to maintain a level of expertise capable of interpreting scientific changes, placing them in perspective and issuing pertinent recommendations to effect the transition from evaluation to management of the radiological risk. Translating scientific complexity into simple rules requires reflection and judgement, hence the importance of controlling the process and indeed the time-frame between scientific publication and the regulations.

Conclusion

The European framework deprives the Member States of some of their independence but it does offer a broader guarantee in a field as sensitive as radiation protection, especially given that the content of the directives is the result of a collective, international consensus. This framework enabled the Member States to develop uses of ionising radiation as and when they saw fit, while guaranteeing an acceptable level of protection for workers, the public, patients and the environment. The system can be further improved and the French players are well-positioned to contribute to this. To maintain balance between stakeholders, greater emphasis should probably be placed on civil society. ■



INSTITUTIONAL CONTEXT AND REGULATORY FRAMEWORK

WENRA: the construction of a European area for nuclear safety and radiation protection

by Jukka Laaksonen, Chairman of WENRA, Director-General of STUK (Finnish regulatory body)

Initial nuclear power programmes in Europe were developed in quite diverse manner in different countries. Extensive construction of nuclear power plants started in the UK in the 1960's, based on indigenous gas cooled reactor designs. Also France and Germany were active in designing and construction of different prototypes of power reactors. Other countries preferred to rely on imported nuclear power plants, mostly from the USA or the USSR.

Nuclear safety was not an issue of public concern in the early years of the nuclear era, and it was not explicitly considered in the Euratom Treaty. The primary objective of the Treaty was the promotion of nuclear energy and the security of supply of nuclear fuel for peaceful programmes. The safety goal incorporated into the Treaty was to protect both the workers and the general public from the ionising radiation resulting from normal operation of nuclear power. Need to prevent nuclear accidents was not emphasized, and means for prevention were not addressed.

First political intention to develop common nuclear safety principles for the EU Member States was expressed in a resolution of the Council of Ministers in 1975. Even if the resolution did not lead to formal harmonization, it gave a mandate for a Reactor Safety Working Group where the nuclear industry, utilities, and regulators from all EU countries were represented. The group met twice a year and exchanged information on national nuclear safety practices. In addition, it formulated recommendations for safety principles and common position papers on a number of safety issues. The group was evidently helpful for adopting consistent approaches in NPP design and operations, but the approaches for safety regulation remained quite different in different countries, especially as concerns issuing national safety regulations and conducting inspections. Some countries preferred to issue quite detailed and prescriptive regulations while in the other extreme a position was taken that the detailed regulations could reduce the responsibility of licensees for safety, and therefore the regulatory organization should limit itself to specifying safety objectives only.

The nuclear safety co-operation driven by the European Commission was gradually terminated in the late 1990's and in the early 2000's because strong views were presented in the European Parliament that such co-operation was promotional for nuclear power and therefore not acceptable to all Member States.

At the same time, however, a concern was voiced about the nuclear safety situation in the prospective new Member States. The political decision makers wanted to ensure that only nuclear power plants with adequately verified safety and with

adequate safety regulation be used in the enlarged Europe. In order to address this political concern and recognizing that no EU institutions had competence to deal with the nuclear safety issues, the Head of the French regulatory organization invited his colleagues from all nine EU countries having nuclear power plants to a meeting held near Paris in March 1998. All of the invited persons responded positively and participated. In this meeting the regulatory Heads decided to offer their advice to the Commission in assessing the nuclear safety in the countries that were seeking for the EU membership. It was also recognized that for assessing the nuclear safety situation in the candidate countries it was necessary to establish a harmonized view on what are the necessary elements and features of adequate nuclear safety level in a country.

One year later the regulatory Heads agreed to start their regular co-operation, and this led to the foundation of WENRA. The efforts towards European nuclear safety harmonization were started in the fall of 1999, in parallel with the ongoing assessment of candidate countries. The assessment of the candidate countries was completed by the end of year 2000.

Subsequently, all countries having been assessed joined the harmonization process on an equal basis together with the original WENRA members.

Harmonization does not mean an adoption of common safety regulations, but it is defined as follows by WENRA:

"There are no substantial differences between countries from the safety point of view in generic formally issued national safety requirements, and in the resulting implementation on the nuclear power plants."

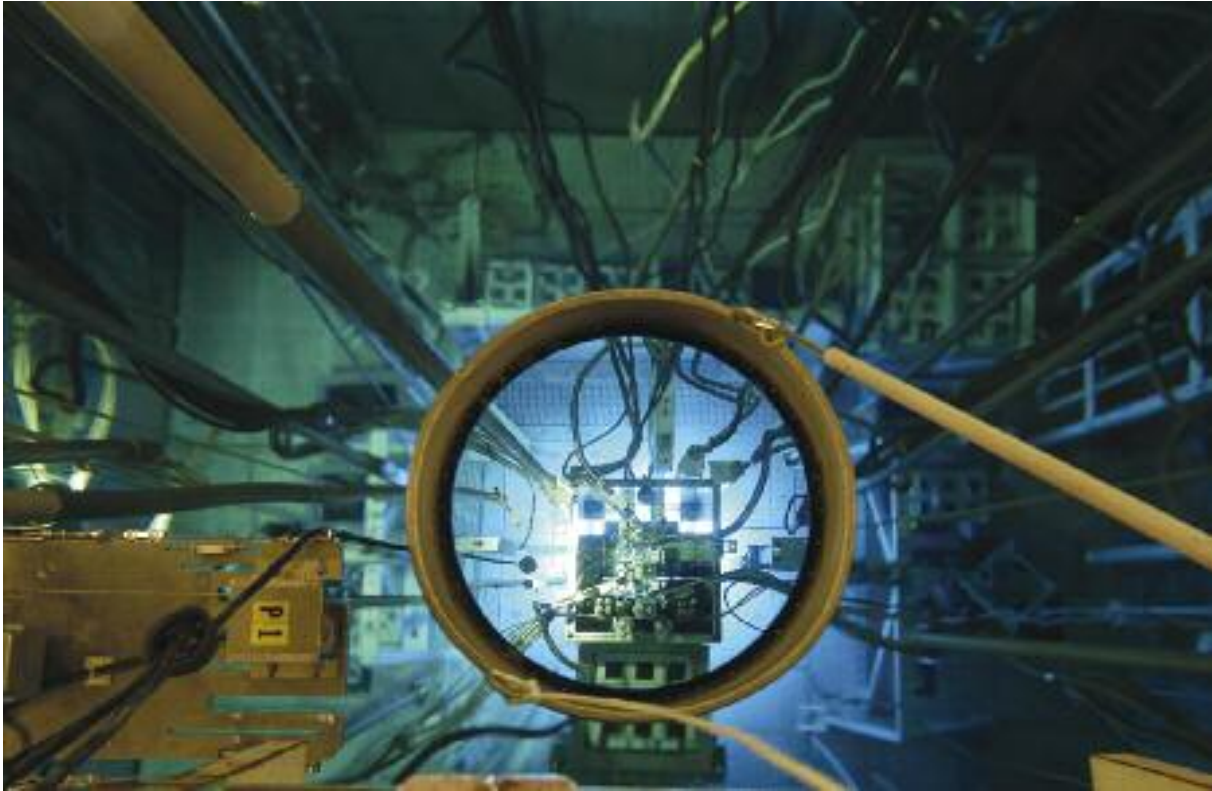
The practical harmonization work of WENRA was allocated to the Reactor Harmonization Working Group that has proved to be most productive and professional and has functioned actively since then. A Working Group on Waste and Decommissioning was established a bit later.

Strong initial drivers for the renewed European nuclear safety co-operation, in addition to the Union enlargement process were the expected deregulation of power markets, the need to license reactors that had been designed in cooperation between European countries, and the growing political will to establish common European nuclear safety practices. All of these called for harmonization of the nuclear regulatory approach and the nuclear safety criteria in the Member States.

An important document that all WENRA members signed in December 2005 was a common policy statement that gives a sound basis for the European approach to nuclear safety.

The leading principle agreed in full consensus by the WENRA members is a continuous strive to improve nuclear safety, both in the operating and in the new nuclear power plants and in the





Overhead view of the OSIRIS pool. The OSIRIS research reactor is located in the Saclay centre. It is not designed for electricity production but for experimentation, primarily for the study of materials

management of nuclear waste. The European regulators want to achieve this by promoting the exchange of experience and learning from each others' best practices. They also want to develop a common approach to nuclear safety and regulation, in particular within the European Union.

The Reactor Harmonization Working Group focused first on the safety of operating nuclear power plants. It has achieved significant results in formulating an extensive set of safety reference levels that are consistent with the IAEA Safety Standards. These reference levels have been or are being implemented in the regulations and in the nuclear safety practices in all Member States and in Switzerland. The work was essentially completed by the end of 2005 and reported to a large audience of European nuclear industry in February 2006. Since then the definition of harmonized safety levels has still been made more clear and accurate, especially based on good comments received from the industry and other interest groups. Most of the national regulators will complete their safety regulations by the end of 2010 to be in consistence with the harmonization report recommendations. Some of the respective safety improvements take more time and will be completed later.

A new challenging task for the Reactor Harmonization Group is to develop common European principles for new nuclear power plants to be constructed in the near future. These plants are not expected to be much different from the operating facilities but they should have improved safety features that have evolved based on the earlier operating experience and on higher public demands on safety. A good start has already been made in this task, and it provides a sound basis for assessing safety of new plants.

Harmonization in the nuclear waste management has been more difficult because some of the WENRA members are not regulating the final disposal of nuclear waste or some other parts of the waste cycle in their own countries. However, good progress has been made also in the respective working group.

In parallel with the harmonization conducted in working groups, WENRA has agreed and documented common views on the importance of the national responsibility and the effective national regulation for nuclear safety. A point that WENRA has consistently emphasized in its communications with the EU Commission is the principle of strong national regulations, as decreed also in the international Convention on Nuclear Safety. Effective regulatory control requires in-depth knowledge of the facilities being regulated, and this knowledge is only with the national regulators.

Harmonization of nuclear regulation and nuclear safety practices only in Europe is not enough but similar work has to be extended to all countries of the world where nuclear power is used. Therefore the harmonization of safety regulations must be promoted at the global level, in cooperation with the IAEA, and the basis of all European nuclear safety regulations must be consistent with the IAEA Safety Standards. This implies, on the other hand, that the WENRA members are proactive and work together in the development of the international standards. The recent experience has shown that this is actually taking place, and the preparatory work made within the WENRA working groups is often setting the global standard.

A principle that WENRA has adopted and strongly promotes also in the global communications is the importance of constant alertness on potential safety hazards, and consequent



continuous development of safety. Safety must not be considered as stagnant and the safety regulators must not be complacent with the situation in their own country. As a strong tool against complacency, WENRA wants to promote well-established peer review mechanisms that help the national regulators to become aware of their needs for development and to adopt the best international practices.

Since 2007, the WENRA members form together with the Commission representatives a group called ENSREG, European Nuclear Safety Regulators' Group. This group has not reduced the need for WENRA because ENSREG is more focused on implementation of the new European nuclear safety directive that was issued after many years of discussion in July 2009. WENRA has remained as an important proactive group that can effectively promote nuclear safety both in Europe and globally, and that can rely on work conducted by the most professional and motivated experts in its working groups.

New topics that are being addressed this year in new working groups are the need for more consistent regulation and safety requirements for research reactors, and harmonization of the regulatory practices for ensuring quality of structures and components. Especially the latter one is important for ensuring smooth and predictable implementation of new nuclear power plant construction and the achievement of consistent high quality in construction.

Expectations on further strengthening of WENRA are connected with recent joining of Russian and Ukrainian regulators as observers, as well as joining of regulators from EU Member States that have no nuclear power plants. The enlargement of WENRA with two countries having large nuclear programmes will certainly strengthen the European voice in the international co-operation of nuclear regulatory bodies, and the involvement of non-nuclear members helps to demonstrate the openness and transparency of the nuclear safety field. ■

INSTITUTIONAL CONTEXT AND REGULATORY FRAMEWORK

HERCA's contribution to the establishment of a European area for radiation protection and safety

A need for closer co-operation between the radiation protection competent Authorities in Europe

by Ole Harbitz, Director-General of the norwegian Radiation Protection Authority and Chairman of the Heads of European Radiological protection Competent Authorities (HERCA)

The Heads of European Radiological protection Competent Authorities are aware of the fact that although European directives exist in the field of radiation protection and the new European Basic Safety Standards is in the pipe-line, challenges in this field still have to be faced. Examples are the safety of radioactive sources, the training of a new generation of radiation protection experts, radiation protection in nuclear installations, justification of practices and criteria for emergency preparedness.

Furthermore, it appears that the radiation protection regulations and practices differ between neighbouring countries. Since these differences may not be really justified and are not understood by the public and the stakeholders, efforts are required in order to reach further harmonization.

The independent professional standing of the Radiation Control Authorities in all European countries is also of relevance when a closer co-operation between them is on the agenda.

In the field of nuclear safety, WENRA (see page 44) was established as an association between European regulators some 10 years ago. It has been a success, ensuring close contacts and common understanding between the nuclear safety regulators across Europe. Although the European Commission has been and is focused on the needs for common understanding and regulation of radiation protection and has a strong and productive forum for this development in the Article 31 Group of Experts, a similar association to the WENRA in the field of radiation protection could be a benefit for all.

Between the five Nordic Countries (Denmark, Sweden, Finland, Iceland and Norway) a close co-operation exists since the 60ties (see page 54). The terms of reference for this co-operation are very similar to the terms of reference of HERCA. The success of the Nordic co-operation has been and is depending on our ad hoc and more permanent Working groups producing deliverables of relevance and importance for future radiation protection and safety without duplicating other international developments. It depends of course also on the ability of the so-called Chiefs-meeting (a meeting once a year between the Heads of the Nordic Radiation Protection and Nuclear Safety Authorities), to order the right deliverables and to decide upon the final results. The Nordic co-operation has been a success, is still vital after more than 40 years, and is an important supplement to other international forums.

Recognising the need for increased co-operation between radiation protection Authorities within Europe, what should then be the objectives for a closer co-operation on a European

level? First of all the networking as such: To build and maintain a network of Radiation Safety Regulators in Europe and to learn from each others best practices. The ambition should also be to further develop a common approach to radiation safety and regulation within Europe on different issues whenever needed, and to express a consensus opinion on significant regulatory issues. In summary: we need for common understanding, mutual approach and whenever possible, harmonization.

Establishing HERCA

In December 2006, ASN sent a questionnaire to European radiation protection Authorities asking for priorities on a list of challenges in radiation protection. The questionnaire listed 27 different areas for co-operation and where further harmonization between the regulators in Europe might be needed. The European radiation protection Authorities were invited to score their priorities from their understanding of important common challenges and need for harmonization. ASN received responses to the questionnaire from 15 colleagues all over Europe, and some of them also added new items and issues for possible future co-operation and harmonization.

Based on the input to the questionnaire, the Heads of Radiological protection Competent Authorities were invited by ASN to Paris to discuss how to develop a closer network and future co-operation. The first meeting of the Heads took place in Paris in May 2007 chaired by Mr. Lacoste (ASN, France). After a thorough discussion and based on the global score to the questionnaire, it was decided to establish five Working groups (WGs). These were:

- WG1 Outside workers & dose passports;
- WG2 Justification of radioactive sources;
- WG3 New medical techniques & patient release;
- WG4 Emergency preparedness & action levels;
- WG5 Stakeholder involvement & medical practices.

After the first meeting in Paris, the Heads of European Radiological protection Competent Authorities (HERCA) have met four times to strengthen their relationship, to further develop international cooperation of their institutions and to follow the progress of its Working Groups. Since HERCA works for a better harmonization of the radiation protection regulations in the different Members States of the European Union, HERCA has also co-opted a representative of the European Commission who is invited to participate in all meetings. In the third plenary meeting of HERCA, the Heads adopted the terms of reference of the association. Delegates



to the plenary sessions of HERCA should be Heads at managerial or technical level. The working groups consist of Heads at technical level and senior experts.

In the third plenary meeting of HERCA, it was decided to establish a new working group: *WG6 on the Surveillance of collective doses from medical exposures*. In the fourth meeting, we merged working groups on medical activities into *WG Medical Applications*.

At present, HERCA has 32 European countries in the contact list.

What has been achieved?

As discussed above, through the establishing of HERCA, a forum for closer co-operation between the radiological protection authorities in Europe is established. Close contacts to the European Commission enables us to avoid unnecessary duplication of work. A few examples of what has been achieved till now could be mentioned:

- a common European passbook has been produced by one of the HERCA working groups and will be soon implemented in Europe;
- a common view on the justification of full body scanners using x-rays for security reasons is being finalised;
- criteria for patient release after I-131 therapy are being developed;
- a dialog with important stakeholders (e.g. the major CT-manufacturers worldwide) is established discussing a future plan of action to ensure avoiding unnecessary and not justified high doses to patients;
- a common European strategy in a nuclear emergency situation is under discussion;
- data on the collective dose contribution from the top 20 most important CT-investigations have been published.

These are some good examples of the outcome of the HERCA association. Now, the challenge is to consolidate this important arena for discussion and harmonization.

Future sustainable development of HERCA

Since the beginning, we have had a good start in establishing HERCA and seen positive outcome of the co-operation enhancing the level of radiation safety, without duplicating work going on in other forums. Time has come to strengthen the associations' working efficiency and to go further and ensure sustainability. To propose measures needed, a Task Force was created in Paris in the fourth meeting of the HERCA plenary in Paris in December 2009. The outcome and proposals from the Task Force were discussed in the fifth meeting in Oslo in June 2010. During the discussion it was agreed that HERCA has become a valuable asset to radiation protection in Europe. Based on the input from the Task Force, the Heads focused on: programme of work, governance, follow-up and assessment of impact, communication of HERCA activities and outcomes, stakeholder involvement, HERCA internal communication, secretariat and financing/funding. The creation of a website, logo and a template for HERCA's presentation was also discussed. Among the conclusions:

- the creation of a website was approved which should be available in a near future;
- HERCA should seek to bring together all European radiological protection competent Authorities: the participation of countries out of the European Free Trade Association (namely Russia, Ukraine and Armenia) as observers in HERCA meetings will be considered in the future;



Cover of the dummy dosimetric passport approved by HERCA

- natural radiation sources will be included in the field of competence of HERCA;
- the frequency of HERCA Board of Heads meetings should be twice per year.

HERCA interaction with other institutions/associations

HERCA is fully aware of the developments in other international forum and organizations. The international IAEA BSS which was discussed in the RASSC-meeting in Vienna last summer, and the Euratom BSS are both of great importance for the further development of radiation safety.

In the last meeting of the Article 31 Group of Experts it was decided that HERCA should be invited to next meetings as other international organization/associations to present the ongoing work.

Also the International Atomic Energy Agency (IAEA) has expressed interest in closer contacts with HERCA and a possible solution to this might be to invite IAEA representatives to HERCA meetings as an observer both to the plenary meetings and to the WG meetings.

The Secretariat has presented HERCA at the annual meeting 2010 of the European Radiation Protection Authorities Network (ERPAN). HERCA will invite ERPAN to present briefly their Network to sixth meeting of HERCA to be held in Paris on 1 December 2010.

HERCA has also been invited to participate in the Advisory board of the European Network on Education and Training in Radiological Protection (ENETRAP-II) and to initiate a dialogue between HERCA and European Federation of Organizations for Medical Physics (EFOMP). Contacts with the Foro Iberoamericano de Organismos Reguladores Radiológicos y Nucleares could also be established.

In the future evolution of HERCA, a common international understanding of the value of HERCA as an important meeting-place and mechanism to develop a common approach to

challenges in the field of radiation protection across Europe, is a necessity. The "raison d'être" of HERCA is the added value produced to ensure further radiation protection to individuals and society.

A summary of the last four HERCA plenary meetings:

HERCA 2 (Paris, 19 May 2008): Plenary meeting chaired by Mr. Lacoste: Preliminary reports and future plans were presented by the WGs. Mr. Harbitz (NRPA, Norway) was elected Chairman of the HERCA.

HERCA 3 (Paris, 12 December 2008): Plenary meeting, chaired by Mr. Harbitz: WG reports presented and discussed. HERCA Terms of reference adopted. WG 6 *Surveillance of collective doses from medical exposures* was established. HERCA input to the IAEA BSS was developed.

HERCA 4 (Paris, 1 December 2009): Plenary meeting chaired by Mr. Harbitz: Update and progress of the working groups. Reorganization of the WGs to merge WGs on medical activities: *WG Medical applications* (WG3 + WG 5 + WG 2 Medical part). Presentation and discussion with the EC representative on the draft Euratom BSS (version October 2009). Setting up of a Task Force on sustainability of HERCA.

HERCA 5 (Oslo, 30 June – 1 July 2010): Plenary meeting chaired by Mr. Harbitz: Update and progress of the working groups – among others:

- proposal of a draft European dose passport;
- proposal on justification of full body scanners using X-rays for security reason;
- proposal on a common European strategy in an emergency situation;
- proposal on patient release in I-131 therapy;
- report on stakeholder dialog with the CT-producers;
- report and discussion of Task force proposals on sustainability.

Presentation of IAEA BSS by RASSC-chair. Comparison of Euratom BSS and IAEA BSS. ■



“INFORMAL” LOCATIONS FOR CONSTRUCTION OF THE EUROPEAN AREA FOR NUCLEAR SAFETY AND RADIATION PROTECTION



Technical Safety Organisations (TSO) contribute to European nuclear safety

by Jacques Repussard, Director General, French Institute for Radiological protection and Nuclear Safety – IRSN

The technical safety organization concept

A nuclear reactor, an irradiated fuel reprocessing plant or a radioactive waste repository are all highly-complex “objects”. Their operation implies the risk of exposure of humans and the environment to ionising radiations, constantly under normal operating conditions or exceptionally in an accident. Nuclear safety, or to employ the wider terminology under the Nuclear Transparency and Security Act of 2006 (TSN act), “nuclear security”, which embraces the safety of facilities, their security in terms of malevolent acts and protection from ionising radiations all together, has since these technologies were first conceived been based mainly on systematic analysis of the validity and adequacy of provisions (for preventing and limiting consequences) proposed by the designer and the plant operator for each potential source of dysfunction or external hazard - fire, earthquake, malevolent intent, etc.

Experience and severe accidents occurring worldwide have shown the need to conduct this analysis both in-depth and critically if its objective was to be reached. This assumed sufficient independence of designers and plant operators as well of course as the necessary scientific and technical expertise. Historically, this expertise existed exclusively, or almost, in “Atomic Energy Commissions”, research bodies created in the major industrial countries after the Second World War to focus on technological development. Experts responsible for risk analysis had to have independent judgement, which meant the gradual emergence of specialised technical bodies, frequently offshoots of the energy commissions. They featured a threefold ability of being capable of justifying their genuine independence of judgement in carrying out their analyses, of basing their conclusions on the best expert assessment practices in accordance with state-of-the-art scientific knowledge and of performing their analyses by taking account of a global overview of risk-causing phenomena, thereby understanding their interactions and thus providing solid support for the recommendations emanating from these analyses.

Problems of nuclear safety at European scale

The lack of an efficient European regime for nuclear safety is proving very costly economically given the interests of an industry which has to rationalise increasingly in terms of European and world market (for both designers and plant operators), but is confronted every day with regulatory fragmentation in each country. It would also be potentially very costly for the European nations which, faced with a new nuclear accident, would have to pay an even higher price through lack of harmony in post-accident management, thereby aggravating the economic and social effect of the accident.

Harmonization is therefore essential, if it is assumed that nuclear energy forms as a major component in the “energy mix” of Member States of the European Union.

But at the same time it is very tricky to achieve, for several reasons: diversity of positions of principle of Member States towards this energy (understandable given the traumatic effects of the Chernobyl accident on Europe), attachment of national Authorities to their exclusive domain of institutional expertise (understandable given their responsibility for protecting populations), complexity of harmonization due to different technical choices made by different States in terms of regulations (differences which in some cases also aimed, historically, to promote national businesses).

Only a one-step-at-a-time policy, applied simultaneously on all fronts based on sufficient political and social consensus in favour of a “top-down” harmonization of nuclear safety european at Union scale and by mobilising appropriate implementation resources, has a chance of succeeding in the medium term in such a context.

One of these fronts is technical expertise. It reflects the complexity of the situation all by itself: the organization of technical safety expertise is linked closely to how the States organize nuclear safety, radiological protection and security - more often than not there are different bodies for these three sectors, all with dissimilar competencies and resources. Each body has its history, its own technical approaches, its working language(s) and so on. They are autonomous, attached to structures of research bodies or universities or are part of the safety Authorities. They vary tremendously in size, depending on the extent of the nuclear industry in the various countries. Technical expertise plays a major role in fashioning nuclear safety in all countries: it influences both the regulatory choices and how the regulations are applied. It also has an indirect influence on the technological, industrial and social choices.

A major objective of European nuclear policy must be building up methodically and gradually areas of expertise which can help harmonise practices in Europe, based on best practices. Can we therefore ultimately conceive of the existence of three major pillars of such a policy:

- the energy policy pillar and its application in the domestic market;
- the regulatory pillar focused on bringing the safety Authorities’ regulations and operating procedures closer together and in the longer term the possible emergence of community competencies for certain subjects (for example, the certification of nuclear reactor design, based on what is conveniently called a preliminary safety analysis report proposed by the designer);



First ENSTTI training session. Staff and participants in module 5 (fuel cycle) in September 2010

– the scientific and technical pillar, where some components already exist via Euratom mechanisms, cooperation with the Joint Research Centre, knowledge acquired from TACIS programmes and discussion and cooperation actions by the TSO.

The gradual emergence of this type of consolidated approach will no doubt also assume that it is supported by social demand relayed politically by the European Parliament. In this sense, parallel actions in several countries by “stakeholders” campaigning for more transparency and involved in the decision-making processes can also help the process. These global notions which deal with the good governance of risk management in nuclear policies can form a solid basis for political consensus within EU competent bodies. It could perhaps be a good idea to provoke, perhaps by applying the Aarhus Convention, the creation of a genuine fourth pillar in this European construction, formed around cooperation at European scale of bodies responsible for organizing national discussions with stakeholders, like in France with the High Commission for Transparency and Information in Nuclear Safety (*Haut Comité pour la Transparence et l’Information sur la Sécurité Nucléaire – HCTISN*) and the Local Information Committees (*Commissions Locales d’Information – CLI*).

TSO contribution to the construction of a European nuclear safety

The TSO are not omniscient. The knowledge they use for their risk assessments comes from three processes created so that this knowledge reflects the state-of-the-art in the subject:

- research focusing specifically on safety and radiological protection issues;
- systematic use of the operating feedback from the operation of nuclear facilities, even other technologies with risks (aeronautics, etc.) This assumes maintaining bonds of confidence with industry and companies operating these

facilities, based on the research concept of mutual benefit rather than control;

- managing knowledge, firstly, through mechanisms for human resource management and continuous training of experts and secondly, the processes for multi-discipline consolidation of expert assessment work, which are essential for putting risk analysis conclusions into priority and which make a tremendous contribution to the emergence of credible reference expertise used to help push nuclear safety forward.

Starting from this shared observation, the European TSOs under the joint impetus of IRSN and GRS¹ - their long-term cooperation has provided a foundation stone - have undertaken to move closer on each of these topics, to create together a relevant expertise resource at the scale of the European continent.

Research

Cooperation in research has been established for some time within the Nuclear Energy Agency’s (NEA) nuclear safety committee (CSNI²) or through Euratom calls for tender. These have produced the SARNET³ network of excellence run by IRSN, which today combines virtually all resources specific to research into severe reactor accidents and which strives to consolidate the computer code system known as ASTEC⁴ used to explore reactor behaviour in accident conditions. More recently, the TSOs have agreed to work together, both as TSO and as research players, within the European research platform called SNETP⁵, where they constitute a pillar represented as such in

1. Gesellschaft für Anlagen-und Reaktorsicherheit.

2. NEA Committee on the Safety of Nuclear Facilities (Comité sur la sûreté des installations nucléaires – CSNI).

3. European Severe Accident Research Network.

4. ASTEC: Accident Source Term Evaluation Code.

5. SNETP: Sustainable Nuclear Energy Technology Platform.



the governance bodies. This produced a chapter devoted to safety issues in the European strategic agenda for nuclear research. Similarly, cooperation between IRSN and BfS in Germany provided the impetus for the creation of another European platform - MELODI⁶. This focuses on research into the effects of low doses of ionising radiations, normally corresponding to long-term exposure at extremely low dose rates. Radiological protection with respect to this exposure is today based on extrapolating results of scientific investigations into biological and health effects carried out for far higher exposure levels. The validity of the extrapolation has yet to be demonstrated.

Analysing operating feedback from nuclear facility operation

This is the second essential dimension in forming knowledge required by the TSOs to succeed with their tasks. Operating feedback has a national connotation in countries with a large number of nuclear facilities and it simply has to be supplemented with additional data from the IAEA's international incident reporting system (IRS). However, this is not true of countries with just a few power reactors, possibly of different designs, and the need for information from other countries becomes vital. The raw data from operating feedback is confidential, however, and cannot normally be passed on systematically to foreign partners. The European Commission's initiative in creating a European Clearinghouse system is most welcome in these circumstances. The concept is a sort of cooperation and design network for analysing operating feedback from power reactors at European scale for those countries wishing to join such a system. The system is based on three pillars: the European Commission's Joint Research Centre, the system's administrator, the safety Authorities in member countries, which provide data and use the analysed results to promote safety in their respective countries, and the TSOs, which are responsible for the scientific and technical analyses from the operating feedback. Their purpose is to extract useful lessons which could, for example, be applicable in facilities other than where the incident providing the operating feedback occurred. IRSN and GRS have played their part in the initial conception of this system, with the European Commission, and a framework contract has now been signed, allowing the Commission to have in-depth technical analyses carried out on subjects identified by the Clearinghouse management committee.



