Effective Nuclear Regulatory Systems

Further Enhancing the Global Nuclear Safety and Security Regime

Proceedings of an International Conference Cape Town, South Africa, 14–18 December 2009



International Atomic Energy Agency

EFFECTIVE NUCLEAR REGULATORY SYSTEMS: FURTHER ENHANCING THE GLOBAL NUCLEAR SAFETY AND SECURITY REGIME The following States are Members of the International Atomic Energy Agency:

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PROCEEDINGS OF AN INTERNATIONAL CONFERENCE ON EFFECTIVE NUCLEAR REGULATORY SYSTEMS: FURTHER ENHANCING THE GLOBAL NUCLEAR SAFETY AND SECURITY REGIME ORGANIZED BY THE INTERNATIONAL ATOMIC ENERGY AGENCY AND HOSTED BY THE GOVERNMENT OF SOUTH AFRICA THROUGH THE NATIONAL NUCLEAR REGULATOR OF SOUTH AFRICA AND HELD IN CAPE TOWN, 14–18 DECEMBER 2009

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FOREWORD

Over the last three decades, Member States, the IAEA and other international organizations have made efforts to strengthen the safety and security of the use of nuclear and radioactive material through strong national infrastructures and consistent international dialogue. To support these efforts, the IAEA has convened a series of major conferences that have addressed topical issues and strategies critical for consideration by the world's nuclear regulators.

More recently, the IAEA organized the first International Conference on Effective Nuclear Regulatory Systems: Facing Safety and Security Challenges, which was held in Moscow, Russian Federation in 2006. The idea of a 'global nuclear safety and security regime' was discussed at this conference. In the meantime, this regime has been established as a cooperative mechanism to share principles, norms, rules and decision making procedures to achieve shared goals in nuclear safety and security while preserving and complementing the sovereignty, authority and ultimate responsibilities of States.

To further enhance this regime, it is necessary to seek definite commitments and set forth concrete steps towards greater international cooperation on, inter alia:

- Addressing emerging regulatory challenges associated with regulating new and existing nuclear power programmes;
- Addressing emerging regulatory challenges associated with regulating radiation applications;
- Enhancing the effective independence of national regulators and continuously improving regulatory effectiveness;
- Addressing the impact of multinational activities on the national responsibility for safety and security;
- Developing initiatives for capacity building, including institutional, organisational arrangements and education and training for sustainable regulatory infrastructure;
- Promoting synergies and possible integration between safety and security.

To address these issues, and to respond to the request by the senior regulators to have a dedicated forum to discuss regulatory effectiveness every three years, the second International Conference on Effective Nuclear Regulatory Systems: Further Enhancing the Global Nuclear Safety and Security Regime was held in Cape Town, South Africa, from 14 to 18 December 2009.

Based on the content of the presentations and the subsequent discussions, the President of the Conference developed issues for consideration by governments and regulatory bodies, issues for future international cooperation, issues for consideration by stakeholders, and the conclusions of the conference. A common understanding among the participants should lead to improved methods and means to further enhancing the global nuclear safety and security regime.

This publication constitutes the record of the conference and includes the opening and closing speeches, the invited papers, and the President's report. The latter report discusses the background of the conference and its objectives, summarizes the opening addresses, the keynote panel, the Topical Issue sessions, and the closing panel discussion, and presents a number of issues that arose during the meeting. A CD-ROM, which is attached to the back of this publication, contains the unedited contributed papers to the conference and the slides that were submitted with some of the invited papers.

The IAEA gratefully acknowledges the support and generous hospitality of the Government of South Africa.

EDITORIAL NOTE

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CONFERENCE SUMMARY

This conference was a follow up to the IAEA's 2006 International Conference on Effective Nuclear Regulatory Systems: Facing Safety and Security Challenges, held in Moscow, where the participants had agreed that the head regulators should meet again within three years to review the progress made based on the findings of this conference and identify new emerging regulatory challenges. The conference in Moscow was the first of a kind because it brought together senior regulators of nuclear safety, radiation safety and security from around the world to discuss how to improve regulatory effectiveness, and hence the protection of the public and the users of nuclear and radioactive materials.

The objectives of the conference were to review and assess the effectiveness of the global nuclear safety and security regime and to propose specific actions to further enhance it in a range of areas. These included: establishing and maintaining independent and effective national regulatory systems; fostering effective international cooperation among regulators for the sharing of regulatory knowledge, practices and information; and prioritizing and addressing emerging issues concerning multinational and national responsibility for nuclear safety and security.

The Conference President was G.B. Jaczko, the Chairman of the United States Nuclear Regulatory Commission. The two Deputy Presidents were N.G. Kutin, the Chairman of Rostechnadzor, Russian Federation, and G. Clapisson, the Acting Chief Executive Officer of the National Nuclear Regulator of South Africa. A total of 250 participants from 57 countries, 7 organizations and 18 observers attended the conference. There were also press representatives to cover the meeting.

The conference programme consisted of an opening session with opening addresses and a Keynote Panel on 'Addressing Needs and Challenges in Global Nuclear Safety and Security: What are the Priorities?', four topical sessions devoted to: 'Emerging Regulatory Challenges'; 'Regulatory Independence and Effectiveness'; 'Impact of Multinational Activities on the National Responsibility for Nuclear Safety and Security'; and 'International Safety and Security Cooperation'. There was also a closing panel discussion on 'Actions to Enhance the Global Nuclear Safety and Security Regime'.

The opening addresses outlined the importance of international cooperation among nuclear regulatory bodies for effective nuclear safety and security regulation at the national and international levels. This role is particularly important given the increased interest in nuclear power worldwide, related, in part, to an enhanced focus on climate change. The presentations highlighted the role and responsibility of governments for global adherence to international instruments relevant to nuclear safety and security, and in establishing and maintaining the legal and governmental infrastructure for nuclear safety and security; The role of an effective regulator at national and international levels, the expectations of society and the role of international organizations for ensuring an effective global nuclear safety and security regime were other subjects for the presentations.

The Keynote Panel set the scene for the conference by presenting and debating policy and technical issues in nuclear safety and security that benefit from international cooperation between governments, regulatory bodies and international organizations. The panellists addressed the following points:

- An effective regulatory programme is a prerequisite to any nuclear programme. Regulatory programmes, including adequate capacity building mechanisms, are essential components of the national safety and security infrastructure.
- The more globalized and dynamically changing world involves new technologies and shifts in the working environment. This requires new strategies for regulators and harmonization of regulatory approaches, where appropriate.
- Competence of the regulatory body staff is essential. Competence needs to be developed and maintained through effective capacity building, including education and training programmes.
- Sharing of experiences and lessons learned among regulatory bodies for effective nuclear regulatory systems are very valuable. Regulatory peer reviews, knowledge networks and review meetings of international instruments are highly effective tools for promoting the sharing of experience and mutual learning.
- The ageing of plants needs to be considered from the beginning in the development or expansion of nuclear power programmes.
- Knowledge networking to share experience and lessons learned and to build a common safety and security culture are key elements for capacity building and safety and security infrastructure. The Asian Nuclear Safety Network, the Ibero American Network for Regulators (FORO) and the recently created forum of nuclear regulatory bodies in Africa were mentioned as examples.

The first Topical Issue session, 'Emerging Regulatory Challenges', addressed the challenges associated with regulating new and existing nuclear power programmes and radiation applications. This includes: maintaining a high level of safety and security in existing nuclear power programmes, launching new

nuclear power programmes; undertaking new reactor builds after a long time gap in the countries with existing nuclear power programmes; establishing national strategies for waste management and decommissioning; regulating medical activities and the mining industry; and addressing the threat of nuclear and radiological terrorism, and strengthening related assessment and response activities.

The second Topical Issue session, 'Regulatory Independence and Effectiveness', continued discussions on key elements and attributes of effective regulatory independence and proposed means by which effective independence of national regulators could be advanced.

The third Topical Issue session, 'Impact of Multinational Activities on the National Responsibility for Nuclear Safety and Security', addressed the regulatory oversight of multinational activities, the interface between nuclear safety and nuclear security, safety and security culture, industry challenges in working in a multinational environment, production and international distribution of radioactive sources and medical isotope and the European Union's nuclear safety directive as a legal framework to strengthen national responsibilities for nuclear safety.

The fourth Topical Issue session, 'International Safety and Security Cooperation', addressed the application of IAEA safety standards, security guidance and operational experience; the use of global and regional knowledge networks; experience with legally binding and non-binding international instruments; international regulatory feedback systems; lessons learned from national International Regulatory Review Service (IRRS) missions; and integration of safety supervision across different types of legacy sites in all stages of remediation.

The closing panel discussion was based on the results and conclusions of the various sessions and was the capstone of the week's activities. It also addressed the challenges identified during the conference to develop the convergent views on actions for enhancing the effectiveness of the global nuclear safety and security regime.

The conference identified several issues for consideration by governments, issues for consideration by regulatory bodies, issues for future international cooperation and issues for consideration by stakeholders.

The main conclusions of the conference were as follows:

- Promotion of the Regulatory Cooperation and Coordination Initiative for the safe introduction and expansion of nuclear power programmes;
- Long term management of radioactive sources, from cradle to grave;
- Capacity building and human resource development;
- Regulatory effectiveness and independence;

CONFERENCE SUMMARY

- Safety and security synergy and coordination;
- Regulatory supervision of legacy sites and remediation.

The conference requested international organizations to implement the action items for international cooperation resulting from this conference.

The conference participants expressed the view that this forum was very valuable and agreed that the head regulators should meet again within three years to review the progress arising from the findings of this conference.

OPENING SESSION

OPENING ADDRESS

Ms. Elizabeth Dipuo Peters, MP Minister of Energy of South Africa, Johannesburg, South Africa

President of the Conference, Mr. G.B. Jaczko, Minister of Energy of the Russian Federation, Mr. Shmatko, Deputy Director General of the IAEA, Mr. Taniguchi, Director-General of the OECD Nuclear Energy Agency, Mr. Echavarri, Chairman of the Forum for Nuclear Regulatory Bodies in Africa, Mr. Elegba, distinguished delegates. Mr. President, thank you for affording me the opportunity to address this important international conference. I would like to take this opportunity to welcome you to the African continent, to South Africa and to the beautiful city of Cape Town.

NUCLEAR RESURGENCE AND COOPERATION

Nuclear energy is seen by many countries as providing a sustainable solution to energy security challenges. In this context, many developing countries are considering the establishment of nuclear power build programmes, while countries with mature nuclear programmes are considering the possibility of further expansion.

The challenges facing countries that are embarking on this new venture include, inter alia, the development of policies, legislation as well as the establishment of appropriate institutions such as regulatory bodies with effective independence to take regulatory decisions.

Regional and international cooperation and coordination are therefore of critical importance. Accordingly, the establishment of the Forum of Regulatory Bodies in Africa is a welcome initiative. We are pleased that the national nuclear programme in post-apartheid South Africa places us in a position to become active global participants in the safe use of nuclear energy for peaceful purposes.

However, we all have an obligation to ensure that the presence of a plethora of cooperation mechanisms such as this body are as inclusive and as supportive as possible. This will help the global community of nations in reaping maximum benefits that surely should arise from these initiatives to ensure security of energy supply. We do not have the luxury to duplicate such bodies.

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The role of the International Atomic Energy Agency in nuclear safety and security cannot be over-emphasized. That alone is the reason that drove the liberation movement of the people of our country, and now the ruling party, fully to conform to all the treaties and conventions that have been drafted by this reputable institution of the peoples of the world.

The same goes for the facilitation of cooperation and the sharing of knowledge and experience. The IAEA is invariably trusted to provide independent views and advice in order to strengthen safety and security while preserving the sovereignty, authority and responsibilities of Member States.

PELINDABA TREATY

We therefore call on the international community to support the legal instruments related to safety and security and the ratification of amendments where these exists. On the African continent, a milestone has been reached with the coming into force of the Pelindaba Treaty.

Parties to this Treaty remain convinced that the African nuclear weapons free zone is an important step towards strengthening of the non-proliferation regime, promoting cooperation in the peaceful use of nuclear energy as well as enhancing regional and international peace and security.

NUCLEAR NON-PROLIFERATION TREATY

The time for the Nuclear Non-Proliferation Treaty review conference is upon us. In very much the same way that the eyes of the world are currently focusing on Copenhagen, we all have a contribution to make so that we emerge, out of the Copenhagen process with a commitment to build a planet that our children can be happy to live in.

We are indeed pleased that our Head of State and Government, President Zuma, will personally lead the South African contingent there. There can be no better testament to our leadership to the creation of an atmosphere free of greenhouse gas emissions, than the symbolism magnified by the presence of our President.

In the same vein, the Non-Proliferation Treaty and its safeguards system, is the single most important instrument available to built confidence in the peaceful nature of national nuclear programmes. This is fundamental if we are to deliver the security that the world seeks and which in fact has eluded us in the past few decades. We therefore hope that at the May 2010 review conference consensus will be reached on measures needed further to strengthen peace and security in the world.

SAFETY ASSURANCE

The assurance of nuclear safety and security forms the basis and the vital cog upon which citizens will inevitably support nuclear energy programmes. It is against this background that there is a need to continuously review and enhance framework governing the national and international nuclear safety and security framework.

Regulators and operators are confronted with the reality that they must find effective ways to deal with safety and security of facilities at different levels such as those that are planned, or those under construction, or even those that have been commissioned. All of this should be done while we continue to pay attention to keep our eyes on the ball insofar as ageing facilities are concerned including decommissioning.

ILLICIT TRAFFICKING

The prevention of illicit trafficking of nuclear materials and equipment requires us to be proactive in our approach to the usage, storage and transportation of these materials as well as the physical protection of associated facilities. South Africa and several other nations have benefited from the work of the IAEA in the area of nuclear security. The preparations for the 2010 FIFA World Cup incorporate a great deal of nuclear security planning. This is currently being undertaken in conjunction with the IAEA.

We have used the reservoir of experience gained during major public events such as the 2006 FIFA World Cup as well as the recent Olympic games. This is being used in our preparations for the upcoming soccer World Cup, which will hit our shores in June next year.

DIRECTOR GENERAL AMANO

On behalf of the Government and the people of South Africa, I would like to again congratulate and welcome Ambassador Amano, who is the Director General of the International Atomic Energy Agency, and express our country's commitment to working with him and supporting him and the Agency in ensuring

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that we create a world that will fully take advantage of using nuclear technologies for peaceful purposes.

Ladies and gentlemen, I wish you fruitful deliberations and a successful conference.

I thank you.

OPENING ADDRESS

T. Taniguchi

Deputy Director General, Department of Nuclear Safety and Security, International Atomic Energy Agency, Vienna

WELCOME AND INTRODUCTION

Good morning distinguished ladies and gentlemen. On behalf of the IAEA, I would like to welcome you to the second International Conference on Effective Nuclear Regulatory Systems. Let me also extend my sincere gratitude and appreciation to the Government of South Africa and the National Nuclear Regulator (NNR) for hosting this important event and providing such excellent arrangements.

Three years ago, the first international conference on Effective Nuclear Regulatory Systems was held in Moscow, Russian Federation. At that conference, nuclear regulators from around the world participated in constructive discussions aimed at improving nuclear safety, radiation safety and security regulation for the benefit of the global community. The value and importance of the conference were widely recognized and it was agreed that the head regulators should meet again in three years to review progress and identify emerging regulatory challenges.

CURRENT REGULATORY STATUS

Since the Moscow conference, the global nuclear regulatory community, with the support of the IAEA, has made good progress on the findings and conclusions from the conference. For instance, during the conference, the top regulators of the G8 countries agreed to host Integrated Regulatory Review Service (IRRS) missions to share experience and mutual learning. Actually, all the G8 member countries except Italy, which has no ongoing nuclear power programme, have invited IRRS missions, and many other IAEA Member States have participated in or have invited IRRS missions. There is also now increased government participation in international instruments such as conventions and codes of conduct. And today, there is broader and further application of the IAEA Safety Standards, security guidelines, peer reviews and advisory services by

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regulatory bodies. The IAEA follows with keen interest the developments of the European Commission in establishing a nuclear safety framework based on the IAEA's Safety Fundamentals and peer reviews. Furthermore, many Member States have helped the IAEA to issue new nuclear security guidance documents and further develop programmes for human resource development.

So, where do we stand today? The safety performance of the nuclear industry has remained at a high level. Various safety performance indicators, such as unplanned reactor shutdowns, safety equipment availability, radiation exposures to the public and workers, radioactive waste volumes and radiation releases to the environment have shown steady improvement over the last two decades, with some levelling off in recent years. Good safety and security performance is a direct indication of corresponding high levels of regulatory effectiveness.

Nevertheless, it is necessary to avoid complacency and to continuously improve and strengthen the existing global nuclear safety and security regime so that the use of nuclear technologies can be introduced or expanded in a safe and credible manner to meet the world's needs for human well-being, growth and development. The IAEA continues to support and promote continuous improvements in the global nuclear safety and security regime as a framework for achieving high levels of safety and security in nuclear activities worldwide and to overcome the inertia of the levelling off of performance. Examples of continuous improvements in this sense include the development of more comprehensive and user friendly safety guides, better safety and security performance indicators, more useful analytical tools for evaluation of regulatory performance, enhanced self-assessment and peer review mechanisms, and more sharing of experience and lessons learned.

ACTION TO ADDRESS TODAY'S EMERGING CHALLENGES

The global nuclear community is experiencing a period of dynamic change and emerging challenges. Important global trends and issues, such as the ambitious introduction of new nuclear power plants, the rapid expansion of existing nuclear power programmes and the wider and more sophisticated use of radioactive sources highlight the need for continued and improved international coordination and cooperation to address the associated challenges. Moreover, the increasingly multinational nature of today's nuclear business and activities underscores this need. It is particularly important to note that the establishment and maintenance of adequate safety and security infrastructure and capacity cannot be left to fall behind the rapid development of nuclear technology use. The IAEA's Fundamental Safety Principles, particularly the first three, are especially relevant in this context. These three principles pertain to the primary responsibility of operators and users for safety, the role of government, and leadership and management for safety.

It is vitally important that we make the most of the time we invest in this week's programme. I emphasize this because I believe there are urgent needs for us to identify and take concrete international actions to meet today's emerging challenges to further enable the safe, secure and reliable use of nuclear and radiation technologies throughout the world. In this regard, I would like to call your attention to three particular challenges. These are new and expanding nuclear power programmes, long term management of nuclear and radioactive materials, and capacity building.

NEW AND EXPANDING NUCLEAR POWER PROGRAMMES

In September, the IAEA released its revised estimates on the future of nuclear power development. There are now nearly 80 Member States that are considering or have expressed interest in developing nuclear power programmes. Many countries have also embarked on ambitious plans for expanding their current programmes. The IAEA's latest update of its projections for the future of nuclear power, and its low and high projections for 2030, are now higher than they were last year. It is expected that approximately 5–20 new countries will be operating nuclear power plants by the year 2030. While prospective new nuclear programmes receive much attention, the expansion of existing programmes is far more significant in terms of the total size of the development, with over 90% of the total amount of the additional generation to be produced by the expansion of existing programmes in the 30 countries with nuclear power. In terms of installed capacity, it can be estimated that 140 to 440 additional 1000 MW equivalent units will need to be newly constructed in the next 20 years, in addition to the replacement of a large number of decommissioned units. This is indeed a significant challenge to the world nuclear community.

The safe and secure expansion or introduction of nuclear power can only be realized with the establishment of sustainable national infrastructures that include effective and independent regulatory systems. The global nuclear community needs to help ensure that plans for rapid introduction or expansion of nuclear power do not proceed more quickly than the plans to establish the necessary safety and security infrastructure and capacity. While the challenge of achieving and maintaining regulatory effectiveness and independence is vital for newcomers, it is also a continual challenge for the regulators of existing nuclear power programmes.

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LONG TERM MANAGEMENT OF RADIOACTIVE AND NUCLEAR MATERIALS

Wider and more sophisticated use of radioactive and nuclear materials can be found throughout the world. This can be seen particularly in the field of medicine and industry, where advanced radiation techniques are being more widely introduced. The long term safety and security of radioactive and nuclear materials continues to be a challenge for the international nuclear community, and for many countries there is a strong need to improve the registering and monitoring of dangerous radioactive sources from cradle to grave. In particular, there is a strong need for adequate storage and disposal facilities for disused sources, which after losing their practical value tend to be left unattended. This is a significant problem that must be urgently addressed.

Additionally, spent fuel and radioactive waste management are particularly challenging tasks faced by new and existing nuclear power countries and a prime concern of the public. This is especially relevant since the lifetime of a nuclear power programme can be up to 100 years or more and the need for the safe and secure management of spent fuel and radioactive waste goes well beyond 100 years.

The global nuclear regulatory community should consider ways to enhance international cooperation for registering, monitoring and life cycle management of radioactive sources, including the use of better information technology and trans-border controls. Consideration should also be given to developing and establishing a better organized and more sustainable mechanism for sharing experience and lessons learned among Member States. Enhanced international cooperation for improved implementation of the Code of Conduct for the Safety and Security of Radioactive Sources and its import and export guidance would be particularly relevant for this purpose. Moreover, this could include consideration of more effective linkages between the Code of Conduct and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

In this regard, the forthcoming Nuclear Security Summit in the spring of 2010 hosted by the United States will provide a good forum at the highest political level to enhance awareness and leadership regarding the urgent needs for the control of not only fissile nuclear materials, but also non-fissile materials and radioactive sources.

OPENING SESSION

CAPACITY BUILDING

Cornerstones of sustainable safety infrastructure, including regulatory bodies, are adequate managerial and technological capacity and competence, along with the needed education and training to build them. In light of today's dynamically changing environment, it is imperative that the broader international nuclear safety community, consisting of regulators, technical support organizations, academia, non-governmental organizations and industry, work together to enhance the coordination and cooperation for capacity building. In this sense, capacity building is much broader than traditional education and training. It includes development of: (1) human resources with the knowledge, skills and access to information that enables them to perform effectively; (2) organizational learning capacity with effective management structures, processes and procedures, not only within organizations but also interactive learning between the different organizations and sectors; and (3) institutional frameworks with adequate legal, regulatory, administrative and management systems that enable organizations and institutions at all levels and sectors to enhance their capacities.

The availability, retention and continuous improvement of qualified personnel are building blocks for organizational, institutional and national capacity. They are vital to the development of an adequate and sustainable nuclear safety and security infrastructure. For this reason, it remains a top priority for the international nuclear community to develop the state-of-the-art skills, knowledge and expertise of individuals across many disciplines. Moreover, it is also necessary to establish the institutional frameworks and practical guidance for such capacity building. While this is certainly a key issue for countries embarking on nuclear power for the first time, it also remains a major challenge for experienced nuclear power countries to maintain and continuously improve their own capacities.

The IAEA is committed to continue help strengthen human, managerial and technological capabilities in its Member States. Nevertheless, we need to be mindful that even the best people require continuous sharpening and updating of their expertise and, moreover, they tend to be recruited by outside organizations for better conditions in the competitive market.

CONCLUDING REMARKS

The global nuclear regulatory community finds itself among many emerging challenges — new and expanding nuclear power programmes, wider and more sophisticated uses of radioactive and nuclear materials, and the urgent need for building sustainable capacity for nuclear safety and security. I must

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emphasize that the necessary capacity cannot be built without a strong commitment by the countries and organizations responsible for safety and security.