Knowledge management tools and expert training

Managing human resources, especially continuous training of experts, and managing scientific and technical knowledge by developing specialist tools (databases, computer codes, simulators) are the third fundamental component in TSO operation. Here also, cooperation between the European TSOs, initiated by IRSN, GRS and the Belgian AVN⁷ (now BELV) encouraged new developments, mainly the holding of annual

Eurosafe conferences. These conferences bring almost three hundred experts together for technical discussions on topics which change every year. Other developments were the creation of the Junior Staff Programme, targeting informal links between the experts of the three bodies, and the Summer School, forerunner of the European Nuclear Safety Training and Tutoring Institute (ENSTTI). From 2008 onwards, the Summer School has been open to other European TSOs and member organizations of the Eurosafe management committee.

Next stages - informal to institutional consolidation

The need to build up solid and legally-legitimate relations with the European institutions naturally implies a gradual move from an informal cooperation network to a more institutional relationship. The first TSO function to adopt this approach was the technical support provided to the safety Authorities in Eastern European and ex-Soviet Union countries during the 1990s. Riskaudit was created as a joint European Economic Interest Grouping (EEIG) between GRS and IRSN to provide services of this type under the European PHARE and TACIS programmes. This Grouping now has framework agreements with the European Commission used to contractualise over-the-counter operations. For its part, Riskaudit commits to involving other European TSOs and those of other destination countries in performing services. Riskaudit has performed a hundred or so operations in about ten countries since its creation. Today new countries are appearing in the European support programmes, mainly in the Middle East and the Far East, through a new European instrument known as INSC⁸.

Having tested the feasibility of pooling training sessions for their experts for many years under a similar approach, IRSN and GRS, supported by other European TSOs, founded ENSTTI in 2010, a training and tutoring institute designed to supplement the safety training of their technical management staff. ENSTTI's main feature is that lecturers and tutors are systematically and exclusively senior experts proposed by the European TSO members of the institute. These training courses and long tutoring placements are also available to managers from safety Authorities or non-member TSOs provided there is space. ENSTTI is governed by a scientific council which ensures the quality of teaching and recruitment procedures and issues training certificates. ENSTTI intends to form a new EEIG and a European regional centre of excellence, recognised as such by IAEA which already sits on the Scientific Council. Similarly, the European Commission could finance through its third world aid programmes the training of candidates from countries benefiting from European financial backing.

Lastly, the association of European TSOs - ETSON - is intending this year to acquire the formal status of an Association. This will give it recognition from the European Commission as a partner organization in carrying out actions in nuclear safety at EU scale. ETSON has in particular working groups responsible

6. MELODI: Multidisciplinary European Low Dose Initiative.

7. AVN Association Vinçotte Nucléaire (technical support for the Belgian Nuclear Safety Authority until 2008).

8. INSC: Instrument for nuclear safety cooperation.



ENSTTI website, www.enstti.eu

for developing elements for harmonizing the TSOs' technical doctrine for safety analysis, in priority subjects.

Once all these inter-TSO cooperation tools are in place, speedier, wider contribution to the harmonization of nuclear safety practices in Europe can be planned. The TSOs already sit on technical committees instituted by the European radiological protection directives and it is perfectly possible to extend this role to nuclear reactor safety and in the future to radioactive waste management. Similarly, the TSOs will be prepared to make a contribution to any emerging initiatives that encourage the development of industrial standards downstream from IAEA standards to facilitate industrial cooperation and the opening of international or European markets.

Beyond the sphere of European institutions, the TSOs are also in a position to create formal consortiums intended to organize the pooling of their resources to provide integrated technical support to third world safety Authorities involved in nuclear power programmes requiring recourse to technical expertise independent of the technology supplier and still insufficiently developed nationally. GRS and IRSN have therefore provided joint support to the Bulgarian safety Authority through their subsidiary Riskaudit to assess the safety of the VVER reactor that this country wishes to build.

Conclusion

Nuclear safety is a global issue as well as European. Actions undertaken at the scale of the European continent must therefore also be analysed in the wider context of international institutions. The European TSOs thus play a major role in the OECD's NEA committees and in the IAEA bodies, where they help make highly-qualified staff available to the Agency in departments or committee and working group structures in charge mainly of developing standards. IAEA is organizing the second conference on the theme of TSOs in Tokyo at the end of October. The goal is to take stock of progress in cooperation between these organizations for the benefit of world nuclear safety and on the ways and means of supporting these organizations which hold entire sections of technical expertise in terms of nuclear safety and security and in radiological protection. A major issue when an increasing number of IAEA Member States are planning, or have already decided, to launch ambitious nuclear power programmes. ■



“INFORMAL” LOCATIONS FOR CONSTRUCTION OF THE EUROPEAN AREA FOR NUCLEAR SAFETY AND RADIATION PROTECTION



Once again outside the community framework, close ties have been forged in Europe between Safety Regulators. In this article, three contributions present some flexible multilateral cooperation initiatives between Regulators, which could lead to cooperation on a broader scale, also helping to build the European safety and radiation protection hub: cooperation between Finland, France and Sweden on the safe management of radioactive waste; cooperation between Finland, Sweden, Norway, Denmark and Iceland on radiation protection and cooperation between Luxembourg, Belgium, Germany and France on harmonizing the countermeasures to be implemented in the event of a nuclear accident.

More than 50 years of Nordic collaboration

by **Mette Øhlenschläger**, Director of Danish Institute of Radiation Protection

The close neighbourhood, the common history, the common culture and the family of languages are all factors which facilitate Nordic co-operation.

Co-operation between the Nordic radiation protection and nuclear safety Authorities has a long history going back to the mid fifties. The first decades are very well described in the work of Bo Lindell: *“The History of Radiation, Radioactivity and Radiation Protection, the Great Work of Hercules, Stockholm 2003”*, (in Swedish).

Rolf Sievert was the driving force in the early days. Following the nuclear tests in the beginning of the fifties he saw a need for co-operation at the highest level between the regulators in the Nordic countries. The first initiative was taken in 1955. Discussions were held during the summer and ended up with a written premorium given guidelines for such co-operation. The premorium was signed by Rolf Sievert representing Sweden and representatives from Denmark and Norway. The focus in the premorium was exchange of information. In addition the premorium stated that meetings should be held at least twice a year, but unfortunately the co-operation was never really implemented and faded slowly. Rolf Sievert who had been the driving force behind the initiative changed his focus to UNSCEAR and ICRP, the two international organizations he was chairing in the same period.



One single event in 1959 revived the Nordic cooperation. An early example of the importance of exchanging information between neighbouring countries and the need for harmonized intervention levels. Measurements of fallout in the environment had been initiated in all the Nordic countries. Measurements of radioactivity in surface water used for drinking water were made on the small Danish island of Saltholm in the narrow Strait of Øresund between Sweden and Denmark. Results of these measurements led in April 1959 the National Board of

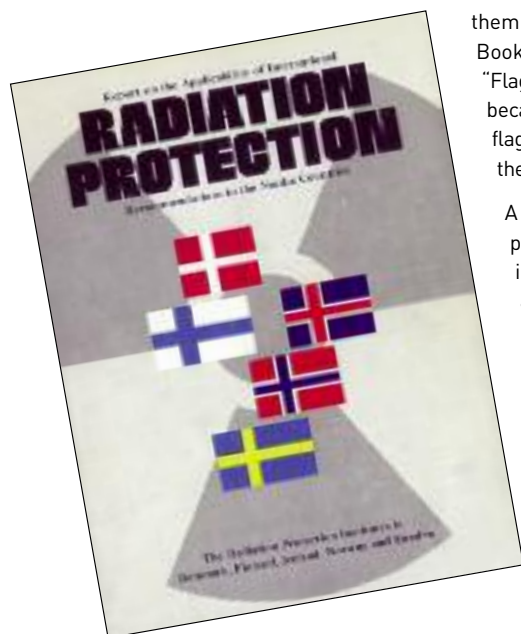
Health in Denmark to ban this water for human consumption. The Nordic mass media immediately started to focus on this news. Rolf Sievert was contacted by the Swedish media and asked questions about the levels of radioactivity in the drinking water on similar Swedish islands at the west coast. In Norway questions were raised for islands along the Norwegian coastline. Over the summer several meetings involving experts and regulators took place. In November 1959 at Rolf Sieverts office in Stockholm an official statement was signed by the regulators in Denmark, Norway, Sweden and Finland stating:

“Nordic experts consider that the radioactive fallout measured until now in the Nordic countries do not in any way require the health Authorities to impose countermeasures ...”.

The actual discrepancy was resolved but had revealed a strong need for a revival of the co-operation between the Nordic countries initiated by Rolf Sievert in 1955. Finland signed the statement and joined the group in 1959.

In the next 15 years the collaboration between the regulatory Authorities was supported by the Nordic Council. During this period Iceland joined the group and the Nordic forum for co-operation between the regulatory Authorities was complete.

Several Nordic working groups have been initiated during the years given rise to recommendations and publications, most of



Nordic basic radiation protection standards published in 1976

them in the Nordic Flag Book Series. The term "Flag Book" was chosen because the five Nordic flags are on the cover on these publications.

A Nordic BSS [361 pages] was published in 1976 with Bo Lindell as the editor. In the preface is stated: "Representatives of the radiation protection institutes in Denmark, Finland, Iceland, Norway and Sweden have agreed to recommend the main principles of radiation protection presented in this document. The text is to a large

extend identical to recommendations issued by ICRP and, to a lesser extend, drawn from publications by ILO, IAEA, WHO and OECD/NEA. Each paragraph, however, has been specifically considered against the special needs of and conditions in the five Nordic countries and has been amended where this has been found essential".

Latest titles in the Flag Book series: "*Naturally Occurring Radioactivity in the Nordic Countries – Recommendations, 2000*" and "*Nordic Intervention Criteria for nuclear or Radiological Emergencies – Recommendations, 2001*".

Time has changed, Denmark, Finland and Sweden are now members of EU and Iceland and Norway are to a large extent following the EU legislation which has overruled the old Nordic recommendations. In addition IAEA Safety Standards are given a much higher attention in the Nordic countries than were the case in the past decades. The old Nordic BSS will never be amended.

However, the Nordic Working Group of Emergency Preparedness, the NEP-group with a history of more than 20 years has initiated a redraft of the Flag Book from 2001 on intervention criteria incorporating the recommendations given in ICRP 103 and 109.

One of the main pillars in the Nordic co-operation is still to formalise and ensure co-operation, communication, harmonized decisions and assistance in emergency situations. A Memorandum of Understanding was signed in 2006 in which the Nordic radiation protection and nuclear safety Authorities declared their willingness to endorse and implement the document: "*Co-operation, Exchange of Information and Assistance Between Nordic Authorities in Nuclear or Radiological Incidents and Emergencies*", [The Nordic Manual].

Nowadays the heads of the Nordic radiation protection Authorities and the nuclear safety Authorities, the "Chiefs Group", meet annually. Several working groups of experts have been established over the years, some have finished their tasks and others like the NEP-group have ongoing tasks. As a consequence of the challenges in the applications of non-ionising radiation, subjects related to this field are now added to the agenda and working groups on the use and the effects of UV and EMF have been established.

The most recent outcome of the co-operation is three position papers signed and published by the Nordic Authorities. In September 2009 the Authorities published a common position paper giving recommendations for radon in dwellings in the Nordic countries. In November 2009 two position papers were published. The first paper is addressing the exposure of the general public to radiofrequency electromagnetic fields and the second paper is recommending a ban of the use of sun beds for people under the age of 18.

These common Nordic position papers have facilitated changes in the national regulations and legislations. Based on the very positive outcome following the publishing of statements on important issues the Chiefs Group has decided to continue the co-operation along this line. Two positions papers are being drafted, one on the justification of CT and one on the use of powerful laser pointers.

The ongoing challenges in the medical and nuclear fields and the focus on non-ionising radiation continuously provide strong arguments for an ongoing and intensive co-operation in our region between the Nordic radiation protection and nuclear safety Authorities and broader including EU, IAEA, HERCA and other related organizations. ■



Informal information exchange and harmonization – the Swedish experience

by Bengt Hedberg, Senior Expert, Section for Disposal of Radioactive Waste, Department of Radioactive Materials, Swedish Radiation Safety Authority

Sweden, Finland and France are considered to be in the forefront of implementing disposal solutions for spent nuclear fuel and/or high level waste from reprocessing of spent nuclear fuel. Although internationally agreed guidance for deep geological disposal exists, the practical implementation of disposal concepts have to be developed on a national basis. Formal internationally agreed requirements related to disposal of spent nuclear fuel and nuclear waste is well established within the framework of IAEA¹, OECD/NEA² and further enhanced in the Joint Convention³. Other important formal cooperation activities take place within the framework of WENRA⁴ and ENSREG⁵.

Informal exchange of information

Sweden and Finland have for a long time arranged annual bilateral meetings between the regulatory Authorities to exchange information on spent fuel and nuclear waste management policies and practices. Corresponding bilateral meetings between Swedish and French nuclear regulators have also taken place. Since the beginning of the 2000's, it was decided to combine these bilateral meetings into annual trilateral meetings between the nuclear safety Authorities in the three countries, i.e. ASN⁶ in France, SSM⁷ in Sweden and STUK⁸ in Finland. One obvious reason was to use time more efficiently. Another reason was to broaden the basis for discussions during the meetings.

Format for meetings

The duties of a host are circulated between the participating organizations. The duration of the meeting is normally two full working days, one reserved for presentations from participants on themes of mutual interest and the other reserved for a site visit. In contrast to more formal meetings in which the organizations are usually represented by senior managers, participants in these trilateral meetings are usually experts within different areas of responsibility, which facilitates the dynamics of the discussions. Participants have changed over

time according to the agreed programme. The items on the agenda have covered a broad range of issues, e.g. regulatory framework and practices, detailed technical details related to disposal concepts, as well as principles for funding mechanisms to cover future costs for decommissioning of nuclear facilities and disposal of spent fuel and nuclear waste. In 2008 it was however decided that future meetings should concentrate on national disposal projects for spent fuel and high level waste.

The most recent meeting took place in Sweden in February 2010 and included site visits to the central interim storage for spent fuel (CLAB), the Äspö Hard Rock Laboratory (Äspö HRL) and the Canister Laboratory in the municipality of Oskarshamn. CLAB stores all spent fuel from Swedish nuclear power reactors. The Äspö and Canister laboratories are important research facilities playing a crucial role in the development of a disposal system for spent fuel. All together the visits provided a good overview of the Swedish system for management as well as plans for the disposal of spent nuclear fuel. The visits were highly appreciated by participating experts from Finland and France.

Lessons learned

Informal information exchange meetings contribute in different ways to improvements in the development of national programmes for the management of spent fuel and nuclear waste. One example is that such meetings provide an arena for experts to discuss with experts from other countries in an open and constructive spirit, without too many formalities. Interaction between representatives from regulators in different countries also provides a sort of peer review exercise, where national activities are discussed in an international perspective. This also facilitates interpretation of internationally agreed requirements into harmonized national approaches.

The less formal structure and more relaxed time schedule for the meetings provide opportunities for spontaneous in-depth discussions. Site visits plays an important part in this respect as they provide inspiration for spontaneous "on-the-spot" discussions which might otherwise never take place. One example is what happened during the last meeting in Sweden, during the site visit to the Äspö HRL where SKB⁹ is carrying out demonstration experiments to prove the feasibility of the techniques planned to be used in a future spent fuel repository. At the end of the meeting our French colleagues concluded that the work by ANDRA¹⁰ had so far focused on research and development of the disposal concept, but that ASN would probably require ANDRA to boost their efforts on actual demonstration of feasibility of technical solutions likely to be used in a French disposal facility.



Conclusion

The informal annual meetings between regulatory Authorities from Sweden, Finland and France provide a forum for valuable

1. International Atomic Energy Agency

2. Nuclear Energy Agency within the Organization for Economic Co-operation Development.

3. The Joint Convention on the safety of spent fuel management and on the safety of radioactive waste management.

4. Western European Nuclear Regulators' Association, Working Group on Decommissioning and Disposal.

5. European Nuclear Safety Regulators Group.

6. Autorité de Sécurité Nucléaire.

7. Swedish Radiation Safety Authority.

8. Radiation and Nuclear Safety Authority in Finland.

9. Swedish Nuclear Fuel and Waste Management Co (a company jointly owned by nuclear power plant operators tasked with developing and implementing disposal solutions for spent fuel and radioactive waste).

10. The French national radioactive waste management agency.



Photo montage that shows how the surface part of the final repository for spent nuclear fuel may look, in the future at Forsmark in Östhammar municipality, location Söderviken

exchange of information on the practical implementation of disposal concepts for spent nuclear fuel and/or high level waste. Although the basis for implementation of disposal concepts is different between participating countries, i.e. national culture as well as legislative and regulatory framework

are quite different, the informal exchange of information provides an added value to the national development work. This is especially important as regards identifying a common approach on how to transpose international established requirements into harmonized national situations. ■



Harmonizing the intervention levels for stable iodine prophylaxis and related counter-measures

by Patrick Breuskin, technical engineer, Natasha Jerusalem, biologist and Patrick Majerus, radiation protection engineer – Division of Radiation Protection – Ministry of Health (Luxembourg)



Luxembourg is characterised by a very unique geographic situation in that within a mere 25-kilometre radius it shares common borders with France, Germany and Belgium, all three of which operate nuclear power plants, with one of the plants (Cattenom) being located fewer than 10 kilometres from the Luxembourg border. In Germany, furthermore, the responsibility for radiation protection in the event of a nuclear emergency lies with the *Länder*. Accordingly, Saarland and Rhineland-Palatinate must be added to the list of crisis management organizations, bringing the total number of centres to five, which implement their own specific emergency plans.

For Luxembourg, therefore, harmonizing the counter-measures put in place to respond to a nuclear accident which cannot fail to affect border regions is more than a mere demand. It is based on a solid body of lessons learned through exercises involving the deployment of emergency plans in the event of a nuclear accident, and it is therefore an unavoidable necessity. Unless this harmonization is achieved, the people living in the Grande Région¹ will be under the impression that they do not benefit from equal protection in an emergency situation if there are divergent national strategies, which may even lead to the deployment of contradictory counter-measures.

At a Franco-Belgian meeting held between ASN/IRSN of France and AFCN/AVN of Belgium on 24 January 2006, when the establishment of a working party of international experts was proposed, Luxembourg, Germany and Switzerland were immediately in favour of taking part in it. Focusing on the nuclear reactors of Chooz, Cattenom and Fessenheim, the initiative was aimed at developing and proposing some harmonization strategies.

The working party came up with a series of recommendations embodying a highly pragmatic approach to defining a flexible and harmonized strategy based on simple, easy-to-implement solutions. The working party concentrated especially on the age groups with the highest radiation sensitivity (critical group), namely, children under the age of 18 and fetuses. These recommendations centred primarily on stable iodine

prophylaxis and related counter-measures to be implemented in the early hours following a nuclear accident, pending the establishment of international dialogue to allow actions to be coordinated. The joint report finalised in June 2007, entitled *"Trans-border harmonization of iodine prophylaxis and other linked protective actions in the first hours of an accident in Belgium, France, Germany, Luxembourg and Switzerland"* suggests that the following common recommendations be incorporated into the national strategy:

1. Each State shall apply the same levels of intervention concerning stable iodine prophylaxis, based on a projected radiation dose to the thyroid of 50 mSv.
2. The source term shall be made available by the country in which the accident took place.
3. The initial projection of the dose determined by the country in which the accident took place, and including all regions potentially exposed, shall be the common basis during the initial phase of the accident.
4. Each State shall issue a recommendation to restrict consumption of potentially contaminated beverages and foods. This recommendation shall be issued automatically and independent of specific evaluations.
5. Prophylaxis shall be decided based on the dose projection.
6. The instruction to administer iodine shall be issued prior to the release of radiation.
7. Stable iodine prophylaxis shall be combined with containment and food control measures.
8. States shall use tablets of potassium iodide (65 mg KI) and all States shall recommend an identical dosage.
9. Prior distribution of tablets to all households located within a radius of at least 5 km around nuclear power plants shall be organized.
10. Prior distribution or stockpiling in the vicinity with an appropriate distribution system shall be organized to ensure sufficient supply for the critical group within a radius of at least 20 km around nuclear power plants.
11. Stable iodine shall be held readily available for the critical group within a radius of up to 100 km.
12. Awareness campaigns targeting the critical group shall be held regularly.
13. A leaflet containing general information on stable iodine prophylaxis shall be provided along with each individual pack of stable iodine tablets. This leaflet should be virtually identical in all participating countries, albeit with certain regional and linguistic differences.
14. Answers to Frequently Asked Questions shall be harmonized.

Luxembourg experts who took part in this working party presented these recommendations to their policy authorities, namely, the Ministry of Health and the Ministry of the Interior. Since the Authorities had approved the recommendations, the Division of Radiation Protection and the Emergency Services Administration began to implement the necessary changes in August 2008.

It is clear that Luxembourg now accepts the dose projections of the country in which the accident occurred as the scientific basis for its decision-making. This is a fundamental change of

1. The "Grande Région" consists of the following partners: Luxembourg – Saarland – Lorraine – Rhineland-Palatinate – Wallonia.



Luxembourg delegation accompanied by ASN visiting the Bure laboratory

doctrine and an example of how the determination to provide the best protection of the population by taking operational realities into account can indeed overcome national sensitivities.

The practice was first tested during the crisis management exercise simulating a nuclear emergency at the Cattenom power plant on 8 April 2010. During this exercise, the French, Luxembourgish and German Authorities activated their respective crisis management centres. The exercise demonstrated that harmonization effort is beginning to bear fruit, particularly in terms of more complete access to the information made available by the various actors, allowing

greater coherence in decision-making. The exercise also highlighted two important areas in which further work is required. It is now mutually agreed that a multilateral decision made on the basis of dose projections established by a single party makes especially crucial the quality of calculations and their prompt transmission to the relevant decision-makers. It will therefore be essential for all these steps to be carried out in a completely transparent and auditable manner. Because of the differences regarding the organization and responsibility for radiological emergencies among the participating countries, it will also be necessary to focus more closely on a more harmonized implementation of recommendations by all parties concerned. ■



“INFORMAL” LOCATIONS FOR CONSTRUCTION OF THE EUROPEAN AREA FOR NUCLEAR SAFETY AND RADIATION PROTECTION

EAN – The European ALARA Network

by Annemarie Schmitt-Hanning, Federal Office for Radiation Protection (BfS) – Germany, Pascal Croüail, François Drouet, Research centre for the assessment of nuclear protection (CEPN) – France, Peter Shaw, Health Protection Agency (HPA) – United Kingdom and Fernand Vermeersch, Belgian Nuclear Research Centre (SCK-CEN) – Belgium

There has been a significant development in the concept and practical implementation of the principle of optimisation of radiological protection over the past three decades. ICRP Publication 101 Part 2 (2006) devoted to the optimisation principle and the revised Recommendations of the ICRP (Publication 103, 2007) define optimisation of radiological protection as a source-related process to keep the magnitude of individual doses, the number of people exposed, and the likelihood of potential exposure as low as reasonably achievable below appropriate dose constraints and reference levels, with economic and societal factors being taken into account. Usually the optimisation principle is referred as the ALARA principle, ALARA being the acronym for “*As Low As Reasonably Achievable*”.

The process of optimisation, which applied whatever the exposure situation - planned, emergency, and existing - must be implemented through an ongoing, cyclical process that involves the evaluation of the exposure situation to identify the need for action, the identification of the possible protective options to keep the exposure as low as reasonably achievable, the selection of the best option under the prevailing circumstances, the implementation of the selected option through an effective optimisation programme, and regular review of the exposure situation to evaluate if the prevailing circumstances call for the implementation of corrective protective actions. However, the way in which the optimisation process should be implemented is now viewed more broadly to reflect the increasing role of individual equity, radiation protection culture, and stakeholder involvement in our modern societies.

The implementation of the ALARA principle in radiological protection in Europe has been a success story. With the strong support of the European Commission during the eighties several organizations contributed to the development of the methodology underlying the optimisation principle. This progressively led to cooperation activities like joint projects or training courses which have been the precursors for the European ALARA Network (EAN). More recently, the work done by the network itself have made important contributions to the practical implementation of the ALARA principle in Europe.

Development of the European ALARA Network

During the early development stages, experts with specialised knowledge and enthusiasm for the ALARA-principle had already begun to co-operate, especially as a result of contacts made within the scope of the ALARA training courses supported by the European Commission. Development of the network's field of activity and structure was mainly based on

the contributors' motivation and enthusiasm with a strong support granted by their organizations, which had an interest in sharing ALARA practices and experiences.

EAN was supported by the European Commission from 1996 to 2004 as one of the projects of the European Framework Programme for Research and Development. The Commission also supported the first 3 EAN Workshops. Since 2005, EAN has been acting as an autonomous organization independent from the European Commission. It is operating as a legal entity established under the French Law.

From the beginning, the coordination of the network was ensured by CEPN (France), together with NRPB (UK) today HPA, and a group of experts from several European countries, having expertise in various fields of radiological protection. This group of experts expanded over the years and constituted the EAN Steering Group. Their participation in the activities of the network is supported by national radiation protection Authorities, or by other institutions or companies that are interested in further development and implementation of the ALARA principle.

In order to ensure the network's sustainability, organizations from 14 countries are financially supporting the coordination work done by EAN. Other countries support special EAN activities such as the workshops. The EAN Administrative Board consists of the Steering Group Members associated with the institutions financially supporting the network coordination. The network is chaired by one of the members of the Administrative Board. Network activities are open to any organization from European countries agreeing with the objectives of EAN and wishing to support them. Participation in EAN activities is always done on a voluntary basis.

EAN objectives

The initial goals of EAN have been enlarged step by step, corresponding to the network's range of action, which was originally only aimed at improving the situation in the field of occupational radiation exposure in industry and research. Subsequently this range of action has been enlarged to occupational radiation exposure in the medical field and in the field of naturally occurring radioactive materials (NORM) and now comprises further areas and types of radiation exposures. This is reflected in the “Terms and Conditions” of the EAN renewed in 2010, which describe the objectives of the Network as follow:

– promote a wider and more uniform implementation of the ALARA principle for the management of worker, public and patient exposures in all situations;

Table 1: organizations represented in the EAN Steering Group in 2010

Organizations	
ASN (Nuclear Safety Authority) - France	NRPA (Norwegian Radiation Protection Authority) - Norway
BfS (Federal Office for Radiation Protection) - Germany	RPII (Radiological Protection Institute of Ireland) - Ireland
CEPN (Nuclear Protection Evaluation Centre) - France,	SCK-CEN (Belgian Nuclear Research Centre) - Belgium
CSN (Nuclear Safety Council) - Spain	Seibersdorf Labor GmbH - Austria
EKOTEH Dosimetry Co. - Croatia	SFOPH (Swiss Federal Office of Public Health) - Switzerland
GAEC (Greek Atomic Energy Commission) - Greece	SIS (National Institute for Radiation Protection) - Denmark
GR (Icelandic Radiation Safety Authority) - Iceland	SRPA (Slovenian Radiation Protection Administration) - Slovenia
HPA (Health Protection Agency) - UK	SSM (Swedish Radiation Safety Authority) - Sweden
ISS (Italian Institute of Health) - Italy	STUK (Radiation and Nuclear Safety Authority) - Finland
ITN (Nuclear and Technological Institute) - Portugal	SUJB (State Office for Nuclear Safety) - Czech Republic
NRG (Nuclear Research and consultancy Group) - The Netherlands	

- provide a focus and a mechanism for the exchange and dissemination of information from practical ALARA experiences;
- identify and investigate topical issues of common interest to further improve the implementation of ALARA.

EAN Memberships

From the beginning, the operation of the network has depended on the voluntary cooperation of experts from various institutions: radiation protection Authorities, industrial companies and services, research institutions, hospitals, etc. Since 1996 the number of countries represented in the EAN Steering Group has increased from 8 to 20. The organizations, members of the EAN Steering Group in 2010, are indicated in Table 1.

EAN Activities

EAN regularly organizes a Workshop on a specific topic. Each EAN Workshop is devoted to a special subject area where the

EAN Steering Group estimates that improvements may be found in terms of practical implementation of ALARA. The Table 2 provides the list of the topics, which were treated during the Workshops. Each of these events brought together 60-120 experts from many countries with extensive personal experience in all areas of radiological protection and very different professional backgrounds. The scope of these Workshops involves not only expert papers but also working groups and poster sessions. Particularly the working groups provide a forum for the discussion of up-to-date topics and for the presentation of discussion results in the plenary session. Recommendations are produced based on the discussion results and addressed to stakeholders dealing with the specific topic under consideration. The recommendations are circulated via the ALARA Newsletter and the EAN website and published in different national radiation protection journals.

From the beginning, EAN has published the ALARA Newsletter twice a year (27 issues in September 2010). The ALARA Newsletter mainly consists in articles describing practical



The 13th EAN seminar on “ALARA principle and the medical sector” - June 2011



Table 2: topics of the AEN Workshops

Topic	Location and year
ALARA and decommissioning	Saclay, France, 1997
Good radiation practices in industry and research	Oxford, United Kingdom, 1998
Managing internal exposure	Munich, Germany, 1999
Management of occupational radiological and non-radiological risks: lessons to be learned	Antwerp, Belgium, 2000
Industrial radiography, improvements in radiation protection	Rome, Italy, 2001
Occupational exposure optimisation in the medical and radio-pharmaceutical sectors	Madrid, Spain, 2002
Decommissioning and site remediation	Arnhem, Netherlands, 2003
Occupational radiological protection control through inspection and self-assessment	Uppsala, Sweden, 2004
Occupational exposure to natural radiation	Augsburg, Germany, 2005
Experience and new developments in implementing ALARA in occupational, public and patient exposures	Prague, Czech Republic, 2006
ALARA in radioactive waste management	Athens, Greece, 2008
ALARA issues arising for safety and security of radiation sources and security screening devices	Vienna, Austria, 2009
ALARA and the medical sector	Oscarborg Fortress, Norway, 2011

cases of ALARA implementation in different sector, examples of good practices, lessons learned and workshop conclusions. The Newsletter is distributed via a number of channels, such as the national contact points, the radiological protection associations and the EAN website. The feedback from several sources reveals that the Newsletters reach several thousands experts and institutions mainly in Europe but also worldwide.

The EAN Website (www.eu-alara.net) permits access to the electronic versions of the Newsletters, the papers presented at the workshops, the summarized conclusions and the recommendations of the workshops as well as different information related to ALARA. About 1000 individuals per month visit the EAN website, and a great number of documents are regularly downloaded, mainly Newsletters, and papers presented at workshops.

Since EAN was a well-established network in 2000, it was decided to use the network as a vehicle to support European Surveys on current topics in radiological protection. The surveys are performed through national contacts and summaries can be downloaded from the website. The different topics, which were discussed, are the following:

- the implementation of the European Basic Safety Standards in Directives 96/29 and 97/43 in national regulations (2006);
- the management of radioactively contaminated soils (2006);
- potential exposures in nuclear installations (2007);
- the Diagnostic Reference Levels (DRLs) in Europe (2007);
- radon exposure management (2010).

EAN Sub-Networks

The recommendations of the first Workshops identified subject areas requiring further consideration. Therefore it was decided to establish sub-networks enabling more detailed discussions with the aim to formulate recommendations or to develop “products” such as guides or handbooks for good ALARA practice.

Following a recommendation of the 8th EAN Workshop, the European Radiation Protection Authorities Network (ERPAN) was set up in 2006 to promote better communication between

national regulatory Authorities, particularly in issues on an operational level. The sub-network voluntarily limits its focus to the non-nuclear sector. ERPAN is comprised of participants with direct responsibility for the management of inspection programmes within regulatory Authorities. The participants meet once a year to exchange experience on some specific issues. Throughout the year, the participants use an email forum to discuss issues and survey regulatory positions across Europe and inspection witnessing exchanges between countries are organized.

The Commission has also supported the European ALARA Network for NORM (Naturally Occurring Radioactive Material) (www.ean-norm.net) for 2 years (2007/2008). It is co-ordinated by the IAF - Radioökologie GmbH in Dresden and currently supported by the Federal Office of Radiation Protection (BfS) in Germany. The objective of this network is to exchange information and promote good radiation protection practice for NORM industry managers.

Another proposal of the EAN, following a recommendation of the 6th EAN workshop, is the establishment of the European Medical ALARA Network (EMAN). This project started in November 2009 and is carried out by European radiation protection institutions together with EFOMP, ESR (European Society of Radiology) and EFRS, supported by the European Commission (DGTREN). EMAN aims to create a sustainable European Medical ALARA Network (EMAN) where different stakeholders within the medical sector have the opportunity to discuss and to exchange information on various topics relating to the implementation of the ALARA principle in the medical field.

The new challenges of EAN

The range of EAN activities has been gradually extended over the last 14 years from optimisation of occupational radiation protection in industry and research, to occupational radiation protection in medicine and in the NORM area, and further on to the optimisation of radiation protection of patients and the general public.

Table 3: strategic objectives of EAN for 2010-2015

Focus the work on challenging issues
<ul style="list-style-type: none"> - Organization of topical Workshops - Undertaking specific surveys - Production of EAN feedback documents and position papers - Establishment of working groups on challenging issues following initiatives from EAN Members or requests from external organizations
Promoting the recognition of EAN as an expert organization on ALARA issues on the international RP scene
<ul style="list-style-type: none"> - Dissemination of EAN documents at the international and national levels - Promotion of EAN through participation and presentations of the network to national and international seminars - Cooperation agreements with international and professional organizations and networks - Participation of EAN to international projects
Encourage the participation of key stakeholders to EAN
<ul style="list-style-type: none"> - Encourage the participation of various stakeholders to EAN activities (workshops, working groups, etc.) - Enlarge the EAN Membership

In 2007, ICRP published its new general recommendations (ICRP 103) in which the optimisation principle is now clearly emphasized for all types of exposure situations, below source-related dose constraints or reference levels. This evolution is very important, especially for emergency and existing exposure situations (e.g. radon and Naturally Occurring Radioactive Materials). Moreover, as the development of national policies for the management of existing exposures situations is increasing in many countries, there is a challenge during the forthcoming years for facilitating the practical implementation of ALARA in such situations.

In the medical sector, even if improvements have been noticed in recent years, there is still a need for the development of ALARA practices, in particular due to the development of new technologies and the constant increase of medical and occupational exposures, and because of a number of serious radiological incidents and accidents. This requires the dissemination of radiation protection and ALARA culture within the medical community.

Development in the medical sector, as well as the increased interest in the use of non-medical exposures (for example for security reasons) also raise the issue of the justification of exposures, which often cannot be disconnected from the optimisation process.

In the nuclear sector, the ageing of existing installations and a large-scale retirement of nuclear workers - including radiation protection specialists - requires a new focus on maintaining and expanding skills, through radiation protection and ALARA education and training. In parallel, new nuclear installations (nuclear power plants, nuclear waste disposal, research reactors, etc.) will be built in the near future. The designers then need advices from the radiation protection community on the way to implement the ALARA principle at the design stage.

In order to meet these future challenges, EAN has worked out a strategic plan on the objectives of the network including a detailed work programme for the next 5 years (2010-2015) on how to achieve these objectives (see Table 3). The focus of the work of EAN will be on sharing experience and promoting the practical implementation of ALARA in all exposure situations - planned, emergency and existing - with special emphasis on the definition, evolution and dissemination of ALARA culture.

EAN: a success story

In the last 14 years, the recommendations of the EAN Workshops have had considerable impact at the European (initiation new projects) and national levels (further development of national radiation protection regulations and provisions).

The activities of the European ALARA Network were also acknowledged at a number of international events organized by organizations such as IAEA and IRPA. EAN representatives joined the IAEA/ILO Action Plan Steering Group and take part in technical support and assistance granted to the foundation of new ALARA Networks in Central and East Europe (RECAN) and in the Asia Pacific Region (ARAN). EAN served as model for the setting up of RECAN and ARAN by the IAEA.

During the first few years, participation in the EAN activities was basically confined to radiation protection experts from regulatory Authorities, research institutions, and major companies. Other institutions have also been invited since 2001 and join the network activities on a regular basis today. In particular, these last years, cooperation agreements have been signed with other European professional associations concerned with radiation protection issues:

- In the medical sector, with:
 - EFOMP - the European Federation of Organizations for Medical Physics (EFOMP);
 - EFRS - the European Federation of Radiographer Societies.
- With the European Federation for Non-Destructive Testing (EFNDT).

Representatives of these organizations are invited to participate to the EAN meetings in the preparation of the EAN events. Mainly, these collaborations favour discussions between the professionals on the practical aspects of the ALARA approach.

Finally EAN provides a forum for discussions among stakeholders, who would have had little or no possibility of interaction otherwise. In such an environment, where no binding decisions have to be made discussions and exchange of opinions are more open, and it is rapidly realized that all efforts have in common one goal, i.e. the practical implementation of the ALARA principle, and it is therefore easier to agree on shared interests and collective recommendations.



Conclusions

Since its creation 14 years ago, the key factor of the success of the European ALARA Network has been the enthusiasm of all the participants and the support of their respective organizations in willing to share their experience with colleagues from other countries and to promote the ALARA principle from a practical point of view. Moreover the informal way of operation is also recognised by all the participants to the network as another important feature of its effectiveness.

The challenge is now to successfully cope with the extension of the ALARA principle to all exposure situations as recommended by ICRP in the nuclear and non-nuclear industry, in the medical sector and in exposure situations related to natural sources, with the focus on sharing experience on the practical implementation of the ALARA principle and disseminating the ALARA culture in all sectors where workers and the public are exposed to ionising radiation. ■

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“INFORMAL” LOCATIONS FOR CONSTRUCTION OF THE EUROPEAN AREA FOR NUCLEAR SAFETY AND RADIATION PROTECTION

The contribution of the industry sector to the construction of a European area of safety and radiation protection

by Dr Werner Zaiss, Director of institutional affairs, ENISS, Guy Parker and Muriel Glibert, Head of institutional affairs, FORATOM

FORATOM – The trade association for the nuclear energy industry in Europe

The European Atomic Forum (FORATOM) is the Brussels-based trade association for the nuclear energy industry in Europe. Its main purpose is to promote the use of nuclear energy in Europe by representing the interests of this important and multi-faceted industrial sector. FORATOM acts as the voice of the industry in energy policy discussions involving the European Union (EU) institutions and provides a “bridge” between the industry and the institutions (Members of the European Parliament and key policy-makers in the European Commission).

The membership of FORATOM is made up of 16 national nuclear associations. FORATOM also represents some of the continent’s largest industrial concerns. Nearly 800 firms are represented. Input from these associations and companies are gathered by FORATOM task forces. It is then channelled into discussions on EU energy issues with the European institutions.

FORATOM also delivers factual information and key messages on nuclear energy issues to the media and the public. In addition, FORATOM cooperates with international organizations and institutions, such as the United Nations’ International Atomic Energy Agency (IAEA) and the Organization for Economic Co-operation and Development’s (OECD) Nuclear Energy Agency (NEA). FORATOM networks with several other major nuclear associations around the world: the Canadian Nuclear Association (CNA), the Nuclear Energy Institute (NEI) in the US, the World Nuclear Association (WNA), the Japan Atomic Industrial Forum (JAIF), the World Association of Nuclear Operators (WANO) and the World Nuclear Transport Institute (WNTI).

Public acceptance of nuclear energy in the EU

The EU institutions have in recent years acknowledged nuclear energy as a key component of Europe’s energy mix. Nuclear energy is today recognised as a sustainable low-carbon technology, which has a role to play combating climate change, enhancing the EU’s competitiveness and ensuring a security of energy supply.

At the same time, the issue of public acceptance of nuclear power and safety have seen important and positive turns for the better. The 2010 Eurobarometer on Nuclear Safety confirms the overall positive evolution of public acceptance towards nuclear showing 56% of EU citizens want nuclear energy to be



FORATOM website, www.foratom.org

maintained or increased (up 8% on the results in the previous Eurobarometer on Nuclear Safety in 2007). The awareness of nuclear’s credentials has remained stable since 2007. The results of the survey show that 68% (-1 point) believe that using more nuclear energy would make Europe less dependent on fuel imports, 51% (+1 point) think that it helps ensure stable prices, and 46% that it contributes to the fight against global warming.

A majority of EU citizens (59%) are confident that nuclear power plants can be operated safely. In countries, which use nuclear energy to produce electricity, people generally believe in the safety of the nuclear power plants (HU= 80%, FI= 78%, SK= 77%, SE= 75%). Most citizens (51%) think that nuclear safety Authorities are capable of ensuring that nuclear power plants are safe. Nevertheless, people are quite divided on the capacity of nuclear operators to run the plants safely (47% trust nuclear companies, against 43% in 2007). If the waste issue was solved, a majority of EU citizens would be in favour of nuclear power (around 61%).

ENISS – The European Nuclear Installation Safety Standard Initiative

Safety is and will always remain the nuclear industry’s top priority. Nuclear installations in the EU have an exemplary



safety record which plant operators are committed to maintaining and improving as far as reasonably achievable. Nuclear power plants are operated under the strict control of national regulatory Authorities. These government agencies enforce state regulations that are mainly based on requirements, guidelines and conventions established by international organizations, such as the IAEA. The development of national safety requirements in EU Member States during the last couple of years was determined by the Safety Reference Levels that WENRA proposed in 2006 for existing nuclear plants, as well as for waste and decommissioning.

The European nuclear industry recognized that with the deregulation of the electricity market, diversity of national regulations could seriously distort competition. Therefore harmonizing regulatory practices is the best way of ensuring that the industry can evolve within a stable legal framework. In order to pool resources, European licensees launched mid 2005 European Nuclear Installation Safety Standard Initiative (ENISS) under the umbrella of FORATOM. The principal mission of ENISS is to bring together decision-makers, operators and specialists from the nuclear industry with national regulators in order to identify and possibly agree upon the scope and substance of harmonized safety standards. ENISS currently represents the nuclear utilities and operating companies from 16 European countries with nuclear power programme.

The ENISS Objectives can be summarized as follows:

- to establish a common licensees' view with respect to the "WENRA RLs" and to present the industry position in discussions with WENRA in a proactive way;
- to support an exchange of information about the interaction of license holders with their national regulators, in order to achieve a harmonized set of new regulations;
- to create an information platform for the European nuclear license holders with respect to new national and international regulatory activities;
- to strengthen the participation of the industry in the revision work of the IAEA Safety Standards;
- to discuss with the European Institutions on regulatory issues in the area of nuclear safety, radiation protection, waste management and decommissioning;
- to collaborate with international associations dealing with regulatory issues.

ENISS first task was to establish a common industry position with regards to the safety reference levels that WENRA proposed in 2006 for existing nuclear plants, as well as for waste and decommissioning. ENISS sees WENRA's action as an important step towards finalising, in close collaboration with the nuclear industry, a blueprint for delivering and implementing improved safety standards. It is also consistent with the industry's improved safety culture. ENISS carried out a thorough analysis of WENRA harmonization reports and made official comments on all three reports at the end of May 2006. ENISS considers that the last version issued by WENRA in January 2008 of the reference levels applicable to reactor

safety represents a decent and delicate equilibrium between the regulator's and industry's positions, with which most NPP operators in Europe could live with.

Following the publication by WENRA in January 2010 of a pilot study on "Safety Objectives for New Power Reactors", a specific organization has been set up to analyse the report and put forward comments which were submitted to WENRA at the end of June 2010. This organization includes ENISS and the EUR group. A cooperation agreement between ENISS and EUR was approved in September 2008 according to which both parties will co-ordinate their positions and actions and co-operate in their relations with WENRA regarding requirements for new reactors. The EUR (European Utility Requirements) organization has been working on the development of harmonized utility requirements (safety and performances) for the European Gen 3 LWR stations since 1991. Started with five partners, the organization today includes the 19 major European utilities, or group of ones, planning to invest and operate in new build.

The main objective, since the inception of the works, has been to level a uniform playing ground on which the vendors could develop standard products that could be used by all the participants with no or only minor design changes. For that two main directions of work have been defined: a generic specification and evaluations of compliance of the designs offered in Europe vs. this

specification. Since the beginning of the 2000's the EUR works have been focused on the evaluations of the designs: As of today seven designs have been evaluated by the EUR utilities in close cooperation with the interested vendors. This has requested a substantial investment by all parties but today the designs that have successfully passed the evaluation process can be legitimately shortlisted by the utilities that open a consultation for new build.

The organization is preparing a revision D of the generic specification, based upon the feedback accumulated in its own activities since 2001 and taking into account the evolution of the regulatory background in Europe as well as at global level. More, some new reactors assessments are likely to be done in the near future. For that, strong relations have been tied with the other international organizations that may impact the designs of the future Gen 3 LWR plants, such as WENRA, IAEA, ENISS and WNA. The objective is to contribute to make the major stakeholders agree on common positions reasonable for industry and regulators.

Another task of ENISS is to strengthen the industry influence in the revision work of the IAEA Safety Standards. In February 2007, the IAEA and ENISS launched their cooperation agreement. ENISS as an NGO is actively involved in the IAEA safety standards revision process in providing comments on draft safety standards and feedback on the experience gained from applying the IAEA safety standards, in particular as regards those where the industry has particular competence or interest. Those areas are NPP design and operation, management systems, assessment and verification, waste



management/treatment, decommissioning and radiation protection with respect to nuclear safety. ENISS send also experts to participate in the IAEA drafting groups and attend the meetings of the IAEA Safety Standards Committees (NUSSC, WASSC, and RASSC) as an observer.

At the European level, ENISS is also monitoring the work of the European Commission on regulatory issues in the area of nuclear safety, waste management, decommissioning and radiation protection.

EU Initiatives – European Nuclear Energy Forum

Support for discussion and debate on nuclear energy has been supported over the past few years by the European Union through the establishment of, for example the European Nuclear Safety Regulators Group (ENSREG) whose role is to help to establish the conditions for continuous improvement and to reach a common understanding in the areas of nuclear safety and radioactive waste management.

Along with the establishment of ENSREG in 2007, the European Commission announced that the Czech Republic and Slovakia would co-host the European Nuclear Energy Forum (ENEF). The announcement in the conclusions of the Spring Council “suggest[ed] that broad discussion takes place among all relevant stakeholders on the opportunities and risks of nuclear energy.” confirmed the growing recognition of the important role nuclear plays in the EU’s energy mix and that a Forum was needed in order to help develop a roadmap for the future of nuclear energy in Europe.

ENEF was established in order to provide a platform for open debate “without any taboo” between the nuclear industry, European institutions, EU Member States, financial institutions, trade associations, civil society and other actors. Ultimately, ENEF is a progression of the overall European energy debate with the EU sending a clear message that nuclear plays a vital role now and in the future of the EU’s electricity supply.

The Forum has a number of Working Groups (opportunities, risks, transparency) aiming to provide advice and guidance to the EC. Under the Working Groups are Sub-Working Groups covering among others issues from nuclear safety, waste management, legal issues, education and training, competitiveness, financing.

FORATOM and ENISS have been a keen supporter and participant of the ENEF process and in particular has been involved on the issue of nuclear safety which is tackled under the ‘Risks’ Working Group inside the Forum. The group undertook in January 2008 an investigation into nuclear safety harmonization in the EU and prepared a document entitled *Considerations on a potential EU Directive based on Common Fundamental Safety Principles for Nuclear Installations*. The paper recommended that an EU Directive regarding safety of nuclear installations should be based on common Fundamental Safety Principles. This paper was adopted as formal input from ENEF on the draft proposal from the European Commission on a Community Framework for Nuclear Safety.

In March 2009, the “Risks” Working Group mandated its Sub-Working Group “Nuclear Installation Safety” to consider possible criteria and safety objectives for long-term operation of NPPs, including the risk-informed approach. The SWG developed a paper entitled: *Considerations on harmonized conditions for safe long-term operation of Nuclear Power Plants in the EU*. The SWG will now prepare a detailed proposal for an EC Recommendation on conditions for long-term operation.

The “Risks” Working Group established also a Sub-Working Group Waste to develop a roadmap to successful implementation of geological disposal in the EU. The Roadmap, adopted by the Working Group Risks in October 2009, presents the basic elements that Member States should consider when developing a national waste management programme, especially for geological disposal of high-level waste.

In the context of the upcoming publication of a possible EU legal instrument for spent fuel and radioactive waste management, the ENEF Sub-Group Waste decided to participate to the stakeholders’ consultation process launched by the European Commission on 31st March 2010. The Sub-WG put forward in a position paper the principles which support the idea that the EU needs to develop a common legislative framework governing the management of spent fuel and radioactive waste. The position paper defines, namely, the scope of the possible legally binding instrument as well as the essential elements to be developed in such an instrument. It also tackles what is required to be included in the EU’s national programs for the management of spent fuel and radioactive waste, and it finally gives support to the fact that deep geological disposal is recognised as the only proven, practical solution for the disposal of high level waste and spent fuel.

Radiation Protection – Revision of the EU Directive

The European Commission decided in 2006 to revise its basic safety standards on radiation protection to reflect the new recommendations of the International Commission on Radiological Protection (ICRP) and to strengthen the Community legislation. In total 5 acts on radioprotection will be recast into a single Commission act. Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation will be revised taking into account operational experience, new scientific evidence and consolidating the existing knowledge. It is expected that the new text will be adopted by the Commission by early 2011.

The EC is working with the Euratom Article 31 Committee to draft the revised text. The Group of Experts referred to in Article 31 of the Euratom Treaty adopted at its February 2010 meeting its final version of the revised BSS Directive. The Expert group opinion was sent to the European Commission for consideration. The Group of Expert’s revised draft has been posted on DG Energy’s website. ENISS and FORATOM as stakeholders have been invited to submit comments on the Group of Experts’ revised draft.

Nuclear safety - A challenge to harmonise safety practices

Nuclear safety of NPPs aims to protect people and the environment against the harmful effects of ionising radiation. To this effect, all practical efforts must be made by the licensee to operate the plant under normal conditions to avoid transients, to prevent nuclear or radiological accidents from occurring and to mitigate any consequences of such events. “Defence-in-depth” has been identified as the main concept here, involving a combination of a number of consecutive and independent levels of protection which ensure that no single technical, human or organizational failure could lead to harmful effects, and that combinations of failures that could give rise to significant harmful effects are of very low probability.

From an organizational point of view, a strong management commitment to safety is required, accompanied by the



implementation of a reliable management system and a strong safety culture. While the prime responsibility for nuclear safety rests with the license holder, the implementation has to be verified and enforced by an effective regulatory framework for nuclear safety.

Therefore nuclear safety is far more than just a technical challenge: Nuclear Safety is the integration of human, technical, organizational and regulatory issues. Resulting from this consideration the harmonization of safety requirements and practices and their implementation should cover all of these issues and be applicable not only to nuclear power plants but to all nuclear installations in all stages (siting, licensing, construction, operation and decommissioning). Due to the process of implementation, the harmonization of safety requirements can be considered as a tool for safety improvement.

The European Nuclear Industry considers that the existing arrangements for ensuring nuclear safety in the EU under the guidance of international nuclear organizations, conventions and under the control of the national safety Authorities have delivered excellent safety records. However, the industry has a role to play in the further harmonization processes and is therefore willing to contribute to the dialogue with all possible stakeholders. ■

BILATERAL ACTIONS

Safety on the ground: the Franco-German cooperation

by **Walter Glöckle**, Head of the Nuclear Safety department of the Ministry of the Environment of Baden-Württemberg, member of the GT1 of the DFK. Germany



Philippsburg nuclear power plant, Germany

The Franco-German Commission on nuclear installation safety issues (DFK) combines the traditional with the modern. Established at the time of the construction of the Fessenheim nuclear power plant, it has nearly four decades of experience dealing with issues of nuclear safety, emergency situations and radiation protection in nuclear power plants located near the border between France and Germany.

The exchange of information that takes place within the framework of the DFK is highly beneficial in terms of keeping national nuclear safety Authorities, as well as the general public, informed. This interchange also serves to identify avenues and suggestions for improvement in national practices, which can lead to a review and an harmonization of regulations.

The DFK functioning

The DFK was established in 1976 under an agreement signed between France's Ministry of Industry and Research and West Germany's federal Ministry of the Interior. The creation of this commission formed an institutional framework for bilateral contacts that had been in existence between the Authorities of the two countries since 1972. The members of the committee are, for Germany: the federal Ministry of the Environment, Protection of Nature and Reactor Nuclear Safety; the Authorities charged with the enforcement of the Atomic Energy Act, and the civil protection services of the states (*Länder*) of Baden-Württemberg, Rhineland-Palatinate and Saarland. For France, commission members are the nuclear safety Authority (ASN) and representatives of the ministries of the Interior, Industry, the Environment, and of the *préfectures*. For specific issues and technical matters, the DFK calls on the experts of the relevant Authorities.

The exchange of information is centred mainly on the French nuclear power plants of Fessenheim and Cattenom located

near the Franco-German border, and the corresponding German plants of Neckarwestheim 1 and Philippsburg 2. The DFK specifically addresses matters relating to incidents which occur in these plants, and to safety-related technical modifications made to the installations. DFK's scope also includes a sharing of data on the monitoring of releases, and discussions of planned measures for dealing with emergency situations.

To allow in-depth study of certain topics, the commission has set up the following working groups (GTs), which operate within the framework of mandates issued by the DFK:

"Safety of pressurised water reactors" (GT1)

covering safety issues related to nuclear installations and equipment

"Emergency situations" (GT2)

covering issues related to planning for emergency situations and international communication

"Radiation protection at Basic Nuclear Installations" (GT3)

covering radiation protection and environmental issues related to nuclear installations

"Radiation protection in small-scale nuclear facilities" (GT4)

covering radiation protection and environmental issues related to nuclear installations other than Basic Nuclear Installations (medicine, research and industry).

The DFK meets once a year for about two days. It gives mandated the working groups and approves their outcomes. The main results of the DFK work and its working groups are sometimes written up in reports and published when appropriate.

GT1 was formerly the DFK core, and the DFK can be said to owe its existence to this working group in some respects. GT1 generally meets once per year, alternating between France and Germany. Speakers address the group in their native language, with interpreters providing simultaneous interpretation.

GT1 works in many areas and much of its work has been written up in technical reports. Some of GT1's key results are presented hereafter.

Comparing the safety levels of nuclear power plants

The value of maintaining Franco-German ties became apparent during the construction of the Fessenheim nuclear power plant located just at the border between the two countries. From the first contacts initiated in 1972, France and Germany wanted to compare safety levels in the French nuclear power plant at Fessenheim and the German plant Neckarwestheim 1. Neckarwestheim 1 was selected as the benchmark facility



because it is also a pressurised water reactor built at approximately the same time as Fessenheim. The aim of the DFK report was to check whether the people living near the Fessenheim nuclear power plant on the one hand and the Neckarwestheim plant on the other had comparable protection against radiological risks. The comparison established by the DFK in 1977 covered not only site selection but also the design and engineering of the installation. The conclusions of this report (*"Comparison of safety levels at the Fessenheim and Neckarwestheim nuclear power plants"*) concludes that *"the safety requirements imposed upon the two plants are comparable but some of the technical solutions for resolving problems are different"* and that *"the population is protected against risk at both nuclear power plants."*

Based on the lessons learned from operating each of these installations, as well as other nuclear reactors, and drawing on technical and scientific advances that have been achieved, modifications and optimisations were made at both of the reference nuclear installations after their construction. The accidents at Three Mile Island (Harrisburg, Pennsylvania) and Chernobyl (Kiev Province, Ukraine) also led to further technical improvements. The changes made to the two reference nuclear plants were discussed in another DFK report dated 1992 (*"Comparison of safety levels pursuant to the changes made to the Fessenheim and Neckarwestheim I nuclear power plants"*). This report supplements and in a sense updates the initial comparison made in 1977, arriving at the following conclusion: *"To sum up, it may be observed that in each of the two nuclear power plants, a large number of changes and installations of additional equipment designed to improve safety have been carried out. Accordingly, the design and condition of the plants have been improved in a targeted manner such that today, the two nuclear power plants show clearly higher and also comparable levels of safety, adapted to the current state of knowledge."*

In still another report dated 2001 (*"New evaluation of the safety of the reference installations of Fessenheim and Neckarwestheim I"*), the DFK compared the methodology and results of the second ten-year inspection of Fessenheim with the periodic safety audit performed at Neckarwestheim I. The report concludes *"that the two installations of Fessenheim and Neckarwestheim I show a high and comparable level of safety, adapted to the current state of knowledge."*

The DFK also carried out similar comparisons between the reference nuclear power plants of Cattenom and Philippsburg 2, which are equipped with 1300-MW reactors with four loops.

Sharing of relevant information for safety

In addition to these comparisons of safety levels at the reference power plants, GT1 regularly investigates incidents that have occurred at the Fessenheim, Neckarwestheim 1, Cattenom and Philippsburg 2 nuclear power plants. The scope of dialogue includes significant safety-related incidents that have occurred in the facilities, as well as the technical modifications made to the plants and the results of the safety inspections and evaluations performed. Additionally, GT1 studies current topics which are important for safety, such as: the management of aging, measures to prevent sump pump clogging by insulation material; consideration of seismic hazard; anomalies detected in steam generators; safety management systems and organizational and human factors.

Within the framework of GT1, reciprocal inspections between the French nuclear safety Authority ASN and its German

counterpart are also arranged. An average of four cross inspections are carried out each year, two in French nuclear power plants, and two in German plants. These inspections are an opportunity to learn about the inspection practices of the neighbouring country and those who take part in them find them particularly constructive.

Comparison of reporting criteria

Exchanging information about incidents that occur in the reference power plants is part of GT1's remit. During this interchange, it became apparent that French nuclear power plants tended to report more incidents than their German counterparts. To understand the reasons for this, the DFK in 2007 asked GT1 to compare the reporting criteria applicable in each country.

GT1 therefore compared French and German reporting regulations and criteria. The working group also examined a series of significant incidents to determine whether each one would have been reported in the other country.

The findings of this study show that although nuclear operators are held to report all significant incidents occurring in their installation to the nuclear safety Authorities, the criteria for this reporting differ between France and Germany. The differences lie in the structure and formulation of the reporting. German criteria are numerous, formulated in very concrete terms and broken down into categories which are associated with different reporting deadlines. French criteria are succinct and formulated in general terms. Germany has 50 reporting criteria versus 10 in France.

The German reporting criteria are strongly focused on equipment-related failures and incidents, whereas the French criteria are geared more towards the consequences of an incident and on the failure to comply with technical operating specifications. In France, moreover, the mere fact that an incident could have resulted in damage is sufficient to make it reportable.

Due to these differences in the approach to the reporting criteria, some incidents must be reported in one country but not the other.

The detailed statistical study performed in this report reveals an average of eleven incidents reported per year and per reactor in France versus about six per year and per reactor in Germany. Of all these incidents, there are only three or four per year and per reactor that are reported in an identical way in the two countries. The other incidents reported are specific to each of the countries concerned.