National governments bear the ultimate responsibility for regulating the safe and secure uses of nuclear and radiation technologies. However, when we bring together the broader network of nuclear regulators from around the world, we have the opportunity to improve ourselves through experience sharing, mutual learning and harmonizing the application of the global nuclear safety and security regime. At this conference, we need to seize this opportunity and identify actions we can implement together in a timely manner as well as actions we can implement in each of our individual countries to achieve and maintain high levels of safety and security performance worldwide.

Finally, let me take this opportunity to thank the conference Programme Committee for its hard work in putting this excellent programme together. I would also like to thank Mr. Gregory Jaczko, Chairman of the United States Nuclear Regulatory Commission, for agreeing to be the President of this conference. And let me also thank the conference Vice-Chairs, Mr. Kutin from the Russian Federation and Mr. Clapisson of South Africa. Their collective leadership and expertise will be a tremendous asset to this conference.

I wish you all a successful conference.

OPENING ADDRESS BY THE CONFERENCE PRESIDENT

The Honorable Gregory B. Jaczko Chairman, United States Nuclear Regulatory Commission,

Washington, D.C., United States of America

Good morning. I am honoured to serve as President of this important conference. As I look around this room, I am reminded of what a complex undertaking a conference like this can be and the distance most of you have travelled to participate in this gathering. I am also reminded of the great opportunity we have this week to make additional progress on the challenges we face. Thank you for the commitment you have made to work together over the next week.

I would like to thank the International Atomic Energy Agency, and especially Deputy Director General Tomihiro Taniguchi and his staff at the Department of Nuclear Safety and Security, for organizing this conference. I would also like to thank the Republic of South Africa, especially Ms. Elizabeth Peters, Minister of Energy and one of our conference Deputy Presidents, Guy Clapisson, and his staff at the South African National Nuclear Regulator (NNR), for serving as our gracious hosts. South Africa is known around the world for its beauty and rich history, and I am looking forward to learning more about this spectacular country.

International and, in particular, regional cooperation around nuclear issues is increasingly important. I would like to acknowledge the important work being done on this continent through the Forum of Nuclear Regulatory Bodies of Africa.

As the Chairman of the US Nuclear Regulatory Commission, I am fully engaged in working toward the development and support of strong, effective and independent nuclear regulatory bodies on an international basis. Three years ago, the IAEA sponsored the first conference of government regulators to share their common perspectives and experience in addressing challenges of nuclear safety and security. The goal of the conference was to develop a global vision and to promote international cooperation. Representatives from more than 50 countries participated in that important gathering. The Moscow conference was the first of its kind, providing regulators a forum for exclusive focus on regulatory issues without limits of time, membership or subject matter.

JACZKO

The conference discussed key cornerstones of effective regulation: the independence of the regulatory body, a firm foundation of adequate financial resources, skilled staff, quality management practices, and public confidence in the regulatory body and its decision making processes. Additionally, several key safety and security challenges were identified. We are honoured to have our Russian colleague Mr. Nikolay Kutyin as a Deputy President of this second conference. He brings with him the expertise and lessons from that conference.

As we heard from Mr. Taniguchi, much progress has been achieved on those goals over the last three years, and I am extremely pleased to see the group reconvene and continue its discussion on these critical issues.

We have a significant challenge to meet this week, and that is to use this unique regulatory forum to continue the progress that we made three years ago. I hope to see us converge around the four major themes of this conference and establish a concrete plan of action by the time we close on Thursday.

Our four themes include:

- Emerging regulatory challenges;
- Regulatory independence and effectiveness;
- Impact of multinational activities on the national responsibility for nuclear safety and security;
- International safety and security communication and cooperation.

A renewed interest in nuclear power worldwide has brought with it an increased focus on these regulatory issues, and I believe we all agree that a strong and effective regulatory program must be a prerequisite to any nuclear power programmes.

At the conference this week, we will examine and discuss our priorities as regulators and work to identify and address the challenges we face — both individually and together — around safety and security. The work we do is critical for each of our countries and for the international community as a whole.

I want to just touch briefly on the four themes for this week to set the stage. A robust regulatory programme has three essential components: legislation and the rules and regulations to ensure safety and security; adequate resources; and technical capability. One of the critical challenges for regulators of mature industries is the need to resist complacency. We must remain vigilant at all times about the safety and security of the existing fleet and nuclear materials.

For those countries that are newcomers to nuclear power development, your greatest challenge may be to establish the infrastructure necessary for an effective and efficient regulatory programme. This is where the assistance of organizations such as this can be invaluable, in helping many of you to identify your regulatory

OPENING SESSION

needs and build your capacity; sharing experience, expertise, and lessons learned; and providing a foundation for international coordination and cooperation.

I believe that one of the most crucial components of a nuclear regulatory program is independence. It is only through establishing and strictly maintaining independence from the industries we regulate that we will be able to effectively and consistently evaluate the safety of plant operations and radioactive materials applications; it is how we will enforce implementation and adherence to regulations; and ultimately, as we heard the Minister of Energy say, earn and maintain the confidence of the public.

One of my top priorities for my tenure as Chairman of the US Nuclear Regulatory Commission is promoting greater openness and transparency in our Commission's decision making procedures. This is a key part of being an effective regulator. Everyone will not always agree with the actions we take, but it is critical that stakeholders and the public understand and respect the processes by which we make decisions. That is the path toward building the enduring credibility of a regulatory body.

Building and maintaining public confidence is a significant issue for both existing and new entrants into the nuclear energy field. Countries with established nuclear industries must be vigilant about maintaining the public confidence they have cultivated from their past work and must not become unresponsive or disconnected from public concerns or questions. New entrants can be open and transparent from the very beginning to ensure the highest level of public confidence as early as possible. All regulators should keep in mind that it is far more difficult to rebuild public confidence after losing it than it is to build and sustain it from the beginning. Again, the challenge this week is to see how we can make concrete progress.

At the same time that we are working to consistently improve our domestic regulatory programs, we must also bear in mind that nuclear safety and security is an international responsibility. The effectiveness of nuclear regulation worldwide depends upon strong international and regional cooperation and this conference is a fine example of how that can work. We all have much to learn from one another.

International organizations like the IAEA play an important role in providing guidance on effective regulation and promoting the sharing of experience, best practices and lessons learned. We have a responsibility to cooperate closely in the context of this global regulatory framework. Strong, effective regulatory structures and well established cooperative relationships will increase safety and security for us all.

I encourage all of you to contemplate how we, as a global regulatory network, can plan for the future to ensure adequate resources to meet the needs of the potential growth in nuclear power plants, while at the same time not losing focus on the safety and security of the existing fleet. We learn from sharing our knowledge and experiences with each other, and we become better and more effective regulators because of that sharing.

I would just conclude with the charge for this week — to seek new and concrete ways to address the challenges we face. Two years from now I hope the more than 300 people from over 80 nations who are here today will still be talking about what a productive nuclear regulatory systems conference we had in beautiful Cape Town. I am appreciative for the opportunity to be amongst such a diverse and talented group of peers this week and look forward to all of us working together to make that goal a reality.

I thank you for your attention and look forward to working with you, both this week and in the years ahead.

EMERGING REGULATORY CHALLENGES

(Topical Issue 1)

Chairpersons

M. ZIAKOVA Slovakia

> **A. HABIB** Pakistan

REGULATORY CHALLENGES FROM NEW BUILDS FOR COUNTRIES WITH EXISTING NUCLEAR PROGRAMMES *The UK nuclear regulator's journey of change**

M. WEIGHTMAN Nuclear Safety Directorate, Health and Safety Executive, Liverpool, United Kingdom

^{*} Although a presentation was given, no abstract or paper was made available. The author's PowerPoint presentation appears in the CD-ROM of contributed papers accompanying this book.

REGULATORY CHALLENGES (AND OPPORTUNITIES) FOR COUNTRIES LAUNCHING A NEW NUCLEAR PROGRAMME

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Abstract

The United Arab Emirates (UAE) is embarking on an ambitious programme to build four nuclear power plants to meet its future energy needs, with the first to come on line in 2017. This decision was based on a study commissioned by the UAE Government that took into account projected energy growth, impact on the environment, cost, and sustainability of energy supplies. In preparation for this project, the UAE Government worked closely with international partners and the International Atomic Energy Agency, clearly stating that the nuclear power programme is peaceful and accedes to all international instruments governing the peaceful use of nuclear energy. The IAEA milestones publication provides valuable guidance for new entrants on how to prepare for launching a new nuclear programme. Over the past year and a half, the UAE established its nuclear law and an independent nuclear regulatory body, which is currently developing regulations that govern the design, construction, commission, operation and decommissioning of nuclear power plants, radiation protection and safeguards. The Authority is also involved in recruiting efforts to hire national and international experts to ensure adequate resources to carry out its mission.

1. BACKGROUND

The United Arab Emirates's (UAE's) interest in nuclear energy is motivated by the need to develop additional sources of electricity to meet future demand projections and to ensure continued rapid development of its economy. While the burning of crude oil or coal is logistically viable, they come at extremely high economic costs and cause degradation to the environment. In a study conducted by the UAE,¹ the known volumes of natural gas, or alternative energies (solar and wind) were deemed insufficient to meet future needs, and nuclear power

¹ Policy of the United Arab Emirates on the Evaluation and Potential Development of Peaceful Nuclear Energy, http://eaa.abudhabi.ae/Sites/EAA/Navigation/EN/media-center, did=126484.html
generation emerged as a proven, environmentally promising and commercially competitive option.

However, as stated in the IAEA publication, Considerations to Launch a Nuclear Power Programme,

"a nuclear power programme involves issues associated with nuclear material, ionizing radiation, safety, security and related challenges. This is a major undertaking requiring careful planning, preparation and investment in a sustainable infrastructure that provides legal, regulatory, technological, human and industrial support to ensure that the nuclear material is used exclusively for peaceful purposes and in a safe and secure manner."

This paper discusses the UAE's experience in starting a nuclear energy programme by focusing on four key challenges and how the UAE is managing them. It includes a specific emphasis on the efforts to establish a new UAE nuclear safety, security and safeguards regulatory organization. In addition to the challenges related to establishing a new regulator, the process has also created opportunities to use world experience to establish an effective regulator from the very beginning of the programme. The UAE's Federal Authority for Nuclear Regulation (FANR) is striving to "get it right, right from the start".

2. CHALLENGE 1 — THE UNAMBIGUOUS OBJECTIVE OF THE NUCLEAR PROGRAMME

The Policy of the UAE on the Evaluation and Potential Development of Peaceful Nuclear Energy provided early and overarching guidance to the development of FANR. The Policy clarified the Government's desire to evaluate and deploy a diversified and secure portfolio of power generation that would include a peaceful civilian nuclear energy programme. To this end, the UAE Policy endorses the following:

- (1) The UAE is committed to complete operational transparency.
- (2) The UAE is committed to pursuing the highest standards of non-proliferation.
- (3) The UAE is committed to the highest standards of safety and security.
- (4) The UAE will work directly with the IAEA and conform to its standards in evaluating and potentially establishing a peaceful nuclear energy programme.

- (5) The UAE hopes to develop peaceful domestic nuclear power capability in partnership with the governments and firms of responsible nations, as well with the assistance of appropriate expert organizations.
- (6) The UAE will approach any peaceful domestic nuclear power programme in a manner that best ensures long term sustainability.

2.1. Working with the international community

Since 1976, the UAE has been working with the international community to enhance confidence, and has ratified a number of international agreements, including the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) and a full scope IAEA safeguards agreement, including an IAEA additional protocol providing for expanded inspection rights for the IAEA for both declared and undeclared facilities.²

2.2. Physical protection

The UAE became a signatory to the IAEA Amendment to the Convention on the Physical Protection of Nuclear Material and has committed to effectively protect nuclear material in domestic use as well as during international transport across its territory.

2.3. Control of trade

The UAE is continuing to strengthen its export control regime to block and respond effectively to illicit trade of nuclear material or equipment. The UAE will seek to participate in the Nuclear Suppliers Group (NSG) and implement import

- The Treaty on the Non-Proliferation of Nuclear Weapons (1995);

- —United Nations International Convention for the Suppression of Acts of Nuclear Terrorism (2005);
- -The IAEA's Additional Protocol to Safeguards Agreement;
- The IAEA's Amendment to the Convention on the Physical Protection of Nuclear Material.

The non-proliferation instrument to be concluded by the UAE is:

² Non-proliferation instruments conducted by the UAE are:

⁻The IAEA 's Comprehensive Safeguards Agreement (2003);

⁻ The IAEA's Convention on the Physical Protection of Nuclear Material (2003);

⁻United Nations Comprehensive Test Ban Treaty (2000);

⁻United Nations Security Council Resolution 1540 (2004);

⁻Nuclear Suppliers Group (NSG) Export Guidelines.

and export control rules for nuclear and nuclear related equipment and technology in strict accordance with NSG Guidelines for Nuclear Transfers.

3. CHALLENGE 2 — ESTABLISHING A LEGAL REGIME

A legal regime for nuclear development and regulation is integral to general national law and is rooted in a risk-benefit approach to technology use, but it recognizes the special nature of nuclear technology and is committed to international treaties and obligations. It empowers the regulator to: (1) establish requirements and regulations; (2) issue licences; (3) inspect and assess facilities and structures connected to facilities; (4) monitor and enforce compliance with regulations; and (5) establish a State system for accounting for and control of nuclear material (SSAC) (including spent fuel and radioactive waste) in accordance with the IAEA safeguards obligations.

The basic principles of the legal regime are safety, security, responsibility of the operator, permission (licensing), sustainable development, independence, transparency, compliance and international cooperation.

On 15 September 2009, His Highness Khalifa Bin Zayed Al Nahyan, President of the UAE, signed Federal Decree No. 6 of 2009, Concerning the Peaceful Uses of Nuclear Energy, which establishes the body of regulation related to fissionable materials, and ionizing radiation and exposure. It also establishes FANR as a fully independent, competent and effective nuclear regulatory authority charged with overseeing, safeguarding and sustaining operational transparency in all the nuclear energy sector of the UAE.

4. CHALLENGE 3 — HUMAN RESOURCES

Establishing and maintaining a national regulatory capacity building programme aimed at developing and sustaining a national regulatory workforce for the nuclear sector in line with international standards is of highest priority. Through targeted human resources management and training and education approaches, all necessary steps must be taken to ensure adequate representation of highly qualified nationals at all levels of management and senior staffing to oversee activities associated with the licensing, operation of nuclear power plants, and use of nuclear material in the State. In addition to developing human resources, which are a key element for national ownership of the nuclear power programme, the nuclear sector, including associated services that will grow around the operation of nuclear facilities, will be a key future growth area for employment and economic activity. In terms of timing, the IAEA milestones publicati³ on recommends that the relevant expertise required for each phase of the nuclear project be established "ahead of facility construction and operation".

The importance of UAE national human resource capability was explicitly recognized by the UAE Policy, which stated that "continued education and training constitute a cornerstone of the critical infrastructure necessary to sustain a nuclear power programme." While there is an existing pool of UAE national human resources working in national industrial and medical entities and companies that use nuclear or radioactive materials, experience in nuclear power and particularly regulation of nuclear power is rare.

Given the UAE nuclear programme deployment schedule, facility construction is anticipated to commence in 2012. This indicates the need to resort to short term as well as medium to long term strategies. In the short term, there will be a considerable reliance on international experts. The long term sustainability of the programme relies on developing a skilled and experienced UAE national workforce capable of regulating and operating nuclear power plants. True national ownership of the peaceful nuclear power programme will only be achieved when citizens of the State are working at all levels of the regulatory authority and the operating entities.

As a UAE Government entity mandated to regulate and oversee the UAE nuclear sector, FANR, recognizes its responsibility to lead a dedicated programme for the development of nuclear regulatory professionals. The policy and strategies have been developed to guide FANR's approach to capacity building in the regulatory sphere, e.g. through the selection for degree programmes in coordination with national plant operator (Energy Nuclear Energy Corporation) and separately by exploring other programmes with universities and nuclear regulatory bodies to jointly develop future training and education opportunities.

5. CHALLENGE 4 — ORGANIZATION IDENTITY

Prevention of harm, protection of health, safety, and the environment, and prevention of diversion or malicious acts are paramount and are taken into account in the design, construction, commissioning, operation, inspection, maintenance and decommissioning of the nuclear power plant. This is achieved

³ INTERNATIONAL ATOMIC ENERGY AGENCY, Milestones in the Development of a National Infrastructure for Nuclear Power, IAEA Nuclear Energy Series No. NG-G-3.1, IAEA, Vienna (2007).

TRAVERS

through consistent policies, reliable structures, systems and components (SSCs), as well as procedures and a strong safety and security culture. To this end, regulations should be developed and measures taken to ensure that the nuclear programme is peaceful, complies with all non-proliferation agreements and is designed to the highest standards to prevent the occurrence of accidents and the releases or loss of control of radioactive materials that could potentially result in significant radiation exposures.

Sufficient resources, efforts and necessary expertise should be provided to guarantee effective implementation and enforcement in accordance with international norms, bearing in mind the importance of full implementation and enforcement of the mandated activities related to safety, security, safeguards and control of trade.

At FANR, our programmes and initiatives are designed to ensure the adequate protection of public health and safety from the operation of nuclear power plants and spent fuel storage systems, and the use of radioactive materials. The major programmes include the development of regulations, licensing and technical reviews, inspection, oversight, enforcement, incident response and emergency preparedness, domestic and international information exchange, and cooperation. FANR is establishing and will maintain a robust quality management system in all activities that affect safety, security and safeguards ('3Ss') as they relate to the design, fabrication, construction, commissioning, operation and decommissioning of nuclear facilities. FANR will also maintain a stable and predictable regulatory environment and regulatory controls without unduly limiting the beneficial use of radioactive materials or activities. Our safety philosophy is conventional, i.e. it conforms to the Fundamental Safety Principles (SF-1) of the IAEA. Finally, FANR will cooperate with its foreign counterpart regulatory bodies and international organizations such as the IAEA to share information, resources, best practices and lessons learned from operating experience, and to influence the development of standards and guidance.

The FANR's Corporate Identity can be summarized as follows:

Vision

— To ensure the long term safety, security and sustainability of programmes for the peaceful use of nuclear energy within the UAE.

Mission

 To carry out regulatory responsibilities by adhering to proven regulation principles including independence, openness, transparency, competence, effectiveness, efficiency, fairness and dependability, and by employing a comprehensive licensing, inspection and enforcement programme for nuclear facilities, radiological materials and activities as defined in the UAE Nuclear Law. It is our intention to accomplish this mission by capacity building, developing indigenous nuclear capability within the UAE.

Core Value 1: Awareness and Responsibility

- Awareness of and responsibility for the unique nature and risks inherent in the use of nuclear power and the responsibility for safety, security and safeguards in the use of nuclear technology;
- To create a dynamic safety culture environment:
 - INSAG-4: "Safety culture is that assembly of characteristics and attitudes in organizations and individuals, which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance."⁴
- Maintain an open, collaborative working environment that value differing views and reward safety conscious thinking.

Core Value 2: Independence

- Fundamental to achieving and sustaining safety and public and international acceptance, independence from the operator (Emirates Nuclear Energy Corporation, ENEC), national energy policy and political influence
- Budget: sufficient and predictable financial resources not subject to undue control by external bodies;
- Technical judgments: provision for adequate capacity in-house as well as for independent third party expertise;
- Government: reporting structures that avoid potential conflicts of interest or direct ministerial control over nuclear safety regulation.

Core Value 3: Transparency

- Intended in a holistic sense: vis-à-vis the public, ENEC, other governmental bodies and the international community;
- Provision of appropriate information to the public and other stakeholders in a technically sound, timely, accurate, reliable and understandable manner;

⁴ INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Safety Culture, INSAG-4, IAEA, Vienna (1991).

- Ability to independently communicate FANR decisions and opinions, and their basis, to the public and other stakeholders:
 - The web site is under construction and staff resources will be available to support public interaction;
 - There will be effective cooperation with other relevant UAE Government authorities.

Core Value 4: Competence

- Essential to effect the safe utilization of complex nuclear technology within the UAE;
- Fundamental to maintain the confidence of the public, the operator and the international community;
- Necessary for the development of national human resources in the short and long term;
- -- Important for the effective interaction with global nuclear safety framework.

6. CONCLUSION

States interested in launching a nuclear power programme must develop a comprehensive strategy to assess their energy needs, and understand the potential role, appropriateness, viability and national and international commitments associated with nuclear energy. This certainly involves several complex and long term interrelated activities. The development of a legal framework covering all aspects of the peaceful uses of nuclear energy is particularly important. It should ensure that there are clear and appropriate institutional authorities and responsibilities for the regulatory authority, and integrate key international instruments. It is recognized that each State's laws, customs, and administrative process are unique, but fundamentally they have one objective in common: to ensure that nuclear power plants are operated at all times in an acceptably safe and secure manner. Toward that objective, the regulatory authority should ensure that its decision making processes are technically sound, consistent from case to case, timely, and transparent and have a clear basis in law and its established regulations. The regulatory framework itself must be consistent with national laws and international treaties, and cover all appropriate aspects of safety, security, and safeguards. The FANR is establishing its new regulatory regime with these goals in mind and attempting to "get it right, right from the start".

There is a worldwide shortage of engineers and scientists with regulatory experience; this will become even more acute with new entrants in the nuclear

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field. To ensure long term sustainability, an education and training programme must be developed to establish and maintain a largely indigenous workforce. Regulatory authorities must be viewed by all stakeholders as technically competent and independent by fostering safety and security culture as paramount objectives.

In its 2008 Policy on Evaluation and Potential Development of Peaceful Nuclear Energy, the UAE worked closely with the international community and the IAEA, and committed to complete operational transparency and the highest standard of safety, security and non-proliferation. As discussed, at FANR, we have accomplished a great deal in our brief history, but there is much more to be done.

In summary:

- Nuclear law, which has been extensively reviewed by many international regulatory authorities and the IAEA, has been issued:
 - The Board of Management is complete;
 - FANR has been created;
- Regulations and guidance documents are being drafted;
- Bilateral agreements have been signed; more are in process;
- Organizational and staffing plan has been defined;
- Several technical support organizations have been engaged; more are being considered;
- Steps to recruit key staff have been taken;
- The application for a construction licence is expected to be accepted in the middle of 2010.

NATIONAL STRATEGIES FOR WASTE MANAGEMENT AND DECOMMISSIONING AND REGULATORY CHALLENGES

O. MYKOLAICHUK

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Abstract

Radioactive waste management and the decommissioning of nuclear facilities are critical issues for public perception of any nuclear development project. There are already some successful cases of completed decommissioning projects as well as up to date disposal facilities for low and intermediate level radioactive waste (LILW); however, for obvious reasons, we still could not refer to any disposal site released after a successful administrative control period. With respect to high level radioactive waste (HLW), including spent fuel or vitrified reprocessing waste, no deep underground repository is even at the construction stage. Thus, there are still many open issues creating serious regulatory challenges. Many international activities are focused on these challenges, including relevant networking and joint research projects. The Joint Convention review process could provide an effective tool to monitor achievements and avoid dead ends.

1. INTRODUCTION

At the early stage of introducing nuclear power, issues of waste management and future decommissioning were not always properly recognized and addressed. Later, they became a major concern together with the safety of reactors. Although a few years ago some countries celebrated the 50th anniversary of their first nuclear power reactors, no proven solution for high level waste (HLW) has yet been demonstrated.