The higher number of incidents reported by French nuclear power plants can thus be explained by the fact that many of them pertain to anomalies that are not reportable in Germany.

Operational safety at the Fessenheim and Neckarwestheim nuclear power plants

Earlier comparisons between the Fessenheim and Neckarwestheim power plants focused mainly on the technical condition of the installations. However, the safety of a nuclear power plant is also contingent upon the way in which it is operated. Bearing this in mind, the DFK decided to produce a new report comparing the operating methods of the two reference power plants. The assignments carried out by the OSART (Operational Safety Review Team) at Neckarwestheim I in 2007 and at Fessenheim in 2009, afforded an opportunity to make this comparison.



Delegation from the German and French nuclear safety Authorities visiting AREVA in Chalon Saint-Marcel – October 2008

OSART missions are carried out by the International Atomic Energy Agency (IAEA). In the course of these assignments, broad scope, in-depth and systematic inspections of the manner in which the installation is run are performed. These assignments are thus particularly well-suited for identifying areas for improvement. The results of OSART assignments were supplemented with information and evaluations by the national nuclear safety Authorities.

The DFK report was approved in June 2010. It is public and may be consulted on the websites of the ASN and the Ministry of Environment of Baden-Württemberg.

The analysis performed in the areas of Organization, Training and Certification, Operational Management and Feedback offers grounds for judging the way in which the two plants are operated. There appear to be great similarities in the means for organizing and guaranteeing operational safety in the two plants. In addition to the management organization, which sets clear targets and clarifies safety-related responsibilities, there is an independent organization that monitors plant safety. The introduction of a process-oriented integrated management system has made it possible to analyse and optimise processes and incorporate them into an overall continual improvement process. The personnel is trained through a tried and tested training program which notably includes simulator exercises. The workplace attitudes and behaviours that underwrite safety are encouraged through human performance programmes. There are detailed operating procedures governing the running of the reactor and the tasks of the various shift teams. These rules define the limit values and technical operating specifications. Compliance with these specifications is monitored intensively. Feedback, lessons learned and operating experience from the plant, as well as from other nuclear power plants, are systematically analysed and evaluated to improve the running of the installation. On the

whole, the systems and procedures in place in the two reference plants, coupled with familiarity with international requirements and practices, result in great similarities in the way the two plants are run.

Despite differences in the details, comparable procedures may be observed to be implemented with the two nuclear power plants presenting a satisfactory level of safety regarding international practices in the field of operational safety.

What role should the DFK play in 2010?

The general public is still relatively unfamiliar with the technical aspects and operation of nuclear power plants. The population has trouble judging operating incidents and accidents that occur at plants. This explains why such incidents often prompt a disproportionate level of concern in neighbouring communities. When plants are located near the border, this feeling is underscored by the fact that inspections are performed by a foreign nuclear safety authority. Furthermore, the language barrier makes it more difficult to communicate and ensure the transparency needed to nurture public confidence.

This is why the bilateral exchanges within the framework of the DFK are so valuable. First of all, they are an opportunity for sharing specialized technical data. Knowledge of technical systems and analyses of incidents help to determine what actions and knowledge are needed to improve the safety level of nuclear installations in both countries.

This dialogue also promotes better understanding between the nuclear safety Authorities and gives them confidence in the control they exercise. Discussions within the framework of the DFK also provide knowledge of the laws, regulations and practices of the partner country. In this way, each country can compare its practices and improve them where necessary. In other words, the dialogue contributes to increasing



convergence between French and German practices. This harmonization is particularly necessary in the area of emergency situation management. For example, the bilateral exchanges in connection with the DFK working group GT2 served to harmonise the iodine dosage and the intervention level for iodine administration in France and Germany.

Finally, this interchange is useful to nuclear safety Authorities for their task of keeping the public informed. Technical data on the installations, the comparison of reporting criteria and knowledge of inspection practices in both countries are of great value when ASN (in France) briefs the *Commission Locale d'Information (CLI* - Local Information Committees) or when the German Authorities answer questions from citizens, local officials and elected representatives.

Personal contacts between authority's personnel and the commitment of all participants are needed to work constructively together. The work and the success of the DFK therefore depend, above all, on the participants. However, without a formal and organized framework, such contacts and bilateral exchanges would be difficult to establish and maintain. The DFK offers just such a framework. Its role is just as necessary today as it was forty years ago. In fact, if the DFK did not exist today, it would have to be created. ■

BILATERAL ACTIONS

Cross-inspections between Nuclear Safety Spanish and French Authorities

by Anne-Cécile Rigail, Bordeaux Regional Head — French Nuclear Safety Authority (ASN)

ASN is an institution which aims to optimise consistency between its head office and its regional divisions, and it was together with the Director General, the International Relation department, and all the functional departments of ASN that the Bordeaux division was tasked with maintaining close operational ties with the Consejo de Seguridad Nuclear (CSN), the Spanish nuclear safety regulator.

The CSN is run by a 5 commissioner board, chaired by Mrs Carmen Martinez Ten. They are appointed by the government for 6 years, after consultation of the industry commission and the chamber of deputies.

The CSN regulates all nuclear and radiation protection activities in the same way as ASN, and its duties were extended by the Act of 7/8 November 2007, which accords greater importance to participation by the public and to transparency. In the same way as ASN, the CSN clearly states its aspirations and ambitions with regard to competence, rigour, independence and transparency.

The Spanish and French cultures concerning the decentralisation of regulatory activities are also reflected in the regional organization.

In its head offices, the CSN has agents who are both experts and inspectors. In the regions, for some small-scale nuclear activities, it relies on delegated inspectors belonging to the Autonomous Communities (equivalent to the regions in France). Each nuclear power plant also has one or two resident inspectors.

The last meeting of the bilateral ASN-CSN steering committee was held in November 2009 in Madrid, in the presence of the ASN and CSN Chairs. Following this meeting, new cooperative agreements were signed by the two safety regulators. At present, two long-term staff exchanges are in progress, one concerning an ASN agent seconded to CSN for three years, with a reciprocal arrangement involving a CSN agent seconded to ASN for a similar period.

Other exchanges take place with ASN's Spanish counterpart. More frequently they take the form of "cross" inspections.

Exchanges as a tool for European cooperation

The Bordeaux division's particular role with respect to the CSN is geographically logical, as the division is to a large extent on the border with Spain. The Bordeaux division is also primarily where the cross inspections take place, as part of the broader bilateral relations between the Chairs and the general directorates of the two institutions.

Relations between the Bordeaux division and the CSN are a good example of the safety regulators' commitment to building a harmonized vision of nuclear safety and radiation protection,



ASN inspectors visiting the CSN – May 2010

even though there is no pressing reason forcing the two bodies to cooperate: the nuclear power plants of the two countries are at a respectable distance from the border.

It is therefore an awareness of the need to share practices and exchange views with our counterparts that was the driving force behind this move.

The rate at which these contacts and field exchanges take place therefore varies, ranging from one to four cross inspections per year, with a good balance between France and Spain on the one hand and between nuclear safety and radiation protection on the other.

Mutual discovery and surprise

The cross inspections are first and foremost a source of discovery "in the field". The regulations and standards applied, the licensees inspected, their structures, their tools



and their procedures, can open minds to new ideas and new possibilities.

During the course of the May 2010 mission to Spain, to look at the topics of nuclear medicine and gamma radiography, the Bordeaux inspectors wanted to inspect a Spanish gamma radiography company which had recently opened an office in the South-West of France.

What was apparently a small gamma radiography office in the Bordeaux region, finally turned out to be the French bridgehead for a company which in Spain carries out nuclear activities on a scale unprecedented in this country: gamma radiography, industrial X-ray applications on-site and in bunkers, bunker particle accelerator, source distribution and gamma radiography device maintenance, an organization approved for medical quality controls, internal radiation protection inspections and external passive dosimetry monitoring.

On the topic of nuclear medicine, the inspectors exchanged information on the methods for managing radioactive effluents leaving medical wards treating patients with iodine 131. A recent ICRP 94 recommendation indicates that storage of urine in tanks to allow radioactive decay is not necessarily a guarantee of better health safety downstream of the establishment's main sewer and recommends dilution of the radioactive effluent. Whereas Spain follows this recommendation, France has a tendency to adopt a "stricter" position than that recommended by IAEA.

For his part, when the CSN inspector came to inspect the Civaux nuclear power plant, specifically with regard to the topic of reactor operation in accidental conditions, he was extremely interested in the N4 reactor series control room, a French technology based on digital I&C, allowing a degree of flexibility in alarm ergonomics. He was so astonished to hear the particular sounds for certain alarms and the audio interface of the accident operation system that the inspector exclaimed: "a control room which plays music and talks, now that's really something!"

Inspections and exchanges on regulatory practices are also a means of discussing and discovering safety regulator organizational procedures and the tools to be implemented to ensure a high level of nuclear safety and radiation protection.

The CSN information system, for example, was identified by all the French inspectors as offering a very high level of performance. It collates all the information concerning a facility: list of sources and generators of ionising radiation, personnel training and qualifications, organization of personnel with competence for radiation protection, dosimetry readings of all staff, authorisation and inspection dossiers. Its ergonomics makes for easy consultation.

With regard to transparency and information of the public, both the CSN and ASN have adopted a policy of full publication of their follow-up letters on their websites. The format adopted by CSN is however more administrative and comparable to an official report. This system is also clearly a two-way street and the party inspected is free to submit comments and remarks and to correct any inaccuracies. The final document released to the public comprises the letter, the licensee's response and the CSN's conclusion concerning each of the licensee's comments.

In the field of nuclear safety, inspection practices in Spain are also heavily influenced by the practices adopted by the NRC in the United States. Depending on equipment unavailability, probabilistic safety analysis are therefore used to provide a



CSN and ASN inspectors conducting a joint inspection in Bordeaux

permanent display of the "calculated" level of safety of the reactor. This continuous rating of reactor safety is available on-line.

The CSN inspectors were impressed by the speed with which an ASN division was able to examine the application and then issue licenses for a small-scale nuclear activity.

To illustrate certain differences in the working organization within each Regulator, it must be pointed out that examination of the small-scale nuclear application files and inspection of the licensed facilities are carried out by separate teams at CSN. This has consequences on the internal working procedures of the institution, but also on the relationship between the inspectors and inspected parties.

Finally, in terms of personnel management, the inspectors are happy to discuss their status, the management of human resources within the two institutions, training, career development possibilities, expertise promotion and, on a particularly pragmatic level, the financial arrangements for the missions. Everyone can therefore dream of the grass, which is necessarily greener, on the other side of the Pyrenees and submit improvement suggestions to their parent organizations.

Reasons for the quality of these exchanges

Based on the experience and exchanges of the past two years, I believe that the following are the main factors behind the success and quality of the exchanges and we should continue to focus on them:

- **preparation for the exchanges:** having targeted the subject of the inspection, discuss it with the national divisions concerned, collect questions to ask the foreign counterparts, and prepare the logistics to ensure that the mission runs smoothly;
- **experienced inspectors:** sending inspectors with experience on their fields enables them to ask pertinent questions of use for their Regulator. During the course of technical discussions and inspections they will be more effectively able to detect any points of interest and any differences with their own baseline and practices;
- **time spent on-site:** it is worth scheduling several days on-site for one day of inspection. The day of preparation is devoted to good use in welcoming the team, conducting institutional exchanges and preparing technically for the inspection. After the inspection, at least a half-day is needed so that the foreign inspectors can ask questions resulting from the cross inspection and so that both parties can summarise this experience;

– **unavoidable reminders:** as the participating inspectors taking part change for each mission, it is important for the technical meetings to be introduced by a brief institutional round-up of the two Regulators and how they operate. This enables more pertinent questions to be asked subsequently;

– **the quality of the welcome:** the entity management make themselves available to welcome the new arrivals and carry out the above-mentioned institutional round-ups. They handle the material and logistical details so that the guests enjoy their stay. Moreover, each member of the welcoming entity must maintain his or her usual level of politeness, friendliness and tact ...

– **reporting:** writing an official report is a means of informing the head offices of the lessons learned from this exchange. Since 2010, we have been asking our Spanish counterparts for their report on the surprise they felt when they visited France. When we go to Spain, we draft a more detailed report on good practices. Some of these can also be written up in progress sheets and thus be incorporated into ASN's continuous progress process.

The importance of the individual commitment by the participants cannot be over-emphasised. Because we do not have any media pressure, it is important that these contacts be frequent and courteous if the exchange process is to stay alive.

In this respect, our correspondent at CSN is extremely proactive and friendly. She accepts with extremely good grace the fact that because of the higher staff turnover at our institution, the person in charge of international relations in the Bordeaux division changes regularly.

Conclusion

The relations created and maintained by the ASN Bordeaux division and the CSN allow the bilateral arrangements developed between the two institutions to be carried out in an operational yet friendly atmosphere.

The cross-inspections are a source of greater mutual understanding and enable us to regularly question our own practices and draw inspiration elsewhere to change the regulations, standards, inspection practices and tools on both sides of the Pyrenees.

These relations are an essential tool in the gradual harmonization of nuclear safety and radiation protection requirements. They are based on the commitment and will of the inspectors in both countries and must be accorded the value they deserve within each institution so that they can carry on and continue to bear fruit. ■



BILATERAL ACTIONS

Contrasting views or staff exchanges between ASN and its foreign counterparts

International mobility nurtures the close relations that ASN wishes to maintain with its foreign counterparts or with international bodies such as IAEA or NEA. This approach encourages the sharing of experiences and helps especially to construct a European safety and radiological protection area. Everyone gets something out of it. On the one hand, ASN enhances its inspectors' skills by letting them acquire new experiences and in return take advantage of good practices applied by its foreign counterparts; on the other hand, the inspector can widen or acquire new knowledge and develop an ability to adapt to a new cultural and professional environment.

The experience shared by ASN and its counterparts for nearly ten years shows that inspector exchange programmes are a major factor in stimulating bilateral relations between the nuclear safety and radiological protection Authorities. We wanted to understand the motivation of ex-pat inspectors - be they ASN inspector working abroad or, conversely, foreign inspectors immersing themselves in the ASN universe.

Contrôle thus sought the views of Jérôme Bai¹, an ASN inspector seconded to the Nuclear Directorate (ND), a unit in the Health and Safety Executive (HSE), Olivier Lareynie², also an ASN inspector working at CSN (Consejo de seguridad nuclear), Carmen Rodriguez-Mate³, ASN inspector the Spanish Safety Authority (CSN) seconded to ASN's Nuclear Power Plant Division (*Direction des Centrales Nucléaires* - DCN) and Victor Hall⁴, Operations Engineer with the American Nuclear Safety Authority (NRC), seconded to ASN project manager. They describe their assignments to us and how they view the practices of their hosts. All four agree that this international mobility is a way of exchanging knowledge and improving individuals.

Contrôle: Why did you decide to go and work in a European Authority for several years?

Jérôme Bai: I had been working for just over five years in one of the ASN Regional Divisions as an inspector of electricity-generating nuclear reactors when the opportunity arose for secondment to our British counterpart, the Nuclear Directorate.

This long-term exchange was also bound to success: I was the third in a line of inspectors seconded to this country and the system was running smoothly! The United Kingdom is also a major nuclear power currently undergoing fresh impetus in this industry. This positive context rendered the exchange even more attractive!

I was not limited to a particular type of post, one advantage of my profile of general nuclear engineer. ASN and ND outlined my assignments jointly: the outcome was an inspection role in the Thorp spent fuel reprocessing plant at Sellafield. This role within the inspection unit on the Sellafield site was complemented by assignments which I view as inherent for anyone on secondment: raising topics of interest for both countries, facilitating exchanges and organizing joint visits/inspections, reporting on the good practices noted to your own organization and suggesting ideas to the host country and lastly answering questions from each country on the practices of its counterpart.

Olivier Lareynie: as for me, I had always planned to spend time abroad professionally at one time or another in my career. I had a multitude of goals: exploring another culture, other ways of seeing things and coping with problems, acquiring other points of reference and working in a foreign language. Some of my duties at ASN had already had an international flavour (participating in IAEA working groups for example) and had given me a foretaste of what could be a longer experience abroad. I therefore did not hesitate when ASN offered me the chance to work for the Spanish Safety Authority (CSN) for three years.

Carmen Rodriguez-Mate: why did I elect to come to France? France is the European country with the most nuclear power plants, second only worldwide to the United States, and it is very important to understand how the safety Authority in this country operates. In addition, the fact that ASN oversees the construction of the EPR reactor at Flamanville was a unique opportunity for me to be able to observe the regulatory



1. Jérôme Bai, seconded to the British Safety Authority (HSE) for four years.
2. Olivier Lareynie, seconded to the Spanish Safety Authority (CSN) for three years.
3. Carmen Rodriguez-Mate, seconded to ASN for three years.
4. Victor Hall, seconded to ASN for one year.

practices of overseeing the construction of a nuclear power plant. I believe this to be a unique opportunity, that would not have presented itself to me in Spain in the near future.

Victor Hall: this one-year exchange is part of the Multinational Design Evaluation Programme (MDEP) which aims to make the design review of new reactors more effective and bring nuclear inspection practices closer together. Ten countries are involved in MDEP, including three from Europe - France, Finland and the United Kingdom. The aim of my exchange was to help maintain the very extensive cooperation between the nuclear Authorities. Harmonizing practices and international standards to oversee service providers is difficult to achieve. Nevertheless, this step has already given rise to joint inspections between countries contributing to MDEP. Harmonization efforts are essential for NRC, which is currently studying the design of the EPR reactor. NRC is at the same time reviewing several licence applications for the construction and operation of EPR reactors in the United States. France and Finland are the pioneers in the nuclear renaissance with the construction of the EPR on the Flamanville site. Sharing experiences from these countries serves to improve the safety of all. The aim being to ensure a higher level of safety thanks to diverse and varied experiences whilst optimising the use of safety Authority resources.

Contrôle: Has your assignment, turned out as you imagined it would? Has it taken much time to adapt, have the host departments included you fully in their activity?

Jérôme Bai: after an induction phase, when I was allocated a tutor, and my grasp of the language had improved, I was quickly considered trustworthy and allocated interesting topics and assignments. I also had some flexibility to explore the various facets of ND. The British inspectors were overall open and curious about me, as were the plant operators encountered. My initial inspection and technical assessment assignments with the Thorp inspector gradually widened to more cross-cutting topics as improving ND inspection practices or the global spent fuel management strategy. I also found myself taking part in assignments on other sites, both at my own request to explore new facilities and at the request of British inspectors who wished to benefit from an outsider's view (as was the case for a unit outage in the only British PWR reactor). I now appear in the ND organizational chart - an indication, perhaps, of successful integration!

Olivier Lareynie: my integration in the CSN activities was a gradual process. Initially - as is often the case when moving jobs, but more especially when seconded abroad - I spent my time exploring how the CSN operated (in-house operation, regulatory context, visits to facilities, etc.). My tasks were then defined based on the skills acquired through my job at ASN and the requirements of my host department.

Carmen Rodriguez-Mate: my first assignment was an exchange limited to a few months with ASN on the theme of extended power plant operation, which is also a topical subject in Spain. In July 2009, CSN had to issue its technical opinion on the continued operation of the Santa Maria de Garoña nuclear power plant beyond forty years. In France, after the meeting of the nuclear reactor standing group of experts, ASN was going to take a stand on the generic aspects of the safety re-assessment under the third ten-yearly inspections of 900 MWe reactors.

In this context and given the joint interest of the two Authorities to exchange views on their regulatory practices, I was invited to join the working group with the task of defining the practical

arrangements of the ASN position on the 900 MWe nuclear reactors continuing to operate for up to forty years.

Given my welcome, the work atmosphere and the professional interest, I requested that my assignment be extended longer (three years). Having received the agreement of ASN and CSN, I was able to dedicate myself thoroughly to more operational assignments. ASN therefore entrusted me with the responsibility of dealing with themes like qualification and maintenance with the same duties and responsibility of any project manager within DCN.

Victor Hall: the transition was very similar to changing jobs in NRC. The first step inherent to the post of inspector was to understand the regulations fully and apply them on a daily basis. I was trained like any other new arrival, following a part of the very elaborate curriculum for DEP inspectors. Like at NRC, inspector training plays a fundamental role and it has helped me supplement my American know-how with knowledge of French practices.

I received a very warm welcome from my colleagues and I was able to integrate myself very quickly with the team thanks to the companionable atmosphere. As a good start, we introduced a weekly custom known as American Lunch, which involved discussions over lunch with ASN colleagues wishing to practise their English!

I very quickly took part in a review inspection of AREVA NP, a major activity for DEP, working as one of the ASN inspectors. My perspective of NRC was useful to us in comparing AREVA practices in terms of both countries.

Contrôle: What surprised you most in the host Authority's organization or practices?

Jérôme Bai: France and the United Kingdom have very different cultures despite their geographical proximity. Major specific features are found in the organization and practices of both Authorities. For example, the military nuclear facilities are part of the ND's inspection portfolio, and it also manages the security aspect of nuclear materials and sensitive data on all sites. Conversely, ND does not cover the environmental aspects and only partially the waste and transport problems. The first thing that struck me on arriving at ND was the standard inspector profile. Any inspector must have ten years of experience from the nuclear industry before being allowed to join the Authority. Most inspectors have long careers in ND where the turnover is particularly low. The result is a relatively mature organization with considerable nuclear experience, offering advantages in terms of knowledge and overall vision of the nuclear world, but showing limited adaptability to changes. The inspection practices also surprised me. The inspectors have great flexibility in how they organize their work, put their inspection programme together and choose the format for their inspections. This is very convenient for the inspector but not necessarily of the best for the organization as a whole. Inspections are far more informal and are adapted to the problems encountered. One aspect worth noting is that the British approach to inspection incorporates the organizational and human aspects more widely, which seems relevant given the lessons learned from major accidents occurring in the industry. Curiously, the verbal culture is very apparent in exchanges between inspector and inspected. These exchanges are infrequently made official in writing and only the major problems are the subject of correspondence. As an example, the conclusions of inspections reported orally during a debriefing are only rarely followed up by a letter to the plant operator, an unexpected practice in a world seeking formalism and traceability.



Olivier Lareynie: I noticed a number of things. The CSN's organization stands out for its "built-in" technical support (unlike ASN which relies on IRSN). The technical expertise departments are therefore part of the organization. It is very interesting to see the advantages and disadvantages of this type of organization and compare them with the French model. Another CSN feature is the career profile of its employees: entry to CSN is via a competitive examination and the vast majority spend their entire career there. There are in fact very few opportunities to move to other organizations. Human resource management and the problem of maintaining skills are therefore addressed totally differently from ASN; for which major characteristic is a high turnover and the large percentage of seconded personnel.

One striking feature of the Spanish regulations for nuclear safety and radiological protection is the considerable use of American standards and references, especially in terms of nuclear power plant inspections (Editor's note: most Spanish reactors are of American design). CSN is very much involved in European activities, but always keeps an eye on the United States. In terms of my area of activity (waste, decommissioning) more especially, the Spanish use of a radioactive waste release is obviously a most interesting point of comparison with French practices, both for the technical aspects and for bearing in mind the challenge of the gradual harmonization of practices and regulations at European level. My assignment goes beyond CSN, giving me a chance to explore the special context of the Spanish nuclear industry. The debate on the country's energy policy is quite unusual, taken between the introduction of a moratorium on nuclear power in 1982 and the actual or planned launch of certain nuclear programmes worldwide (especially in Europe), the place of renewable energies (Spain is very advanced in this area) and a public opinion mostly against nuclear power.

Carmen Rodriguez-Mate: in terms of organization, CSN personnel in Spain have the role of Nuclear Safety Authority and of technical support at the same time. We are all specialists in a particular field, as is also the case for the American Authority. Personally, I am a specialist in chemistry and material degradation.

In terms of human resources, I have observed that unlike CSN, ASN agents do not spend their entire careers in the nuclear sector. Some agents change jobs regularly to diversify their regulatory knowledge in other industrial sectors, mainly as inspectors in chemical, at-risk industries or other industry-related fields.

I was also surprised by the "park effect". In DCN, I was faced with problems relating to the specific features of the French nuclear park, their size, their uniformity and their single operator. Conversely, Spanish plants are of limited size, with reactors of different design; they have several plant operators and several contract holders for each power plant.

Victor Hall: obviously, we are different. Our practices have evolved from parallel, but clearly distinct backgrounds. What strikes me most is that ASN was created to oversee the only plant operator in France, EDF. There are 26 companies operating the 104 reactors in the United States. NRC inspectors rely on more elaborate methods, codes and standards because all our plant operators must be overseen in identical fashion. Take quality assurance, for example, a mainstay of my activity. The American and French regulations do not differ greatly. However, the NRC-approved standard used universally by the plant operators - ASME NQA-1 - is extremely detailed. The document contains over a hundred

pages. The EDF General Quality Assurance Specifications is around ten times shorter. Safety is not measured in pages, but this difference illustrates the fact that the details seen as necessary can be very different.

Contrôle: How do you envisage making the most of the experience you have acquired on your return to your home Authority? What is your view on the value of international exchanges within the framework of the construction of a European centre for safety and radiological protection?

Jérôme Bai: the benefits for the Authority which seconds an inspector are not just apparent when he returns to his original organization. Regular contacts with ASN during my stay abroad meant that information and good practices were sent back and joint visits and inspections were organized. These exchanges form a sort of on-going operating feedback which can be used by ASN.

How does a secondeé to the British Authority take part in such construction? I do not sit on working groups striving at European level to define provisions and standards applicable to all States and therefore I do not contribute directly to constructing a European area. I am however convinced that inspector secondments contribute indirectly to this European construction process. The seconded person stimulates and promotes the exchange of information and openness, develops the desire to understand foreign practices, to discuss his own references and understand the differences, in a word, to think outside the box! This contribution goes beyond formal exchanges between Authorities. It is expressed through daily contacts with the British inspectors and plant operators, who frequently end up with a "by the way, how do you do this in France?". For this reason, inter-Authority staff exchanges help to develop a state of mind which promotes the exchange and search for best practices, forerunners of a "top-down" harmonization of practices.

Olivier Lareynie: the topics I am currently working on allow me to widen my technical skills in certain fields, which I shall then be able to put to good advantage when carrying out new duties as appropriate. My knowledge of the Spanish Safety Authority will be far more detailed - its organization, the wider context in which it finds itself, the people working there, etc. At a time when numerous discussions cannot simply relate to one country, this experience is genuine added value for both the agent and his governing Authority.

Clearly, this type of staff exchange between Safety Authorities makes a modest contribution to the gradual construction of a joint European foundation stone for nuclear safety and radiological protection, mainly by making exchanges between Safety Authorities easier and by allowing the exchange of good practices. The most significant aspect is that these exchanges between European Safety Authorities weaves a first, operational network, which extends beyond traditional bilateral relationships (meetings, selected working groups, etc.).

Carmen Rodriguez-Mate: I have acquired new knowledge through being faced with new themes. This has given me a more general overview than previously, given my specialisation, to address topics in CSN from a more operational angle. I have had a chance to understand the differences between the French and Spanish approach better. Thus, knowing the ASN organization and above all its representatives is going to make exchanges between CSN and ASN easier and help harmonise the processing of problems common to both Authorities. On another scale, exchanges of personnel make the foreign practices more familiar. Building lasting exchanges within

Europe not only strengthens the links between participating countries but also creates a joint knowledge base which can be used to harmonise the nuclear safety and radiological protection practices of the Old World.

Victor Hall: the benefits of this exchange are the improved understanding of our counterparts' practices in controlling the EPR. As France uses the operating feedback from the Finnish EPR reactor at Olkiluoto 3, so the United States will benefit from the experience of other countries.

As a general rule, the Authorities are bound to benefit from the international exchanges in which they take part. The European countries have thus opened the way in this area, especially through an organization such as WENRA. The exchange encourages the harmonization of safety requirements in the countries involved, to a certain extent making its contribution

to the construction of a European centre for nuclear safety. It is however important to bear in mind that the Authorities must not for all that swerve from their sovereign responsibilities in this context. ■



THE VIEW OF THE INTERNATIONAL ORGANIZATIONS

Cooperation between the International Atomic Energy Agency and the European Union in the field of nuclear safety

by Philippe Jamet, Director, Division of Nuclear Installation Safety – International Atomic Energy Agency (IAEA)

The establishment of safety standards is one of the tasks conferred upon the International Atomic Energy Agency (IAEA) by its statute. These standards are intended to protect the health of persons and reduce as far as possible the hazards related to the harmful effects of ionising radiation on persons and property.

The IAEA must apply these standards to its own activities. States must apply them to the operations that they carry out with IAEA assistance. The IAEA provides support for the use or application of its standards to States that request it. This support may take the form of training programmes or expert task forces.

The nuclear safety activities of the IAEA, based essentially on its safety standards and on the support provided to its Member States, give rise to very substantial cooperation programmes with the European Union.

IAEA Safety Standards

The IAEA safety standards are the formal expression of an international consensus on the principles, the requirements and the measures to be taken in order to achieve a high level of safety, protecting public and the environment against the harmful effects of ionising radiation. They formalise fundamental safety principles, requirements and recommended practices in order to limit exposure of persons and releases of radioactive materials into the environment, prevent situations that might lead to accidental radioactive releases and limit the consequences of such releases should they occur. The safety standards apply to installations and activities that give rise to radiological risks, including nuclear installations, use of radiation and radioactive sources, transport of radioactive materials and management of radioactive waste. The safety standards are applicable throughout the lifetime of installations and activities, whether existing or new. They cover all areas relevant to safety: legislative and regulatory framework, organization, management, skills, and technical aspects.