The issue becomes very controversial when governments announce plans to expand or launch a nuclear power programme. Their ability to provide 'cradle to grave' solutions becomes a major issue, both for creating public opinion favourable to nuclear development and for attracting investments for new builds.¹

¹ Figures showing the view of public opinion on radioactive waste management for nuclear development may be found in reports summarizing the relevant Eurobarometer survey in 2008 [1] and the Ukrainian national survey in August 2006 [2].

MYKOLAICHUK

The 2008 Eurobarometer survey [1] has clearly shown that people are skeptical about the prospects of waste solutions: while 93% of respondents agree that the solution for HLW should be developed now and not left for future generations, 72% are of the opinion that there is no safe way of 'getting rid' of HLW and only 35% consider that deep underground disposal represents the most appropriate solution for its long term management. This is not surprising since, for most governments, the back-end of the nuclear fuel cycle is still a major challenge, and capability to respond to it highly depends on the ability of a national nuclear regulator to establish relevant regulatory framework, and to demonstrate efficiency and effectiveness.

2. RADIOACTIVE WASTE AND REGULATORY CHALLENGES

2.1. Current status of waste management in different countries and common challenges at the national level

In many countries, waste generating activities started before the proper national waste management infrastructure was established.

A nuclear facility is usually equipped with installations for the preliminary processing of radioactive waste and with on-site temporary storage modules for liquid and solid radioactive waste. However, the lifetime of such storage facilities is limited by the design operational lifetime, after which the radioactive waste placed in them must be retrieved and brought to a final disposal facility; the relevant conditioning may be performed either on-site or by a disposal facility operator.

A similar situation is possible for waste generated from the application of radiation sources in industry, agriculture, medicine and research. For instance, special facilities, specialized radon enterprises, were constructed in the former Soviet Union countries. Such facilities were designed in the 1960s and intended for radioactive waste management and disposal. However, at present, these facilities do not meet internationally acceptable safety requirements. Furthermore, the waste retrieval also requires design modifications.

Consequently, in many countries, significant amounts of radioactive waste have been accumulated at outdated facilities while regulatory requirements have become more and more rigid over the last decades, thus imposing the following challenges:

- Development of national strategies for radioactive waste management taking into consideration all waste flows, which implementation shall be aimed at achieving the ultimate stage of radioactive waste management, i.e. safe disposal;
- Design and establishment of infrastructure for radioactive waste management that is capable of processing waste and manufacturing packages acceptable for disposal at near-surface or geological storage; if the latter is not available, then it is intended for long term radioactive waste storage;
- Updating and implementation of strategies for radioactive waste management considering long range plans of construction of new nuclear facilities and decommissioning facilities where design operational lifetime is exhausted.

2.2. Challenges related to particular LILW facilities and regulatory response

At the current time, there are not only nuclear legacy sites with primitive radwaste burial available, but there is also a significant amount of radioactive waste accumulated as a result of the use of ionizing radiation sources in industry, research and medicine. This waste is often stored in conditions that do not correspond to safety standards for radioactive waste disposal or standards for safe radioactive waste storage. In addition, information regarding the waste, such as its precise amount, activity and radionuclide composition, is often not available. This raises a series of questions on defining the status of such facilities, including the need for waste removal for its processing and ultimate disposal.

Many countries have accumulated significant practical experience and knowledge in designing and constructing storage facilities for disposal of low and intermediate level short lived waste. In addition, certain European countries have introduced a category of very low level radioactive waste in the radioactive waste classification and successfully implement technologies for its processing and disposal in practice.

Currently, the important regulatory challenges are as follows:

— Development and introduction of guidance for a long term safety assessment of low and intermediate level radioactive waste (LILW) disposal facilities, including human intrusion consideration, substantiation of need and duration of institutional control and integration of security considerations, etc;

- Development of requirements for safety assessment of facilities that have historic waste in order to establish their status and, based on safety justification, make decisions on their management, i.e. 'removal, conditioning and disposal' or 'non-intervention';
- Introduction of low activity radioactive waste category and demonstration of relevant safe management technologies, from sorting to disposal;
- Development of waste acceptance criteria, particularly for special cases (NORM, alpha emitters, non-radiological components);
- Development of requirements for post-closure monitoring programmes and periodic safety review, taking into account possible institutional changes and the evolution of safety concepts.

There are also many issues that will result in particular challenges in daily regulatory routine. For example, the issue of non-conformity or even noncompliance of waste packages that cannot always be simply rejected. Many problems can be generated by delays in commissioning or breaks in operation of some of radwaste facilities. Moreover, regulatory delays can hardly be avoided, but can be minimized through early dialogue and better interaction.

Further, one of the major challenges is the appropriateness of the green field concept for LLW disposal sites in 300 years, considering both technical (alphaemitters, non-radiological components) and non-technical factors (who will take decisions and on which basis).

2.3. HLW challenges — how to predict the situation in millions of years

All challenging issues for LILW are no less, and often more, important for spent fuel and other HLW. It is not possible to share lessons learned for finding a final solution, since even the most advanced countries are still at the stage of site investigation and conceptual design.

Each country, especially those that operate large nuclear programmes as a part of their national strategy, confronts the need to find ways of solving issues of highly active waste. In the meantime, safe short or long term temporary storage of such radioactive waste must be assured until geological storages are created.

It is now importune for the countries to face the following challenges:

- Development of a harmonized methodology for safety assessment of geological disposal, with due consideration of the integration of safety, security and safeguards concepts;
- Development of a safety case for geological disposal according to modern methodologies, taking into account all the pros and cons of retrievability and its possible adverse effects on safety and security;

 Construction of national geological disposal or considering participation in regional disposal projects, particularly for countries with small nuclear power programmes.

Nevertheless, no assurances are provided on the accuracy of safety assessment in the very long term — more than 10 000 years. Other open issues is timeframes and content of periodic safety reviews, particularly after closure, as well as who should be legally responsible for it, taking into account time gaps between different stages of a facility's lifetime.

3. DECOMMISSIONING STRATEGIES AND REGULATORY CHALLENGES

3.1. Designing decommissioning policy at the national level and a decommissioning strategy for a particular facility

There are three key decisions to be made in designing a national decommissioning policy:

- How to secure funding to finance activities at the stage when the facility no longer provides any income;
- Whether some special organizational arrangements are needed or an existing facility operator should also deal with decommissioning;
- Which decommissioning strategy(ies) is(are) appropriate.

Up to now, 122 nuclear power installations have already been permanently shut down, 15 of which (11 in the USA, three in Germany, one in Japan) having completed their decommissioning process up to site release, and three of which (all in the USA) having been entombed on-site [3]. Thus, there are already some reference cases as well as experience feedback to be used at the facility or national level. Also, some experience has been gained on the decommissioning of research reactors [4].

3.2. Regulatory challenges depending on decommissioning approach chosen

There are basically three options for a decommissioning strategy:

- Immediate dismantling (DECON);
- Deferred dismantling (SAFESTOR);
- Safe enclosure on site (ENTOMB).

The DECON approach seems very attractive since it places less burden on future generations and does not require complicated measures to ensure funding in long term post-shutdown period. However, special attention should be paid to a collective dose evaluation as well as to the availability of a respective waste infrastructure. Also, while understanding all benefits of a green field approach, the pros and cons of movement of enormous amounts of waste should be considered, particularly for countries with small nuclear programmes.

The ENTOMB approach provides for less collective dose and is probably more cost effective; however, for countries with large nuclear programmes, it may result in too many waste management sites.

The SAFESTOR approach could provide both less collective dose and time allowance to develop waste infrastructure; however, it involves risks of a loss of knowledge, particularly for countries phasing out nuclear power development, as well as a loss of accumulated funding in the long term due to changes in the national economy. Clearly, this means a liability for future generations.

The nuclear regulator should therefore provide advice to the government on the pros and cons of each approach and be ready to deal with problems associated with the strategy chosen.

3.3. Special cases of decommissioning

In addition to the above-mentioned challenges for a routine decommissioning after smooth design-based operation, specific problems could arise in the following cases:

- Prescheduled decommissioning due to a political decision or other reasons (economical considerations, inability to meet increased safety or security requirements, etc.);
- Prescheduled decommissioning of a unit after a severe accident;
- Decommissioning after long term (60 years or more) operation;
- Decommissioning of a unit of a multi-unit plant with prospects of operating other on-site units for more than ten years.

In all cases of prescheduled decommissioning, the possible challenges are lack of funding, infrastructure, preparations as well as a bad attitude of operating staff and unavailability of organizational arrangements. All these issues must be taken into consideration by the regulator while designing a particular plan of regulatory actions.

A particular case of decommissioning after a major accident is represented by the Chernobyl nuclear power plant (NPP). For units 1–3, those permanently shut down after only 11–19 years of operation, one of the main issues was the unavailability of basic prerequisites (funds, programmes, infrastructure, knowledge). As a result, the relevant comprehensive decommissioning programme was eventually approved approximately one decade after the last unit was taken out of operation. The strategy chosen is based on the deferred dismantling approach; however, there are still some doubts about the reasonability and applicability of such an approach to the site significantly contaminated after the major accident and situated in the middle of a contaminated area.

The main problems in this case come from the aftermath of the Chernobyl accident, therefore including an unusual contamination pattern as well as the destroyed unit 4 and unstable shelter constructions. Even the planned New Safe Confinement does not provide any permanent solution, especially for the 'fuel-containing masses'. There are still a lack of technical solutions for specific issues, e.g. Shelter liquid waste treatment or long term stability of fuel containing masses. Decommissioning of the Chernobyl Nuclear Power Plant therefore appears to remain a major challenge for quite a long period of time.

Decommissioning after long term operation seems to be less problematic, but in this case, the principal issue is a proper long term information management.

An availability of operating units on-site requires careful planning and vigorous implementation of decommissioning activities to avoid any inadvertent impact on safety of operating units.

4. THE ROLE OF INTERNATIONAL COOPERATION IN ADDRESSING RADIOACTIVE WASTE MANAGEMENT AND DECOMMISSIONING

Recognition of the value of radioactive waste management issues for economic development and for the environment as well as a lack of proven solutions has triggered many international activities.

Today, any country could base radioactive waste related activities on the Joint Convention on Safety of Radioactive Waste and Safety of Spent Fuel as well as on the relevant IAEA Safety Standards. The latter are periodically revised to integrate the most recent state of the art knowledge and experience.

To date, the third round of the Joint Convention peer review process has been completed, and the third Review Meeting provided the participating countries not only with a kind of international audit of related activities, but also with an important lessons learned from other Contracting Parties' practices. Consequently, while designing or evaluating a national legal and regulatory framework, each country could use not only international consensus documents, but also good practices of countries with different sizes of nuclear programmes.

These international consensus documents are also complemented with international databases and networking, including:

- DISPONET International Low Level Waste Disposal Network. DISPONET is a tool to encourage and facilitate information and experience sharing and knowledge transfer on different issues related to LILW disposal as well as to obtain relevant feedback for the IAEA's programme on low level waste disposal;
- LABONET Training in and Demonstration of Characterization Laboratories of Low and Intermediate Level Waste;
- Underground Research Facilities (URF) Network Training in and Demonstration of Waste Disposal Technologies in Underground Research Facilities. The URF Network is a mechanism to ensure Member States' awareness of the latest state of the art technology in geological disposal;
- International Decommissioning Network (IDN) In 2007, the IAEA launched the IDN to provide a continuing forum for the sharing of practical decommissioning experience in response to the needs expressed at the International Conference on Lessons Learned from the Decommissioning of Nuclear Facilities and the Safe Termination of Nuclear Activities, held in Greece in 2006. IDN brings together existing decommissioning initiatives, both inside and outside the IAEA;
- ENVIRONET Environmental Management and Remediation Network. Environet is being established by the IAEA as a facilitator to increase effectiveness and efficiency in the sharing of international experience on good practices for remediation of radiologically contaminated sited. The network is also aimed at introducing the life-cycle approach to nuclear and non-nuclear operations in order to minimize the need of future remediation measures.

There are also both completed and ongoing cooperation projects focused on finding answers to the most critical practical questions:

— Strategic Action Plan for Implementation of European Regional Repositories (SAPIERR) — the Project on Strategic Action Plan for Implementation of European Regional Repositories established under the auspices of the European Commission is devoted to pilot studies on the feasibility of shared regional storage facilities and geological repositories, for use by European countries;

- PRISM the Project on Practical Illustration and Use of the Safety Case Concept in Management of Near-Surface Disposal;
- GEOSAF the International Project on Demonstrating the Safety of Geological Disposal;
- European Pilot Study the international project focused on regulatory expectations for the different milestones and addressing uncertainty management, taking into account that the safety authorities in a number of European countries were interested in exploring the possibility of a harmonized approach to the demonstration of safety of geological disposals.
- FaSa the International Project on the Use of Safety Assessment in Planning and Implementation of Decommissioning of Facilities using Radioactive Materials;
- DeSa the International Project on the Evaluation and Demonstration of Safety during Decommissioning of Nuclear Facilities (2004–2007).

All the above international activities could provide nuclear regulators with knowledge and proven solutions to meet particular challenges related to radioactive waste management and decommissioning.

5. CONCLUSIONS

There are still many unsolved technical issues, and all radwaste and decommissioning challenges can become regulatory ones.

The Joint Convention and the IAEA Safety Standards have already created a solid basis for developing a national legal and regulatory framework for radwaste management and decommissioning, provided that some degree of flexibility in technical solutions to meet safety goals is allowed, and feedback from both practical experience and research is adequately adopted.

Also, the regulator should consider all relations and interfaces while dealing with separate facility or activity, and should be open for early dialogue and moderation between the waste producer and the waste operator, considering the overall picture while paying attention to technical issues. It is important to be ready to deal with delays, non-conformities and non-compliances.

The regulatory community should not forget to promote and participate actively in the Joint Convention review process, the development and implementation of the IAEA Safety Standards, relevant networking and international cooperation activities. Special efforts should focus on openness and transparency as well as global knowledge exchange.

Our joint actions and coordinated efforts could really make a difference.

MYKOLAICHUK

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VIEWS ON NUCLEAR AND RADIOLOGICAL TERRORISM THREAT ASSESSMENT AND RESPONSE

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Abstract

The paper offers some views from an international perspective on the nuclear and radiological terrorism threat assessment and response. It introduces the political, institutional and regulatory issues associated with this threat. This paper analyses the reactions and mechanisms implemented by the international community aimed at fighting nuclear terrorism and the role of the IAEA. It also describes national needs in order to ensure national security against attacks with nuclear or radioactive material. The paper takes into account the security community's viewpoint on the subject of standards and on the need to recognize that a nuclear regulatory body does not represent the entire community of stakeholders in the security field.

1. THE NUCLEAR AND RADIOLOGICAL THREAT

The potential for a terrorist attack involving nuclear or radioactive materials is one of the greatest challenges of the international community (Fig. 1). This recognition has changed the way we understand the safety of the applications of nuclear energy and the concept of 'nuclear proliferation'. Nuclear terrorism adds to the traditional concepts of nuclear safety, radiation protection, radiological risk and safeguards, those of nuclear security and nuclear proliferation risk. In addition, nuclear proliferation is no longer considered an activity exclusive to the States, but includes the activities of "non-State actors" — the potential use by extremist groups of nuclear or radioactive materials, including the use of nuclear weapons (Fig. 2).

The nuclear and radiological terrorism threat is international by nature. Non-State actors are organized and operate outside national borders; however, their targets are individual states. Therefore, the radiological, economic and social consequences of such an attack must be managed, mainly on a national basis. As a consequence, and in order to combat nuclear terrorism, we need not only global actions in order to create a solid, multidisciplinary and practical multilateral network for international cooperation, but also soundly funded,



FIG. 1. The threat. The potential use of nuclear or other radioactive materials by extremist groups is one of the greatest threats to the international community.

structured and organized integrated national security systems. This new global threat also introduces major international and national political, structural and institutional changes. New actors (organizations, institutions, administrations, etc.) have emerged on the national and international nuclear security scene.

2. THE INTERNATIONAL RESPONSE: A NEW INTERNATIONAL ARCHITECTURE FOR NUCLEAR SECURITY?¹

The international community has responded to this new phenomenon by:

¹ The term 'nuclear security' is defined as "the prevention and detection of, and response to, theft, sabotage, unauthorized access, illegal transfer or other malicious acts involving nuclear material, other radioactive substances or their associated facilities". This working definition was established by the IAEA's Advisory Group on Nuclear Security (AdSec) during its 1–5 December 2003 meeting.



FIG. 2. Size of the threat. To assess the proper size of the threat, it is critical to design global actions and national security systems to prevent and respond to nuclear terrorism.

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- Developing, adopting and amending international conventions related to nuclear security;
- Reinforcing and activating all the existing mechanisms of the United Nations system; developing specific Security Council resolutions, creating an Office for Nuclear Security within the IAEA and providing it with the appropriate resources to develop and implement an international action plan against nuclear terrorism. As part of these measures, in January 2002, the IAEA Director General established the Advisory Group on Nuclear Security (AdSec) in order to advise him "on the Agency's activities related to preventing, detecting and responding to terrorist or other malicious acts involving nuclear and other radioactive materials and nuclear facilities".
- Developing international nuclear security cooperative mechanisms in order to combat partial or global aspects of the fight against nuclear terrorism, for instance, the Global Initiative to Combat Nuclear Terrorism (GICNT), the G-8 Global Partnership, the Megaport Initiative, the Nuclear Threat Initiative and the Proliferation Security Initiative (PSI) (Fig. 3). More recently, President Obama of the United States of America called for a Nuclear Security Summit in April 2010, aiming to contribute to secure nuclear material, break up black markets, detect and intercept materials in transit, and use financial tools to disrupt illicit trade of nuclear materials;



FIG. 3. International nuclear security mechanisms. The Global Initiative to Combat Nuclear Terrorism is a vital international political mechanism against the nuclear threat. The Initiative aims to develop a sustainable work programme offering practical outcomes.

— Adapting the International Regime for Nuclear Non-Proliferation to the new situation, including actions and specific recommendations for the development of the treaties and dispositions contained therein, in particular the Treaty on the Non-Proliferation of Nuclear Weapons.

In light of these developments, it is essential to recognize the need to ensure that the various existing international mechanisms for cooperation on nuclear security are complementary and mutually reinforcing. The development of an 'international multilateral architecture for nuclear security' could contribute to an effective and efficient coordination of all these international initiatives and activities. Figure 4 outlines a structure for this international architecture.

The future international multilateral architecture for nuclear security will be supported by an international legal framework (see text box 1). The primary contributors to the development of this legal framework are the United Nations Security Council and other international organizations, in particular the IAEA.

The ideal international multilateral structure should include three different fora or areas of activity that should be well coordinated with one another (see Fig. 4):



FIG. 4. Basic structure and components of the future international architecture for nuclear security.

— A political forum;

- A governmental, institutional, regulatory and technical forum;
- An industrial and professional forum.

There are a number of multilateral organizations, institutions and initiatives which could be part of this architecture. Today, those which are playing an important role in the international fight against nuclear terrorism and the development of an international regime for nuclear security are:

- The United Nations Security Council;
- The IAEA: In the governmental, institutional, regulatory and technical context, the IAEA is the only multilateral international institution with the political and technical capacities to become the international reference for nuclear security;
- The International Nuclear Security Mechanism: These include the Global Initiative to Combat Nuclear Terrorism, the Nuclear Threat Initiative, the Megaport Initiative and the Proliferation Security Initiative;
- The World Institute for Nuclear Security. The international community has pinned its hopes on the role that this new Institute will play in the industrial context.

The international agenda in the coming months could provide interesting and important developments in defining and strengthening the international multilateral architecture for nuclear security.

3. THE NATIONAL RESPONSE

The 'integrated national security systems' not only have to be prepared to prevent — and give a rapid and effective response to — a nuclear or radiological attack, but they must also incorporate all the necessary national, political and institutional changes in order to fight this new threat effectively (Fig. 5).

There are a number of national institutions playing an important role in fighting nuclear terrorism, not only law enforcement forces and intelligence services, but also political, governmental, technical and regulatory agencies (Text Box 1). In particular, the scope of the fight against nuclear terrorism goes beyond the current functions of the nuclear regulatory agencies (Fig. 6). Their main function is to guarantee the protection of people and environment in the peaceful use of the nuclear energy. On the other hand, the national fight against nuclear terrorism seeks to ensure national security and even more, to contribute to the global international security.



FIG. 5. The technical capacity of a national nuclear security system is not the only aspect to consider for its development and operation.



FIG. 6. A broad range of institutions and organizations are part of a national security system. Therefore, it is important to recognize that the traditional concept of 'nuclear regulatory body' does not represent the entire community of stakeholders in the security field.

The characteristics, minimum requirements and components of an effective national response to nuclear threat are:

(1) A clear political will and momentum by national authorities. This should not be limited to the national level; moreover, it should be framed within the international arena and be compatible with the global actions being decided and coordinated by the international community;

Text Box 1 NATIONAL ACTORS IN THE NUCLEAR SECURITY SCENE

- Ministry of the Interior (Homeland Security, law enforcement forces)
- Ministry of Foreign affairs
- Ministry of Industry, Trade and Commerce
- Ministry of Justice
- Nuclear regulatory authorities
- Customs departments (borders control)
- Prime Minister's Office
- National government delegations (regional)
- Regional governments
- Municipalities
- Intelligence centres
- Office of Civil Protection (emergency response)
- Ministry of Defence
- National agencies for radioactive waste management
- -Research centres
- Universities and institutes
 - How are national actors structured and organized?
 - What are the leading institutions?
 - Which institution(s) serve(s) as the IAEA counterpart?
- (2) Mechanisms to properly characterize, size and assess the nuclear threat;
- (3) Processes for identification, organization and coordination of all national institutions and resources related to nuclear terrorism. Their responsibilities and roles within the national system shall be clearly identified and specified;
- (4) Adequate national legal and regulatory frameworks consistent with the international legal framework for nuclear security;
- (5) A national action plan to combat nuclear terrorism and ensure nuclear security, including methodologies and working procedures. Education and training will be an essential part of this national action plan, which shall include, as a minimum:
 - Accounting, control and physical protection systems for nuclear and other radioactive materials;
 - Physical protection of nuclear and radioactive facilities and transport of nuclear and radioactive materials;

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- Ability to detect nuclear and other radioactive materials in order to prevent illicit trafficking or malicious use in public domain;
- Capabilities to seek, confiscate, and establish safe control over unlawfully held nuclear or other radioactive materials;
- The prevention of safe havens and financial or economic resources provided to terrorists;
- Capabilities for response, mitigation, investigation and prosecution in cases of nuclear or radiological attacks;
- Capabilities for Intelligence and information sharing;
- (6) Effective mechanisms for communication and improving risk perception: awareness of the political class, civil society and national economic and industrial sectors.

The IAEA's role in the development of adequate national responses is essential for risk reduction nationally and globally.

4. THE CENTRAL ROLE OF THE IAEA

The IAEA plays a fundamental political and technical role in establishing an international nuclear security regime in order to prevent and respond to nuclear terrorism. The IAEA is the only multilateral international organization with the political and technical capacity to develop and implement a political and technical action plan aiming to ensure the nuclear security of the international community. It has the necessary legal mandate and instruments, infrastructures, qualified personnel and know-how to lead the international fight against 'the nuclear threat' (Fig. 7).



FIG. 7. The international technical activities on nuclear security are mainly based on the work of the IAEA, some international nuclear security cooperative mechanisms and WINS. The IAEA is the cornerstone of this international institutional triangle.

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The IAEA's nuclear security mandate and functions have evolved within a legal framework (see Text Box 2). The IAEA's own legal framework includes its Statute, resolutions adopted by the IAEA Board of Governors and General Conference, and relevant resolutions adopted by the United Nations Security Council and General Assembly. Several international conventions, adopted under IAEA and other auspices, have also contributed to the IAEA's mandate and functions in the area of nuclear security.

Since the early 1970s, the IAEA has been called on to play an ever-evolving role in assisting States to strengthen their national legal and physical infrastructures as well as to facilitate regional and international efforts to enhance nuclear security and to combat nuclear terrorism. In 1975, the IAEA issued recommendations for physical protection of nuclear material. In 1997, the Security of material programme was established. The IAEA's first comprehensive Plan of Action to protect against nuclear terrorism was approved in March 2002. At the same time, the Nuclear Security Fund was approved as the financial platform to implement the Plan. In September 2005, the Board of Governors approved the Security Plan for 2010–2013, aiming to establish and achieve global acceptance of an agreed international framework for nuclear security and support its application (Fig. 8).

In fulfilling this task, the IAEA is facing great challenges as the dimension of the problem goes beyond the scope of their traditional activities: safeguards, nuclear safety, technical cooperation, research and development and the promotion of peaceful uses of nuclear energy. For example, the nuclear safety community still visualizes 'nuclear security' as part of 'nuclear safety', not taking into account the fact that the concept of 'nuclear security' (see AdSec definition, footnote 1) goes beyond the technological and radiological safety of facilities and materials.



FIG. 8. The role of the IAEA — The IAEA is the cornerstone of the international regime for nuclear security. It is playing a central role in the political and technical context. Its action plan to prevent nuclear terrorism is aiming to produce practical outcomes.

Text Box 2 INTERNATIONAL LEGAL FRAMEWORK FOR NUCLEAR SECURITY

• Legally binding international instruments

Under the auspices of the IAEA:

- \circ The Convention on the Physical Protection of Nuclear Material and its 2005 Amendment
- The Convention on Early Notification of a Nuclear Accident
- The Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.
- The Convention on Nuclear Safety
- The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

Under the auspices of the United Nations:

- International Convention for the Suppression of Acts of Nuclear Terrorism
- United Nations Security Council Resolutions 1373 (2001) and 1540 (2004), 1887 (2009).

Under the auspices of the International Maritime Organization:

- The Convention for the Suppression of Unlawful Acts against the Safety of Maritime Navigation.
- The Protocol for the Suppression of Unlawful Acts against the Safety of Fixed Platforms located on the Continental Shelf.

Non-legally binding international instruments:

- INFCIRC/225/Rev.4 (corr.). The Physical Protection of Nuclear Material and Nuclear Facilities.
- The Code of Conduct on the Safety and Security of Radioactive Sources and the supplementary Guidance on the Import and Export of Radioactive Sources.
- ° Security Fundamentals (GC, 2001).

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The IAEA will eventually have to decide formally whether it should simply incorporate 'nuclear security' into its traditional activities to promote and ensure the safe use of nuclear facilities and materials, or go beyond, accepting nuclear security (the fight against nuclear and radiological terrorism) as an IAEA institutional objective. This recognition will involve a redefinition of its functions and its national and international counterparts.

The AdSec Group is exploring the issues related to synergies and interfaces between safeguard, nuclear safety, radiation protection and nuclear security. In order to make progress on the nuclear safety and security synergies and interfaces, the AdSec — Commission on Safety Standards (CSS) joint Task Force was established with the objective, among others, of ensuring that the new 'Nuclear Security Guidelines' would have full coverage of nuclear safety related issues.

5. CONCLUSIONS

In conclusion, nuclear terrorism is a threat to the international community from a global and national perspective. The scope of the fight against this threat with its nuclear and radiological consequences exceeds the objectives of, and goes beyond, the traditional institutional structures to ensure nuclear safety in the nuclear industry. The challenge now is to develop a prompt and appropriate response to this new threat.

The IAEA is the cornerstone of the international regime for nuclear security and should continue to provide assistant to:

- Building an international architecture for nuclear security;
- Developing integrated national nuclear security systems;
- Building the international legal framework for nuclear security, leading the development and implementation of international 'Guidance on Nuclear Security'.

The AdSec Group is working closely with the nuclear security, the nuclear and radiation safety, and the non-proliferation communities in order to advise the IAEA Director General on the definition of the policy to be followed by the IAEA on this issue, in particular, on the development of a comprehensive and coherent set of international standards on nuclear security for the entire community of stakeholders in the security field.

REGULATING MEDICAL FACILITIES AND ACTIVITIES

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Abstract

Canada's nuclear regulator, the Canadian Nuclear Safety Commission (CNSC), is the federal agency responsible for regulating Canadian nuclear activities and facilities. These encompass the full nuclear cycle, from uranium mining to power and research reactor operation, to radioisotope production and processing, through to a wide range of radioisotope applications and waste management. The CNSC's regulatory scope includes Canadian medical facilities and activities utilizing nuclear substances in nuclear medicine for diagnosis, treatment and research. As in many countries, Canadian diagnostic nuclear medicine procedures predominantly use technetium-99m (99mTc), supplies of which have been recently compromised. 99mTc shortages have resulted in increased use of alternative radioisotopes and other diagnostic procedures, such as positron emission tomography/computed tomography (PET/CT), combined with an urgent need to develop alternate processes for the production of ^{99m}Tc. An ageing population and the resulting increase in cancer incidence have resulted in an ongoing steady increase in the number of radiation therapy treatment facilities. These developments, in addition to a government issued directive to the CNSC to balance the health and safety of persons and their environment with the medical need for nuclear substances, have resulted in an increasingly complex and demanding regulatory environment for CNSC staff with regard to medical facilities and activities in Canada. The paper will discuss the CNSC's regulatory oversight of medical facilities and activities from a licensing and compliance perspective.

1. INTRODUCTION

The Canadian Nuclear Safety Commission (CNSC) is Canada's independent nuclear regulator. The CNSC's mandate under the Nuclear Safety and Control Act (NSCA) and associated regulations is to regulate nuclear activities and facilities in Canada for the protection of the health, safety and security of persons and the environment, and to ensure that Canada's international commitments on the peaceful use of nuclear energy are respected.

The CNSC regulates the full nuclear cycle in Canada, from uranium mining to power and research reactor operation, to radioisotope production and processing, through to a wide range of radioisotope applications and waste management. Nuclear medicine and radiation therapy are included among the many regulated uses of nuclear substances within the CNSC's mandate. The CNSC oversees approximately 2050 licensees holding approximately 3300 licences.

The CNSC itself is an independent, quasi-judicial tribunal of up to seven members. The Commission makes licensing decisions for larger facilities such as nuclear power and research reactors, uranium mines and mills, fuel fabrication and processing, and high energy particle accelerators, via a public hearing process.

The Commission has delegated licensing authority for other activities and facilities, including nuclear medicine and radiation therapy, to Designated Officers. CNSC staff assesses licence applications and makes recommendations to the Commission or Designated Officers regarding the acceptability of each licence application. Such recommendations also identify any licence conditions that may be necessary to ensure that the activity to be licensed will be conducted safely. Subsequent to a licence being issued, CNSC staff monitors compliance with licences, the NSCA and regulations, through a combination of inspections and reviews. In the event that a licensee does not comply with requirements, a range of enforcement options is available to bring the licensee into compliance.

2. NUCLEAR MEDICINE AND RADIATION THERAPY IN CANADA

The CNSC licenses nuclear substances (radioisotopes) used in medical facilities and activities in two modalities: nuclear medicine and radiation therapy. Nuclear medicine involves the use of unsealed nuclear substances for either diagnosis (detection and staging) or treatment of diseases. Radiation therapy involves the use of sealed sources and prescribed equipment to deliver very high doses of radiation to tumour sites via highly collimated external beam radiation (teletherapy) or implanted radioactive sources (brachytherapy) [1].

Radioisotopes used in nuclear medicine and radiation therapy are produced in either nuclear reactors or high energy particle accelerators [2]. Examples of radioisotope producing nuclear reactors and some of the radioisotopes produced include: Pickering, Bruce and Gentilly-2 nuclear power reactors (cobalt-60 (⁶⁰Co)); the National Research Universal (NRU) nuclear reactor (molybdenum-99 (⁹⁹Mo), iodine-125 and iodine-131); and McMaster University's nuclear reactor (iodine-125).

Radioisotopes for positron emission tomography (PET) are typically produced using cyclotron accelerators. These radioisotopes have very short half-lives and consequently are generally produced in very close proximity to the imaging suite. There are currently fully operational PET cyclotrons in Montreal,

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Sherbrooke, Ottawa, Toronto, Hamilton and Edmonton, with additional facilities under construction or being commissioned in London, Winnipeg and Halifax. Common radioisotopes produced include fluorine-18 (¹⁸F), carbon-11, nitrogen-13, oxygen-15, gallium-67 and thallium-201, with the vast majority of clinical applications utilizing ¹⁸F.

3. THE REGULATION OF MEDICAL FACILITIES AND ACTIVITIES IN CANADA

The CNSC regulates virtually every step in the production and use of medical isotopes except the actual dose prescription to patients, which is conducted under the direction of qualified medical practitioners. This includes production of radioisotopes both in reactors and accelerators, processing of radiopharmaceuticals, manufacture of medically used sealed sources such as ⁶⁰Co, safe handling and exposure control within the hospitals and clinics where these isotopes are used, and radioactive waste management. The CNSC also regulates the packaging and transport of these materials between the various sites at which it is produced, processed, manufactured, used and stored.

The production of medical isotopes in nuclear power and research reactors, and the associated fuel processing and waste management facilities are regulated as part of the nuclear fuel cycle by the CNSC.

All other aspects of the production and use of medical isotopes are regulated by the CNSC's Directorate of Nuclear Substance Regulation, according to a risk based regulatory programme. In order to ensure effective and efficient regulatory oversight of these licensed activities, medical facilities and activities are categorized into two broad risk categories — medium risk and high risk. This risk ranking is based on a variety of parameters, with the primary considerations being the potential radiological and environmental risks posed by the radioactive material or equipment used. This model provides risk based ratings for each licensed activity or facility, including an evaluation of the regulatory effort required to ensure compliance and the basis on which to focus resources into specific areas as necessary. The categorization of risk types is consistent with international best practices and is the format recommended in the IAEA's Code of Conduct [3].

Within this framework, safe handling and exposure control for both nuclear medicine and radiation therapy activities at hospitals and clinics are assessed by evaluating each licensee's radiation safety programme against the requirements contained in the CNSC's Radiation Protection Regulations and the relevant sections of the Nuclear Substance and Radiation Device Regulations, the Class II Nuclear Facilities and Prescribed Equipment Regulations, and the General

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Nuclear Safety and Control Regulations. The CNSC also assesses the design of such facilities to ensure that the radiation shielding they incorporate is adequate to keep radiation exposure of both workers and the general public (other than the patient) at levels that are consistent with the concept of ALARA (as low as reasonably achievable) and below the dose limits contained in the CNSC's Radiation Protection Regulations.

In addition, radiation therapy facilities for cancer treatment must incorporate safety systems, such as entrance interlocks, warning lights and emergency stops, which are prescribed in the CNSC's Class II Nuclear Facilities and Prescribed Equipment Regulations.

Type approval for radiopharmaceuticals to be administered to patients is the responsibility of Canada's Federal Health Authority, Health Canada. Authorization for individual physicians to administer radiopharmaceuticals or to prescribe radiation therapy doses for patients is a provincial responsibility.

4. CURRENT AND FUTURE CHALLENGES AND TRENDS

In Canada, as elsewhere in the world, technetium-99m (^{99m}Tc) is the most commonly used medical radioisotope for diagnostic nuclear medicine. ^{99m}Tc is produced from the decay of ⁹⁹Mo, which in turn is produced by a very small number of research reactors around the world. The NRU nuclear reactor of the Atomic Energy of Canada Limited (AECL) located at Chalk River Laboratories, about 180 kilometres west of Ottawa, is one of the world's leading suppliers of ⁹⁹Mo. However, since November 2007, the NRU has experienced a number of unplanned outages, which have contributed to ^{99m}Tc supply shortages, most directly affecting the North American market.

During the Fall 2007 NRU outage, the Federal Cabinet issued a directive to the CNSC that the CNSC, in regulating the production, possession and use of nuclear substances in order to prevent unreasonable risk to the health of persons, shall take into account the health of Canadians who, for medical purposes, depend on nuclear substances produced by nuclear reactors. The outage concluded with the Parliament of Canada enacting legislation authorizing the return to service of the NRU. Throughout the outage, the CNSC used appropriate regulatory tools, including licence amendments for possession limits, alternative isotopes and transportation requirements to provide licensees with flexibility in responding to supply shortages, while still ensuring the protection of the health, safety and security of persons and the environment.

In May 2009, the NRU was shut down to repair a heavy water leak from the reactor vessel. The facility is still not operational and AECL expects to return the NRU to service in the first calendar quarter of 2010. The CNSC continues to

exercise strong regulatory oversight over AECL's return to service activities, and is still making available the appropriate regulatory tools to allow licensees flexibility in addressing supply shortages.

In response to the NRU outages, the Government of Canada established an Expert Review Panel on Isotope Production to review and report on proposals for the long term production of ⁹⁹Mo. The CNSC has offered its technical support to the panel and has reviewed numerous proposals for accelerator and research reactor production of ⁹⁹Mo.

Although Canada was a pioneer in the development of PET scanning, which has been used worldwide since 1995 in diagnostic oncology for cancer staging, until recently Canada has not been a pioneer in adopting diagnostic PET for routine clinical use. However, during the ^{99m}Tc supply shortage, PET/computed tomography (CT) has increasingly become one of the favoured alternatives for diagnostic imaging, and a number of Canadian provinces plan to increase the number of available PET scanners. This will necessitate a significant increase in the installation and use of cyclotrons for PET isotope production.

From 2006 to 2009, the CNSC witnessed an unprecedented three-fold increase in construction applications for new cancer centres, which includes the expansion and retrofitting of existing facilities. When fully operational, these centres will result in 18 000 more patients receiving radiation therapy treatment annually. 'Modular' radiation therapy bunkers (temporary treatment rooms) have been used in some instances in order to alleviate shortages in treatment availability while permanent facilities are being constructed. All such radiation therapy treatment facilities involve targeting extremely high radiation dose rates on the tumour volume. Consequently, the potential radiological risk can be very high, and such centres are classified as high risk in the risk based regulatory programme. This in turn mandates the need for extensive regulatory oversight for these facilities, resulting in an increased workload pressure on regulatory staff in the years ahead.

The demand for more and better cancer treatment has also resulted in an increased use of new technologies. This includes increasing use of newer, more complex treatment methodologies, such as intensity modulated radiation therapy (IMRT) and image guided radiation therapy (IGRT). CNSC staff must be diligent in ensuring that the radiation protection measures in place are adequate to protect the health and safety of persons when new technologies such as these are implemented.
5. CONCLUSIONS

Medical facilities and activities in Canada related to nuclear medicine and radiation therapy are undergoing evolution and expansion. Their importance will grow as the Canadian population ages and grows, and as new applications are developed by the medical community. The potential for radiation exposure to persons and the environment from these facilities and activities is ever-present, and strong oversight is needed to ensure that the health, safety and security of persons and the environment is protected. The CNSC ensures that these facilities and activities are conducted safely and according to a risk based regulatory programme.

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REGULATION OF MINING AND MINERAL PROCESSING ACTIVITIES IN SOUTH AFRICA

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Abstract

In South Africa, the regulation of mining and mineral processing activities involving radioactive ores commenced in 1990. The paper provides an overview of the regulation of mining and mineral processing activities and the evolution of the authorization process from 1990 until recent times. Key developments in respect of controlling public exposure, occupational exposure, and environmental protection are provided. Future and present challenges are also identified with the resurgence of activities related to nuclear power generation linked to uranium mining. The centrality of nuclear and radiation safety requirements in the context of introducing improvements for effectively regulating mining are also cited and put forward. Reference is made to the role of the South African nuclear regulatory system and the impact of the nuclear safety and security regime.

1. INTRODUCTION

In 1990, after consultation between the Government Mining Engineer and the South African National Nuclear Regulator, it was decided to proceed with the authorization of mining and mineral processing operations in terms of the Nuclear Energy Act. This Act was the outcome of the need to separate promotion from regulation, and was called the Nuclear Energy Amendment Act, No. 56 of 1988. The authorization process commenced with 13 mines that were or had been producers of uranium. In South Africa, uranium had been produced mainly as a by-product of the gold mining process. Following the establishment of the erstwhile Council for Nuclear Safety, the mining industry was subjected to regulation in respect of controlling radiological hazards associated with the mining and mineral processing of ores. To date, the regulatory base for authorization holders involved with natural sources material has expanded to 132 facilities.



FIG. 1. Geographical location of mining and mineral processing facilities in South Africa. The number of facilities (as of 31 October 2009) regulated by the NNR according to the Provincial location are given in the legend above:

The geographical location of mining and mineral processing facilities in South Africa is provided in Fig. 1.

The types of facilities regulated and the number of them are given in Table 1.

2. SOUTH AFRICAN REGULATORY INFRASTRUCTURE

The regulation of mining and mineral processing operations has now taken place for approximately 20 years. The principal legislation for the NNR is Act No. 47 of the National Nuclear Regulator Act (NNRA) 1999. It provides for safety standards and regulatory practices for the protection of persons, property and the environment against nuclear damage.

The structure of regulatory infrastructure is shown in Fig. 2. Regulation in mining is based on international and national standards, legislation and regulatory requirements captured in regulatory documents.

TABLE 1. TYPES AND NUMBER OF FACILITIES REGULATED BY THE NNR

Facilities	Number
Mining and mineral processing	70
Scrap processsors	25
Small users	17
Service providers	12
Fertilizer manufacturers	7
Scrap smelter	1
Total	132 ^a

^a Data collected up until 31 October 2009.



FIG. 2. The nuclear regulatory infrastructure in South Africa.

Section 20 (3) of the NNRA states, "No person may engage in any action, contemplated in the Act, except under the authorization of a certificate of registration (CoR)". In contrast, a nuclear power plant is authorized by means of a nuclear installation licence and a facility handling naturally occurring radioactive material (NORM) by a CoR.

The typical CoR contains eight principal conditions:

- Operational radiation protection;
- Radioactive waste management;
- Transportation;

- Physical security;
- Hazard assessment;
- Operational limitations;
- Quality management;
- Reporting of incidents.

At this stage, the NNR issues five types of CoRs for various facilities, namely small users, scrap processors, fertilizer manufacturers, small mines and large mines.

In the third tier of the regulatory infrastructure, the NNR has issued regulatory requirements for these facilities by means of regulatory documents (RDs). Essential international standards such as the IAEA Regulations for the Safe Transport of Radioactive Material (IAEA Safety Standards Series No. TS-R-1) have been adopted for use for this industry.

In order to ensure that an acceptable level of compliance assurance is maintained, inspections and audits are carried out. The NNR has introduced announced inspections as part of an effort to improve compliance.

3. KEY DEVELOPMENTS IN MINING REGULATION

After a consignment of scrap from South Africa triggered off a radiation monitor in August 1993 at a steel works in Sheffield, United Kingdom, a large scale campaign began in South Africa to control contaminated scrap metal. This incident also gave rise to the discovery of 47 off-site contaminated areas in the vicinity of operating mines in Gauteng. A large workforce was deployed making use of radiation protection staff from Eskom and Necsa (the South African Nuclear Energy Corporation) to identify contaminated areas. Later, a rehabilitation study was launched to determine the extent of contamination and also to obtain an initial estimate for the cost of remediation. An Executive Coordinating Group (ECG) was established to oversee remedial work. The ECG is comprised of the Senior Officers of the South African Nuclear Safety Regulator and the Chamber of Mines.

In 1998, dose results from underground workers indicated that 19% of miners were exceeding the dose limit of 20 milli-sievert per annum (mSv/a). These same workers were also receiving doses that were less than 50 mSv/a. In 1999, it was decided to form an industry working group consisting of the regulator, the mines and labour to monitor progress made in the reduction of doses from radon-222 to the workforce. The mines where the potential to exceed the dose limit due to radon gas inhalation for underground workers became



FIG. 3. Occupational exposure for mine workers from 2004 to 2008.

known as the Special Case Mines (SCMs). In the ensuing years, a great deal of effort has been expended on monitoring such mines by the NNR.

The dose distribution for mine workers is illustrated in Fig. 3 for the years 2004–2008. There is an overall reduction in doses over five years for doses between the range of 10 mSv to 20mSv, and 20 mSv to 50 mSv.

In June 2007, the uranium spot price reached an astounding level of \$136 per pound as rising oil prices and concerns over fossil fuel pollution ignited global interest in nuclear power. A direct spinoff of the spike in the spot price of uranium was the increase in activities in prospecting and exploration of uranium in South Africa. Linked to this factor, the NNR has issued 17 new authorizations over the past two years for the exploration of uranium.

The Nuclear Energy Policy of South Africa was approved in June 2008. The vision enshrined in the policy is to attain industrial and technological leadership for the peaceful utilization of nuclear energy and technology. The policy also constitutes a framework within which prospecting, mining and milling, and the use of uranium resources shall be carried out in a sustainable manner.

The other noteworthy development in recent years is the historical contamination from previous mining activities in the Wonderfonteinspruit Catchment Area (WCA), north-west of Johannesburg. This matter received special attention from the NNR, which developed a radiological assessment of

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the WCA in August 2007. The NNR and other regulatory bodies have constituted a National Steering Committee that has been spearheading a strategy for the long term remediation of the WCA. In October and November 2009, several public participation meetings were held as part of the managerial framework to remediate the area.

4. SAFETY STANDARDS AND REGULATORY PRACTICES

On 28 April 2006, the Safety Standards are Regulatory Practices regulation was issued in the Government gazette. This regulation represents an important milestone in the history of regulation for mining as significant safety measures and standards were promulgated for the industry. This regulation is progressive in that it is based on the IAEA International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. The principal elements covered in the regulation are listed below:

- Exclusion and exemption;
- Licensing, registration and clearance;
- Dose and risk limits;
- Optimization of radiation protection;
- Prior safety assessment;
- Good engineering practice;
- Safety culture;
- Defence in depth;
- Quality management;
- Operational safety assessments;
- Controls and limitation on operation;
- Maintenance and inspection programme;
- Staff and qualification;
- Radioactive waste management;
- Environmental monitoring and surveillance;
- Transportation of radioactive material;
- Physical security;
- Records and reports;
- Monitoring of workers;
- Application of radon exposure;
- Decommissioning;
- Release of radioactively contaminated land;
- Accidents, incidents and emergencies.

TOPICAL ISSUE 1

5. RADIOLOGICAL HAZARDS THAT NEED TO BE ASSESSED

In the process of authorizing a mining operation, the NNR requires the authorization holder to undertake a public hazard assessment. The purpose of the assessment is to establish the extent of radiological risks to the public. Although this requirement was retrospective, it provided an important baseline for the regulatory regime for the mining operation. It also set out to create as quantitative assessment of potential risk posed by all the exposure pathways due to mining. The hazards that are assessed are as follows:

- Exposure to external radiation levels (γ and γ - β dose rates) by irradiation;
- Surface contamination levels (α and β emitters);
- Long lived alpha emitting radionuclides in the air and the inhalation hazard of U₃O₈;
- Emanation of short lived ²²²Rn and ²²⁰Rn daughter products in air;
- Contaminated waste equipment;
- ²²²Rngas levels in underground mines;
- Groundwater contamination.