Historically, the IAEA safety standards were developed separately in each area, whether radiation protection, transport of radioactive materials, safety of installations or management of radioactive waste. A unified process and a centralised organization were introduced from 1996 to guarantee the consistency and uniformity of the standards, whatever the area concerned. The overall system is supervised by the Commission on Safety Standards (CSS) and includes four technical committees with responsibility for installation safety (NUSSC), radiation protection (RASSC), safety of radioactive waste management (WASSC) and transport of radioactive



IAEA headquarters in Vienna

materials (TRANSSC). The members of the Commission on Safety Standards are appointed by the IAEA director general. The members of the technical committees are nominated by the Member States of the Agency and include senior officials involved in the establishment of national regulations and experts. Observers from international organizations, industry or stakeholders may attend technical committee meetings under well-defined conditions in order to present their points of view, while maintaining the necessary independence of judgement of the committees. For example, the European Commission has observer status at the CSS and on all the technical committees.

The development process for IAEA standards involves systematic consultation of all Member States on each draft standard. The higher-level texts (Safety Fundamentals and Safety Requirements) are finally adopted by the Board of Governors of the Agency, while the Safety Guides are adopted by the Director General.

When the unified process was introduced, the IAEA also initiated a programme to organize the standards into three categories related by a clear hierarchy and links between them. The last step in this programme was taken in 2008, with the approval by the Commission on Safety Standards of a long-term structure and a road-map, with the aim of developing the missing standards and revising the existing standards, in order to unify them and organize them according to the new structure. The adopted structure is shown in the figure in next page.

The Safety Fundamentals are collected in a single document forming the apex of the structure. This document gives formal expression to the objectives and the principles that govern all the other standards.

The Safety Requirements set out the requirements that must be met in order to comply with the Safety Fundamentals. The Safety Requirements are organized in two main categories: general requirements, which cover generic aspects of safety, and specific requirements, which apply to a given type of installation or activity. The various Safety Requirements are shown in the figure in page 82.

The Safety Guides provide recommendations and guidance on how to comply with the Safety Requirements. They describe international good practices and increasingly reflect the best such practices, enabling a high level of safety to be achieved.

In general, the IAEA Safety Standards use a regulatory style favouring their use by the competent national authorities. However, their use is far from being limited to such authorities. The IAEA Safety Standards are also used by many organizations that design, build and operate nuclear installations and by users of radiation and radioactive sources. In this way they contribute to international harmonization of safety.

Furthermore, the IAEA Safety Standards are a consistent and reliable benchmark enabling effective compliance with the obligations applying to the contracting parties of the various international agreements on safety, such as the Convention on Nuclear Safety. The IAEA Safety Standards play a similar role with regard to codes of conduct, such as the Code of Conduct on the Safety of Research Reactors.

IAEA expert reviews

IAEA expert reviews have three different potential objectives. They may be organized to explain the content of the IAEA standards, resembling training courses. They may be in response to a request from a Member State for assistance in transposing the standards into its legislative system or implementing them. They may take the form of expert reviews, conducted by peers. These reviews assess the application of IAEA standards, share international best practices and make appropriate recommendations to the requesting State. Their

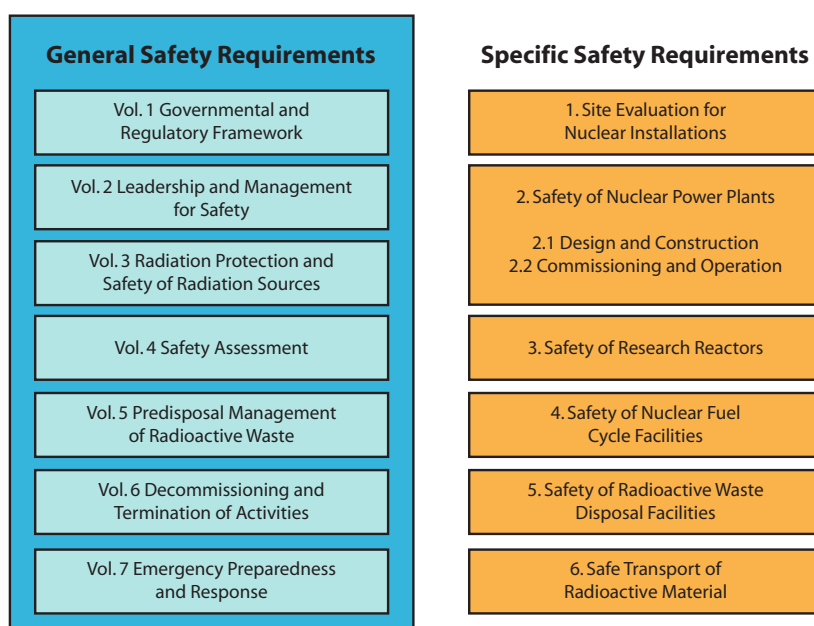
results, given formal form in a review report and recommendations, are made public, unless the requesting State opposes this. The expert reviews are based on the willingness of Member States to be open to international collaboration and sharing of experience. They represent an aspiration to excellence through transparency, and as such are of particular importance.

Expert reviews cover all areas of safety and radiation protection: legislative and regulatory framework, safety management, radiation protection, expert appraisal, radioactive sources, radioactive waste, termination of activity and decommissioning, site assessment, design and operation of facilities, transport. In each area covered, the expert reviews refer to the applicable IAEA requirements. For example, the requirements related to the governmental, legal and regulatory framework form the benchmark used by the IRRS (Integrated Regulatory Review Service) missions. The OSART (Operational Safety Assessment Review Team) missions make similar use of the requirements related to nuclear power plant operation.

The teams conducting the reviews consist of international experts selected by the IAEA and belonging to the most competent organizations. The reviews themselves are conducted according to procedures based on best international practices and on the experience accumulated by the IAEA over several decades. They comprise several steps: self-assessment by the institution or entity concerned, a preparatory mission, the mission proper and a follow-up mission. For the major missions these steps may take between two and three years to complete.

Examples of cooperation between the IAEA and the European Union in the field of safety

Cooperation between the IAEA and the European Union on safety covers a range of topics. The examples below are selected to illustrate this cooperation, with no intention of providing a complete inventory.



Structure of the IAEA Safety Requirements



IAEA standards and European Directive on radiation protection

The first IAEA radiation protection requirements were approved in 1962 by the Board of Governors. They have since been revised several times. The latest version, currently referred to as "BSS" (Basic Safety Standards), was published in 1996, under the title "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources", jointly sponsored by the United Nations Food and Agriculture Organization, the IAEA, the International Labour Office, the OECD Nuclear Energy Agency, the Pan-American Health Organization and the World Health Organization. The BSS are currently being revised, in accordance with the road-map adopted by the Commission on Safety Standards in 2008.

In parallel, the Council of the European Union adopted directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. The revision of this directive has also been undertaken, with the possibility of redrafting with other directives covering related topics.

European Commission observers take part in the working groups tasked with preparing the revision of the BSS. Reciprocally, IAEA observers take part in the meetings of the experts defined in article 31 of the Euratom Treaty, who advise the European Commission on the revision of the directive. These reciprocal participations optimise the consistency of the two drafts and harmonize them, while taking account of the differences between the status of a standard and that of a legally-binding directive.

The IAEA and representatives of the European Commission also take part in the working groups set up by each organization on particular topics, such as radiation protection related to medical irradiation.

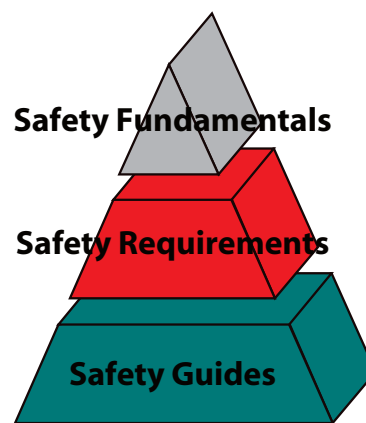
IAEA contribution to the drafting and application of the European Directive on nuclear safety

European directive 2009/71/Euratom, adopted by the Council of the European Union on 25 June 2009, establishes a Community framework for the safety of nuclear installations. It also has the objective of making sure that the Member States of the European Union take the necessary national measures to ensure a high level of safety of such installations.

To prepare this directive, the European Commission relied on a consultative group (ENSREG) composed of officials from the nuclear safety and radiation protection Authorities of the Member States of the European Union. An IAEA representative attends ENSREG meetings as an observer.

During the preparation of the Directive, at the request of the European Commission and ENSREG, the IAEA contributed to optimising the consistency of the draft with the Convention on Nuclear Safety and the IAEA Safety Fundamentals.

The Directive stipulates that "Member States shall at least every 10 years arrange for periodic self-assessments of their national framework and competent regulatory Authorities and invite an international peer review of relevant segments of their national framework and/or Authorities with the aim of continuously improving nuclear safety". The European Commission, in accordance with the ENSREG recommendations, has decided to call upon the IAEA in order



Structure of the IAEA Safety Standards

to implement this provision. The general framework of the IRRS missions will be used in this context, with the necessary adaptations for Europe.

The adoption of the European Directive is considered to be a major event by the IAEA. The Directive is consistent with IAEA policy favouring the constitution of regional networks dedicated to nuclear safety and radiation protection. The IAEA also appreciates the ambition affirmed by the European Union to play a leading role in nuclear safety at world level and share its progress within the framework of international conventions and IAEA expert reviews.

The European Commission has recently undertaken the preparation of a directive on the management of spent fuel and radioactive waste. Collaboration with the IAEA will continue on this draft in a similar manner to that on the nuclear safety directive.

Cooperation on emergency preparedness

Each country has a national reporting system for safety-related events. The IAEA and the European Commission have also set up reporting systems covering all their respective member countries. Harmonization of reporting criteria is an important challenge in order to share information and the lessons to be learned and, if necessary, to ensure good coordination in taking the necessary measures. The IAEA and the European Commission are collaborating on this topic, with the objective of achieving harmonization of their respective systems and, more broadly, international harmonization of reporting system criteria.

The IAEA has also set up a mutual assistance network (RANET) for emergencies resulting from nuclear incidents or accidents. Participation by Member States in this network is organized on a voluntary basis. The European Commission actively supports the establishment and the enlargement of this network. It has set up a specific programme to make its Member States aware of RANET and encourage them to join it.

Overall nuclear safety assessment of nuclear power plants in Ukraine

In 2005 the European Union and Ukraine signed a general agreement to work towards the introduction of a single energy market. A working programme was also established, in which nuclear safety in Ukraine is a clearly-identified topic.

In this context, a joint project between the European Commission, the IAEA and Ukraine was set up in 2007 to assess compliance with IAEA standards in all aspects of nuclear electricity generation in Ukraine. Four areas were examined: power plant design, plant operating safety, radioactive waste management and decommissioning, and the governmental, legal and regulatory framework for safety. The assessment was conducted by the IAEA, which organized expert missions for each area. This programme was implemented between 2008 and 2010, and involved a considerable effort by Ukraine, the IAEA and the European Commission. A total of fifteen missions were organized, with contributions by 92 experts from 20 different countries and from the European Commission itself, along with 32 participants from the IAEA. Overall it was shown that most IAEA safety requirements are met in Ukraine and that progress measures have been introduced in cases where deviations were observed.

The magnitude of the programme described above deserves to be emphasised, as it is the world's first example of an overall assessment on the scale of an entire country. The programme resulted in many contributions to nuclear safety in Ukraine and demonstrated the value of an approach integrating the various fields concerned. It is an undisputable example of ambitious and fruitful cooperation between the IAEA and the European Commission, based on the IAEA safety standards and expert reviews.

Cooperation between the IAEA and the European Commission in countries outside Europe

The IAEA and the European Commission are cooperating in the field of safety outside European countries. The European Commission contributes to IAEA actions on the remediation of former uranium mining sites in Central Asia. The IAEA and the European Commission are also coordinating their work on improving the safety of the Medzamor power plant in Armenia and on radioactive waste management and decommissioning of the Chernobyl power plant.

In addition to these cooperation measures, which are intended to be pursued or reinforced, the IAEA and the European Commission recently declared their willingness to significantly expand their cooperation outside European countries. Participation in many programmes conducted by the IAEA has been proposed to the Commission. The first of these are scheduled to come into effect before the end of 2010. New projects, defined jointly, are also planned. There are many topics of future cooperation, covering a very wide range:

- improvement of radiation protection and of safety of radioactive source and waste management in the developing countries, and support for the Authorities concerned;
- improvement of the safety of research reactors;
- reinforcement of emergency preparedness;
- support for the safety Authorities of countries planning to introduce nuclear power;
- establishment or reinforcement of regional nuclear safety training centres;
- support for regional networks organized by the IAEA in the field of safety, for example in Asia (ANSN);
- participation in generic actions for developing knowledge and safety standards, for example in the seismic field.

The effort planned by the European Commission is very substantial. It will make the European Union one of the preferred partners of the IAEA for the international promotion of nuclear safety.

Conclusion

The IAEA provides its support to the European Union in its efforts to become a regional entity with its own framework in the area of nuclear safety. The IAEA and the European Union are also developing their cooperation on safety and radiation protection outside the European Union.

Safety cooperation between the IAEA and the European Union is based mainly on the IAEA safety standards and expert reviews. This cooperation is effective and has clearly demonstrated its value, producing substantial results in many areas.

The ambition displayed by the European Union to play a leading role in nuclear safety at international level, the efforts that it is making and its willingness to share its acquired experience and its advances through cooperation with the IAEA are crucial factors in the worldwide promotion of nuclear safety. ■



THE VIEW OF THE INTERNATIONAL ORGANIZATIONS

European developments on radiation protection in health care. An international public health perspective

by the Dr Maria Neira, Director, Department Public Health and Environment, World Health Organization and Dr Maria del Rosario Pérez, Scientist, Department Public Health and Environment, World Health Organization (WHO)

Environmental risk factors are key determinants of human health. The World Health Organization (WHO) has estimated that approximately one-quarter of the global burden of disease, and more than one-third of the burden among children, is due to modifiable physical, chemical and biological environmental factors^{1,2}. Burden of disease from radiation exposure, as such, has not been quantified globally. However, there is longstanding recognition of risks, and consequent well-established lines of cooperation between WHO and other global, regional and national actors in the field of radiation protection. Areas of cooperation include the protection of patients, workers and the general public in planned, existing and emergency exposure situations. Among these, patients safety is a growing priority in light of the expanding use of ionizing radiation in the diagnosis and treatment of disease. There is a worldwide trend of a major increase of the number of radiological procedures, medical uses of ionizing radiation being the largest artificial source of radiation exposure today.

In response to this trend, WHO in December 2008 launched a *Global Initiative on Radiation Safety in Health Care Settings* to mobilize the health sector towards safer and effective use of radiation in medicine. This brings together health Authorities, international organizations, professional bodies, scientific societies and academic institutions in concerted action to improve the implementation of basic radiation safety standards³ in healthcare settings. The initiative complements the International Action Plan for the Radiological Protection of Patients established by the IAEA⁴ in 2002.

The ultimate goal of the *Global Initiative* is to ensure appropriate use of radiation in all countries globally. However, it has also created opportunities for intensified co-operation with European countries. In particular, the Global Initiative offers European countries an opportunity to expand the horizons of their achievements globally, contributing to improved radiation protection worldwide.

This article reviews European developments in radiation protection in health care – from an international public health perspective. It then discusses some key challenges in risk

assessment and risk management where collaborations with European countries are supporting effective review and revision of norms and standards as well as development of guidelines and tools for the implementation of policies and interventions. Finally, the article explores how European countries may move from 'pioneers' to global champions of radiation safety in health care.

Leadership and governance - key developments

The development of coherent norms and standards at both the regional and the global level is fundamental to good governance in the field of radiation safety. Europe has led the development of a robust framework of radiation safety norms and standards for its region. Through collaborations with international actors, including WHO, it has contributed substantially to development, review and revision of norms and standards for safe and effective use of radiation in medicine internationally.

European framework

The European legal framework for radiation protection is anchored in two groups of instruments – instruments under Euratom Treaty⁵ provisions and instruments under European Commission (EC) provisions. Protection of workers and the general public is defined by the Euratom Basic Safety Standards⁶. The Medical Exposure Council Directive⁷ supplements this, providing more specific requirements for medical exposures. Its promulgation in 1997 represented a major milestone in standard-setting for radiation safety in health care. A Standing Committee made up of scientific experts gives advice on the development and implementation of these standards⁸. These instruments are currently being 'recast' into a single, consolidated Directive. This will strengthen governance and allow better integration of safety requirements to protect patients, workers and the public. In parallel, the European Commission (EC) has provided a framework for the development of other legal instruments.

1. Global health risks, mortality and burden of disease attributable to selected major risks. Geneva, World Health Organization, 2009. Available at www.who.int/healthinfo/global_burden_disease/global_health_risks/en

2. Prüss-Ustün A. and Corvalán C. Preventing Disease Through Healthy Environments: Towards an Estimate of the Environmental Burden of Disease, Geneva (2006). Available at www.who.int/quantifying_ehimpacts/publications/preventingdisease.pdf

3. The International Basic Safety Standards (BSS) for Protection against Ionising Radiation and for the Safety of Radiation Sources were published in 1996. Currently under revision, the BSS are co-sponsored by IAEA, WHO, PAHO, ILO, FAO, EC, UNEP and NEA/OECD.

4. IAEA: International Atomic Energy Agency

5. The Euratom Treaty establishing the European Atomic Energy Community (Euratom) was initially created to coordinate the Member States' research programmes for the peaceful use of nuclear energy. More information at http://ec.europa.eu/energy/nuclear/euratom/euratom_en.htm

6. Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.

7. Council Directive 97/43/Euratom of 30 June 1997, on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0029:EN:HTML>

8. Article 31 Working Party is a group of scientific experts with advisory status called upon to assume the function of adviser to the EC on preparing, revising and supplementing the BSS. WHO participates as an observer in this WP. More information at: http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

These have included Council Directive 93/42/EEC, related to medical devices and amended by Directive 2007/47/EC. European countries transpose this EC and Euratom framework into national laws and regulations.

International framework

Published in 1996, the *International Basic Safety Standards (BSS) for Protection against Ionizing Radiation and for the Safety of Radiation Sources* represents an unprecedented international effort towards global harmonization of standards in all aspects of radiation protection of patients, workers and the public. Co-sponsored by six international agencies (IAEA, WHO, PAHO, ILO, FAO and NEA/OECD)⁹, the BSS provides the leading international benchmark for standard-setting, policies and decision-making. Since 2006, a joint co-sponsors secretariat has been working to revise these standards; this secretariat now also includes the United Nations Environment Programme and the European Commission – whose presence reflects increased European engagement globally on this issue. WHO is fully engaged in the current revision process of the International BSS, and will continue supporting its 193 Member States in their implementation.

The very good formal lines of cooperation established between the EC and all cosponsors of the International Basic Safety Standards (BSS) have contributed to the consistency of International and European standards, providing a cornerstone for global harmonization of standards. In addition, a wide range of experts representing individual European countries, institutions or agencies have also participated very actively in these processes.

Current challenges and opportunities: joint efforts to tackle issues

Ionizing radiation is an essential tool for the diagnosis and treatment of human diseases. As the benefits for patients gain recognition, the use of ionizing radiation in medicine continues to increase. Like all medical procedures, radiological medical procedures present both benefits and risks. On the benefit site, new technologies, applications and equipment are constantly being developed to improve the safety and efficacy procedures. At the same time, incorrect or inappropriate handling of these increasingly complex technologies can also introduce potential health hazards for patients and staff. This demands public health policies that both recognize the multiple health benefits that can be obtained, while addressing and minimizing health risks. In particular, risk assessment and the correct and appropriate use of increasingly complex technologies imply present-day challenges that are the focus of multiple collaborations involving European actors. These issues are described briefly below alongside relevant ongoing collaborations.

Research to inform policy and actions

The challenges

In the area of risk assessment, there is a recognized need for more focused research to evaluate health risks following medical exposures, including cancer and non-cancer effects.



International conference on radiotherapy organized by ASN in Versailles (France) – December 2009

Most vulnerable populations such as children, young adults and pregnant women require particular consideration. To support such research, there is a parallel need to improve data collection on frequency of radiological medical procedures and population dose distribution, particularly in developing countries where this information is scarce.

The opportunities

Research in this arena is a focus of collaboration between WHO and European countries. The WHO Global Initiative includes a strategy for developing a global research agenda on health effects of medical radiation exposures, in collaboration with UNSCEAR¹⁰. In 2008, the European Commission (EC) and several European countries set up a High Level Expert Group (HLEG) to create a platform dedicated to low dose risk research. This platform, called MELODI (Multidisciplinary European Low Dose Initiative), seeks to facilitate a dialogue between stakeholders for the development and implementation of a long-term strategic research agenda on the effects of low dose of ionizing radiation. The European HLEG, as well as research institutions in the United States of America and Japan¹¹, in turn have provided technical support to WHO to foster a global research agenda. In September 2009, WHO and the EC jointly cosponsored the First Open International MELODI Workshop in Stuttgart. This event gathered key stakeholders from the region as well as from outside Europe. The collaboration is ongoing, and new achievements are being presented during the Second International MELODI Workshop in Paris (October 2010).

In the context of the Global Initiative, UNSCEAR and WHO also are collaborating to improve data collection on frequency of medical exposures, particularly in developing countries where this information is still scarce. This collaboration includes capacity-building and technical support to conduct national surveys. A methodology based on the DOSE DATAMED approach¹², developed through a multinational European project, has been proposed for population dose estimation. Several countries that participated in the DOSE DATAMED

9. FAO: Food and Agriculture Organization; IAEA: International Atomic Energy Agency; ILO: International Labour Organization; NEA/OECD: Nuclear Energy Agency/Organization for Economic Co-operation and Development; PAHO: Pan American Health Organization; and WHO: World Health Organization.

10. UNSCEAR: United Nations Scientific Committee on the Effects of Atomic Radiation.

11. US: Low Dose Research Programme of the Department of Energy (DoE); Japan: National Institute of Radiological Science (NIRS).

12. EC RADIATION PROTECTION N° 154 European Guidance on Estimating Population Doses from Medical X-Ray Procedures (2008).



project are now contributing to the WHO Global Initiative. Their expertise in the field of data collection can therefore be applied in other regions of the world.

Collaboration in radiation safety in radiotherapy

The challenges

Human factors such as incorrect handling are involved in most incidents and accidents. According to the ICRP publication *Prevention of accidents to patients undergoing radiation therapy*¹³ more than 2,000 patients worldwide are reported every year to be accidentally overexposed during radiotherapy. Many other cases may occur that are not reported or even not recognized. Accidental and unintended exposures also occur in diagnostic imaging and nuclear medicine. Skin burns and other injuries are increasingly observed in patients undergoing fluoroscopic-guided interventional procedures. The development of new technologies has, meanwhile, introduced new challenges in terms of quality assurance, equipment safety, education, training and staffing – which require a stronger culture of safety amongst healthcare providers.

The opportunities

WHO established a patient safety programme (PSP) in 2004 in response to a resolution of the World Health Assembly calling for the “establishment and strengthening of science-based systems, necessary for improving patients’ safety and quality of health care”¹⁴. The PSP promotes patient safety reporting and learning systems, and is working on an international classification for patient safety¹⁵.

Quality assurance and continuing education are two major measures that can help prevent incidents and accidents within the health care system. Even small breaks in the quality chain and errors can compromise treatment outcome if allowed to go undetected. A coincidence of several errors can lead to radiation incidents and accidents. In radiotherapy, this may result in large groups of patients being overexposed or receiving under-dosage which denies them the chance of cure. Primary prevention being essential, incident reporting systems are a cornerstone to improving safety culture, by translating reporting into learning and using this knowledge to improve the safety of frontline care.

The European incident reporting system called ROSIS¹⁶ is a voluntary web-based safety information database based on professional front-line staff in radiotherapy services. The ROSIS group delivers, on an annual basis, the course “Working towards safer healthcare delivery”, endorsed by the European Society for Therapeutic Radiology and Oncology (ESTRO). One of the objectives of this course is to enable international collaboration in incident reporting and to encourage a culture of reporting incidents.

Risk profiles, lessons learned, methods of prevention, detection, correction and reporting of incidents were some of the topics addressed by the 360 participants from 50 countries that attended the International Conference on Modern Radiotherapy- Advances and Challenges in Radiation Protection

of Patients¹⁷ organized by the French Nuclear Safety Authority (ASN) in cooperation with the EC, the IAEA and WHO (Versailles, December 2009). The outcomes of this Conference, organized by an European agency in cooperation with relevant international organizations, achieved global impact.

Collaboration to ensure appropriate use of procedures

The challenges

Inappropriate use of radiation in health care leads to unnecessary radiation exposures and thus preventable risks. Management of such risks depends on two principles of radiation protection: justification for prescribing and performing each procedure, and optimization of protection to manage the radiation dose commensurate with the medical purpose.

Considerable disparities also exists between and within countries with respect to the use of radiation technologies. While most developing countries still lack adequate capacity and resources to provide radiation therapies on a widespread basis, developed countries are increasingly facing the risk of overuse. One area of special concern is the unnecessary use of radiation imaging in cases where clinical evaluation or other imaging modalities could provide an accurate diagnosis. This is particularly critical in the context of paediatric health care, since children are especially vulnerable to environmental threats and have a longer life-span to develop long-term radiation-induced health effects like cancer.

The opportunities

When choosing the best medical imaging procedure for a given clinical condition the referring doctors (e.g. general practitioners, paediatricians, emergency physicians, and other specialists) have to take appropriate decisions, accounting for both benefits and risks. Cost, local expertise, available resources and accessibility are additional aspects to be considered. Changing the culture of medical practice to encourage more thoughtful use of radiation in health care would empower the health profession to ensure that patients benefit from continued innovation and health resources are cost-effectively allocated.

Evidence-based referral guidelines for appropriate use of radiation imaging can significantly improve the use of healthcare resources and reduce unnecessary population radiation exposure. As decision-aiding tools, referral guidelines provide a basis for good medical practice for referrers and medical imaging practitioners.

Guidelines for making the best use of clinical radiology services have been published in Europe since 1989¹⁸. In its article 6.2, the Council Directive 97/43/Euratom on medical exposures states “Member States shall ensure that recommendations concerning referral criteria for medical exposure, including radiation doses, are available to the prescribers of medical exposure”. This Directive is mandatory and countries had to transpose it into national law by 2000. In order to support the implementation of this Directive, referral criteria were first published by the EC in 2000¹⁹, and European countries adopted those guidelines or adapted them to their local conditions.

13. International Commission on Radiological Protection, Publication 86 Prevention of Accidents to Patients. Undergoing Radiation Therapy, Elsevier, 2001.

14. Fifty Fifth World Health Assembly, resolution WHA55.18 http://apps.who.int/gb/archive/pdf_files/WHA55/ewha5518.pdf

15. WHO Patient Safety Programme. Access at www.who.int/patientsafety/about/en/index.html

16. ROSIS is short for “Radiation Oncology Safety Information System” www.clin.rad-fys.lu.se/default.asp

17. More information at www.asn.fr/index.php/Haut-de-page/Professionnels/Evenements-professionnels/International-Conference-on-Modern-Radiotherapy-2-4-December-2009

18. In UK, the Royal College of Radiologists first published these guidelines in 1989 and the 7th edition is planned for 2011.

19. Radiation Protection 118- Referral Guidelines for Imaging. Available at: http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/118_en.pdf



Positioning a patient prior to a radiotherapy session

Referral guidelines have been developed by professional bodies in other regions of the world²⁰. However, they are not available worldwide, particularly in developing countries. Even in those countries where guidelines exist, concerted efforts are still needed to integrate them into daily medical practice. An international collaboration involving 23 international, regional and national agencies and professional societies²¹ was established within the WHO Global Initiative to make available global evidence-based referral guidelines for appropriate use of radiation imaging, to facilitate their implementation, monitor their use and evaluate their impact in different clinical settings.

The contribution of Europe to this global effort is implemented through interaction with key stakeholders at regional and national level, including:

- the European Commission;
- regional professional associations e.g. the European Society of Radiology (ESR) and the European Association of Nuclear Medicine (EANM);
- national professional societies directly involved in the development of referral guidelines in their countries e.g. the Royal College of Radiologists (RCR, UK); and
- national competent Authorities e.g. the French Nuclear Regulatory Authority (ASN, France) and Federal Office for Radiation Protection (BfS, Germany).

This collaboration includes plans from some European countries to support the implementation of referral guidelines in developing countries from other regions, including pilot testing and capacity building.

Education of referrers is a key issue in ensuring implementation of referral guidelines. To improve safety culture in health professionals, the inclusion of radiation protection contents in the curricula of medical and dental schools is advocated within the WHO Global Initiative. Referral guidelines can also serve as education tools for medical students and young doctors, to facilitate their integration in the

clinical practice. Guidelines on training of medical staff in radiation protection have been developed in Europe under multinational projects. The EC has plans to update and expand those tools with the participation of key stakeholders such as professional bodies, scientific societies, and competent Authorities. WHO welcomes these initiatives and offers the Global Initiative as a platform to facilitate the dissemination of those products at a global level.

From pioneers to champions

Improving health care requires a multi-sectoral approach and partnerships with a range of stakeholders. While WHO plays a unique stewardship role in bringing together diverse stakeholders to promote the review and translation of evidence into new global policies and standards, Member States are the essential partners, both as initiators and implementers of new policies.

From the early part of the last century, Europe has played a pioneering role in the promotion of safer and more effective use of radiation in health care. The International Commission on Radiological Protection was first created in Stockholm in 1928 at the Second Congress of Radiology (1928). More recently, the First International Conference on the Radiological Protection of Patients hosted by the Government of Spain in 2001 became a cornerstone for patient radiation safety worldwide.