6. IMPROVING THE EFFECTIVENESS OF THE REGULATORY FRAMEWORK IN SOUTH AFRICA

As part of an essential strategic objective and in conjunction with the bold expansion plans for the nuclear industry in South Africa, the NNR has embarked on measured initiatives that will result in substantive improvements in the regulatory framework.

Efforts are under way to ensure that the overall regulatory framework is improved. This includes a self-assessment exercise, consolidating past experience, incorporating internal best practices in regulation, and outlining strategies aimed at the regulation of uranium mining. An implementation plan is in place that consists of 25 subprojects including principles of nuclear safety and radiation protection and covering safety, security, and safeguards. In recognition of the growing concerns about global nuclear security, the NNR has established a nuclear security management function that will provide expertise in this area.

The NNR has also developed an enforcement policy that seeks to introduce a system of fines for holders that do not comply with the requirements of the NNR. The philosophy adopted is that punitive measures should be progressively commensurate with the violation.

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The Radioactive Waste Management Policy also represents an important milestone for the regulation of radioactive waste management. Nine comprehensive policy principles taken from the IAEA have been adopted for, inter alia, the safe management of radioactive waste.

Gaining leverage from the bilateral agreements with other countries, the NNR also uses this platform for information exchange obtain insight to international good practices. The NNR also participates in international technical meetings and conferences to stay abreast of developments in the NORM industry.

Capacity building for optimum regulation of the mines also becomes crucial as the workforce ages, and continuity of good regulatory practices is needed. The NNR has committed to annually increase its budget allocation for training and development.

7. CONCLUSIONS

- Renewed interest and activity in uranium mining has resulted in the need to update the South African regulatory framework associated with uranium mining.
- In response to these developments, the NNR has embarked on broad initiatives to optimize this regulatory framework.
- Dose limitation for radon gas inhalation for underground mining has been successfully implemented by the NNR.
- Challenges in regard to large scale remediation of contaminated land from previous mining activity are being faced and steady progress made.
- Strengthening the enforcement of safety requirements for mining and mineral processing involving NORM will improve effectiveness.
- The NNR plans to review the national radiation protection standards in view of international developments in this area.
- Nuclear security related to the transportation of uraniferous material is receiving more emphasis at the NNR.
- A regulatory strategy has been developed in response to the need to ensure that an effective regulatory system is put in place for mining and mineral processing regulation.

REGULATORY INDEPENDENCE AND EFFECTIVENESS

(Topical Issue 2)

Chairpersons

A. RAJA Malaysia

M. HERTTRICH Germany

ATTRIBUTES OF EFFECTIVE INDEPENDENCE*

A.-C. LACOSTE French Nuclear Safety Authority, Paris, France

^{*} Although a presentation was given, no abstract or paper was made available. The author's PowerPoint presentation appears in the CD-ROM of contributed papers accompanying this book.

LEADERSHIP AND SAFETY MANAGEMENT: REGULATORY INITIATIVES FOR ENHANCING NUCLEAR SAFETY IN THE REPUBLIC OF KOREA

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Abstract

Since the construction of the first nuclear power plant (NPP) in the Republic of Korea in 1978, a high level of nuclear safety has continued to be maintained. This has been the important basis on which the continuous construction of NPPs has been possible in the country. To date, regulatory initiatives, leaderships and strategies adopting well harmonized regulatory systems and practices of advanced countries have contributed to improving the effectiveness and efficiency of safety regulation and further enhancing nuclear safety. The outcomes have resulted in a high level of safety and performance of Korean NPPs, attributing largely to the safety promotion policy. Recently, with the support of the Korean Ministry of Education, Science and Technology (MEST), the Korea Institute of Nuclear Safety Master's Degree Programme. Further, it developed multilateral and bilateral cooperation with other agencies to promote global nuclear safety, with the aim of providing knowledge and training to new entrant countries in establishing the safety infrastructure necessary for ensuring an acceptable level of nuclear safety.

1. INTRODUCTION

Safety and operating performance represents two sides of a coin; if safety performance is not good, high operating performance cannot be achieved. However, when operating performance is given priority over safety, safety will be compromised, which will eventually erode plant performance. Whereas plant performance can be represented by a tangible outcome, safety cannot be measured. The tasks of the regulators can be achieved only through the operators or other workers in the field, not by themselves. Accordingly, regulatory leadership should be considered a vital element to ensure safety. Leadership is a process by which a person influences others to accomplish an objective and directs an organization towards greater cohesiveness and coherence. Leaders must achieve this through their leadership attributes, such as beliefs, values, ethics, character, knowledge and skills. The aim of regulatory leadership is to stimulate operators towards reaching higher goals, rather than simply demanding obedience.

Since the construction of the first nuclear power plant (NPP) in the Republic of Korea in 1978, a high level of safety has been maintained. This has been the important basis on which the continuous construction of NPPs has been possible in this country, even with the two serious nuclear accidents, at Three Mile Island and Chernobyl, which substantially impacted the nuclear power programme worldwide. To date, the regulatory body of the Republic of Korea has facilitated licensees to achieve a high level of nuclear safety through their leadership skills. In particular, since the first standardized reactor model, Younggwang units 3 and 4, safety improvements have continuously been made by fitting the construction and operation experiences into the subsequent reactor design, which resulted in minimizing the increase of cumulated total risk of nuclear reactors. Otherwise, it would increase linearly, proportional to the number of reactors deployed in the Republic of Korea.

As safety culture is considered an essential element in maintaining a high level of safety, a number of regulatory initiatives have been put in place: the Nuclear Safety Policy Statement issued in 1994, and the designation of the second Tuesday of September as Nuclear Safety Day in 1995. This day is commemorated, on a national scale, to encourage the employees working in safety related areas. Accordingly, the 'safety first' mindset can be demonstrated and celebrated in most working places.

2. STRATEGY FOR REGULATORY EFFICIENCY AND EFFECTIVENESS

2.1. Establishment of regulatory expert organization

The Republic of Korea began the development of its nuclear power programme in the early 1960s and after almost ten years of preparation, the construction began in the early 1970s. As the new entrant to the nuclear power programme, the first three nuclear power plants (two PWRs and one PHWR) were constructed on a turn-key basis, and the technical codes and standards were based on those of countries of origin. The technical safety review for these three reactors was undertaken by governmental technocrats and researchers. After the first reactor was put into operation in 1978 and two more reactors were under construction, the important issues of how to secure safety expertise and ensure regulatory independence became very important in the early 1980s. This led to the creation of a new safety expert organization, the Nuclear Safety Center (NSC), in 1981, within the boundary of Korea Atomic Energy Research Institute (KAERI).

The Government of the Republic of Korea launched a national programme to localize the key nuclear technology for NPPs to minimize technology dependence on other countries. During this period, KAERI became one of the most important players in this technology localization programme, and the issue of regulatory independence became an issue of even greater debate. As a result, in 1990, the NSC became an independent regulatory expert organization and changed its name to the Korea Institute of Nuclear Safety (KINS). It should be noted that when KINS was established, the Government decided that all technical matters should be legally delegated to the Institute, including safety review for licensing, inspection, establishing norms for safety regulation, training of regulatory competence, relevant research and development (R&D), and international cooperation. Since government officers in the Republic of Korea are transferred from one post to another relatively frequently, technical expertise cannot be built up if technical authority remains with them. In this light, an excellent approach in achieving a very high level of regulatory capacity in a short period of time in the country would be for the government officer to assume overall responsibility and for technical authority to be assigned to the regulatory expert organization.

2.2. Strategy for improving safety at the early stage of a nuclear programme

The strategy in NPP licensing of the Government of the Republic of Korea was the best mix of regulatory practices of advanced countries, the United States of America, Canada and Japan. In addition to the regulatory system of the country of origin, other good practices were in place. One example is the Report for the Design and Construction Method, a relatively large document, in addition to the Preliminary Safety Analysis Report (PSAR) for the Application of Construction Permit (CP). This report originated from the Japanese regulation that focused on the design of components and systems, and construction technology, rather than the safety viewpoint. At the initial stage of the nuclear power programme, this would be burdensome to the operator to some extent. However, to overcome the disadvantage of insufficient experience at the early stage of nuclear power programme in the Republic of Korea, this report was very beneficial. Not only did it benefit the regulators, allowing them to obtain appropriate information and knowledge for the design and construction at the very early stage of the construction, but it helped the operator better simulate the design work with construction at the site in advance. The submission of this report was removed from the licensing prerequisites when nuclear technology was successfully

localized in the mid-1990s. Because the reactor design was standardized, the differences in the construction methods between reactors were relatively small.

2.3. Harmonization of regulatory requirements

As aforementioned, the first three reactors were introduced on a turn-key basis and all the regulatory requirements were adopted from those of the countries of origins. This resulted in some differences in the licensing documents, depending on the practices of the country of origin. For instance, the Operating Policies and Principles (OP&P) were used for the PHWR, which was written in more general terms than the PWR technical specification. As concerns the PHWR design, most of the design documents provided by the designer had been referred to as safety requirements. This is the reason that the PSAR and the Final Safety Analysis Report (FSAR) of PHWR are more concise and less detailed than those of PWR. Also, it was not completely clear as to what extent the references should be considered regulatory binding. These PHWR practices were based on regulation that was more consultative than prescriptive, such as those of the United States. This caused some inconsistency in the interpretation of the requirements depending on the reactor types. To make more consistent regulatory decisions and to provide greater clarity on the level of depth in the licensing documents, the regulatory body required that the subsequent three PHWRs, Wolsong units 2, 3 and 4, submit PSAR/FSAR equivalent to those of PWRs and Technical Specifications, rather than the OP&P. Recently, the first PHWR, Wolsong unit 1, updated its FSAR and changed the OP&P, which had been used since 1983, to the Technical Specifications similar to those of the other PHWRs. This provides more abundant necessary safety information on the FSAR and a clearer definition on the operators' actions during operation.

2.4. Minimization of the business uncertainty from regulation

In most cases, the safety reviews of the regulatory body are conducted at the open-end base to ensure that all safety concerns are cleared up before issuing a licence. This is a good way to secure enough time in terms of safety; however, it is one of the most critical factors that creates uncertainty in the construction schedule, which eventually becomes a heavy burden for the operator. In the Republic of Korea, to minimize the business uncertainty from regulation, the Enforcement Decree of Atomic Energy Act stipulates that the processing period of a permit for a new reactor application should not exceed 24 months for new reactors and 15 months for those identically designed with the previously licensed reactors or for the reactor in conformity with a certified design. Nonetheless, to ensure that the application is in compliance with relevant safety requirements, the processing period of a permit is not bound by the above limit under these conditions: when the processing period requires supplementing or revising the application documents, and when further processing time is required for justifiable reasons such as additional experiments, etc. for confirming safety. During the past two decades, there have been several important safety cases, but those that greatly exceeded the time limitation in the regulatory processing period were rare as a result of collaborative efforts of the licensee and also the regulatory activities were in line with the construction schedule as much as possible.

3. POLICY INITIATIVES AND MEASURES FOR ENHANCING NUCLEAR SAFETY

3.1. Nuclear safety related policies and plan

After an accident occurred at the Chernobyl NPP in the former Soviet Union in April 1986, substantial investigation was conducted internationally to identify its causes. In addition, much effort was devoted to finding measures for preventing a recurrence of another severe accident. To cooperate more closely among Member States for ensuring nuclear safety at a globally acceptable level, the Convention on Nuclear Safety was agreed in September 1994 and came into force in October 1996. Another international consensus was the need for a cultural approach that could improve the safety attitudes of the employees. To promote safety culture more systematically, in 1991, the International Nuclear Safety Advisory Group (INSAG) published a report, INSAG-4, providing the definition, elements of safety culture and indicators to be used. Incorporating this international trend, the Government announced the Nuclear Safety Policy Statement that expressed commitment of safety as top priority as well as to cope with the increasing number of NPPs that might potentially increase the radiation risk. It aimed to show the strong commitment of the regulatory body toward nuclear safety and to stress the importance of establishing safety culture in the nuclear community. It specifies five nuclear regulatory principles Independence, Openness, Clarity, Efficiency and Reliability - and provides the 11 regulatory policy directions.

Another policy statement issued on severe accident by the regulatory body required licensees to take measures to minimize the possibility of severe accidents and to take proper measures to minimize the radiation exposure to the public. In order to be prepared for such accidents, the regulatory body in the Republic of Korea declared the Policy on Severe Accident of Nuclear Power Plants in 2001. With its implementation, to date, all NPPs in the country have consequently applied the PSA.

There has been also a measure for safety made by the regulatory body every year. For directing short term regulatory policies, the regulatory body issues 'Yearly Regulatory Policy Direction' at the beginning of every year. It contains the analysis of domestic and international nuclear trends, achievements of the previous year, new regulatory directions and major tasks to be done in that year. All relevant organizations should annually establish the specific plans of their own, reflecting the yearly regulatory policy direction and implement them. This yearly policy direction also has contributed to the enhancement of nuclear safety.

Currently, the Comprehensive Nuclear Safety Plan is being developed by the regulatory body as a five year national plan for nuclear safety (Fig. 1). This comprehensive plan takes into account the safety vision for Green Growth, an incumbent Government national policy objective to cope with the global climate change. This Plan consists of 19 major action items under the five safety policy goals: enhancement of nuclear safety regulation system; optimization of nuclear safety regulation; improvement on radiation protection and emergency preparedness; enhancement of nuclear regulatory infrastructure; strengthening global leadership; and putting safety culture in place. The public hearing for this Plan was held on 3 December and will be approved by the Nuclear Safety Commission at the end of this year. This Plan is expected to provide more predictable, consistent, transparent, and reliable nuclear safety regulation in the Republic of Korea.



FIG. 1. Framework of 'The Nuclear Safety Policy' in the Republic of Korea.

TOPICAL ISSUE 2

4. PROMOTION OF NUCLEAR SAFETY CULTURE

In 1994, the first standardized reactor based on localized technology was granted an operating licence and put into operation. At that time, the safety sector was likely to be overshadowed by the promotion side that achieved great success through the national nuclear localization programme. Hence, there was the need to take measures for encouraging the people working for nuclear safety. It was also necessary to implement some tangible measures for enhancing and improving safety culture of the organizations, which was emphasized in the Nuclear Safety Policy Statement issued in 1994. The Government therefore designated September 10 as 'Nuclear Safety Day' in 1995 and holds regular events annually to emphasize safety and to inspire safety consciousness into the workers engaged in nuclear industries. Accordingly, on Nuclear Safety Day, a commemorative ceremony is held every year under the supervision of the Prime Minister and in the presence of hundreds of persons engaged in nuclear power communities. Personnel who contributed to the enhancement of safety are awarded and encouraged on this occasion. The preparation of commemorative events is conducted, with the initiative of Government and KINS, with the participation of related organizations, including, among others, the Korea Hydro & Nuclear Power Co. Ltd (KHNP), the Korea Power Engineering Company, Inc. (KOPEC), the Korea Atomic Energy Research Institute (KAERI). Various events including academic meetings and seminars are also held after the commemorative ceremony. To date, these events have contributed to the promotion of nuclear safety culture, which was reported in the first review meeting of the Convention on Nuclear Safety and received the attention of contracting parties in 1999.

In order to maintain an appropriate level of alertness among field workers and management in the nuclear arena, the regulatory authority launched a new campaign: it designated the first Tuesday of every month as 'Nuclear Safety Alert Day' in March 2003. All the organizations including the operators, manufacturers, designers, construction companies, and even regulatory bodies have participated in this campaign by opening a round table meeting of the top management level, conducting safety checks in areas likely to be overlooked and disseminating safety culture to field workers, etc.

Although NPPs in this country have shown very excellent performance to date, there is currently increasing concern over complacency in the nuclear industries, which could be the sign of a deteriorating safety culture. Recognizing this issue, KINS has been continuously providing the licensees with safety culture education. Since 2008, special lectures on safety culture for employees at all NPP sites and KAERI have been provided, and a total of 1043 licensee employees have participated. These lectures, whose main topics relate to the

regulator's concern about the complacency of operators in the environment of nuclear renaissance, have been conducted by KINS safety culture specialists. This unique education provides the licensees with the regulator's perspective on the safety attitudes of the licensees.

5. CONTRIBUTION TO GLOBAL NUCLEAR SAFETY

Faced with an energy shortage and climate change in the world, nuclear energy needs to be commonly explored regardless of haves or have-nots. In the past, NPPs were built and operated mostly in developed countries. However, today, many developing countries have expressed a strong desire to launch nuclear power programmes. Most of these countries are striving to develop their safety infrastructure and relevant human resources in line with the IAEA's safety and energy guidance. The Government of the Republic of Korea has shown its commitment to share and exchange information and knowledge of its nuclear experiences with Member States to promote international nuclear safety. One of those initiatives was to establish an International Nuclear Safety School (INSS) in January 2008. Since then, various training programmes in collaboration with the IAEA are being provided by the INSS to the Member States, such as the Basic Professional Training Course, the Tailored Course, and on the job training programmes to help them establish a robust nuclear safety infrastructure. At the same time, ceaseless efforts have been made to facilitate international exchange of regulatory information and techniques by offering workshops and seminars. In 2009 alone, more than 130 trainees from 24 countries visited the INSS to participate in those various programmes.

To ensure a high level of nuclear safety, a nuclear power project must be undertaken fpr a well established and sustainable nuclear safety infrastructure. A country wishing to introduce NPPs needs to focus on developing high quality human resources. Underlining the importance of education and training as key components of safety infrastructure, the General Conferences of the IAEA continue to encourage the promotion of higher education programme. In response to this global need, the INSS has developed the KINS-KAIST International Nuclear Safety Master's Degree Programme. The objective of this programme is to educate and train high calibre students, allowing them to become nuclear safety leaders in their countries. The ultimate goal of the programme is to produce high level policy makers to develop legal and governmental infrastructure, nuclear regulators to conduct regulatory activities, and safety experts to deal with technical safety matters. It is organized through the cooperation of KINS and the Korea Advanced Institute of Science and Technology (KAIST). KINS is responsible for delivering curricula on safety regulation and on the job training, while KAIST provides courses on nuclear academia. With the safety experts trained in this programme, new entrants or developing countries could better develop their safety infrastructure, which is also another initiative of the regulatory authority in the Republic of Korea.

Another KINS initiative is to develop an integrated support package to help countries that are actively considering embarking on a nuclear programme. This Integrated Regulatory Infrastructure Support (IRIS) package provides support to demonstrate that they are meeting the global regime by establishing a regulatory infrastructure as a set of institutional, organizational, and technical elements and conditions. The objective of this IRIS package is to provide guidance on the establishment of a regulatory infrastructure and to strengthen competencies of regulatory bodies. It is progressively applied by the fundamentals, the requirements and the safety guides in accordance with the IAEA safety standards and is to be used with flexibility. It aims in particular to contribute to the early establishment of a strong leadership for regulatory framework in a meaningful and timely manner.

6. CONCLUSIONS

In the Republic of Korea, the regulatory initiatives, leadership and strategies that have adopted well harmonized regulatory systems and practices of advanced countries in the early stages of a nuclear power programme have indeed improved the effectiveness and efficiency of safety regulation and have further enhanced nuclear safety to date. Several initiatives have been taken at the early stages of nuclear development in due consideration of the nuclear environment in the Republic of Korea. The outcomes have resulted in a high level of safety and performance of NPPs in the Republic of Korea, attributing largely to the safety promotion policy, such as the declaration of the Nuclear Safety Policy Statement, the Policy on Severe Accidents and the announcement of the Yearly Regulatory Plan. The designation of Nuclear Safety Day on a national scale is a unique case in the world, showing the Government's will in prioritizing safety.

We have been making efforts in global nuclear safety by establishing the INSS and creating the Nuclear Safety Master's Degree Programme and also progressive multilateral and bilateral cooperation with other agencies. As in the past, KINS will continue to make every effort to improve regulatory effectiveness, optimize the regulatory decision making process and enhance global nuclear safety. Above all, we are determined to provide assistance to new entrant countries in establishing the safety infrastructure necessary for ensuring an acceptable level of nuclear safety.

BALANCED INTEGRATED REGULATORY OVERSIGHT

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Abstract

Reactor safety, protecting the public health and safety, and protecting the environment must always be the nuclear regulator's top priorities. Enabling the use of nuclear power for the benefit of society, while protecting the public and the environment requires the regulator to balance many factors. In addition, the regulator is only one part of the overall government that must consider many factors as it carries out its societal responsibilities. Some of the factors that must be balanced and the practical impacts on how the regulator carries out its responsibilities will be addressed. The first International Conference on Effective Regulatory Systems, held in Moscow, Russian Federation, in 2006, focused on safety and security challenges with a goal of improving regulatory effectiveness through cooperation and sharing of information and best practices. The challenge of meeting both safety and security objectives is one example of potentially competing programmes that must be balanced. Other balances that must be evaluated include the benefits of safety improvements compared to the cost of implementation, the use of deterministic and probabilistic approaches, communication openness balanced with the protection of information that could be used for detrimental purposes, and timeliness of regulatory decision making balanced with the need to perform quality work in support of oversight responsibilities. A balanced and integrated approach to regulatory oversight is vital to ensuring that the regulatory body remains effective in its mission to enable the use of nuclear power while protecting the public and the environment. This concept is applicable to nations beginning a nuclear programme as well as established and experienced regulatory bodies.

The job of a nuclear regulator is in some respects very straightforward. Our mission is to protect public health and safety, and the environment. In this regard, the Nuclear Regulatory Commission (NRC) is no different than any other government body devoted to safety. Protecting a nation's citizens and its land from harm is always the mission. This simple and straightforward goal is a great asset. I think it is fair to say that the public, the companies we regulate and every employee at the NRC know why our agency exists, and what we are working so hard at to accomplish. Having a clear, well-defined mission is one of the reasons that NRC staff take great pride in coming to work every day.

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I have also had the pleasure to work closely with enough individuals from nuclear regulators from around the world to be convinced that this same sense of pride and clear safety focus is not unique to the NRC, but rather, a fundamental attribute of being a nuclear safety regulator.

But as is often the case, a closer inspection reveals that things are not as simple as they may seem. A recent publication of the Nuclear Energy Agency, Improving Nuclear Regulation, notes that there are many different ways that a nuclear safety mission can be described, including:

- No unreasonable risk;
- Adequate protection of public health and safety (according to the NRC definition);
- Risk as low as reasonably practicable;
- Safety as high as reasonable achievable; or
- The limiting of risk by use of the best technologies at acceptable economic costs.

These definitions are similar because they define broadly *what* a nuclear regulator aims for — its goal or mission. But understanding the *how* is a bit more complicated. Terms like 'reasonable', 'adequate', 'achievable' and 'acceptable' reveal that a safety regulator must balance many factors and priorities. These include weighing the impact of security requirements on safety, considering the cost-benefit ratio of new requirements, deciding whether to issue guidelines versus rules, and balancing risk informed and deterministic decision making. I will explain these concepts later in my remarks.

All of these factors are considered part of the NRC's overarching goal of creating clear, timely and reasonable regulations that are effective at promoting safety and security. Poor regulations can be ineffective in achieving their purpose: in the worst case, they could even be detrimental to safety, and in a broad sense, they can undermine confidence in the regulator.