Over the past decade, a range of important expert networks have been established in Europe to address specific topics related to radiation protection in health care. Different stakeholders within the medical sector thus have the opportunity to discuss and to exchange information relating to the implementation of the radiation safety standards. The fact that the European Commission provides a framework for such collaborations, with funding attached, facilitates their sustainability. Many activities organized within the framework of these networks are inclusive of other countries outside Europe, and even globally. Such integration serves as a powerful catalyst to harmonization and benchmarking.

It is important to remember that European countries exhibit many diverse levels of development as well as socio-economic conditions – requiring flexibility in the adaptation of new policies and approaches. At the same time, the highest standards of technical excellence, patient safety and care remain as the benchmark for all countries in the region. Experiences in Europe can thus be relevant to policymaking in many other parts of the world. Looking towards the future, this sharing new ideas and lessons learned will provide an ever-widening opportunity for European countries to move from 'pioneers' to 'champions', to support radiation protection in health care worldwide. ■

20. e.g. American College of Radiology (ACR), Canadian Association of Radiologists (CAR), Hong Kong College of Radiologists (HKCR), Royal Australian and New Zealand College of Radiologists (RANZCR).

21. The following institutions are collaborating with WHO: Alliance for Radiation Safety in Pediatric Imaging- Image Gently Campaign, American College of Radiologists, Argentine Society of Radiology (SAR), African Society of Radiology (ASR), Association of General Practitioners (Geneva), Canadian Association of Radiologists, Chinese Society of Radiology, European Commission (EC), European Society of Radiology (ESR), Federal Office for Radiation Protection (BfS, Germany), Hong Kong College of Radiologists, Inter-American College of Radiologists, International Atomic Energy Agency (IAEA), International Pediatric Association (IPA), International Radiology Quality Network (IRQN), International Society of Radiology (ISR), International Society of Radiographers and Radiological Technologists (ISRRT), National Centre for Child Health and Development (Japan), Nuclear Safety Authority (ASN, France), Pan American Health Organization (PAHO), Royal Australian and New Zealand College of Radiologists, Royal College of Radiology (RCR, UK).



THE VIEW OF THE FOREIGN AUTHORITIES

Point of view of the US Nuclear Regulatory Commission on Europe

by Gregory Jaczko, Chairman, US Nuclear Safety Authority (US-NRC)

The subject matter of this issue of *Contrôle* is of considerable interest to the U.S. Nuclear Regulatory Commission, and I am honored to present my views alongside those of many of my European colleagues. The NRC has enjoyed close cooperative relationships with its regulatory partners in Europe for decades, and has seen that cooperation expand as the European regulatory landscape has changed. Together, we have long realized the importance of collaboration on nuclear and radiation safety. We have recognized the benefits that can be attained from open and frank discussions on good practices, lessons learned, and experiences that have informed our national programs, and we have utilized this cooperation to leverage our resources as interest in nuclear power grows worldwide. The NRC has watched with interest as the European Union has undertaken efforts to harmonize its nuclear safety and radiation protection practices, culminating in the issuance of the Nuclear Safety Directive.

The benefits of international collaboration in nuclear safety are significant. The presence of high-level safety standards provides national regulatory Authorities with a collective goal, while the presence of multinational organizations actively engaged in nuclear safety issues provides countries with a consistent source of guidance and peer review. Such collaboration also has important practical applications. For example, when the Davis-Besse nuclear power plant in the United States experienced a serious corrosion issue, the United States drew on experience from France in addressing the issue of reactor head replacement. There are myriad examples of such cooperation among countries operating similar nuclear power plants or working with radioactive materials. Sharing information helps to prevent problems before they occur, which directly contributes to maintaining safety worldwide in this diverse and ever-changing field.

Recent efforts on the part of the European Union to achieve an over-arching level of harmonization and collaboration provide a positive example to countries embarking on new nuclear programs. Together with other standardization activities, such as those of the International Atomic Energy Agency, the Council Directive and other initiatives provide a useful frame of reference for countries with evolving regulatory programs. The collaborative groups themselves, including the European Nuclear Safety Regulators Group (ENSREG) and the Western European Nuclear Regulators Association (WENRA), also serve as models for groups of small or developing regulatory bodies and encourage productive discussion at the regional level on issues of mutual interest. Supporting this spirit of cooperation is a high priority for the NRC, which is pleased to have served as an observer in various ENSREG activities and looks forward to continued cooperation with this organization and with individual European regulatory counterparts.

The NRC has benefitted greatly from its involvement in international standards development. By participating in such

activities, the NRC exchanges information with other regulators, thus strengthening the regulatory process of each participating organization. The outcomes also enhance the NRC's domestic program by allowing us to compare NRC standards against other international standards and to identify potential gaps in our program.

The government system in the United States is such that a regular and open dialogue is maintained between the NRC and its stakeholders at all levels, including the Congress, non-governmental organizations and the public. These stakeholders have sometimes inquired as to how the NRC's regulations compare to those of our counterparts around the world, or to international standards. International cooperation and peer review activities provide answers to these questions and contribute positively to NRC's goal of continuous improvement.

All countries approach legally binding domestic standard-setting under the specific framework that is legislatively mandated by their government. Mandates differ from country to country, and so do domestic approaches to standard-setting. These differences will invariably lead to some differences in regulatory approaches and standards. In the United States, for example, additions and modifications to regulations require a public comment process. This, in turn, requires regulators to foster transparency by explaining to the public the reasons for potential changes or additions. While the process is a product of our government system and allows for beneficial input from stakeholders, it also means that regulatory changes require layers of scrutiny and review. Other factors, including the size and maturity of a country's nuclear program, the type of legislative system in place, and even the country's political relationships, have a direct impact on the type of domestic regulations it develops and how those regulations change over time. For this reason, it is not realistic for a country to adopt any single set of multinational standards in place of domestic regulations.

The United States can offer a practical example to illustrate this point. The tragic events of September 11, 2001 prompted the United States to implement significant changes to its security regulations. The unprecedented impact of the terrorist attacks warranted immediate action on the part of NRC licensees to upgrade their security measures. Subsequently, we have worked diligently to ensure that these security requirements do not impede or contradict safety measures. The events of September 11 prompted changes that were specific to the United States' domestic regulations, which would have been difficult to implement in the timely manner dictated by the circumstances if the regulations required a multinational review. Similarly, different countries must respond to these types of events in different ways – a harmonized international approach cannot realistically reach to the most detailed, technical levels, and countries must have the flexibility to



Davis-Besse nuclear power plant, United States

respond to an emergency in a way that is appropriate for their specific situation. Conversely, however, the September 11 terrorist attacks also led to substantial international coordination on safety and security measures for both nuclear applications and the way these measures should best intersect.

As interest in nuclear power appears to be increasing around the world, both new and established regulatory programs face new challenges. One such challenge is the vast array of new reactor designs under consideration. While a harmonized approach to safety with a focus on international cooperation can have a cohesive effect on global nuclear safety, it is not feasible for any single regulatory approach to govern the worldwide nuclear community. Regulatory frameworks exist in different legal, cultural and political systems and each sovereign state has a right to demand higher standards for its citizens if it so chooses. Although regulatory frameworks may differ, the different requirements are not conflicting. If a design is of a high standard, it should be able to be licensed irrespective of the regulatory regime in force, with the same design proposal meeting regulatory requirements internationally. Therefore, industry has a role to play in making standardization possible.

So-called "new entrant" countries are seeking assistance in their efforts to establish nuclear regulatory programs from multinational organizations and countries with established programs. The increase in assistance requests has presented a challenge for the NRC and many of its counterparts, whose budgets cannot support every request that is received. Regional cooperation is quite important in this regard. Cooperation certainly relieves some of the resource constraints we would experience if we sought to assist each country individually. In addition, some regions have similar political considerations, making their experiences more readily understood and applicable. Most importantly, it is more beneficial to enable a country to develop a strong foundation for establishing a robust safety infrastructure, thus empowering it to provide similar advice to its neighbors.

Recent measures to align nuclear safety practices in Europe provide an important example of regional cooperation which can serve as a model to other groups. In particular, I would highlight the fine work of the recently-established Forum for Nuclear Regulatory Bodies in Africa as an example of how regional

cooperation can benefit from diverse regulatory programs of varying degrees of development. Regional cooperation can succeed at varying levels of political harmonization, again dependent on the impact of domestic circumstances.

In the European Union's case, the promulgation of a high-level safety directive has clearly aided European nuclear regulatory Authorities in defining the expectations for excellence in safety in their domestic programs and also provided strong guiding principles that new entrant countries may wish to consider as they establish their own programs.

The work of the IAEA and the OECD's Nuclear Energy Agency represents the perspectives of experts from around the world and are of significant value to new and mature programs because they allow countries to benefit from the collective perspectives in a way that an examination of individual countries' domestic regulations would not. In addition, the Convention on Nuclear Safety, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, and other international instruments provide an important peer review mechanism that enables countries to benefit from one another's experience.

The NRC upholds nuclear safety and security priorities above all others, including economic factors. As Chairman of the NRC, I am proud to highlight not only the strong safety record my country's nuclear program has maintained, but also the comprehensive manner in which we have incorporated the lessons we have learned from domestic and international incidents.

The NRC values its long-standing, comprehensive cooperation with its European counterparts. We share important goals and practices, and we have all benefitted greatly from our collaboration. We have seen the impact of a global economy on the nuclear industry, and know that continued cooperation on a regional and multinational basis is essential to continue robust safety and security practices in our respective countries. The NRC and the regulators of the European Union will continue to explore new avenues for cooperation. We look forward to continuing our work, both with individual regulatory Authorities and with ENSREG, WENRA and other European organizations. ■



THE VIEW OF THE FOREIGN AUTHORITIES

Nuclear Safety and Radiation Protection in Europe – a common approach

by the Dr Ann McGarry, Chief Executive, Radiological Protection Institute of Ireland (RPII)

The situation in Ireland

Ireland has no civil nuclear power stations or research reactors. However, irradiating apparatus and radioactive materials, in the form of sealed and unsealed sources, are used routinely in medicine, in industry and for educational purposes. These activities are the primary focus of radiation protection regulation in Ireland. In addition, exposures to natural radiation sources in the workplace, including radon, NORM and cosmic radiation (in the case of aircrew), are also subject to regulatory control.

The estimated average dose to the population from all sources of radiation is 3950 micro-Sievert (μSv). Radon is the principal source of radiation exposure, representing over 56% of the dose received by the Irish population. The average indoor radon concentration in Ireland is 89 becquerels per cubic metre (Bq/m^3) and some of the highest radon concentrations found anywhere in Europe have been found in homes and workplaces in Ireland.

Medical exposure of patients represents by far the largest man-made contributor to collective dose contributing about 14% of the total. Other sources such as fallout from nuclear weapons tests and following the Chernobyl accident, as well as the impact of routine discharges from Sellafield on Ireland, are much smaller by comparison. The occupational exposure of staff working with radiation in hospitals, industry and education/research is also low.

Although Ireland itself has no nuclear industry, there has long been a concern among the population about nuclear activities elsewhere in Europe and in particular about the management of operations at Sellafield in the UK.

In the absence of nuclear power or nuclear fuel cycle facilities, no high level radioactive waste is produced in Ireland. Radioactive waste in the form of disused sealed and unsealed radioactive material arising from medical, industrial and research/educational applications would all be categorised as either intermediate or low-level, depending on the activity and activity concentration of the material in question. Since the licensing system was introduced in 1977, activities involving sealed radioactive sources are permitted only if the licence applicant can satisfy the RPII that an agreement has been made with the supplier or manufacturer of the source to take it back when no longer required. Radioactive materials acquired before 1977, or from suppliers who have ceased trading, are held on the premises in which they were previously used. The Government has established a High Level Interdepartmental Committee to investigate possible options for the future management and disposal of radioactive material and this work is ongoing.

A common approach in Europe?

In radiation protection

The first adoption in 1959 of a European Directive setting out the basis safety standards for the protection of the health of workers and the general public against the dangers of ionising radiation (EU BSS), and its successive updating since then, has been a key element in the achievement of high standards of radiation protection across Europe. As the European Union has expanded, new Member States have implemented the EU BSS into their own legislation. Each new version of the EU BSS (most recently 96/29 Euratom) has been based on the most up-to-date scientific knowledge on radiation protection as set out in the recommendations of the International Commission on Radiological Protection (ICRP) and has highlighted those areas which most need to be addressed in a European context. The process leading to the development of the EU BSS involving input from independent scientific experts from the Member States (the Article 31 Group established under the Euratom Treaty to advise the Commission) ensures that the standards are free of external influence. Other radiation protection related EU directives, including the Medical Exposures Directive (97/43/Euratom) and the High Activity Sealed Sources Directive (2003/122/Euratom), also contribute to the common basis for radiation protection in Europe.

While the BSS and other related EU directives set out the detailed framework for radiation protection, implementation of radiation protection measures remains the responsibility of the Member States and the directives provide for some flexibility in their implementation. This flexibility is important as it allows for some variation in approach to take account of the differing systems and cultures in different Member States. The BSS also allows for the adoption by Member States of provisions which are more restrictive.

From an Irish perspective, the adoption of common standards for radiation protection across Europe is very beneficial. The process ensures that the standards are based on the most up-to-date scientific knowledge and on a wide range of expert views. It also facilitates public confidence in the quality of the standards.

While the BSS provides for a common basis in the standards adopted, it is also true that the implementation of the standards in different countries can be different. For example, in Ireland all users of ionising radiation are licensed by the RPII, whereas in some countries radiation sources such as x-ray machines used by dentists and others are subject to registration only. Differing approaches are valid depending on the circumstances that apply in the Member States. In general, the differing

approaches between Ireland and the UK, with whom it shares a border to the north of the country, have not given rise to any particular problems.

The establishment a few years ago of the network of the Heads of the European Radiological protection Competent Authorities (HERCA) has provided a forum for more in-depth discussion on the implementation of radiation protection standards within Europe and an opportunity to develop common approaches, where this is appropriate. In particular, in the area of medical exposure, HERCA provides a useful opportunity for discussion among regulators.

In emergency preparedness and response

Following the Chernobyl Accident in 1986, much has been done to ensure effective early notification arrangements and sharing of expertise and resources at the European level in the event of further incidents or accidents. The European Union has established the European Community Urgent Radiological Information Exchange (ECURIE) system to make early-notification and reliable radiological information available to EU Member States. The European Radiological Data Platform (EURDEP) makes radiological monitoring data from most European countries available on a routine daily basis – and in close to real-time in emergencies. All EU Member States are signatories to the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency. These international conventions, which are primary legal instruments, establish an international framework to facilitate the exchange of information and the prompt provision of assistance in the event of a nuclear accident or radiological emergency.

These EU initiatives and initiatives at the international level by the International Atomic Energy Agency (IAEA) and the Nuclear Energy Agency (NEA) in this field provide for a much more effective response to any future accidents.

In Nuclear Safety

In June 2009, the European Commission adopted a Directive (2009/71/Euratom) establishing a Community framework for the nuclear safety of nuclear installations. The Directive, due to be implemented in Member States by June 2011, provides binding legal force to the main international nuclear safety principles. It comprises provisions relating to the establishment of a national legislative and regulatory framework for nuclear safety of nuclear installations, to the organization, duties and responsibilities of the competent regulatory Authorities, to the obligations of the licence holders, to the education and training of all parties' staff, and to the provision of information to the public. From an Irish perspective, the Directive is welcome as it establishes specific provisions within Europe with the particular aim of maintaining and continuously improving nuclear safety. The inclusion of international peer reviews of nuclear safety in EU Member States will aid transparency. The European Nuclear Safety Regulators Group (ENSREG), through its work programme, is developing a common approach towards the implementing measures required for the Directive, thereby, facilitating a consistent and high standard in its implementation.

The adoption of a second directive on policy for the management of spent fuel and radioactive waste is also under active development by the Commission. If adopted, the directive will have the benefit of establishing a common framework for the management of radioactive waste and spent fuel within the European Union and should help to address



Gamma spectrometry software, used to analyze high resolution gamma spectra measured using high purity germanium detectors

some of the concerns expressed by European citizens on this issue in recent Eurobarometer surveys.

From an Irish perspective, the adoption and implementation of the Nuclear Safety Directive is an important development. While it was clear that the network of the national nuclear regulatory Authorities in Europe (Western European Nuclear Regulators Association – WENRA) had, through its work, greatly advanced the objective of a harmonized approach to nuclear safety regulation, the adoption of legally binding instrument provides for greater consistency and transparency. It is inevitable that non-nuclear countries will have greater confidence in and ownership of instruments to which they have had the possibility of providing input.

Research

In Europe, funded research in nuclear fission and radiation protection research aims to establish a sound scientific and technical basis for the safe long-term management of long-lived radioactive waste, to promote a safer, more resource-efficient and competitive exploitation of nuclear energy and to ensure a robust and socially acceptable system of protection of man and the environment against the effects of ionising radiation.

European wide research in these areas is extremely important in contributing to the state of knowledge and in ensuring that high quality graduates continue to be attracted into these fields. For a small country, the possibility of participating in large research programmes, either as a funded collaborative project or as a network of excellence is very beneficial.

Further development of common approaches to radiation protection and nuclear safety within Europe

As indicated above, much progress has been made in advancing a common approach to many radiation protection and nuclear safety related issues within Europe. As might be expected given that the EU BSS has been in place since the late 1950's, the process for agreeing common standards for radiation protection is more embedded. From the perspective of the regulatory authority of a small non-nuclear country, the development of common approaches in these fields has many advantages. In particular, it

- Allows the standards which are agreed to be based on the best available knowledge and a wide range of expertise and experience (e.g. EU BSS, Nuclear Safety Directive, etc.).





Testing for radioactivity in samples in the laboratory of the Radiological Protection Institute of Ireland

- Provides for greater transparency in the field of nuclear safety and waste management. The active involvement of nuclear and non-nuclear countries in discussions at ENSREG helps to foster mutual understanding of the issues.
- Facilitates greater confidence among the public that the national system provides an appropriate level of protection.
- Provides for sharing experience and the establishment of networks.
- Makes best use of the available resources.

There are, however, a number of issues arising which warrant consideration in the future development of common approaches.

- Increasingly, radiation protection and nuclear safety Authorities understand their role in the context of the wider society rather than as narrow “technical” specialisms. They recognise the need to integrate their activities into the societal decision making process rather than the other way around. Radiation protection and nuclear safety are essentially about ensuring that people and the environment, individually and collectively, are adequately protected from the harmful effects of ionising radiation while still being able to benefit from its use. This role for radiation protection and nuclear safety Authorities is challenging and requires a range of skills beyond the “technical”. Authorities can benefit from collaboration on how best to adapt to meet this challenge.
- While the agreement of common approaches among regulators to issues in the fields of radiation protection and nuclear safety has many advantages, the increasing need to involve other stakeholders, and in particular the public, means

that the common approaches agreed have, in particular circumstances, to allow for other inputs to be incorporated. For example, practical experience of the release of radioactive materials from regulatory control shows that while the use of generic numerical values are helpful in the decision making process, their widespread application has not always been universally accepted. In these cases site-specific discussions to determine the optimum protection solution, possibly using the generic numerical values as a starting point, are increasingly the norm. In embarking on the development of a common approach in a particular area, it is important to be clear where and how to incorporate flexibility if it is considered necessary.

- At a time when national (and international) resources are under severe pressure, it is important that the remit of each European-wide group or association is clearly defined and that the number of groups is optimised to provide for active participation by as many countries as possible. In my view, the success of common approaches to date is that they are based on a wide range of expertise and views and have the support of the maximum number of countries. The servicing of a large number of groups is an issue for smaller countries but also affects the larger countries.

- As regards research, it is important for the current and future state of knowledge that Europe continues to be to the forefront in radiation protection research and research on the management of radioactive waste.

- An issue that is increasingly the focus of attention in recent years is the medical exposure of patients and the need to balance the benefit of such exposures with the individual and societal risks. This is a very complex area. The issue is also complicated from a regulatory point of view in that the traditional approach for other uses of ionising radiation, whereby they are justified and optimised at the generic level before being allowed in a particular individual circumstance, is very difficult, if not impossible, to apply. The recent initiative by HERCA to meet with an industry group involved in the manufacture of diagnostic radiology equipment is an important step forward in addressing this issue.

While individual national regulators can meet with industry groups or other professional groups involved in the medical area in their own countries, I believe that a collective approach to the issue involving discussions between European-wide groups is also needed to ensure that the discussions have a positive outcome. For example, RPII’s engagement with the Irish public health Authorities on radon was much more successful when the international health body, in this case the World Health Organization, also highlighted the issue.

- Historically, in a number of countries the regulation of nuclear safety and radiation protection have been separated. At the European level, although coming under the Euratom framework, there is also a certain level of separation. There is also some separation of protection of the environment generally and protection of the environment in the context of radiation protection. From the perspective of citizens, their main concerns are to do with the risks associated with ionising radiation either in the nuclear field or where radioactive materials are used for other purposes. There is an opportunity to better integrate nuclear safety and radiation protection, and to integrate nuclear/radiation issues with other public health and environment concerns. ■

THE VIEW OF THE FOREIGN AUTHORITIES

Europe's progress towards joint regulation of nuclear safety

by Gerald Hennenhöfer, Director General for the safety of nuclear installations and radiation protection, Ministry for the Environment, the Protection of Nature and Nuclear Safety (BMU) – Germany

A hopeful beginning

The development and construction of nuclear power plants after the Second World War took place in different ways in a divided Europe. Western European projects were first of all based on American models, which later gave way to independent reactor concepts. In Eastern Europe, the Soviet Union were soon pushing through developments of their own. Questions of safety always played an important role, but priority was given to the rapid development of a nuclear power park. Huge demand for electricity was expected and nuclear energy was seen as an almost inexhaustible and cheap source. The technical risks inextricably bound up with nuclear power were initially seen as a secondary issue, as were questions of long-term waste disposal.

Euphoria reigned a natural concomitant to the general economic recovery in Europe after the war. The German Atomic Energy Act, the legal basis for the use of nuclear power in Germany, was passed unopposed in Parliament, and took effect on 1 January 1960. So it is that we can now look back on the fifty-year history of the regulatory system in Germany.

International Cooperation from the outset

The development of the nuclear industry in Europe was marked from the beginning by intensive international cooperation perhaps unsurprisingly, as it was a new technology and it quickly became clear that nuclear material control issues could only be tackled through such cooperation.

The most important platform for this international cooperation was and is the International Atomic Energy Agency (IAEA), whose main concern is the promotion of nuclear energy and nuclear material control. It certainly addressed safety issues from a very early stage and remains a crucial forum for cooperation between regulators. Besides this, there were always bilateral contacts between regulators, especially those states where nuclear power plants of similar design were in operation.

The EURATOM Treaty as a European foundation

At the European level, the Euratom Treaty of 1957 formed the basis for cooperation in nuclear energy use. The main purpose of the Treaty is to ensure the supply of nuclear fuel and the control of fissile material. Furthermore, it served primarily to promote the development of nuclear energy in Member States. Under Euratom, however, Member States also committed to make joint arrangements to protect the health of workers and the public from the dangers of ionising radiation. To this day Euratom basic standards form the basis of radiation protection

regimes in the Member States of the European Union.

The corresponding provisions of the Euratom Treaty also constitute the contractual basis for the regulation of safety issues in the EU. The relevant powers of the Euratom treaty are defined very broadly according to the jurisdiction of the European Court of Justice. However the treaty respects the right of Member States, to independently determine the technical requirements for the safety of their nuclear power plants. It imposes no uniform European standards on the plant-engineering field.

The independent development of European safety Authorities

Accordingly, there was at first no clear sense of cooperation between nuclear safety Authorities at European level. This was one consequence of the differing power plant concepts being pursued by the individual Member States, who initially submitted only to limited regulatory standards. In some countries, initial efforts to rapidly establish nuclear power plants encountered a major obstacle in the form of the debate with opponents of nuclear energy. In Germany, confrontations over individual power plant projects led to the formation of a broad-based resistance movement, around emerged grew the Green Party.

Regulatory development in the nuclear arena in Europe was thus initially uneven, despite the formation of a common market. The platform for cooperation between safety agencies was the IAEA in Vienna, where common standards and principles were developed. There seemed to be little scope for additional European initiatives.

Chernobyl as a signal

The activities of European safety Authorities were also dramatically affected by the Chernobyl disaster. The wide-ranging impact of an event that few had thought possible suddenly became clear from a radiological perspective and even more so from a political one. The radioactive cloud was no respecter of borders, and demonstrated the necessity of East-West cooperation on safety matters, despite the existence of the Iron Curtain. Particularly clear was the need for monitoring by safety Authorities independent of the operators themselves. The immediate initial consequences of the accident were joint efforts within the IAEA to clarify the causes and an agreement on early notification in case of accidents.

Of particular significance, however, are those conventions on nuclear safety and the safety of fuel elements and radioactive waste, drawn up with a significant initial contribution from Germany. A report and review mechanism was established





Organization chart of RISKAUDIT, a European economic interest grouping

within the IAEA, which respects the autonomy of the Member States in the field of nuclear safety while nevertheless requiring the disclosure of their regulatory activities and creates an instrument for mutual control through the peer-review process. This considerably strengthened the control powers of safety Authorities, whose independence from operators was enshrined in the conventions. The IAEA 'Safety Principles' together with the policies and their review mechanisms enshrined in the conventions constitute an essential pillar of international cooperation in the field of nuclear safety.

The integration of Eastern Europe

The opening of Eastern Europe provided an initial catalyst for European safety co-operation. Western safety Authorities and their Technical Support Organizations worked together on behalf of the European Community to familiarise their colleagues from Eastern Europe with Western concepts and to foster their role in improving safety in Eastern European reactors. This East-West cooperation also required greater cooperation between safety Authorities and their support organizations in Western Europe. An example of this was the joint formation of the RISKAUDIT subsidiary by the German expert organization for Plant and Reactor Safety (GRS) and the French Nuclear Safety Institut (IRSN). Initial discussions were held about the integration of Eastern European countries, where Russian-built nuclear power plants were being operated, into the European Community. It quickly became clear, however, that the IAEA standards were insufficient to encapsulate common concepts of the safe operation of nuclear plants in the EU.

The European Commission, responsible for accession negotiations, was unable to resolve the issue, possessing neither the competence nor the experience in the field of nuclear safety. Consequently, the Western European safety Authorities took the initiative of establishing an informal organization, a 'Club' known as the 'Western European Nuclear Regulators Association' (WENRA). The foundation of WENRA was based on the common belief that European safety awareness could not be prescribed from the 'top down,' but needs to be engaged with on a voluntary basis. This in turn gave rise to the WENRA Reference Levels, which today form the basis of the joint understanding of safety in the EU.

The search for a European framework

At the same time, there was increasing call for the creation of a formal framework for nuclear safety within the community. It was seen as paradoxical that while very detailed EU technical regulations exist in non-nuclear domains, the nuclear industry was still not regulated from Brussels. The result was a debate over many years about the need for European legislation on nuclear safety.

The obstacles lining the path to this Directive were significant. On the one hand, a European system had to 'add value' to existing IAEA cooperation. On the other hand there had to be respect for the different levels of development and the variety of technologies in the Member States. The development of common safety standards for facilities that already exist is useful only to a limited extent. If the rules are expressed in too general a way, they have no practical effect and make no contribution to safety; they even risk being misused, so as to formally legitimise unsafe facilities.

Safety Directive

Against this background, the European Safety Directive adopted in 2009 has made good progress. It ties in explicitly with the framework of IAEA 'Safety Principles' and review structures, making these the basis for European cooperation. A framework is prescribed but responsibility remains with Member States. The previously voluntary 'Integrated Regulatory Review Services' of the IAEA to monitor safety Authorities are now mandatory within the EU.

The framework prescribed by the Directive now has to be put into action. It will involve strengthening European cooperation, without at the same time diminishing the responsibility of Member States for the nuclear power plants operating in their territories. It is important that it retains a 'bottom up' approach, as prescribed by WENRA, and no bureaucratic guidelines are issued by the European Commission. The safety Authorities should therefore expand their technical cooperation further, for example through the exchange of technical experts, but also by the formation of joint technical organizations. The Technical Support Organizations could conceivably form a joint institution within the EU along the lines of 'RISKAUDIT,' enabling ongoing cooperation.

New reactors as a challenge

One particular opportunity and challenge for the cooperation of safety Authorities in Europe is the building of the next generation of reactors. In the 1990's, the German Ministry of the Environment and the French Nuclear Safety Authority,

along with their Technical Support Organizations GRS and IRSN, worked closely together to develop safety requirements for the design of the EPR. Although the development of nuclear power plants in Germany has now been abandoned, the EPR, which Chancellor Angela Merkel last year estimated to be among the 'best reactors in the world, can be labelled a true Franco-German, development.

Germany will critically support the establishment of a third generation of reactors in Europe in the future in respect of technical safety requirements, even though it will be building no new nuclear power plants of its own.

A European Agency for Nuclear Safety?

This explains Germany's ongoing interest in the integration of European safety Authorities. There is still some way to go before a joint European authority is established, an undertaking which cannot proceed too quickly, if it is not to undermine national responsibilities.

The next move might be the creation of a 'European Agency for Nuclear Safety' as a joint institution of the Member States. Safety assessments and analyses could be developed there, which could then form the basis for a common European understanding. This would represent a serious step forward towards nuclear safety across Europe. ■



THE VIEW OF THE STAKEHOLDERS (NGOs)

For sustainable participation by civil society in Europe in the oversight of nuclear activities

by Jean-Claude Delalonde, President of the ANCCLI (National Association of Local Information Commissions and Committees), President of EUROCLI (European Associations of Local Information Committees and European dialogue forums)

In the context of its 2007-2009 action plan, "An energy policy for Europe", on 8 and 9 March 2007 the European Council defined an action plan for a European energy policy. The European Council confirmed that it is up to each Member State to decide whether it will use nuclear energy and also suggested that there be extensive discussions between all the stakeholders on the potential and risks of nuclear energy. This proposal led to the establishment of a European forum on the risks and opportunities of nuclear energy. This forum, ENEF (European Nuclear Energy Forum), is run by the Directorate-General for Energy (DG ENER).