In a simplistic world, with safety and security as our mission, we would focus exclusively on safety. And while safety and security will always be our top priority, the reality is more complicated. In accomplishing our mission, we operate in many spheres of concern including safety, regulatory and the political–public spheres. The NRC, like every regulatory body, is part of, or authorized by, a national government, which is itself accountable to the people. As a government body, our tools are primarily the power to issue and enforce regulations. All three of these aspects come into play in defining how we function: the safety mission, regulatory activity (which should be the same or nearly the same, but it may not always be the case) and accountability to a national government and the public. While our independence as an effective safety regulator is vital, that independence does not imply isolation from acknowledging and addressing political and public concerns.

Operating in several spheres at the same time can be challenging and make our work complex. It is when our work is not so straightforward that we need to be focused on our core operating principles and on our safety mission. These principles of good regulation form the basis of how the NRC accomplishes its mission and does its day to day jobs. These principles are:

- Independence: Regulatory decisions must be based on objective and unbiased assessments of all available information. The regulator must have the necessary resources and authorities to accomplish its mission without undue or inappropriate influence from any entity. Nothing but the highest possible standards of ethical performance and professionalism should influence regulation.
- **Openness:** Nuclear regulation is the public's business and must be transacted publicly and candidly. Transparency is the key to public trust. Decisions must be made in a fair, predictable, and open manner while also protecting proprietary and security related information.
- Efficiency: The taxpayer, the rate-paying consumer and the regulated community are all entitled to the best possible management and administration of public resources.
- Clarity: Regulations should be coherent, logical and practical. There should be a clear nexus between regulations and intended goals and objectives, whether explicitly or implicitly stated. Regulatory positions should be readily understood and easily applied.
- Reliability: Regulations should be based on the best available knowledge from research and experience. Regulatory actions should always be fully consistent with written regulations and should be promptly, fairly and decisively administered.

I am now going to discuss the concepts of balanced and integrated regulatory activity through a series of joined or paired priorities. In discussing these pairs, it is important to recall that it is not a matter of a win/lose competition between these objectives, but rather finding the optimum approach to a sensible solution. So I will explain the different considerations and priorities mentioned above, and discuss how the NRC integrates and balances them.

First, I would like address the balance between safety and security. When the United States of America created the NRC, the decision was made to give the agency authority over both safety and security of nuclear materials: this was found to be extremely useful for understanding and balancing the needs of both. While all nuclear nations have a safety regulator, most give all or part of the

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security responsibility to a separate agency. These are decisions made by national governments, and I have no intention at all of second-guessing them. Any nations considering adopting a nuclear energy programme for the first time should at least consider the possibility of combining the authority for nuclear safety and security into a single organization.

Safety and security needs can complement each other, but they can also pull in opposite directions, as shown with the example of access points. Viewed strictly from a security perspective, a nuclear power plant should have only one entry and exit point in order to minimize the possibility of illicit access. The plant owners might even want to install additional access barriers inside the plant in order to provide another level of security. But from a safety standpoint, the operators and regulatory staff should have wide and open access to wherever they need in order to inspect, and if necessary, adjust or repair safety-related equipment. A balanced approach that weighs each of these needs can help find a way to achieve both objectives.

This is the most common example, and people sometimes think it is the only one. But the balance between safety and security also comes into play in a number of other areas, such as determining the plant's containment structure. Thick, hard concrete is better at protecting the plant from a potential hostile attack. From a security standpoint, therefore, the containment building could never be too solid or too strong. This is obviously not the only consideration. Nuclear power plants also need to be designed to keep the employees and the reactor vessel safe in the event of natural disasters, such as an earthquake. As any structural engineer will point out, a more flexible building is safer in an earthquake. So safety considerations require that a degree of flexibility in the containment building is also necessary. Again, the optimum solution considers both objectives.

At the NRC, decisions aim to be mindful of cost–benefit considerations. The agency does not support or oppose the commercial use of nuclear materials. Rather, our job is to set standards for safety and security that are high but not impossible or unreasonable.

We seek to ensure that our requirements are proportional to the problem or risk, and that the cost of meeting these standards is not needlessly high. Finding this balance requires a detailed regulatory analysis to ensure that the ultimate decision protects public health and safety. We strive for a systematic and disciplined process that is also open and transparent. As part of the cost-benefit analysis, possible alternatives for achieving the same goal are assessed.

One example is medical isotopes. Following the terrorist attacks of 11 September 2001 (9/11), there has been an increased focus on enhancing regulatory controls of radioactive sources. The US National Academy of Sciences issued a report that emphasized that replacement technologies be

considered for caesium-chloride, a highly radioactive chemical form of Cs-137. Caesium-chloride, used in nuclear medicine, research and industry, is typically double sealed and contained in a stainless steel capsule for safety reasons. In light of the views on alternative technologies as a replacement, NRC convened public workshops to seek input from various stakeholders. We also commissioned a study by the NRC's Advisory Committee on the Medical Uses of Isotopes. After carefully considering all these inputs, as well as the NRC's own internal analysis, our agency concluded that near-term replacement of caesium-chloride devices was not practicable, and would be detrimental to the delivery of medical care and research.

Let me now turn to the subject of risk information. Challenges to public health and safety include both normal and accidental exposures to radiation. Normal exposures can be planned, minimized and monitored. But information on the probability and consequences of accidental exposures must come from statistics or risk assessments. Risk information is a technical description of things that can go wrong, the likelihood of this happening, and the consequences if this were to happen. This information can be both quantitative and qualitative. Regulatory decisions weigh this risk information with what we call 'deterministic inputs'. These are specific requirements such as redundant safety measures and safety margins, specific licence conditions and requirements, and technical specifications. A decision based on the right balance of risk-informed and deterministic inputs leads to a more effective regulatory programme.

One result of the NRC's movement toward risk informing its regulations is a greater focus on outcomes and performance. The NRC developed the Reactor Oversight Process to monitor the performance of its licence holders in reactor safety, radiation safety and security. This approach was developed when it was realized that previous NRC inspections, assessments and enforcement were not always focused on the most important safety issues. The concept of balance is inherent in the NRC's improved oversight process and focuses on objective performance indicators data such as unplanned reactor shutdowns, safety system failures and unplanned radioactive releases as well as inspections and results. The use of both performance data and inspection findings results in an assessment process that is more comprehensive and more effective than the previous process.

The subject of reactors leads to another area of balance: the need to manage our increased licensing activities while remaining focused on the safety of the existing fleet of reactors. In addition to increased applications for new fuel cycle facilities, operating plant licence extensions and reactor power uprates, we have also received nearly 20 applications to build new power plants in the last few years. To deal with these new build applications in a timely manner, the NRC created a separate Office of New Reactors, as well as a new construction inspection office at one of its regional offices in Atlanta, Georgia. This allows its

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Nuclear Reactor Regulation Office to remain focused exclusively on the safety and security of the currently operating plants.

Another area of balance involves guidelines versus. rules. The NRC sometimes faces the question of whether an action it takes should be a guideline or a firm requirement; there is merit to both. Detailed rules and regulations have their advantages and their drawbacks. Clear rules, when written well, are relatively easy to interpret and enforce, and tend to command immediate action. They build confidence. Stakeholders can understand regulations that are set down in clear language. However, the volume and complexity of rules can also present drawbacks. An excess of specific mandates can be confusing, open to differing interpretations, and may potentially conflict with each other.

A regulatory approach based on broad guidelines, on the other hand, is flexible enough to adapt to the evolving conditions of the situation. Principles and guidelines become evolving standards, which can adjust to different circumstances and changing needs. They could also encourage continuous improvement over time. But guidelines can be difficult to enforce. Rules and guidelines are not necessarily always mutually exclusive. The reality is that both are needed to achieve the most effective regulation possible. And that is where the ability to balance through a structured framework becomes important. The cumulative effect of too much rule-making, guidance and other measures can be detrimental to safety by causing the license holder to become fixated on 'following the rules', rather than seeing safety as an ongoing process of maintaining constant vigilance. The NRC therefore seeks to set out a reasonable, consistent and clear framework, and then follow it.

In any event, whether we issue rules or guidelines, our responsibility as regulators cannot be delegated, contracted or transferred. This does not mean, however, that it operates in isolation. The NRC is part of the US Federal Government, and its activities are integrated and coordinated with many national, state and local authorities. For example, emergency plans for NRC licensed nuclear plants and fuel facilities rely heavily on local and state government authorities for important functions such as evacuation plans. During a severe hurricane that struck south Florida, USA, two commercial pressurized water reactors in the area were shut down in an orderly fashion. The storm caused only minor damage to the non-safety portions of the plant, but it caused substantial infrastructure damage to the city of Miami and its surroundings. Hospitals, local police forces, fire and ambulance services, and water supplies were affected.

After the minor damage at the plants was repaired, they were restarted with NRC concurrence. But the Federal Emergency Management Agency immediately objected to this decision because local emergency preparedness capability was severely hampered. The units were then shut down and only restarted one week later, after local emergency response abilities were sufficiently

recovered. Subsequently, the NCR's coordination and communication protocol was reevaluated and successfully applied during the next major hurricane, this time affecting New Orleans, Louisiana, USA, a few years later.

Although the NRC is independent in many respects, it is not isolated. Its success in protecting public health and safety and security is proportional to how well it coordinates, communicates and collaborates with stakeholders and other agencies.

Finally, let me address the balance between openness and the protection of sensitive information. The NRC sees itself as conducting the people's business, striving to maintain as much transparency as possible in its decision making. Hundreds of public meetings are held each year and a great deal of information made available to the public, both in print and online. Nearly all of the nuclear power plants in the United States of America are operated by private companies, so the NRC has an obligation to protect their proprietary information. And since the NRC also oversees the security of nuclear facilities and materials, it must restrict access to certain security related information, such as how a nuclear power plant would respond to a hostile attack. As with the other above-mentioned examples, fulfilling these equally important goals is not an either-or question, but a matter of finding the right approach that serves both priorities.

There are a number of other areas I could touch on such as the balance between ensuring professional, high quality reviews of licence applications and the timeliness of our decision making, as well as the weight given to strict analytical rigour versus the professional judgement of an experienced engineer.

But in the interest of time, let me stop here and note that a balanced and integrated approach to decision making is essential for regulatory effectiveness and for ensuring the safe, secure use of nuclear energy and radioactive materials.

OPENNESS AND TRANSPARENCY, STAKEHOLDER INVOLVEMENT

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Abstract

The paper will discuss the 'independence principle' with respect to the Brazilian Nuclear Programme, considering the degree of development of the country. The Brazilian regulatory body, the Comissão Nacional de Energia Nuclear (Brazilian Nuclear Energy Commission (CNEN), has both promotional and regulatory functions, independence being provided by different structures within the institution. With the recent, renewed interest in nuclear activities, especially for electricity generation, a significant increase in the number of nuclear institutions, as well as in the use of nuclear techniques is expected, demanding a complete revision of the legal framework and of the structure of the governmental nuclear area. This revision has been prepared and includes a proposal for the creation of a new regulatory body, separate from CNEN. The Brazilian case is evidence that this model could be the appropriate one, since it has provided safe and secure development, and fulfilled the international commitments to non-proliferation, safety and security principles. The role of human resources, cultural aspects, legislation, openness, transparency, costs versus benefits, technical support organizations, relations with stakeholders and the IAEA will be briefly addressed in order to verify the importance of each of these aspects in the effectiveness of the regulatory body.

1. THE CONCEPT OF INDEPENDENCE

The concept of independence of a regulatory body is found in many IAEA standards and in the most relevant Conventions. It is well defined in the report Independence in Regulatory Decision Making $(INSAG-17)^1$. Three main functions are expected from a regulatory body: (a) to develop a set of appropriate, comprehensive and sound regulations; (b) to verify compliance with those rules; and (c) to enforce the regulations, applying the proper corrective measures.

¹ INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Independence in Regulatory Decision Making, INSAG-17, IAEA, Vienna (2004).

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The same document states four key features for effectively performing the main functions: (a) resistance to unexpected external influences, but with dialogue and consultation with licensees and public; (b) decisions taken on scientific bases and using proven technology, reported clearly and explained well; (c) consistency and predictability in relation to objectives and legal and technical criteria; and (d) transparency and traceability.

The report also states, on the other hand, that "it is recognized that a regulatory body cannot be absolutely independent in all respects of the rest of the government: it must function within a national system of laws and under budget constraints" (INSAG-17, page 2, para. 6), and that it should be granted appeal mechanisms against discriminatory decisions by the regulatory body.

It should be stressed that there is no mention of the place that the regulatory body should occupy inside the government structure, being cited just that "there must be an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy", not being clear exactly what "effective separation" means (INSAG-17, page 1, para. 3). Another interesting aspect is that the document states "the regulatory body should more resemble the judicial branch (the courts of law) than the executive branch of the government" (INSAG-17, page 2, para. 6).

2. REFLECTIONS ON THE CONCEPT

The points stressed in the previous section raise some issues. The first concerns the comparison made between the nuclear regulatory system and the government system. Usually, in a democracy, the system is composed of three independent powers: the Congress, which proposes and votes on the laws; the Government, which is responsible for the enforcement of the laws; and the Judiciary, which judges cases of misconduct with respect to the laws. The commonly accepted concept of independence of the nuclear regulator is broader, since the regulator develops and issues the norms and standards (which frequently have the power of law, guaranteed by the national legislation), verifies compliance to these rules, and enforces them by applying sanctions to the offenders. In this sense, it could be bluntly stated that the nuclear independence concept is not truly democratic.

With respect to the issues above, there is a problem concerning the question of appeal. Since most of the disagreements between licensees and regulators are related to technical issues, who will judge the appeal? Usually, it is a superior authority in the very same institution that compromises the independence of the judgment.

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In our opinion, the most obscure point in the definition of independence is the meaning of 'effective separation' and 'effective independence' in the IAEA documents. Since the structure itself is not discussed in the publications, interpreting what is effective remains to be answered by each party, which is appropriate because the specificity and sovereignty of each country must be respected. But the point still remains because, according to the Collins Cobuild English Dictionary, "effective" is defined as something that "works well and produces the results that are intended". 'Effective' is a national concept, which therefore, may include different results from those considered by the IAEA.

Obviously, there is a 'gestalt' concept of independence underlying the long (and sometimes inefficient) discussions held in Vienna during regulatory meetings and conferences. The main reason for these comments is to show that the issue is not as clear as it may seem and that a proper evaluation of a nuclear regulatory body would need more than just a check list.

3. THE BRAZILIAN CASE

3.1. The Brazilian nuclear programme

Articles 21 and 177 of the Brazilian Federal Constitution of 1988 state that the Union has the exclusive competence for managing and handling all nuclear energy activities, including the operation of nuclear power plants. The Union also holds the monopoly for the survey, mining, milling, exploitation and exploration of nuclear minerals, as well as the activities related to industrialization and commerce of nuclear minerals and materials. All these activities are to be carried out solely for peaceful uses and always under the approval of the National Congress.

Brazilian Governmental institutions involved with nuclear activities and/or utilization of ionizing radiation, with the exception of X rays, are depicted in Fig. 1, where the main actors are in green. CNEN, responsible for regulation and research and development (R&D), is part of the Ministry of Science and Technology. Some research institutions are also producing radioisotopes and radiopharmaceuticals. CNEN is the main shareholder of Industrias Nucleares do Brasil (INB), responsible for the entire fuel cycle, and of Nuclebrás Equipamentos Pesados (NUCLEP), a heavy engineering workshop, but the administrations of the industries are autonomous. The nuclear power plants are owned by a governmental company, Eletronuclear, part of the Ministry of Mining and Energy. A research institution, Centro Tecnológico da Marinha at São Paulo, is responsible for the development and construction of the ultracentrifuges used for uranium enrichment.

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FIG. 1. Brazilian Governmental institutions involved with nuclear activities and/or utilization of ionizing radiation, with the exception of X rays.

Currently, Brazil has two nuclear power plants in operation (Angra 1, 657 MW(e) gross/626 MW net, two loop PWR and Angra 2, 1345 MW(e) gross/1275 MW(e) net, four loop PWR), and one under construction (Angra 3, 1312 MW(e) gross/1229 MW net, four loop PWR). Angra 3 construction has been interrupted since 1991, but was restarted last September. Angra 1, 2 and 3 are located at a common site, near the city of Angra dos Reis, about 130 km from Rio de Janeiro.

Brazil has developed technology for uranium conversion and enrichment, as a consequence of a strong R&D programme. Over 15 000 individuals are involved in these activities. Brazil ranks sixth in the world in terms of uranium ore reserves. Brazilian reserves amount to approximately 310 000 tonnes of U_3O_8 in situ, recoverable at low costs.

Brazil has invested in the nuclear area in two phases, the first in the 1970s when Angra I was built, and the second in the 1980s, when an agreement with Germany for the construction of eight reactors was signed. The agreement was not a success, because only Angra II was finished and commissioned only in 2000. At that time, the main parts of Angra III were bought, which have been maintained with proper storage at a cost of approximately \$20 million per year. The reasons for the modest success can be related to the fact that in both occasions Brazil did not really need nuclear energy as a source of electricity, given the then abundant hydro potential. The situation is different today. With

water reserves located mainly in the Amazon, in areas of native population reserves or ecological reserves that prevent the construction of large reservoirs, diversification of the electricity production matrix is necessary. Add that to the fact that the volume of water reservoirs fall significantly in the period from September to November and the competitive price of nuclear energy today, it is easy to understand the need to consider nuclear energy.

Since 2005 Brazil has been carrying out a new nuclear plan, with goals to be achieved for the next 20 years. The main points of this programme are:

- Nuclear energy: The aim is to reach about 5% of the Brazilian electricity production in 2030, finishing Angra 3 (2015) and building between four and eight new reactors of 1000 MW by 2030 (in two sites).
- Fuel cycle: Considering the uranium abundance in the country and Brazilian technical capacity, the aim is to reach 100% of the national fuel demands by 2014, including enrichment.
- Applications: The aims are to continue to invest in science and technology in nuclear applications such as medical, industry and agrobusiness, and to reach self-sufficiency in the production of radioisotopes and radiopharmaceuticals in ten years.
- Regulation: The aim is to create a new regulatory agency separate from CNEN.

3.2. CNEN — Regulator and promoter

CNEN was created in 1956 to be responsible for all nuclear activities in Brazil. Later, CNEN was reorganized and its responsibilities were established by Law 4118/62. Thereafter, CNEN became the regulatory body in charge of regulating, licensing and controlling nuclear energy. Since 2000, CNEN has been reporting to the Ministério de Ciência e Tecnologia (Ministry of Science and Technology (MCT)). Other governmental bodies are also involved in the licensing process, such as the Brazilian Institute for the Environment and Renewable Natural Resources (IBAMA).

CNEN authority is a direct consequence of Law 4118/62 and its alterations determined by Laws 6189/74 and 7781/89, which created CNEN. These laws established that CNEN has the authority "to issue regulations, licenses and authorizations related to nuclear installations", "to inspect licensed installations", and "to enforce the laws and its own regulations".

Effective separation between the functions of the regulatory body (CNEN) and the organization concerned with the promotion and utilization of nuclear energy for electricity generation (Eletronuclear) is provided by the structure of the Brazilian Government in this area. While CNEN is under the Ministry of
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Science and Technology (MCT), Eletronuclear is fully owned by Eletrobrás, a national holding company for the electric system, under the Ministry of Mines and Energy (MME) (see Fig. 1).

The organizational unit responsible for the licensing of nuclear power plants is the Directorate for Radiation Protection and Nuclear Safety (DRS). Nevertheless, technical resources can be drawn from any other CNEN unit to support licensing activities, mainly from the Institute for Radiation Protection and Dosimetry (IRD), which is the main technical support organization for safety and security regulation.

A total staff of 2800, of which 85% are technical staff, are available at CNEN and its research institutes. Forty-eight per cent of the staff are university graduates, 19% hold a Masters degree and 9% hold a doctoral degree. Around one-seventh (400) of CNEN employees are in DRS, responsible for regulatory issues.

Financial resources for CNEN are provided directly from the Government budget. Since 1998, taxes and fees are charged to the licensees, but this income is deducted from the Government funds allocated to CNEN.

Salaries of CNEN staff are subject to Federal Government policies and administration. The most important concern now related to technical staff is that most of the personnel are close to retirement age.

4. LESSONS LEARNED

A number of lessons learned and converted into basic principles are presented below. Most of them have been listed in IAEA documents as well as in INSAG-17, with some differences in details that are mentioned below.

Human capacities — The first and main condition. To be effective, a regulatory body needs, inter alia, engineers, physicists, geologists and chemists. The required training could take months to a decade. One unusual detail from our experience is that regulators reason differently from the traditional researcher or scientist, because he or she needs efficiency, efficacy, routine, schedule and hierarchy — aspects not learned in a scientific career.

Avoidance of repressive police behaviour. In Brazil, the regulatory activity and most of the employees were subject to different political regimes; under some of them, appeals against authority decisions were not allowed under some of them. This could lead to authoritarian behaviour, which should always be avoided. Being proactive is always the best way to achieve a safety culture, including providing guidance to the licensees about how to do things properly. It is important to keep in mind that the main goals are in the national and public interest. **Have consistent legislation**. Provide different sanction grades and allow room to deal differently with the different situations.

Consult the operators to learn about the quality, efficiency and propriety of your service. A very useful tool is to promote joint events with the operators, improving good and effective communication channels. Consider their opinions and suggestions.

Be transparent. Inform the public about rules, risks and benefits of ionizing radiation and about operator status. This could be carried out through a user-friendly home page with all relevant information. The most important aspect is never to hide or delay the dissemination of information.

Do not try to control everything. Take into account risks, benefits and costs. Consider the IAEA source classification when drawing limits for the controlled universe. Establish a prioritization for the installations aiming different scopes of control. But try to keep track of **all** radioactive sources and equipment in the country. Figure 2 is very useful, even considering that the uncertainty in drawing limits for epidemiological and short term effect ranges ishuge.

The IAEA standards are state of the art. They should be adapted to facilities and capacities. Sometimes it is better to do less but more effectively, always considering risks and benefits. Look at the different approaches. For example, US and European regulatory norms and guides could be surprisingly useful. It should be recalled that another country may have already dealt with similar problems and situations. Contact it.



FIG. 2. Limits for epidemiology and short term effect.

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Think carefully about the independence principle. As discussed at the beginning of this paper, how really independent can an institution be? Is separation of promotion (R&D) and regulation a guarantee of independence? Does the institutional independence (and even the economic assurance) guarantee the effectiveness of control? Or does the accident record and public transparency permit evaluation of the effectiveness and efficiency of the control? For Brazil, it was important to wait for the proper time to create a nuclear regulatory body separated from the Nuclear Energy Commission, in order to guarantee the sustainability of both institutions.

PROMOTING NUCLEAR SAFETY AND SECURITY THROUGH SELF-ASSESSMENT AND NETWORKING The case of the African region

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Abstract

The use of ionizing radiation and radioactive sources is on the increase in the African region. All the African countries are involved in one or more medical applications of ionizing radiation, either for diagnosis or therapy. Industrial applications are equally well spread, either in the form nuclear gauging, industrial radiography or nuclear well logging, especially in the oil producing states. Furthermore, the ravaging energy poverty in the region against the continuing rise in population, and the rising global demand for low carbon emitting energy supplies to fuel sustainable development have resulted in demand for nuclear electricity in the region and the global demand for uranium, with which Africa is well endowed. This widening scope and intensity of applications call for greater concerns for safety and security. Maximum benefits of these applications can only be delivered if they are supported by a well developed regulatory infrastructure, which will enable Member States to control and minimize the associated risks through a functional, effective and efficient regulatory regime. There is therefore the need for adequate attention to the development of regulatory infrastructures commensurate with the magnitude and nature of the associated risks to be controlled and enhancement of the performance of regulatory bodies. It is against this background that the IAEA in 1994 launched an Interregional Model Project, Strengthening Radiation Protection Infrastructure, whose main objective was to eliminate the shortcomings in the safety infrastructure and control of radiation sources of Member States, including African countries. With the completion of the Model Project in 2004, the IAEA had continued over the past five years to strengthen regulatory infrastructure through the ongoing five thematic regional projects. In an effort to consolidate the achievements of the Model Project and to optimize the assistance of the IAEA and from other partners, regulatory bodies in Africa resolved to establish the Forum of Nuclear Regulatory Bodies in Africa (FNRBA). Using self-assessment and networking as management tools, FNRBA is partnering with the IAEA in its Five-Year Strategic Plan 2010-2014 to identify and examine any gaps relative to the international standards. The status of the region's regulatory infrastructures and the level of compliance with the international standards will also be assessed. The feedback from the self-assessment will be shared though the Regional Network as a valuable tool for continuous improvement of the region's regulatory infrastructure

1. INTRODUCTION

Today in Africa, there is an increasing trend to use sources of ionizing radiation and radioactive materials in various socioeconomic development activities. The growing application of radiation and nuclear technology is widespread, ranging from health and agriculture sectors to the petroleum sector and manufacturing industry. The application of nuclear technology is rapidly expanding to other areas, including uranium mining and milling and research reactors. Recently, there has been an expressed interest by Member States to pursue nuclear options for power generation. These developments are driven by the global economic, technological, social and environmental factors, and the concomitant increase of awareness and recognition of the beneficial role of nuclear technology in the development of the African continent's socioeconomic landscape. The change is also witnessed by the increased technical cooperation activities between the IAEA and its Member States in the African region.

It is pertinent to recall the international initiative launched by the IAEA in 1994, the Interregional Model Project on Strengthening Radiation Protection Infrastructure. The main objective was to eliminate the shortcomings in the safety infrastructure and control of radiation sources in Member States. The Model Project was based on five Milestones set to meet the requirements of the International Basic Safety Standards for Radiation Protection against Ionizing Radiation and for the Safety of Radiation Sources, which is popularly referred to as the BSS. The Model Project consisted of comprehensive work plans with well identified sets of activities, the implementation of which mark the completion of a milestone. These are:

- Milestone 1: Establishment of Legislative and Regulatory Infrastructure;
- Milestone 2: Establishment of Occupational Exposure Control Programme;
- Milestone 3: Establishment of Medical Exposure Control Programme;
- Milestone 4: Establishment of Public Exposure Control Programme;
- --- Milestone 5: Establishment of Emergency Preparedness and Response Programme.

The Model Project was brought to a close in 2004, but the level of achievement of the Milestones needs to be continuously self-assessed as well as by peers in the region, and finally, by the international community. In addition, radiation safety must be continuously improved in all applications of ionizing radiation. This is the goal of all the nuclear regulatory authorities, which can be achieved through capacity building, self-assessment and networking. The Model Project definitely achieved a great deal in the ten years of operation. Its end marked the 'coming of age' of the regulatory authorities in Africa, which was

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compelled by the need to consolidate and sustain the achievements of the Model Project. This resulted in searching for alternative mechanisms for building on the success of the Model Project and finding ways and means of expanding its scope without the sole sponsorship of or promotion by the IAEA. In other words, can the African Member Sates take ownership of radiation safety, nuclear safety and security? Doing so is in their best interests. This question, five years later, led to the establishment of the Forum of Nuclear Regulatory Authorities in Africa, in March 2009.

2. FORUM OF NUCLEAR REGULATORY AUTHORITIES IN AFRICA

The Forum has a nine member **Steering Committee** representing all the five subregions of the continent and its activities are guided by a *Charter*. The **Plenary** is the highest organ of the **Forum** and comprises of all the Heads of the Member Regulatory Bodies. Membership of the Forum is open to all nuclear regulatory bodies in the region and it is voluntary. Today, there are 32 member regulatory bodies in the **Forum**. The objectives of the Forum are to:

- Provide a platform for fostering regional cooperation;
- Provide for the exchange of expertise, information and experience;
- Provide opportunity for mutual support and coordination of regional initiatives;
- Leverage the development and optimization of resource utilization.

In carrying out these objectives, the Forum has identified seven thematic areas of interest that require immediate attention and action. Correspondingly, seven Technical Working Groups (TWGs) were constituted, each with a coordinator, to address these areas of need. These are:

- TWG1: Upgrading Legislative and Regulatory Infrastructure;
- TWG2: Upgrading Safety in Radiotherapy;
- TWG3: Upgrading Safety in Uranium Mining and Milling;
- TWG4: Regulatory Framework for Licensing of Nuclear Power Plant;
- TWG5: Upgrading Safety in Nuclear Research Reactor;
- TWG6: Education and Training and Knowledge Management;
- TWG7: Upgrading Safety of Radioactive Waste Management Infrastructure.

3. THE IAEA–FORUM PARTNERSHIP

In collaboration with the Forum, in 2009 the IAEA launched the Regional Project RAF9038: Promoting Self-Assessment of Regulatory Infrastructures for Safety and Networking of Regulatory Bodies in Africa. This project will facilitate the benchmarking of nuclear safety and security in each of the seven areas through self-assessment and peer review using the platform of the Forum.

TWG1: Upgrading Legislative and Regulatory Infrastructure

Much was achieved under the Model Project, but there are still several Member States in the region without either legislative or/and regulatory infrastructure for radiation protection, nuclear safety and security. Yet there are several legacy practices in these Member States, while some of their neighbours plan to embark on a nuclear power programme. This is a major challenge for the Forum and will require the support of manufacturers of equipment and machines generating ionizing radiation or radioactive sources.

TWG2: Upgrading Safety in Radiotherapy

Cancer has been recognized to afflict both the developed and the developing countries. All the Member States in the region import machines for diagnosis and therapy. There are frequent reports of imported obsolete machines without adequate guarantee for maintenance that affect safety of both the patients and the workers. Inadequate calibration facilities in Africa equally affect both safety and efficacy. Here again, the Forum seeks the support of the major manufacturers to partner with the regulatory bodies in the recipient countries.

TWG3: Upgrading Safety in Uranium Mining and Milling

About eight new African countries have shown interest in the exploitation of their uranium deposits. Four decades ago, there was uranium exploitation in some of the countries with uranium mining activities, but there was no legislation for regulating ionizing radiation and the consequences of uranium mining and milling, and the impact on ground water and the environment at large. Cooperation is needed with the regulatory bodies in the developed countries in general and with the home regulatory bodies of the uranium mining companies.

TWG4: Regulatory Framework for Licensing of a Nuclear Power Plant

About 20 African Member States have made political commitment to embark on a nuclear power programme. There are challenges of staffing and training institutions, weak industrial, financial and regulatory infrastructure. According to Dr. Mohamed ElBaradei, it is the right of Member States to use nuclear energy for peaceful purposes, but it is equally their responsibility to use it safely. This responsibility for safety will be greatly facilitated by ensuring that all these Member States embarking on a nuclear power programme in the African region should establish independent and effective regulators and adhere to international safety, security and non-proliferation instruments by becoming parties to the various international instruments. Such instruments include the Convention on Nuclear Safety, the Joint Convention on the Safe Management of Spent Fuel and Safe Management of Radioactive Waste, and the Convention on Nuclear Liability. The Forum will therefore require cooperation with the regulatory bodies of the vendor countries in building human resources and infrastructure. The "primary responsibility for all aspects of a nuclear power programme — and in particular for safety, security and safeguards — lies with the countries concerned. This cannot be outsourced." Suppliers of nuclear technology owe a duty of care to the recipients and to the world at large. This is yet another reason for a regional approach to nuclear safety and security, and partnership between the Forum and the regulatory authorities of the supplier countries.

TWG5: Upgrading Safety in Nuclear Research Reactor

Presently, there are eight Member States with nuclear research reactors, most of which are under-utilized. It is a general rule that when a major facility is under-utilized, safety is the first casualty. There is thus the need to benchmark safety issues in all the research reactors in the region and thereby stimulate utilization.

TWG6: Education and Training and Knowledge Management

Training of regulators in the region in areas such as radiation, transport and waste safety is still a challenge. There are, however, some training institutions in the region, but there is inadequate information among Member States, and the mechanism for sponsorship is yet to be developed. This is another reason for the establishment of independent and adequately funded regulatory bodies and partnership with manufacturers and vendors.

ELEGBA

TWG7: Upgrading Safety of Radioactive Waste Management Infrastructure

Africa has a large quantity of 'legacy' radioactive waste arising from the pre-regulatory era. This is either in the form of spent sealed sources, whose owners may be known but who lack either the financial resources or the regulatory responsibility to dispose of such sources in an appropriate manner; or in the form of mine tailings, which have accumulated for decades without any legislative requirement for their proper management. Here again, cooperation is sought with both manufacturers of sealed sources and mining companies, and therefore with the regulatory bodies of the home countries of these companies. In addition to all of these challenges, there is an emerging tendency associated with the collapsing state authorities, which is being exploited by some unscrupulous business groups to export radioactive waste to such countries. Similarly, there are reports of export of contaminated scrap metal to some African countries, most of which lack the appropriate technology to detect such dangerous imports; this is an area in which the Forum will require the support and the cooperation of the IAEA and the World Customs Organization.

In support of these activities, the IAEA, under the Regional Project RAF9038, organized two training courses, in English and French to demonstrate the Self-Assessment Methodology. Member regulatory authorities have now conducted national training workshops on the methodology and will later apply the Self-Assessment Tool (SAT) to all of the thematic areas listed above. The result of such national exercises can then be shared with other members of the particular TWG, and the IAEA could then provide an expert for the evaluation of the Self-Assessment exercises in the region. The outcome of such an evaluation will produce one or two countries as 'shining examples' in safety for the particular practice. This report will form the basis of the Work Plan, which can be shared with both partners and manufacturers. Preparatory to this development, the Forum under the aegis of the Regional Project RAF9038 has developed the Five-Year Strategic Plan 2010–2014, which will be launched during the course of this Conference.

Similarly, in the area of Networking, the Forum has launched its web site, www.fnrba.org, and this is gradually being linked to the web sites of Member Regulatory Authorities (MRAs) and the IAEA. Presently, the web site is hosted in Africa by one of the MRAs, while exploratory work is in progress to transfer the web site hosting to the IAEA under the RAF9038 Project.

4. CONCLUSIONS

The establishment of the Forum of Nuclear Regulatory Bodies in Africa is a major step towards consolidating the gains of the Model Project. It is also recognized that the region faces common challenges and difficulties in the area of safety. The Forum in partnership with the IAEA has embarked on a regional project on self-assessment and networking, which will serve as a tool to identify areas of common challenges and difficulties. The report on the self-assessment exercises will lead to the harmonization of policies, regulatory practices and application of international standards by regularly sharing experience and good practices. Furthermore, networking among the members of the Forum will provide an effective instrument for enhancing the sharing of knowledge and experience essential to the prevention of accidents and to the implementation of radiation safety and security measures. The Forum, in collaboration with the IAEA has now developed a Five-Year Strategic Plan, which will be made available to prospective partners for support.

COMPETENCE AND KNOWLEDGE MANAGEMENT

N. LASMAN BAPETEN, Jakarta, Indonesia

Presented by K. Huda

Abstract

The main objective of a nuclear regulatory body is to ensure that the nuclear energy applications fulfill the aspect of safety, security and safeguards to protect people and the environment from hazards associated with nuclear facilities or nuclear materials. Therefore, staff competencies of the regulatory body are essential and should be maintained. The continued control of nuclear facilities is needed. In addition, the retirement age of the employees should be calculated as part of human resource planning. In this context, knowledge management has a major role in transferring knowledge to ensure that nuclear energy and its associated technologies can be used safely and that society has greater confidence and trust in the regulator. The nuclear industry can then be assured that it is being regulated competently and fairly.

1. INTRODUCTION

The most valuable asset of the regulatory body is its employees. Developing their skills and knowledge is an investment in each employee, bringing a positive impact to the organization. Competency in the regulatory framework should be based on achieving the safety, security and safeguards of each nuclear facility. Therefore, the policy for fulfilling the competency of the human resources of the regulatory body is needed to effectively perform regulation, licensing, inspection, review and assessment, as well as enforcement functions.

Experience in effectively performing regulation, licensing, inspection, review and assessment as well as enforcement functions should be communicated and shared internally within the regulatory body and/or between regulatory bodies through knowledge management. This would result in a positive impact on increasing the quality of each regulatory body and also increase society's trust in the regulatory body.

2. COMPETENCE

Competence is a standardized requirement for an individual to properly perform a specific job. It encompasses a combination of knowledge, skills and behaviour needed to improve performance, in this case to improve the quality of the regulatory body. Regulators must be competent and have adequate resources to accomplish their mission, ensuring the protection of the public and the environment, and assuring the government and the public that their nuclear industry is safe. The safety and security of nuclear facilities, nuclear materials and radioactive materials require effective coordination of safety and security regulation.

The effective performance of the regulatory body requires that it has sufficient staff who are highly competent, with adequate knowledge, experience, training and motivation to perform their work and to make independent regulatory decisions. The staff must therefore be capable of carrying out their current responsibilities at an established level of competence established by the corporate management. The learning activities should be in line with, and contribute to the achievement of, the regulatory body's mission.

Building employee skills and knowledge is an investment in each employee, which will make an impact on the future of the organization. Accordingly, some activities need to be conducted in order to have highly competent staff:

- Training programme. The training programme should build competences needed for effective performance, which depends on a combination of knowledge, skills, attitudes, opportunities, efforts and motivations.
- **Maintaining competence.** Staff competences should be effectively maintained. This could be achieved through continuous technical training.
- Education. Employees should have the opportunity of a higher education for increasing their competence.
- Use of the e-network. This is a simple means by which employees can set up their own e-learning programme.

In this context, a combination of self-study, formal training courses, workshops, seminars and on the job training serves as a platform for the regulatory training programme.

In order to ensure an efficient and effective regulatory body, the four quadrant competency model could be applied (Fig. 1) [1].

 Legal basis and regulatory processes competencies 1.1. Legal basis 1.2. Regulatory process 1.3. Regulatory guidance documents 1.4. License and licensing documents 1.5. Enforcement process 	2. Technical discipline competencies2.1. Basic technology2.2. Applied technology2.3. Specialized technology
 Regulatory practices competencies Safety focused analytical techniques Inspection techniques Auditing techniques Investigation techniques 	 4. Personal and interpersonal effectiveness competencies 4.1. Analytical thinking, problem solving and decision making 4.2. Personal effectiveness 4.3. Communication 4.4. Team work 4.5. Management

FIG. 1. Four quadrant competency model.

3. KNOWLEDGE MANAGEMENT

The IAEA defines 'knowledge management' as an integrated, systematic approach to identifying, managing and sharing an organization's knowledge, and enabling persons to create new knowledge collectively in order to help achieve the objectives of that organization.

Organizations should develop a knowledge management strategy, provide an organizational structure for its implementation, allocate an adequate budget for the planned activities, and provide incentives to the staff to implement and improve the process. At the end of each activity, they should compare the performance to the expected results to allow feedback for continuous improvement of the process.

Examples of current knowledge management activities for regulatory bodies include:

- A drafting experience programme;
- A licensing experience programme;
- An inspection experience programme in the fields of safety, security and safeguards;
- An emergency preparedness experience programme;
- A technical support organization (TSO) experience programme;

- A controlling assessment programme;
- Quality assurance and quality management;
- Corrective action systems;
- Training programme effectiveness;
- -Human resource management;
- A public information programme.

Knowledge management is a catalyst to increase the benefits to the regulatory body by providing an integrated approach for:

- Increasing the value of existing knowledge;¹
- Collecting, developing and integrating tacit knowledge (Note: Tacit knowledge is the knowledge that is held in a person's mind and has typically not been captured or transferred in any formal way).

A difference between explicit knowledge and tacit knowledge is that the former is easily duplicated and distributed while the latter is not. In order to reduce duplication, it is vital to capture tacit knowledge prior to the loss of key individuals and the various knowledge they maintain for personal use. Tacit knowledge of every employee must be captured, especially of those with several years' experience who are close to retirement. This is important for the effective and efficient work of the organization and to ensure that the knowledge and experience of senior staff are not lost due to retirement.

Knowledge management urgently requires developing training material from experienced people and video recordings of work in order to capture processes and skills. Finally, the development and maintenance of a database of good practices in knowledge management is essential.

Some knowledge preservation activities could be carried out through:

- Appropriate human resource planning and continuous technical training;
- Capturing and preserving knowledge by using IT systems;
- Collaboration with universities for developing the database of knowledge management;
- Collection and dissemination of scientific information and transfer of technology.

¹ While there are a variety of definitions for 'knowledge', one of the most common is "familiarity, awareness or understanding gained through experience or study". 'Explicit knowledge' refers to knowledge in documents, drawings, calculations, designs, databases or procedures and manuals).

4. IMPLEMENTATION OF KNOWLEDGE MANAGEMENT IN BAPETEN

BAPETEN, the Nuclear Energy Regulatory Agency of Indonesia, developed a blueprint for Human Resources Development, which contains, inter alia, the following:

- The required competences for a regulatory body;
- An ideal staff composition divided among senior and junior employees;
- The number of employees based on scope of work and BAPETEN challenges;
- Training needs assessment, based on the four quadrant competency model (Fig.1).

The training programme in BAPETEN is designed in Table 1. The Basic Training Course consists of:

- Introduction;
- Radiation Protection;
- Nuclear Safety.

The Advanced Training is addressed to:

- The Inspector of Nuclear Installation and Material;
- The Inspector of Radiation Facilities and Radioactive Material;
- The Safeguards Inspector.

Another functional training course is conducted for technical employees, including regulation, licensing and emergency preparedness.

Through networking with a foreign regulatory body, it is possible to carry out an on the job training programme, which also exchanges information through the IT networking system, such as the Asian Nuclear Safety Network (ANSN). The use of the International Nuclear Information System (INIS), the World Nuclear University (WNU) and other recent international networks is beneficial. Another possibility is sending employees to universities to obtain a high level education. For three years now, BAPETEN has sent employees to study in universities in Indonesia and abroad.

The senior employees have developed training materials based on their knowledge and experience, and have an opportunity to transfer this in the training course programme. Another activity includes managing BAPETEN information, records and documents, which are essential elements of knowledge management.

TABLE 1. ELABORATION	OF	THE	FOUR	QUADRANT	COMPETENCY
MODEL					

Basic training			Advanced training										
Technical employee	Basic training	Radi prote	ation ction	Nuclear safety	Inspector training, nuclear installation and material				allation				
(TET)	orientation	trair	ning	basic 1 training course	1	Level 1	Level 2	Level 3	Level 4				
	of control	cou	rse,			Training	Training	Training	Training				
					Inspector radioactiv	training, r ve material	ad.facilitie	s and					
					2	Level 1	Level 2	Level 3	Level 4				
						Training	Training	Training	Training				
						Inspector	training, s	afeguards					
					3	Level 1	Level 2	Level 3	Level 4				
						Training	Training	Training	Training				
									Fu em	nctional tra	aining cour	se for tech	nical
				Fu em	Functional training course for non-technical employees								
	Non-TET Non- Prot TET Rad		Drot	Functional training course for technical employees				loyees					
Non-TET			Functional training course for non-technical employees										

Notes: 1. Nuclear installation and material;

2. Radiation facilities and radioactive material;

3. Safeguards.

Each year, BAPETEN produces the *Nuclear Safety Yearly Report*. This report, which is open to the public, contains the conditions of nuclear installations and radiation facilities in Indonesia. The public therefore is well familiar with the level of nuclear safety in the country. This effort is part of public transparency.

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Another public transparency effort is holding executive meetings twice a year, i.e. on nuclear reactors and industry licensees, and on medical licensees. These meetings are part of communications between BAPETEN and the licensees, and serve as a vehicle for BAPETEN to obtain input from the licensees.

The regulation for introducing the first nuclear power plant in Indonesia is completed. The regulation has been set up and based on IAEA guidance, from the assessment results of Japanese regulation, especially for siting, and also from the United States Nuclear Regulatory Commission (NRC). At present, BAPETEN is conducting the NPP licensing self-assessment programme.

5. CONCLUSIONS

Competence and knowledge management are important in order to meet emerging regulatory challenges associated with the nuclear power programme. These initiatives aim to build capacity — institutional, organizational arrangements, and education and training — for sustainable regulatory infrastructure. Therefore, for a continuous improvement of safety and security throughout the world, competence and knowledge management of each country should be set up appropriately in all aspects.

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IMPACT OF MULTINATIONAL ACTIVITIES ON THE NATIONAL RESPONSIBILITY FOR NUCLEAR SAFETY AND SECURITY

(Topical Issue 3)

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REGULATORY OVERSIGHT OF NUCLEAR ACTIVITIES IN THE MULTINATIONAL CONTEXT

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Abstract

The national responsibility for the safety of nuclear installations is the fundamental principle endorsed by the Convention on Nuclear Safety. An important role for meeting this responsibility is assigned to the regulatory authority. In addition to fulfilling their national duties, the nuclear regulators must have a common global goal: jointly providing a consistently high level of safety at all nuclear power plants in the world, which ensures an extremely low probability of large radioactive release from a nuclear accident. This goal can be achieved only through an active multinational cooperation. It is necessary to develop harmonized safety requirements that can be approved with consensus and establish harmonized regulatory practices that give confidence that these requirements are actually met. With successful cooperation, it could be possible to licence in any country a nuclear power plant that has been licensed in another, without making other modifications than those that are found necessary due to the specific local conditions. Striving for standardized plant designs would have many safety benefits, such as adequate resources available for careful design of details and for independent safety analysis. Standardization would also make it possible to learn from experience and to address potential problems promptly at all similar plants. Successful regulatory cooperation would enable the use of the same manufacturing and construction standards for the systems, structures and components, which could then be purchased from any qualified manufacturer operating in the global markets. The paper discusses the current situation and future challenges in these areas.

1. INTRODUCTION

The national responsibility for the safety of nuclear installations is the fundamental principle endorsed by the Convention on Nuclear Safety. An important role for meeting this responsibility is assigned to the regulatory authority. In addition to fulfilling their national duties, the nuclear regulators must have a common global goal: jointly providing a consistently high level of safety at all nuclear power plants in the world, which ensures an extremely low probability of large radioactive release from a nuclear accident. This goal can be achieved only through active multinational cooperation. We have to develop harmonized safety requirements that can be approved with consensus and

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establish harmonized regulatory practices that give confidence that these requirements are actually met. With successful cooperation, it could be possible to licence in any country a nuclear power plant that has been licensed in another, without making other modifications than those that are found necessary due to the specific local conditions. Striving for standardized plant designs would have many safety benefits, such as adequate resources available for careful design of details and for independent safety analysis. Standardization would also make it possible to learn from experience and to address potential problems promptly at all similar plants. Successful regulatory cooperation would enable the use of the same manufacturing and construction standards for the systems, structures and components, which could then be purchased from any qualified manufacturer operating in the global markets.