The ANCCLI took part in the inaugural meeting of the ENEF forum in Bratislava in November 2007. This participation resulted in full recognition of the issue of transparency as a topic in its own right, at the same level as the issues of risks and opportunities. Following the Bratislava forum, DG TREN set up three working groups: "Risks", "Opportunities" and "Transparency".

At one of the first meetings of the "Transparency" working group, organized by the European Commission and the European Economic and Social Council in January 2008, the ANCCLI was given lead responsibility for the preparation of a discussion paper on participation and implementation of the Aarhus Convention in the nuclear field. The objective was to highlight the experiments, good practices and principles of participation implemented in the nuclear field and which correspond to an implementation of the Aarhus convention.

The Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters was signed in 1998 by the European Community and European countries including the 27 Member

States of the European Union (EU). In the same year, the Committee of the Regions passed a resolution on nuclear safety and local/regional democracy. These two documents indicate strong political and legal recognition of access to information and of participation in the nuclear field. A decade later, it seemed to us important to observe how these principles are implemented in practical terms.

The establishment of local committees in various European countries is one of the leading good practices. The conclusions of this work were presented at the European Nuclear Energy Forum (ENEF) in the Spring of 2008.

The ACN initiative: a forum for open dialogue with civil society on implementation of the Aarhus Convention in the nuclear field

Following this first feedback from participation, the ANCCLI proposed to start a work programme for 2009-2010 to examine this issue in greater depth in partnership with the ENEF and the French Ministry of Ecology and Sustainable Development (MEEDDM), in coordination with the presidencies of the European Union.

The principle of this ACN (Aarhus Convention and Nuclear) approach is to encourage feedback on practical implementation of the Aarhus Convention in the nuclear field in various European countries, and to pool this feedback in order to identify difficulties and good practices and initiate a movement for progress in consultation with the various stakeholders (Authorities, civil society, licensees, experts, local Authorities, etc.). This feedback will enable the stakeholders to identify potential lines of progress, through dialogue and sharing. In addition, a European overview will enable determination of the actions that can be undertaken sustainably at European level to improve transparency in the nuclear field.

To encourage broad participation in this discussion by representatives of civil society from various Member States, the ANCCLI and the European Commission organized a European feedback workshop in Luxembourg on 24-25 June 2009. This first European event brought together more than 80 participants from fifteen European countries, with a large representation of civil society and experts on the Aarhus Convention. It confirmed and extended a diagnosis, benefiting from a number of accounts and a wide range of citizen expertise: the Aarhus convention is implemented in the texts but progress must be made in its practical implementation. To accomplish this, ownership and experimentation are necessary in local and national contexts, and must be conducted by a number of actors from both civil society and institutions. This workshop confirmed the need to take these discussions further forward at national level in order to move on from a general

Action of ANCCLI

The development of nuclear regulation and the governance of nuclear activities more generally are taking shape at European and international levels. The ANCCLI considers that it is important to participate in European bodies when aspects affecting the information and oversight missions of the CLIs (Local Information Committees) are discussed. Article 22 Title VII of the TSN act of 13 June 2006 on transparency makes provision for action to this aim by the ANCCLI: *"The local information committees may establish a federation, in the form of an association, given the responsibility of representing them to the national and European Authorities and providing assistance to the committees on issues of joint interest."*



Extract from DÉCLIC magazine no. 10 from the ANCLI – April 2006

discussion on principles and 'good practices' to detailed analysis of the areas for change in the context specific to each country. This participative discussion corresponds to the spirit of the convention. (The proceedings of the European ACN workshop in June 2009 can be viewed on the ANCCLI website www.ancli.fr.)

Consequently, from September 2009, the ANCCLI and the European Commission opened a European space for dialogue on the practical implementation of the Aarhus Convention in the nuclear field, over a period of 18 months, with three parts: – national round tables at the initiative of civil society entities and institutions in the countries interested by the approach.

The national round tables form a multi-strand group with significant civil society representation. They are organized autonomously in each country. The participants observe and analyse the practices and difficulties encountered in the implementation of the Aarhus Convention in the nuclear field in their country, in the form of feedback from actual cases. Discussion is opened on the actions and measures that can be taken in the country at local and national levels to improve practical implementation of the Aarhus Convention in the nuclear field and to make suggestions on the actions to be taken at European level.

Round tables have been or are being set up in France, Hungary, Rumania, Slovenia, Belgium, Bulgaria, Ukraine and Latvia. These are generally joint initiatives by a civil society organization and institutions (e.g. parliament, ombudsman). The French round table is organized under the aegis of the HCTISIN¹ and the ANCCLI.

– three European round tables on cross-cutting issues are organized by interested organizations and Member States, with support from the European Commission and the ANCCLI. The first round table was held in April 2010 on the implementation of the Aarhus Convention in the area of radioactive waste

management. A second European round table will be organized on access to expertise and increasing competency. The topic suggested for the third round table is the linkage between the Aarhus Convention and the Euratom Treaty, and more broadly the issues of access to information and confidentiality;

– this procedure will be concluded in 2011 by a European conference at which the conclusions of the round tables will be presented. This event will be an opportunity to develop a European overview and determine the practical actions that can be taken to improve transparency in a lasting manner in the nuclear field at national and European levels.

To oversee this procedure and prepare the 2011 conference, a steering committee has been established comprising institutions and civil society entities, including the participants in the national round tables: ANCCLI, European Commission, REC, Greenpeace, Aarhus Convention secretariat, ENEF, MEEDDM, NEA, AREVA, ASN, European Economic and Social Council, EDF, ETSO, GMF, HCTISIN, IRSN, successive EU presidencies, WENRA, etc.

An initial inventory of the implementation of the Aarhus Convention in the nuclear field

The discussions in ACN have shown that a number of experiments and good practices are available in Europe. They are evidence of the richness of the democratic cultures of the Member States. Moreover, the Aarhus Convention has been transposed into Community law and into the national law of the Member States. It is directly applicable to all nuclear activities.

However, at present the actors of civil society are unsatisfied to a certain extent with implementation. Although the principles of transparency are incorporated into the letter of the law, is the spirit of the Aarhus Convention, reinforcing the role of civil society, actually present? Going beyond formal implementation, how can practical implementation of the principles of information, participation and access to justice, which provide concrete responses to the expectations of the citizens, be developed and reinforced? On the basis of the general principles set out in the Aarhus Convention, how can information and participation in the specific area of nuclear activities be implemented in a practical manner, in the context specific to each European country?

The presentations and discussions at the European workshop in June 2009, and those of the first European round table on waste management, highlight the main issues of implementing the Aarhus Convention.

Access to information

Implementation of access to information involves genuine difficulties, relating to demands that are equally legitimate but difficult to render compatible, such as transparency and confidentiality (for commercial or security reasons). This issue, current in the Member States, has a particular resonance at European level, in that the scope of European Union competence in nuclear matters is governed by the Euratom Treaty, which includes provisions contrary to the Convention in the field of information. There are experiments to enable civil society stakeholders to exercise a critical regard over secret documents under the seal of confidentiality. These experiments deserve to be extended.

1. French High Committee for Transparency and Information on Nuclear Security.



According to the Aarhus Convention, the rights of access to information cover environmental information. A jurisprudence is being defined on what should be considered as environmental information in the nuclear field. Requests for information on the cost of waste management have recently had positive outcomes in Belgium and in the United Kingdom.

One of the lessons learned from dialogue between the stakeholders has been the recognition that institutional communication by organizations, legitimate though it may be, does not directly satisfy all demands for access to information. Citizens are seeking certain information that they judge pertinent in order to investigate the issues that seem to them to be important. The discussions have shown the need for civil society actors to produce their own information, if there are currently no answers to their questions or if the conditions for public trust in the available information are not met, and necessitate specific investigations.

Participation

The commitment of local actors and citizens to the oversight of nuclear activities is a considerable effort, generally on a volunteer basis, from which they expect in return effective improvement in safety and in protection of persons and the environment. The participation of civil society actors requires time, specific resources, and conditions of access to multiple information from several sources, not just plant licensees. For this they must have access to public expert assessment but also have their own means of expert assessment.

Various examples of support structures for participation were presented in April 2010 in the field of waste: *community model* in Sweden, partnerships in Belgium and in Slovenia, and others. The composition, autonomy, funding, sustainability and influence of these instruments are all important aspects for determining their effectiveness in terms of participation.

The Aarhus Convention defines minimum conditions for public participation in the impact analysis procedures and in the preparation of plans and programmes. The convention also calls for participation sufficiently upstream of decisions, i.e. when the options are still open. Feedback obtained in ACN shows clearly that a commitment of civil society to issues as complicated as nuclear energy demands time. The vigilance role of civil society cannot be developed only in formal participation procedures, which are by nature limited –short in terms of time, circumscribed in terms of purpose. Because they work on a continuous basis, the CLIs in France can ‘detect’ issues that are important with regard both to territorial security and to transparency and democracy.

Through the example of European projects such as *Cowam in Practice* and *Argona*, the European round table on waste management has also identified the value of establishing neutral spaces of dialogue between institutions and civil society, where those involved can discuss the conditions of governance and the potential for progress. We need these places of dialogue, removed from the often urgent time-scale of decision-making, to advance together towards more transparent and equitable decision-making processes.

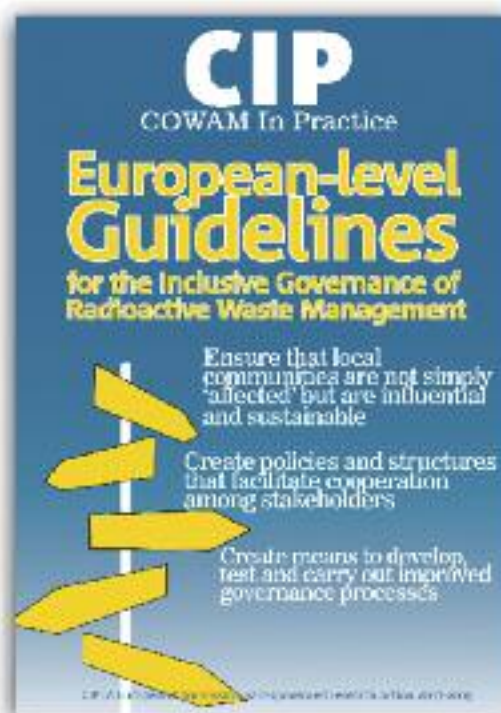
Access to justice

By giving the possibility of legal action, this third pillar of the Aarhus Convention is a guarantee for the various parties that access to information and participation will be implemented. The cases presented in ACN provided evidence of the

complementarity of the actions: from national judges to the Aarhus Convention Compliance Committee, via mediators, ombudsmen and others. The discussions also result in action to favour better knowledge of the Aarhus Convention by those responsible for implementing it or having it implemented.

EUROCLI: civil society in ACN

Profound changes are taking shape in the nuclear field: development of decommissioning activities, waste management, trends in the world energy situation, new nuclear plants, tendency towards transnational and private-sector nuclear industry conglomerates, pressure for international safety standardisation, to mention just a few. These changes have an impact on the security and the development of our territories. Civil society must be able to make sure that such changes are not made at the price of distancing local actors so that they can no longer fulfil their duty of vigilance: local actors must have a place in the regulatory bodies, have access to information and be able to exert an influence on decisions at international as well as national levels. Far from being instruments of obstruction, information and participation are essential tools of our democracy. Transparency is the condition for contribution of civil society and local actors to safety, to the protection of persons and the environment. The ACN experience shows that civil society, through its role of vigilance, makes a positive contribution in the nuclear field regarding security and transparency. This contribution is essential. Citizen participation is an indispensable component of sustainable development durable (Rio Convention). It can even be stated that a safety policy which does not include the conditions for transparency is not credible. In his inaugural speech to the Organization for Economic Cooperation and Development (OECD) conference on access to civil nuclear energy on 8 March 2010, the President of France restated that civil nuclear energy was not possible without a commitment to



European guide to radioactive waste management

transparency. This conviction is widely shared in ACN. Furthermore, it is not enough to discuss the procedures for implementing nuclear energy when the decisions have already been taken. The appropriateness of civil nuclear activities must be discussed without ideological preconceptions in each national and territorial context with regard to the constraints, the potential energy options and the conditions under which such activities are carried out (safety framework, but also transparency framework, in each country).

Given this situation, a legal framework is necessary but not sufficient. There is a great need for a cultural change in order to achieve genuine transparency. For this, all actors concerned must be involved in experiments in the context of each activity, but also in each cultural, political, legal and historical context.

In 2006, the ANCCLI proposed the formation of a European network of local information committees and the civil society actors concerned by the oversight of nuclear activities and transparency. The aim of this network, EUROCLI, is to promote participative democracy in the governance of nuclear activities in Europe, to make the multiple voices of civil society heard by Europe, relaying its questions, concerns, comments and contributions.

Through ACN, this network has expanded. It has shown all the usefulness of a contribution by civil society to dialogue on the practical implementation of the Aarhus Convention in order to make practical progress in transparency in the nuclear field. It meets an indispensable need in the Member States, as well as at European level. This network is based on voluntary commitment by the civil society actors in the various European countries involved, and support from the European Commission. Is this contribution by civil society in Europe on nuclear matters sustainable? Today I hope that, through EUROCLI, the ANCCLI and the other civil society partners consider this question. By drawing the initial lessons from ACN, we can prefigure the conditions for a sustainable contribution by civil society to the governance of nuclear activities, in terms of oversight and participation. I am convinced that a network such as EUROCLI must be able to favour the implementation of the principles of the Aarhus Convention, in compliance with the principle of subsidiarity, the plurality of points of view and the independence of the participants. European civil society is an asset. Transparency can be reinforced by the diversity of our European democratic experiences. ■



THE VIEW OF THE STAKEHOLDERS (NGOs)



Nuclear Energy in Europe does not involve only Economic and Technical issues

by Michel Lallier, CGT representative on the higher committee for transparency and information on nuclear safety, Bruno Blanchon, Head of the Atomic Energy sector at the FNME-CGT and Jean Barra, Deputy head of the Economy and Industry centre at the FNME-CGT

At a time when a number of European countries are resuming their nuclear power programmes or planning to do so, the construction of a European Area for Nuclear Safety and Radiation Protection appears increasingly necessary. This is an opportunity to discuss the issues related to nuclear activities, issues which are not limited just to technical, industrial or commercial considerations.

Nuclear power is not "just another technology": the problems that it raises are societal and transnational. But it is also a technology that does not function in isolation. Thousands of men and women work every day to design, produce, build, manufacture sources, operate facilities, maintain them, monitor, process and dispose of waste, etc. Their role is obviously essential in the functioning of these industries and services, but it is above all crucial for nuclear safety. In other words, to discuss safety without discussing the work and those who do it, i.e. the conditions in which they do it, is to overlook that which structures nuclear safety day by day.

If this aspect is examined in greater detail here, it is not only because it appears to us to be essential, but also because it is rarely considered when nuclear energy, and particularly nuclear safety, are discussed. When it is considered, it is to highlight the essential role of instructions in mitigating the risks inherent in human activity. However, analysis of the work shows that things are more complicated than that. We maintain that there is a social dimension to nuclear safety.

Considerable progress has been made in nuclear safety over the last twenty years. But this progress mainly concerns the 'technical' aspects of safety, such as the reinforcement of the principle of defence in depth. The demonstration of nuclear safety is still based on a deterministic approach, supplemented by probabilistic analyses of accidents and their consequences. These procedures have been reinforced and improved, resulting in progress. But in this concept the human element remains totally overlooked, or appears only as the 'weak link' in the system.

This concept, derived from technical and scientific rationality and instrumental rationality (efficiency, productivity), in the final analysis ignores the fact that the system does not work on its own, simply through the genius of its internal logic or that of its designers. It works because people make it work.

In 2003, the unions at EDF organized a conference on "le Nucléaire et l'Homme" (nuclear energy and Man) which highlighted the essential role of the human element in nuclear safety. For the human is not the weak link, but rather the reliable link, the ultimate barrier to the unpredicted event or the inadequate instruction, or even the arbitrator in the face of accumulation of potentially contradictory instructions.

Discussion of the human at work necessitates consideration of the 'human element' in all its dimensions: physical, psychological and social. Human error is very rare; often there are only potentially deleterious work situations which lead humans to make mistakes. The human factor is often blamed for what is a consequence of the organizational factor. And that is often because determination of legal responsibility takes precedence over social responsibility, so it is more convenient to focus on individual responsibility rather than collective responsibility.

But it is precisely this issue of work that is raised.

A safety culture is above all a culture of professionalism. And between safety and professionalism there is work, for it is in working activity that professionalism and thus skills are applied.

All aspects of working conditions are involved here: social, material and organizational. This concerns conditions of employment, status and job protection, skills and training, as well as conditions related to the working environment, occupational health, safety, work load, working hours, role and effectiveness of working groups, but also the quality of labour relations and above all the potential extent of involvement of workers in the organization and the objectives of their work. The place of the workers in society is another aspect, with regard to social recognition (recognition of their work and its utility by society), their direct and indirect remuneration, their working conditions and their place in civil society; and on several of these points there has been regression for nuclear industry workers in recent years.

All nuclear facility operators make extensive use of subcontracting in their nuclear installation construction and maintenance operations. In normal operation, more than half the working hours are carried out by subcontractor employees, sometimes with cascades reaching five or six levels. The consequences regarding reduction of employee rights and protection have been pointed out previously on many occasions; they are similar in the nuclear industry to those observed in the other industries. But in hazardous industries this raises additional questions. This was demonstrated by the AZF accident (it should be remembered that the AZF plant had been inspected many times by the administrative authority and no serious anomalies had been detected).

It is known that this subcontracting of provision of services is leading in Europe to delocalisation and increased insecurity of labour, manifested by placing employees in a situation of competition through their statuses, their remuneration and their social protection. The nuclear industry is not free of this social dumping at present. Even if the social conditions of the



Poster of the conference on “Nuclear energy and Man” organized by the EDF unions – October 2002

employees involved in nuclear power plant civil engineering works has no direct influence on the safety of the future installations, it is nonetheless worth noting that on the EPR construction site in Flamanville, more than 20% of the employees are foreign workers most of them Rumanian or Polish, and the local trade unions still do not know how much they are paid. Recently at Cadarache, Portuguese temporary workers of African origin working on the Jules Horowitz reactor site were dismissed without notice, despite an eight-month contract, and were not paid for the two months they had already completed: kicked out, ordered to return the keys of the insalubrious accommodation rented to them in return for the ceding of their meal allowances, without pay slips and with a contract stipulating that their personal protective equipment would be deducted from their wages... These issues related to social aspects are directly related to the social acceptability of this industry: all the public meetings organized by the Commission Particulière du Débat Public (French national public consultation commission) for the Penly 2 EPR were marked by this debate.

When the issue of the human factor is discussed, it is often from the aspect of skills. There is obviously a very broad consensus that skills are essential. But it is not enough to have skills; work organizations enabling everyone to apply their skills with complete clarity are needed. Having skilled employees is necessary but not sufficient to guarantee a high level of safety. There is a dual requirement: not just skills, but also the conditions allowing them to be applied, are needed. This may seem obvious, but it is an issue that arises in practice when the reality of working in industrial and medical nuclear facilities is examined in detail. Financial constraints, which in turn generate time constraints, among others, increasing the density and the intensity of the work; the lack of personnel, the

individualisation of work situations which eliminates work groups along with collective skills, which are themselves much more than the simple addition of individual skills, are all obstacles to the implementation of skills. The turnover inherent in subcontracting compromises the know-how, occupational cultures and strategies of caution which are all assets in safety culture. All these elements, characterising the conditions under which skills are implemented and essential to nuclear safety, are currently being degraded, as shown by all the research¹ and surveys on working conditions conducted in the field over the last decade.

This leads to a paradox in which there is an increased level of safety in technical and industrial terms while safety is being weakened by the conditions under which it is implemented. However, these conditions are rarely investigated, as they are under the responsibility of separate regulatory Authorities in most European States. In many states intending to introduce nuclear power there are no Authorities regulating working conditions where there is no labour law and trade unions are prohibited, including for the immigrants who form most of the labour force. But above all because the approach to risk does not take sufficient account of the linkage between industrial risks and occupational risks. Technical aspects are not neutral, and the issues of work, considering all its aspects, are at the heart of the industrial issues.

One of the challenges of a future European nuclear safety area will therefore be to place the issue of work in the nuclear industry at the centre of its concerns. This obviously concerns all sectors, both industrial and medical, and both nuclear safety itself and radiation protection. At European level over the coming years there will be considerable movements of workers between the states in the professional sectors concerned, from construction to medicine via electricity generation and research. The employment conditions offered to these workers, particularly the subcontractors, would then risk becoming economic adjustment variables, to the detriment of nuclear safety. Harmonization of rules and inspections must also be accompanied by best-practice harmonization of the terms and conditions of employment of nuclear industry workers.

In the area of radiation protection, i.e. in the prevention of radiological risks, nuclear energy is an exception. In contrast to other carcinogenic risks, the principle of justification is applied, not the principle of substitution. The advantages gained by its use are set against the risks that it generates. These advantages must be substantially greater than the risks, rather than simply “compensating” for them as stated in the current draft European directive on radiation protection. The issue concerns the processes leading to a decision. In a medical practice this consists of a discussion between the doctor and the patient, resulting in a joint decision. Such a process is impossible in industry; decision-making is referred to discussions between experts, discussions in which the workers are represented by trade unions (although even this is not always the case) and result in opinions which experience shows are only consultative, not decisive in any way.

It is worrying to observe that radiation protection in industry is reduced to just its technical aspects, ignoring any relation with the human nature of work groups, a nevertheless fundamental concept when ensuring day-to-day radiological protection of personnel.

1. Bibliographic record, Daniel Lorient, 2003.





Website for the Penly EPR public debate,
www.debatpublic-penly3.org

The temptation to consider radiation protection as a constraint rather than as a key factor in the operation of nuclear facilities leads to minimisation of the needs for trained radiation protection technicians (radiation protection is an occupational field in its own right) and multiplication of self-protection practices.

The most recent epidemiological² studies show that the relative excess cancer risk for nuclear industry workers is greater than that concerning exposure to other carcinogens in other industries. Moreover, many nuclear industry workers are exposed during their careers to a large number of carcinogens, and they are often the most vulnerable in terms of employment conditions and labour law. Some nuclear decontamination contractors are also specialised in asbestos removal, and the same employees aggregate the risks.

All these elements linked with the relations between nuclear safety, working conditions, employment protection and radiation protection must lead to strengthening of the employment and health protection of the workers concerned. The European industrial project must be accompanied by a genuine social project; the second is even an existential condition for the first, as societal acceptance of the nuclear industry depends on the social project.

Recent decades have been marked by two major events.

First, the Chernobyl accident, which has amply demonstrated that its direct and indirect impact crossed the borders of the country in which it occurred and that it did not affect only the electricity utility, the plant builder and the responsible safety authority. Already, nearly 10 years previously, the Three Mile Island incident had led to upgrading of many nuclear facilities around the world.

Second, the completion of construction of the French nuclear power plant fleet, which was organized with a determinedly

national approach bringing together an electricity utility, a plant builder and a safety authority, the three of them specifically national.

Today builders, operators and safety authorities are confronted with a situation very different from that in France at the beginning of the 1980s. This means that in each case a balance must be found between plant design, plant licensee actions and regulatory Authority role. There is no basis in principle for excluding the possibility that this balance differs between countries, according to their domestic political, social and of course economic equilibrium. Given the substantial weight of operating conditions in actual safety, societal issues, from analysis of wage disparities and the resources available for social needs to the real acceptance of nuclear power by the population, must be taken into account.

From this point of view, it does not appear that all the conclusions have been drawn from experience.

Similarly, to assess the actual safety of an installation, whether current or future, other factors have to be taken into account, including:

- the existence of a nuclear culture in a given country. This was the case in China before 1986. It has been considerably reinforced since then, with help from other countries including France. It is not the case today in Abu Dhabi, and it is reasonable to think that expertise and regulation are going to have to be built up there practically from scratch;
- the capacity of a country to obtain regular supplies of high-quality nuclear fuel, to manage the new or spent fuel, and manage waste and spent fuel in a safe manner. The incidence on safety of economic constraints on the fuel cycle, over which many countries do not have control at present, must obviously be analysed. This is what is driving the CGT to put forward the idea of an international nuclear fuel fund, providing an international and democratic means of supplying the fuel necessary for an increasing number of countries.

These issues are part of a worldwide approach to nuclear safety, and also show the limits of a specifically European approach.

At the same time, the necessary adaptation of a general concept of nuclear safety to the reality of each country must not lead to a disparate juxtaposition of variable-geometry rules around the world. The current experience with the EPR – including the industrial and commercial failure of French companies in Abu Dhabi – shows that an aggregation of existing rules, inadequately thought out and standardized, is not sufficient to obtain international acceptance.

It could be wondered whether confrontation with the reality of other countries might lead to the addition of new requirements without improving the actual level of safety, or even reducing it, by not taking into account the characteristics of the work of the employees as described above under the actual conditions in the different countries or the industrial practices in these countries.

The difficulties observed in establishing a dialogue on these issues (State, companies, employee organizations) unfortunately illustrate the deficit of democracy from which the nuclear sector suffers today, a deficit completely prejudicial to its development in France, in Europe and worldwide. Safety issues do not avoid this rule.

A few weeks before the explosion of the Union-Carbide plant in Bhopal, the trade unions had warned the company

2. D. Hubert, "Travailleurs du nucléaire; données actuelles et études en cours: communication aux "rencontres nucléaires, rayonnements et santé-actualité", January 2010. Ellen IMBERNON, cancers professionnels: vers une meilleure connaissance, InVS Report – 2009.

management and the government of Madhya Pradesh province in India about the dangerous state of the plant, essential safety items of which were not longer being maintained. They were evidently not heard; worse, some of its union leaders were dismissed. But the question should be asked frankly: if the trade unions at a nuclear plant in Europe and particularly in France issued such a warning, would they really be heard? The answer, also evident, shows how much ground must still be covered in the area of social dialogue in Europe on issues as essential as the links between industrial risks and occupational risks and between nuclear safety and employment protection. A difficult dialogue between company managers at present sticking rigidly to technical and commercial certainties and trade unions divided between frustration at not being heard (which may eventually lead them to minimise the risk) and fear that media exposure of such a risk would have negative effects on the jobs of employees or on the very principle of using nuclear energy.

That is why reinforcement and harmonization of requirements and their regulatory control by the States and independent administrative Authorities must be supplemented by true social monitoring, carried out by the citizens externally and by the workers internally. This necessitates reinforcement of transparency and social dialogue.

For these reasons the CGT has taken the initiative of organizing a European conference to be held in Paris in 2011 on the topic "Nuclear safety and radiation protection: the challenges of social dialogue in the nuclear industry in Europe". ■



THE VIEW OF THE STAKEHOLDERS (NGOs)

Europe and patient radiation protection: room for improvement

by Professor Guy Frija, Member of the Executive Council of the European Society of Radiology (ESR), Chairman of the National Societies Committee

Radiologists feel very concerned by Euratom directives, principally those on radiation protection of workers and patients. In what follows particular attention will be paid to the latter, as it sets out principles that determine in great depth the practices of radiologists and their organization.

Fundamental principles: how can they be better applied?

The major aspects of the Directive on the radiation protection of patients (DRP) can be summarized as follows: examinations must be justified, and they must be conducted in an optimised manner to minimise the radiation dose. The dose must be recorded in the report, the equipment must undergo periodic quality controls, and clinical audits must be conducted to assess the implementation of these provisions. The conditions necessary for application of this directive include production of a guide to proper use of radiological examinations and effective application of this guide when an examination is prescribed. Optimising the execution of the examinations requires the establishment of dose reference levels that must be kept up to date. Recording the dose in the report requires automatic transmission of the dose using information systems integrated into the DICOM environment, as will be seen below. The implementation of clinical audits has been delayed, and was very recently the subject of a European Commission recommendation; nevertheless, the implementation of these audits requires the definition of a suitable methodology and the availability of the necessary human, material and financial resources. It is important to emphasise that the implementation of all the aspects of the directive is taking place in a context of very strong growth in collective doses for medical reasons, as a consequence mainly of the increase in the number of indications for CT scan examinations and an alleged increase in the number of deaths caused by this greater radiation doses by CT scans, according to a number of articles published in the leading international journals.

There are good reasons to think that the DRP is applied very incompletely, although no comprehensive information is available on this topic, whether at national or European levels. The first difficulty involves the concept of justification of practices: the example of France is eloquent in this regard. The *Société française de radiologie* (French radiology society) has published a guide, but lack of resources has meant that it has never been possible to distribute it to the examination prescribers! And even if this guide had been distributed as intended, would it have been used? The available information suggests that only two countries in Europe (France, through the *Société française de radiologie*, and the United Kingdom, through the Royal College of Radiologists) have drawn up guides to acceptable indications. If other countries have not

produced their own guides, it is because the procedure is long, complex and expensive. For this reason the majority of Member States has preferred either to use the guide provided by the European Commission or to translate the Royal College guide or that of the *Société française de radiologie*.

There is abundant evidence in the literature to show that issuing recommendations, publishing guides or organizing consensus conferences is not enough to modify practices. It is uncertain whether the new European directive on radiation protection, now in preparation, will have a significant impact on radiation protection of patients. Moreover, it has been very widely demonstrated, for example in the United States, that the implementation of a prescription aid system for drugs increases effectiveness while reducing errors and costs. Although there are few examples in the literature concerning imaging, those available (Boston) are sufficiently convincing to suggest that the benefits obtained for drugs could also be obtained in the field of imaging. Private insurers in the United States have developed a pre-authorisation system and can thus refuse reimbursement of about 20% to 25% of CT-scan, MRI and PET-CT requests. This confirms that it is not sufficient to establish reference documents on good practices, but that it is also necessary to introduce a system to apply it: it seems that the example of drugs could be followed for imaging.

Recording of the dose in the report was made compulsory by the DRP; on the initiative of the *Société française de radiologie*, an interoperability profile (IHE) has been developed to address the dose automatically to the report from the imaging modalities. However, this recent advance is not yet offered systematically by the manufacturers. The problem also arises of integration of this automation into the existing equipment park. Nevertheless, this automation could be the precursor of the establishment of local, national or even European databases. A number of voices are now being raised in the United States in favour of the establishment of a national register.

The report must provide the justification, the optimised examination protocol and, as stated above, the dose. All this information exists, but separately: in the referral, or in the appointment module, or in the acquisition console, or in the PACS. Only its automatic integration in the report would allow effective authentication and tracking of the implementation of the basic principles of the DRP. This overall and integrated concept requires the development of suitable information systems fully complying with the interoperability standards. Inclusion of relevant information in the report, once automated, would open the door to a number of possibilities, for example the use of the report for the purposes of clinical audit, or the compilation of registers.

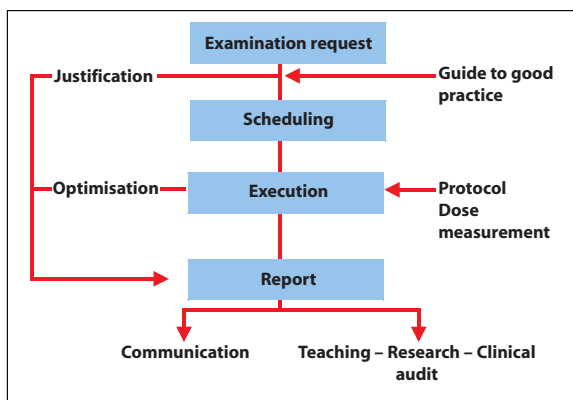


Figure 1: overall integrated concept from examination request to report: information on justification, optimisation and dose measurements must appear in the report. The report may be used for communication of the results, teaching, research and the development of clinical audits.

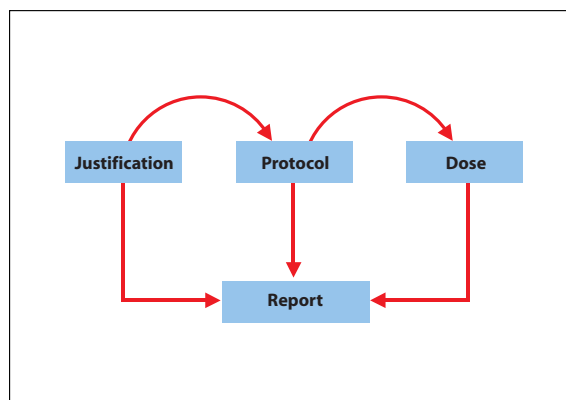


Figure 2: the justification information defines the protocol, which determines the dose level. This interaction produces scattered information, which must be collected to be included in the report. Only an overall information system enabling automation of these processes could accomplish this in a complete manner.

A fragmented Europe

The European directives on the radiation protection of patients and workers depend principally on the Directorate-General for Energy, the involvement of the Directorate-General for Health (DG SANCO) lacking visibility. The development of an integrated information system would necessitate dedicated funding for research and development; however, these programmes are under the responsibility of another Directorate-General (DG INFSO) without considering the possible involvement of DG Research. It is thus very difficult, in this fragmented context, to have an overall approach to the solutions that would be required for the full implementation of the DRP. This can be illustrated by one of several examples: recently the European Commission's call for tenders for the production of a guideline documents on good practices was judged fruitless for reasons of methodology and cost. The European Society of Radiology and the Commission have so far not been able to reach an agreement on these points nor on the development and continuity of a decision-making aid system. To this can be added the fact that the World Health Organization and the International Atomic Energy Agency are also interested in this issue, which only adds confusion in the search for practical solutions. It should be emphasised that increased awareness is emerging in the United States of the problems of medical irradiation, substantially later than in Europe, principally because of the increment of CT scan procedures. The recent initiative (March 2010) by the Food and Drug Administration (FDA), which organized a meeting involving the various stakeholders (manufacturers, academics, patient representatives, practitioners), is one of the most interesting aspects of this. However, given the fragmentation at European level highlighted above, it is difficult to see how such an initiative, which has a number of merits, could happen in Europe.

The Heads of European Radiological protection Competent Authorities association (HERCA), established in 2007, intends to take a central role in reinforcing the links between radiation protection competent Authorities and developing a common approach to regulation and its practical implementation. HERCA took the initiative of meeting the manufacturers of CT in 2010 to ask them to work on reducing doses. It is simply regrettable that so far this initiative has not involved the users, through their institutions (the European Society of Radiology,

for example). Yet the European Society of Radiology has information on the level of implementation of the DRP through a survey conducted almost four years ago. This survey revealed very great heterogeneity within the Member States, which can only make the construction of a European radiation protection area more complex.

Suggestions

In our opinion, only an overall and integrated (in the IT meaning of the term) approach to the three phases of the process – examination request, optimised execution, report – would enable effective implementation of the DRP (figures 1 and 2). This requires the development of dedicated interoperable information systems which must incorporate prescription aid systems based on scientifically-established benchmarks, methods of automatic transmission of the validated indication, the examination protocol and the dose into the report, and indicators for measuring the compliance of practices with all the benchmarks. Such an approach, already running smoothly in the field of drugs, could be used as a guide by the various Directorates of the European Commission that are concerned by this issue: Health, Energy, Research, Information Society.

Europe could also make use of its specific nature in the international institutions (WHO, IAEA) that also take an interest in this issue. It could also call upon the various societies and associations representing the users, of which EMAN (European Medical ALARA Network), funded by the European Commission, provides an excellent snapshot. In this context, the European Society of Radiology (ESR) has organized working groups (table 1) on radiation protection and information technologies. It is consequently fully ready and resolved to stimulate a concerted approach within the European Commission and to play its role in it, while recognising the federating role of HERCA in terms of regulation, practical implementation and harmonization. Such a concerted approach within the different Directorate-Generals of the European Commission would establish the basis of a collaboration with the American institutions that are involved (the FDA, for example). The latter point is extremely important, because the numerous and enriching recent topics of discussion include that of the principle of marketing authorisation of radiology equipment: should this principle remain generic, as is currently the case, or on the contrary evolve for the sake of radiation protection to specific



Table 1: European Society of Radiology (ESR)

Committee on Radioprotection Chair: Peter Vock (Switzerland)
Committee on Information Technology Chair: Peter Mildemberger (Germany)
EMAN European Medical ALARA Network Co-Chair: Peter Vock (Switzerland)

Examples of European Society of Radiology working groups. Further information: www.myesr.org

After having established the European regulatory framework for radiation protection of workers and patients, the European Commission should now focus its action on three aspects in the context of the formation of a European radiation protection area: first, establish the conditions for an overall approach to radiation protection; then fund decision-making aid systems to reduce unnecessary examinations, and software integrating data that is currently fragmentary; lastly, federate the various partners in radiation protection in order to avoid dispersal and redundancies. This will be necessary for the future compilation of national and European databases and the introduction of a benchmarking framework that will be much needed by the users and the Authorities. Active participation by the various actors concerned is a guarantee of success both with HERCA and with the Commission. ■

applications? It would be highly regrettable for Europe and the United States to have different approaches on this crucial point. The work on the revision of the directive on medical devices should include this aspect, but it is clear that, here also, it would be preferable to act in a manner consistent with the Directorate-Generals concerned by radiation protection.

In conclusion

The DRP has had the immense merit of providing a framework for the issues with a view to improving the quality of practices while reducing the risks related to radiation. Promulgated in 1997, it is now evident that this directive is only marginally applied, essentially because only scattered information is available to the radiologist, which is in practice difficult to collect systematically in a report and even more so in a database.

THE VIEW OF THE STAKEHOLDERS (NGOs)

The bad debt of nuclear responsibility

On policies to reduce the risks

by Jan Haverkamp, Greenpeace EU policy campaigner dirty energy

When the Greek titan Prometheus brought fire to Earth, little did he know of the consequences. Over the centuries, people have tried to manage the danger of the flames. Children were taught to stay away from fire, fire-brigades were organized, and fire-retardants developed, yet mankind never managed to totally control it. In short, we have always been playing with fire. But by comparison, the power of concentrated radioactivity casts a long shadow over any dangers from fire well and truly in the dark.

Nuclear regulation plays an important role in keeping the visible and invisible threats of radioactivity at bay. Society relies on the independence and expertise of nuclear regulators to protect it from the risks that concentrated radiation poses to people. People, that have not necessarily chosen to run the risk of being exposed to the rays. And often people that do not fully understand the dangers. Whether this is from exposure from the Chernobyl catastrophe, the Tricastin leaks, the leaks from the Centre de Stockage de La Manche, the tritium emissions from the CANDU reactors in Cernavoda or the potential risks from radioactive waste to future generations.

The task of managing these risks is enormous, and different European countries, different European cultures show different degrees of coping.

During the last three decades, I have personally been confronted with many attempts by regulatory Authorities to downplay risks. Many examples of regulatory bias in favour of those wanting to use nuclear technology for technical pride or financial gain. I have also seen attempts to live up to the ideal – at least to a certain extent. As nuclear campaigner – a voice on the side of people that have not chosen for nuclear energy – I have often wished that regulators in Bulgaria, Romania, Slovakia or the Czech Republic would be at least as rigorous as their colleagues from Finland or Germany, realising of course that different cultures, different social and political power relations and difficult histories may make that a challenge. And I have often wished that regulators in Finland, Germany, France or the UK would dare to draw the ultimate consequence from their expertise and experience and openly speak out against the creation of more risks.

Nuclear phase-out

There are several issues that urgently need to be addressed to improve nuclear safety in Europe. In Belgium, as example, over 80% of the volume of long lived and medium radioactive waste comes from the nuclear energy industry¹, and even 100% of the high-level waste. This together contains over 99% of the total radiation in all categories of radioactive waste². If we expand that picture to a global level, it is safe to assume that the nuclear energy sector and military sector together produce radioactive material that contains a large majority of the radioactivity in man-made substances. For a hazardous substance like mercury, world-wide policies were developed to reduce its risks, and goals set to phase out its use. Learning from the toxic substances debate, the logical consequence of the nuclear safety debate is a phase-out of the most alarming sources of nuclear risk, nuclear power and nuclear weapons – sources for which there are economically, socially and environmentally viable and preferable alternatives. The nuclear sector, however, still doggedly separates discussions about nuclear safety and the use of these largest sources.

For nuclear power, alternatives exist in the form of energy efficiency and renewable energy sources. This is illustrated in a series of recent scenario studies by among others Price-Waterhouse-Coopers³, McKinsey⁴ as well as the Energy [R]evolution scenario developed by Greenpeace and the European Renewable Energy Council⁵, all showing that the most stable and beneficial development of the energy sector towards 2050 is one based on a phase-out of nuclear power and at the same time decarbonisation of the energy sector.

A phase-out in the military sector requires rethinking of security doctrines and full transparency about all current dangers that the possession of nuclear weapons is posing.

Full accountability, independence and transparency of regulators

Czech nuclear regulator inspection report 15/2001/SUJB is for Greenpeace a central symbol of failing nuclear regulation in Europe. This report discusses the seriousness of whistleblower

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2. Peter Raeymaekers, *Comment décider de la gestion à long terme des déchets radioactifs de haute activité et de longue durée de vie?*, Brussels [2009] Fondation Roi Boudouin, page 13; www.kbs-frb.be/uploadedFiles/KBS-FRB/05%29_Pictures_documents_and_external_sites/09%29_Publications/ONDRAF-DEF.pdf

3. Price-Waterhouse-Coopers, PIK, IASA, ECF, 100% renewable electricity; A roadmap to 2050 for Europe and North Africa, London [2010] Price-Waterhouse-Coopers; www.pwc.co.uk/eng/publications/100_percent_renewable_electricity.html

4. McKinsey & Company, KEMA, The Energy Futures Lab at Imperial College London, Oxford Economics and the ECF, Roadmap 2050 - a practical guide to a prosperous, low-carbon Europe, Berlin [2010] European Climate Foundation; www.roadmap2050.eu/downloads

5. Sven Teske [ed.], energy [r]evolution - towards a fully renewable energy supply in the EU 27, Brussels [2010] Greenpeace / EREC; www.greenpeace.org/eu-unit/press-centre/reports/EU-Energy-%28R%29-evolution-scenario

6. Jiří Tutter, Jan Haverkamp, Tajná oprava svaru potrubí primárního okruhu s reaktorovou nádobou na 1. bloku jaderné elektrárny Temelín, Prague [2001] Greenpeace; <http://old.greenpeace.cz/archiv/faktax.pdf>

Jiří Tutter, Jan Haverkamp, The Risks of Škoda - Unsettling facts on the Temelín Nuclear Power Plant concerning faulty welding work and documentation in Temelín block 1 - Fact sheet, version 5.02, Prague [2006] Greenpeace; www.wisebrno.cz/dokument.php?id=51





Greenpeace protests the lack of secondary containment of the Mochovce 3,4 nuclear power plant during the European Nuclear Energy Forum, 2008 in Bratislava. The author is standing on the right hand side.

allegations of an illegal repair of weld 1-4-5 in the Temelín nuclear power plant in South Bohemia⁶. The repair took place in 1993 after a Russian supervisor saw that one of the eight main cooling pipes had been welded 180 degrees the wrong way to the reactor vessel. In order to prevent penalties for the contractor and sub-contractor involved, welders were ordered to cut the weld on the seam, turn the pipe and re-weld. Documentation was adapted to cover up the scandal. A whistleblower surfaced seven years later. A group of five Czech nuclear regulator (SUJB) inspectors investigated the claims and produced report 15/2001/SUJB, confirming that there was a problem that needed to be investigated further. SUJB management buried the report, ordered at least five other investigations, each excluding weld 1-4-5. Access to report 15/2001/SUJB is refused to Greenpeace up to today – nine years after the initial request – and our access to information request has finally reached the Constitutional Court of the Czech Republic, which is expected to come to a decision before the end of this year. In the mean time, inspectors and witnesses were intimidated, criminal investigations stopped without justification, court cases cancelled – in my opinion to prevent witnesses from speaking out. Most worryingly of all, Temelín block 1 has operated for almost ten years with what is possibly a compromised crucial weld.

Episodes like this are unforgivable. Not only do they undermine the credibility of the regulatory regime globally, they are demonstrative of a wide range of structural problems that could be the basis of another nuclear catastrophe of Chernobyl-like proportions.

With one of largest overview reports of international and Russian language scientific research⁷, Greenpeace was deeply involved in debunking attempts by the nuclear sector and its global regulator, the International Atomic Energy Agency (IAEA), to downplay the number of victims from the Chernobyl disaster. We also brought radioactive samples from the village of Bobr – one of the villages just outside the forbidden zone of

Chernobyl – into the offices of the IAEA in Vienna⁸. The move helped force the IAEA to concede that it was wrong to advise people to return to the evacuated villages. The IAEA is maybe the clearest example where a mandate to regulate collides with a mandate to promote nuclear power.

For the general public, nuclear regulators should be fully reliable and accountable. Not in order to give credibility to the nuclear sector, but in order to protect the population and environment from harm. Nuclear regulators are not service organizations for the nuclear industry. They are control institutions acting on behalf of the people in order to try and keep an inherently dangerous industry contained. To maximise nuclear safety today, nuclear regulators should be fully independent, transparent and accountable to the people.

National regulatory structures are bound by Europe-wide regulations concerning independence and transparency. One example is the Aarhus Convention on transparency, public participation and access to justice in environmental matters⁹. But even in countries that are signatories to the convention, quite a few Authorities, including some nuclear regulators, feel they can restrict transparency, public participation and access to justice if it concerns nuclear matters. On EU level, the Euratom Treaty – not a signatory to Aarhus – is on several points in direct conflict with the convention.

An extreme example of nuclear lack of transparency in conflict with Aarhus recently arose in Slovakia, where its parliament, under pressure of the Slovak nuclear industry, adopted changes to the nuclear law and the law on access to information that declare all nuclear information outside Environmental Impact Assessments off-limits¹⁰. Slovak regulator UJD did not protest or try to prevent this from happening. This robbed the public – and civil society – of its essential watch-dog function. In 1977, the Austrian philosopher Robert Jungk predicted in his book “Der Atomstaat”¹¹ the emergence of a nuclear to state expertocrat but fundamentally fallible. He argued that the “Atomstaat” was inevitably necessary to force society to accept a large amount of nuclear technology. Slovakia shows that the “Atomstaat” destroys the self-regulatory mechanisms of a vital democracy. The question is whether this is healthy for nuclear safety.

If a high level of transparency means that painful questions are asked, it is for the nuclear industry to take up that challenge, and for regulators to facilitate this debate. Today's reality is, however, that industry clams up every time a critical question surfaces, and that regulatory Authorities often step back. As one regulator once put it to me: “We rely on good relations with the operator. Otherwise we simply may not get the information we need.” Understandable, but deeply worrying.

Safety rules based on best available technology and best regulatory practice

When Greenpeace, Friends of the Earth and le Réseau Sortir du Nucleaire (as the only invited non-governmental organizations) were still participating in the European Nuclear Energy Forum, it agreed in its 2008 Prague¹² and Bratislava¹³ conclusions, that

7. Yablokov, A. I. Labunska, I. Blokov (eds.), *The Chernobyl Catastrophe – Consequences on Human Health*, Amsterdam (2006), Greenpeace; www.greenpeace.org/international/Global/international/planet-2/report/2006/4/chernobylthealth-report.pdf

8. Jan van der Putte, *Greenpeace Chernobyl sampling operation* (October 2005), Amsterdam (2005) Greenpeace; www.greenpeace.org/international/en/publications/reports/chernobyl-sampling-operation-b/

9. www.unece.org/env/pp/

10. http://spectator.sme.sk/articles/view/38198/10/classified_data_about_nuclear_power_goes_against_eu_rules.html

11. Robert Jungk, *Der Atomstaat – Vom Fortschritt in die Unmenschlichkeit*, München (1977) Kindler, ISBN 3-463-00704-5

12. http://ec.europa.eu/energy/nuclear/forum/meetings/doc/2008_05_22/2008_05_22_conclusions_enef.pdf

13. http://ec.europa.eu/energy/nuclear/forum/meetings/doc/2008_11_03/conclusionsbratislava08.pdf

nuclear safety standards in Europe should be based on best available technology (BAT) and best regulatory practice (BRP). The European Commission only quoted the part of the sentence stating that the Forum wanted to see European regulation of standards, without mentioning the conditions of BAT or BRP. For us, this was one of the many reasons to leave the Forum in 2009. It had become a platform for alibi-ism for the nuclear industry, and discussions about a serious approach at European level towards increased nuclear safety had become impossible.

The principle of BAT is broadly accepted for containing the risks of hazardous substances. Not so for the nuclear sector. Here we see standards set by the IAEA and WENRA. Being accepted on the basis of consensus from all UN Member States, respectively WENRA members, these standards are based on the lowest common denominator. We are once and again confronted with nuclear operators, and regulators, who argue that outdated technical solutions may be implemented – or even “got the green light” – because they meet the IAEA and WENRA standards. This includes the lack of a secondary containment for the Mochovce 3,4 nuclear power station – a new-build project in Slovakia based on the 1970s Russian VVER440/213 design. It also includes the acceptance of high tritium emission levels, a positive void factor, as well as pre-9/11 malevolent attack protection standards for the CANDU reactors in the Cernavoda 3,4 project in Romania. It makes completely outdated approaches and techniques ‘acceptable’ for nuclear reactors that after their projected life-time of 30 or 40 years request permission for a life-time extension to as much as 60 years of operation.

The general lack of ambition to increase the ceiling of safety standards to the level of BAT is spreading throughout the nuclear fuel chain: intending to give the public the impression that radioactive waste is fully under control, unfinished research projects, like that into possibilities for deep geological storage or disposal in Finland, Sweden and France, are presented as solutions without waiting for the outcomes of the research. There is only one sector known to me where we see a similar flagrant breach of proper scientific standards for the sake of public relations, and that is in the debate around genetically modified crops.

If industry pushes for the use of nuclear technology in whatever area, society simply has a right on the use of best available technology and the best regulatory practices. The cost that that brings, is a justified internalised cost related to nuclear technology. Cutting corners is an unacceptable externalisation of risks.

The radioactive legacy of this generation – nuclear safety challenges for future generations

Our generation is responsible for the construction of over 550 nuclear reactors for energy production. Over a hundred have already been closed down, most are still cooling. Even though next generations will not be able to benefit from the electricity produced by these power stations, they will need to take responsibility for proper decommissioning of nuclear installations and management of radioactive wastes – a period of responsibility beyond human imagination. Decommissioning of recently built reactors will likely not take place this century. Low level waste sites need guarding and regulatory overview for 300 years. Middle and high level waste needs to be kept out of the environment and human hands for tens to hundreds of thousands of years. The nuclear safety concerns related to such time spans go beyond anything humankind has ever encountered.

More than anyone else, nuclear regulators, familiar with the complexity of nuclear safety in the here and now, will be called upon to define criteria that will safeguard future generations from our nuclear legacy. And where no certain answers are possible, it will be important that regulators point out the uncertainties that are faced – not only the quantitative ones, but also qualitative questions around the predicting capacity of mathematical models, as well as the predictability of political stability, economic stability, development of technique and other factors that will influence the level of nuclear safety posed by legacy machinery, installations and wastes. In Greenpeace’s view, current management of the largest uses of radioactive materials – nuclear energy production and possession of nuclear weapons – as well as decisions about future use of nuclear technology need to reflect fully the as yet unanswered questions around this legacy. Our generation has to feel and bear the full technical, financial, safety and security responsibility for its decision to use radioactive substances for energy production and military security.

The Euratom Nuclear Safety Directive – the smallest possible step forward

Last year, the European Council accepted a new Euratom Nuclear Safety Directive, that was widely hailed by the nuclear industry as a landmark step, and a basis on which decisions for new nuclear projects could be taken. Greenpeace, but also other non-governmental organizations, disagree strongly. Overall, the directive does not add much to the lowest-common-denominator approach that was already in place with the IAEA and WENRA safety guidelines. In practice, this means that when nuclear reactors are given a life-time extension, their safety does not have to be upgraded to what is considered today as best available technology. They are allowed to continue operating on the basis of outdated perceptions of nuclear safety. But also new built second generation reactors like the Mochovce 3,4 project in Slovakia and the Cernavoda 3,4 project in Romania can continue as if nothing moved on since the 1980s. Under the directive, operators and investors can only be corrected for things they were not supposed to do anyway before the directive came into place.

The only step forward is possibly the codification of independence for the nuclear regulator: “Art. 5(2) – *Member States shall ensure that the competent regulatory authority is functionally separate from any other body or organization concerned with the promotion, or utilisation of nuclear energy, including electricity production, in order to ensure effective independence from undue influence in its regulatory decision making.*” This is important, because as the above mentioned example of the Temelín welding case and the IAEA show, if there is in any way a functional link of dependence, consequences can be far-reaching. This directive article can also become an important trend-setter. Such an independence clause should not only be valid for nuclear regulators, but for instance also for nuclear waste Authorities and funds for decommissioning and waste. These institutions have a responsibility that goes far beyond the economic well-being of nuclear operators. Their primary responsibility is to the general public and future generations.

14. Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations; <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0071:EN:HTML:NOT>



Greenpeace demands improvements in nuclear safety

Twenty four years after Chernobyl, there seems to be slackening in public awareness around nuclear safety. This was, for instance, recognisable in reactions to the recent Deepwater Horizon oil blow-out, which prompted several commentators to plead for a shift towards more nuclear instead of oil. If Deepwater Horizon has shown anything, it is that even when the highest level of technology is used in an industry in which safety culture is said to be deeply engrained, the unexpected can still happen – and if it happens, the consequences are catastrophic. We do not want another accident of the magnitude of Chernobyl or Deepwater Horizon to alert the public, Authorities and operators to the risks of the use of concentrated radioactive substances.

When the risks posed by radiation are properly considered, the following priorities become clear:

1. a phase-out of nuclear energy and nuclear weapons;
2. introduction of BAT and BRP as leading principles for remaining nuclear licensing procedures and nuclear safety legislation;
3. the realisation of full independence for nuclear regulators, nuclear waste Authorities and nuclear decommissioning and waste funds;
4. maximum transparency throughout the nuclear fuel chain to create maximum public and expert feedback to maintain the highest level of nuclear safety.

In the ideal world, nuclear regulators, as representatives of the people and future generations, should be led by the



Activists from Greenpeace project slogans such as “Nuclear Undermines Climate Protection” and “Energy [R]evolution Now!” over the panorama with Prague Castle in the background. The action is to draw attention to the risk of weakening of European nuclear safety standards and seriously biased discussion in advance of today’s opening of the second meeting of the European Nuclear Energy Forum.

precautionary principle. In truth, they should be the ones pleading for nuclear phase-out, fight for their own independence, for the introduction of BAT and BRP and for maximum transparency. Today, despite the occasional example of courage and professionalism of some inspectors to live this ideal and the odd attempts from others to improve structures, Europe still has a very long way to go to reach these vital goals. ■

Contrôle review’s articles present the ASN view of the subject covered and gives an opportunity for the various stakeholders concerned to express themselves freely with regard to the law.

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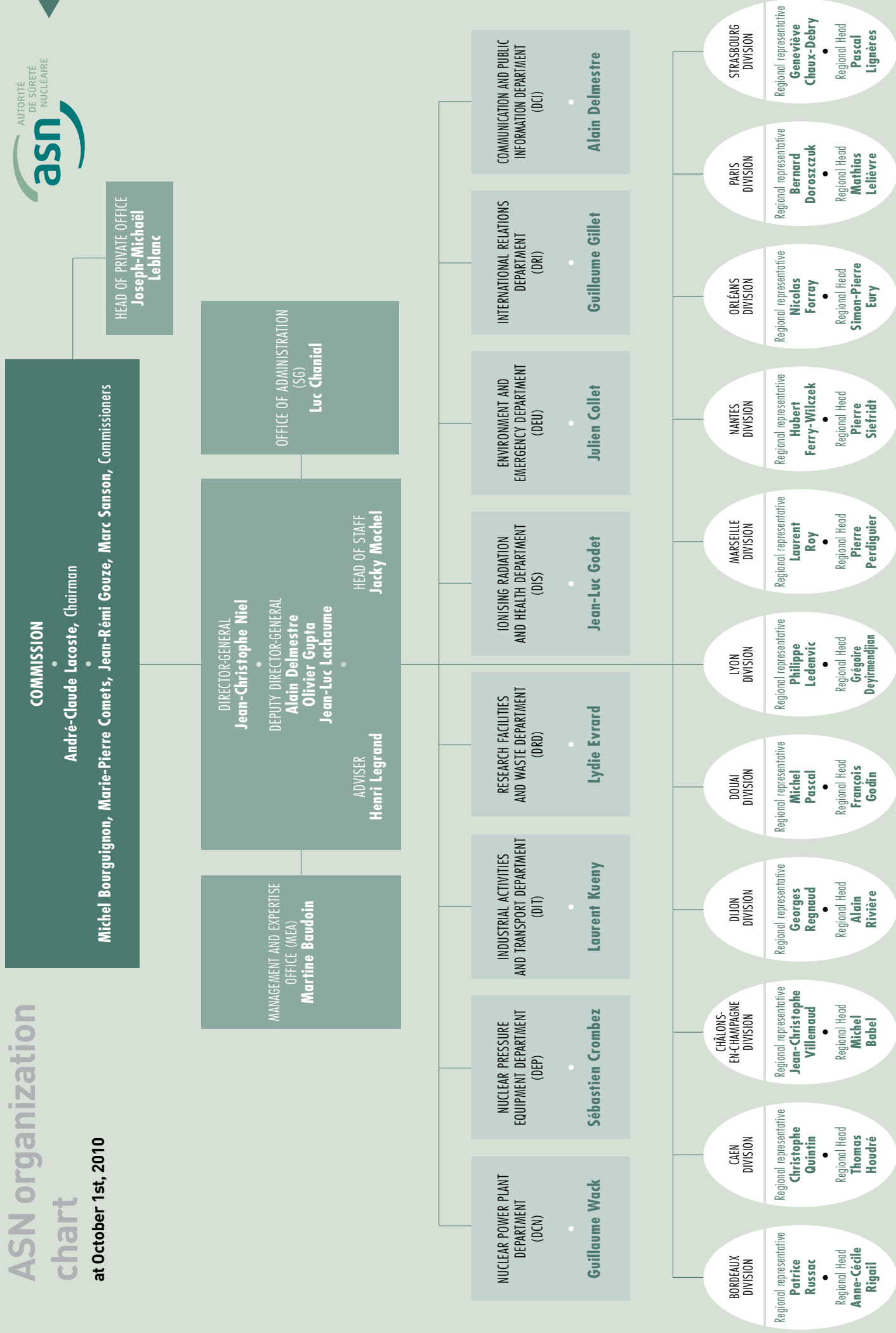
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