2. ROLE AND RESPONSIBILITY OF THE NATIONAL REGULATOR

The recently revised IAEA Safety Standard GS-R-1, Governmental Legal and Regulatory Framework for Nuclear Safety, clearly states that a country producing nuclear power must establish and maintain a regulatory body that has the competence and the resources necessary to fulfil its obligations. Among these obligations, a process developed and implemented by the regulatory body shall provide a high degree of confidence that:

- Safety assessments carried out for each nuclear power plant demonstrate that an adequate level of safety has been achieved and that the objectives and criteria for safety have been met;
- Site evaluation confirms the consistency of the site conditions with the design requirements and the adequacy of the local civil infrastructure to support safe operation of each plant;
- Each plant is designed and constructed to meet the relevant regulatory requirements; and
- Each plant is operated within the limits and conditions specified in the safety assessment and established in the authorization, and operations are carried out safely under a proper management system.

It is thus evident that the national regulatory body must not simply rely on the work done by a regulatory body in another country. Although a design approval by a well recognized regulatory body can be very helpful, it must at least be validated as part of the licensing process. Validation should include a safety review conducted by national experts with their combined basic knowledge on all technical areas relevant to nuclear safety, which should result in detailed knowledge on the plant features. Without such knowledge, the national regulator cannot conduct a meaningful regulatory oversight during the operation of the plant. Experience has shown that some tens of person-years are needed within the regulatory body to gain adequate understanding of the key safety features of a nuclear power plant.

Experience has also shown that a strong national regulatory body working in a professional and transparent manner is needed to achieve public confidence in the safety of a nuclear facility.

3. HARMONIZATION OF NUCLEAR SAFETY REGULATIONS

The basis for harmonized safety requirements is provided by the IAEA Safety Standards. However, it should be noted that these standards do not give accurate prescriptions on design, manufacturing, operation and regulation, etc. They give principles to be followed and indicate the topics that have to be considered, but there is ample room for their flexible interpretation. Consistent application of the IAEA Safety Standards in each practical situation therefore requires direct cooperation between the regulators.

Multinational cooperation between the regulators has significantly increased in recent years. A good example is the work carried out by the Western European Nuclear Regulator's Association (WENRA). Over several years, it developed harmonized safety reference levels for nuclear power plants operating in Europe and for the management of nuclear waste. These levels were largely based on the IAEA Safety Standards, but were clarified by extensive discussions among experts from 17 regulatory bodies. Although each regulatory body had conducted a self-assessment against the preliminary safety reference levels, it was only after discussions that the participants understood how these levels were interpreted in each participating country and how the respective requirements would be adequately implemented at the nuclear power plants.

As a more recent task, WENRA has almost completed development of common safety objectives for new power reactors. After one more round of WENRA comments, these objectives will be published on WENRA's website in early 2010 for open comments by interested parties. The new safety objectives specified by WENRA lead to more stringent safety requirements than those currently found in the IAEA Safety Standards. This evidently requires reconsidering the IAEA Safety Standard development (e.g. drafting a revised NS-R-1 on NPP design). Relevant comments arising from the WENRA work will be sent by the Member States as part of the regular process of the development of the IAEA Safety Standards.

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Another multinational cooperation between the regulators is the Multinational Design Evaluation Programme (MDEP), conducted under the auspices of the Nuclear Energy Agency (NEA). The programme is neither developing harmonized regulations nor aiming to certify the designs being evaluated; instead, in the MDEP working groups, the regulatory bodies exchange information and seek common positions on the practical application of safety requirements to specific designs. Currently, work is underway on two different new power plant designs — EPR designed by Areva and AP-1000 designed by Westinghouse. With respect to the EPR, the topics being worked on are: severe accidents, PRA, accident and transient analysis, and instrumentation and control (I&C) systems. With respect to the AP-1000, the working group addresses civil engineering, control rod drive mechanisms, and squib valves designed to initiate passive functions. Other plant designs can be included as soon as there are at least three regulatory bodies working on a concrete licensing process of a specific design. In addition to cooperation in the plant specific working groups, the regulatory bodies participating in MDEP are seeking consistent ways to use different industry standards in their licensing processes and to cooperate in the inspections of component manufacturers.

4. TRANSFER OF REGULATORY PRACTICES AND METHODS

In the transfer of regulatory practices and methods, one should consider separately the exchange between countries with large experience from nuclear power plant operation on the one hand, and the transfer from technically advanced countries to those that are only starting their nuclear programme on the other hand

MDEP is an example of transfer of detailed information between countries with extensive experience. It facilitates the safety reviews and inspections of new build reactors by transferring information at a very practical level between regulatory experts working on similar technical issues. It can save resources by exchanging results and conclusions of detailed regulatory reviews of certain systems and on independent analysis conducted by the regulatory bodies or by their technical support organizations or contractors. It can also bring new issues that deserve specific considerations to the attention of other regulatory bodies, some of which may be based on experiences gained during the construction of new plants.

The regulatory practices in inspecting construction and manufacturing have become quite different in different countries. As manufacturing becomes increasingly international, it will be valuable to know how other regulatory bodies are inspecting manufacturers. The goal is to increase the consistency of the regulatory inspections to such an extent that each regulatory body could count on the work performed by their foreign colleagues, thus avoiding duplication.

As concerns the transfer of regulatory practices and methods, from countries with experience to new entrants, the latter must be active, and develop their own strategy and plan for building their organization and gain the necessary knowledge. Support from the IAEA and bilateral or multilateral support from countries with large experience is needed, but this cannot replace the determined work of the new entrant country's regulatory body. This new regulatory body will need to obtain from experienced countries information on the competences and resources that it will need; however, it must manage its own development. While some basic ideas can be obtained during short term visits (i.e. a few days to a few weeks), good understanding of work processes in a host country and using it to develop one's own national arrangements requires at least a few months of work within the regulatory body of that country. Such work should preferably be conducted on regulations for a plant similar to the one that will be constructed in the new entrant country. It is also worthwhile for a country planning a small nuclear programme to become acquainted with regulatory practices in a host country with a programme of the same size. Another useful approach would be to have experienced foreign regulatory experts consulting in the long term in the development of a regulatory body in a new entrant country.

5. RESPONDING TO INDUSTRY CHALLENGES

A difficulty for each vendor exporting nuclear power plants is that the technical requirements by the customer and the safety requirements by the regulatory body of the customer country are often different. Since individual design solutions that are different from other countries may not be optimum for achieving a safe plant, efforts should be made to ensure that plants of the same type in different countries are as similar as possible.

What the regulators can do is to work towards harmonizing nuclear safety requirements and to cooperate in their interpretation when they are applied in practical situations, as discussed above in Section 2. As concerns the application of requirements to a certain design, good cooperation should also involve the vendor's participation. Since only the vendor is aware of different requirements presented in different countries with respect to changing its standardized design, they should bring these different views to the attention of the respective regulatory bodies. Since there should be no valid reason for requirements on safety to be different in different countries, the regulators should work together to find common views.

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Standardization of a design is certainly most beneficial for the vendor because it could avoid significant costs of redesign and would also bring some safety benefits. In addition, there is a continuous accumulation of experience from construction and operation, and general technical development. The customers and the regulators may not be willing to accept technology and designs that do not take into account the latest developments, which leads to a conflicting situation for the vendors. In order to avoid such a conflict, an agreement on the preferable approach should be reached, where the benefits of standardization are weighed against the benefits of always offering the latest technology. The optimum solution could be to opt for a limited standardized series of plants and planning new plant versions every few years

A conflict situation could also appear when the plant owners are planning modernization or replacing ageing systems. Questions could arise with respect to who the owner of the design is, the role and responsibility of the original vendor if changes are made in the design, and whether the originally similar plants in different countries should be kept similar when modernized. In this connection, reference is often made to the practice in the aircraft industry: the airplanes of a certain type are kept as similar as possible; the changes found necessary for safety reasons are planned and proposed by the original plane designer; and the changes are approved by the organization that has certified the design, usually in the home country of the designer. However, the situation in the nuclear industry is different: there are fewer similar nuclear power plants than similar airplanes, and the safety criteria seem more ambiguous than in flying, where the ultimate criteria is to keep the airplane safely in the air and to ensure its capability for safe landing. In the nuclear field, the lifespan of the plant is expected to be much longer than that of the vendor organizations or the designers, and therefore it is more important to emphasize the responsibility of the plant owner and the respective national regulator. Good networks should be established and maintained between the owners and the regulators in different countries, and close cooperation should be sought in all major modernization projects or in addressing new safety concerns.

6. MANUFACTURING STANDARDS IN GLOBALIZED INDUSTRIES

A variety of industrial standards to be used for design and manufacturing of the equipment and for the design and construction of the civil structures have been issued by the international organizations and the national organizations in countries exporting nuclear power plants. At the initiative of MDEP, standardization organizations of different countries have made inter-comparisons between their standards, which have generally shown that if used in the right manner and in the right context (e.g. together with the national industrial practice and regulatory system), the standards provide the same level of safety and are thus adequate for achieving the specified targets of manufacturing and construction.

In the 1970s in Finland, similar conclusions had already been made when the main components of the Loviisa NPP nuclear island were manufactured using GOST norms of the USSR and the safety assessment was also made against the ASME Code. Since then, the practice adopted in Finland is that the equipment manufacturers are able to use the standards best known to them, assuming of course that the scope of application is within the intended boundaries of the standard. Standard applicability is always assessed separately during the design documentation review, which is conducted by the regulatory body for the Safety Class 1 and 2 equipment. A similar approach can also be recommended to other regulators, if the components are imported from suppliers not generally using the national standards of the customer country.

7. CONCLUSIONS

In recent years, national regulators have started to actively cooperate in responding to challenges from the internationalization of the nuclear business and to the expected nuclear new build in many countries, including some new entrants to nuclear power. Much more work needs to be done to facilitate the construction of safe, standardized nuclear power plants in different countries. The possibilities for international certification seem remote, and such certification may not even serve global nuclear safety optimally. However, practical progress has been made towards establishing a consistently high level of safety in all countries operating nuclear power plants.

INTERFACE OF NUCLEAR SAFETY AND SECURITY, SAFETY AND SECURITY CULTURE

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Abstract

The development of nuclear power engineering is related to the need to satisfy the increasing demands for electric power. This is currently being intensively implemented by increasing the number of the power units, which are basically single-unit plants. While ensuring the same level of equipment reliability and operation quality at every power unit, the potential of an accident generally increases in proportion to the number of the power units. Nuclear facilities are highly sophisticated systems, operated under conditions of various hazards, the consequences of which may be disastrous for the life and health of the public and the environment if the arrangements for safety assurance prove insufficient. Therefore, safety assurance is an imperative for the activities carried out at nuclear facilities, which must be regulated by the state and implemented by the operators. The objectives of this paper are to provide a general outlook of the existing hazards and the safety systems that are required to counteract them, and to exchange ideas both on the existing challenges related to the formulation of a uniform safety concept and on the possible solutions to these problems.

1. HAZARDS AND COUNTERACTION SYSTEMS

It is clear that there is a need for a comprehensive analysis of all possible initiating events that may result in undesirable radiation consequences. It has been repeatedly pointed out that radiation and other undesirable consequences of an accident at a nuclear facility or any other atomic energy utilization facility will be equally detrimental to the population and the environment, irrespective of whether they were caused by human-induced or natural factors, human errors or deliberate acts of violators.

To prevent and counteract these hazards, the following systems are being established: the equipment quality assurance system, the personnel training system and the facility physical protection system, which are schematically illustrated in Table 1.

The above systems are not completely independent, but interact despite the specific features intrinsic to each of them; data are exchanged between the systems.

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TABLE 1.	SYSTEMS	ESTABLIS	SHED TO	PREVENT	AND	COUNTERA	CT
HAZARD	S AND OBS	ERVED OU	JTCOMES	S			

Hazards	Counteractions	Observed Outcome				
Physical protection (security)						
Theft of nuclear materialSabotage	 Control of nuclear material carry-through and carriage Access monitoring and control In-house special safety mode 	 Suppression of attempt of nuclear material theft Detention of the intruder 				
Nuclear safety						
• Accident leading to radiation consequences	• In-process monitoring of nuclear material parameters	• Activities as per emergency action programme				
System of governmental control and accounting of nuclear material						
 Illegal accumulation and theft Shift to activities not applied for Illegal transfer Lack of control and losses of nuclear materials Breach of IAEA safeguards 	 Physical inventory stocktaking Control during transfers Monitoring facilities Confirmatory measurements Accounting during transit Departmental control Departmental inspections Self-control and self-inspections 	 Investigations in case of detecting any anomaly or an incident Arrangements for elimination of found violations of codes and rules and licence validity terms and conditions. 				

When constructing such systems, the following principles are applied:

- Uniform strength of barriers against hazards;
- Lack of gaps;
- Minimum redundant backup of functions;
- Defense in depth.

The balance of requirements for the construction of safety systems is achieved by participating in the development and agreement of documents of all organizations concerned with the involvement of experts.

These safety systems are highly isolated, which is justified by objective reasons and cannot be considered a priori a negative factor. It is indisputable that society must be provided with sufficient confidence that potential hazards have been adequately assessed with respect to the actual situation, and that the measures taken are adequate to prevent their occurence or to avoid unacceptable consequences should they occur.

2. ESSENTIAL DIFFERENCES BETWEEN NUCLEAR SAFETY AND NUCLEAR SECURITY, AND THE CONSERVATIVE AND REALISTIC APPROACHES

Irrespective of the need to consider the safety of a nuclear facility as an integral combination of nuclear and radiation safety, physical security and non-proliferation regime, actual practice has demonstrated the efficiency and suitability of having at least three sufficiently isolated systems: the process safety system, the physical protection (security) system and the accounting and control (warranties) system. Each of these systems is inherently designed to counteract a certain group of hazards, which are well known and which will not be discussed here in detail.

There are clear reasons for differences between the approaches to the construction of the process safety system and the physical security system.

Understanding the causes and consequences of a nuclear accident related to equipment damage or human error is more specific and deliberate. This understanding is based on abundant statistics and the relevant databases on the equipment parameters and reliability. The scenarios of any accident are relatively predictable. All of the above enables application of a conservative approach assuming the worst-case accident scenario.

As far as physical security is concerned, the situation is different: the hazards are hypothetical and the actual statistics with reference to nuclear facilities are not available.

In the situation of intruders in nuclear facilities, the time and the associated scene of action are not known a priori; the number of intruders, their armament and tactics are unknown. In such a situation, a conservative approach cannot be soundly applied; thus, one should use a realistic approach, which is based on expert assessments and takes into account the intrinsic stability of the facility to external effects caused by natural, human induced or other factors.

The specifics related to the construction of a design based hazard for the actual facility usually contain confidential information, which limits the possibilities of discussing this issue at the expert level. The information pertaining to physical security of the facility may be treated in two ways. First, as recommended in IAEA documents, it may plant uncertainty in the potential intruder about being successful in carrying out an act of sabotage or theft. Such uncertainty may be planted particularly by disseminating information about high

level physical security and other systems that would be impossible to breach. An intruder's motivation is based on at least two components:

- Expected outcome;

- Assessment of the possibility of implementing the illegal act.

The second component may be considerably weakened by the appropriate impact of disseminated information.

However, it is clear that information on the physical protection (security) system should be restricted to a minimum, to avoid sabotage or theft of nuclear material, as much as possible. It should be noted here that we can never be sure that such information is not disclosed to the potential intruder. Moreover, we must assume that the potential intruder is informed well enough about a potential object of sabotage and theft.

In this connection, the problem of finding a balance between public information and restricted information seems relevant. This issue could be a separate topic of discussion with experts.

Another problem pertaining to the application of a realistic approach consists in establishing the efficiency criteria for the physical protection system. The Russian regulatory documents, like those of many other countries possessing nuclear facilities, establish the requirement for the operator to assess efficiency of the physical protection system. To fulfill this requirement, various methods and combinations thereof are applied, such as calculations, modeling and in situ exercises.

There is also a requirement stating that the efficiency index of the physical protection system shall be maintained at the level not lower than the permissible minimum preset value. It is interesting and important to discuss the approaches and methodology for establishing such criteria. In practice, it turned out to be a rather complicated issue.

Recently, such phenomenon as information terrorism has emerged. One should emphasize this relatively new hazard, which is not directly related to radiation impacts. Dissemination of deliberately false information in the mass media such as Internet about the accidents that allegedly occurred at large nuclear facilities may give rise to panic, and mass movement of populations from the areas where the facilities are located. Such 'information terrorism' could be successful in conditions where there is a lack of objective and timely information provided by the competent authority and directly by the operator.

If the information on the current safety status at the nuclear power plant (NPP) were reported on a regular basis and made available the same way as, for instance, weather forecasts, it would reduce the efficiency of fraudulent information.

It is possible that such requirements with reference to information and its minimum scope could be established as obligatory for the licensee.

There is no sense in trying to create a uniform universal safety system rather than the existing nuclear radiation safety systems and nuclear security systems. It should be emphasized that it is objectively important to achieve such a state and such conditions under which all hazards would be considered and an efficient counteracting mechanism would be created for each. Society should be confident that such is indeed the case. The problem of instilling such confidence is that one should have the possibility to assess completeness and comprehensiveness of analysis without leaving any gaps at the turn of nuclear safety and security. The second problem is related to the fact that nuclear safety arrangements and nuclear security arrangements should not enter into competition and conflict with each other, or at least the objective nature of such competition should be reasonably resolved. The classical example consists in the need to ensure free evacuation of personnel and access of emergency forces during an accident, on the one hand, and the requirement for ensuring control and restriction of access to the nuclear facility in terms of physical security requirements, on the other hand. But there are also other examples, and there is a practical interest in the ways they are resolved. Overcoming the conflict of interest between nuclear safety and security might be a topic for a more detailed discussion.

3. NUCLEAR SECURITY CULTURE AND SEVERAL EXAMPLES OF BEST PRACTICES

The events at Three Mile Island and Chernobyl led to the development of the safety culture concept and gave a rise to practical implementation of this concept at nuclear facilities. Similarly, the events of 11 September 2001 demonstrated the significance of the terrorist act hazard and the need for an adequate consideration of this challenge.

There are good reasons to believe that safety culture in its broad sense comprises the security culture together with safety culture process as its integral parts; moreover, the security culture and the safety culture have the right to exist purely in the context of safety culture in the broad sense. Therefore, it does not seem justified speaking about the priority of the nuclear security culture over the safety culture or vice versa.

Conceptually, a security culture has been only defined with some delay due to the delay in understanding the reality and significance of the hazard of intruder actions with regard to the nuclear facility. Security culture is intrinsically similar to the process of safety culture. The main difference probably lies in the fact that different groups of specialists speak about these two 'cultures' at the specialized workshops and forums. Since the ultimate demonstration of the safety culture of the individual consists in his or her deliberate and qualified implementation of the applicable instructions and rules of conduct, the forming of this deliberate perception shall be based on clear understanding of what might happen if these rules are violated. If there is no such understanding, and very often it is actually not reached in the field related to security, the operator will have to implement instructions for fear of being subjected to sanctions by the inspector if the latter finds any violations. There are neither clear and illustrative examples nor convincing arguments providing insight into the consequences of violating the nuclear security regime. This is partly due to the fact that such examples were not observed in practice. Nevertheless, it would be useful if possible scenarios were to be developed and demonstrated to the personnel of a nuclear facility.

Several examples of positive practices from the Russian experience should be noted:

- In order to establish a high grade security culture at the operator level, a certain hierarchy is required, according to which personal responsibility for the security should be imposed on the top manager. Energoatom, the Russian operator, uniting ten operating NPPs, holds annual meetings devoted to security (physical protection) issues. Traditionally, every NPP is represented at the meeting by its director, who makes a report and personally answers the questions of the meeting participants. The positive result of such arrangement of activities is evident.
- Regulatory documents on nuclear and radiation safety, i.e. federal rules and regulations, irrespective of their subject areas contain obligatory general provisions on physical protection, accounting and control. At the same time, there are specific detailed documents directly devoted to physical protection, accounting and control, which in their turn generally describe (in one way or another) the issues related to nuclear and radiation safety.
- The licensing procedure comprises obligatory consideration of issues pertaining to physical protection, accounting and control, although such issues are to be discussed by the special structural units and specialized experts. The licence validity terms and conditions comprise separate sections including the specific requirements for physical protection, accounting and control. Similarly, when applying for a licence for control of a nuclear facility, which is granted personally to the top managers, the latter must pass an examination on physical protection, accounting and control inasmuch as they are responsible for these issues.

— Refusal to give a licence due to insufficient knowledge of physical security (physical protection) has a highly significant effect on forming a serious attitude towards this issue. The operator's understanding that the regulator imposes strict requirements and scrupulously supervises implementation promotes the development of a safety culture.

The company shall not only establish the organizational structure capable of efficiently controlling physical security functions, but it shall also inform personnel about their responsibility for assuring physical security, the existing hazards and the objective of all employees, i.e. assurance of physical security. In this case, responsibility of each employee for the physical security shall be documented, i.e. the job descriptions of every employee should contain specific provisions pertaining to the physical security taking into account the duties of a certain employee. Understanding that an internal violator constitutes the greatest hazard should also be reflected in the requirements for personnel. Every deviation by an employee from the established rules of work shall be treated as an unauthorized action and then registered and analysed to find elements of deliberate violation. The same refers to actions not covered by the rules, including insider information that was no part of an employee's duties. Explanatory work should be also aimed at demonstrating that any violation will inevitably be recorded and duly investigated.

If systematically and competently conducted, explanatory work among the process staff and the population of adjoining territories usually gives good results. For example, during a terrorist attack simulation exercise at one of the facilities, some 'terrorists' and participating staff of special units appeared in the area where the facility was located. It seemed to them that they appeared secretly. However, as the head of the facility security service stated later, he received various phone calls from the population of the adjoining populated area stating that some strangers were seen in the area where the facility was located.

In conclusion, we are open to a wide discussion of the issues related to interaction between and synergies between various aspects of safety and safety culture, since we are aware that developing a safety culture is a long term and complicated process. At the same time, as soon as a safety culture is developed and provided with the necessary support, it will become an effective guarantee that safety will be ensured in the long term, and the funds allocated to technology and other material facilities will be used as efficiently as possible.
INDUSTRY CHALLENGES IN WORKING IN A MULTINATIONAL ENVIRONMENT*

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^{*} Although a presentation was given, no abstract or paper was made available. The author's PowerPoint presentation appears in the CD-ROM of contributed papers accompanying this book.

PRODUCTION AND INTERNATIONAL DISTRIBUTION OF RADIOACTIVE MEDICAL ISOTOPES Patient care and nuclear safety

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Abstract

For a few years deformations in the primary coolant system of the High Flux Reactor (HFR) in Petten were observed and monitored. In summer 2008, a pinhole was revealed by a bubble jet, making repair necessary. In December 2008, the worldwide demand for medical isotopes lead to the question whether or not the High Flux Reactor could be put back in service on a temporary basis, without the repair. Both NRG and the Dutch authorities were facing a dilemma between nuclear safety and patient care: on the one hand, operating the reactor with a degraded coolant system might be insufficiently safe; and on the other hand, leaving the reactor out of service for a longer period would lead to insufficient health care. The paper describes how the Dutch authorities succeeded in turning this dilemma into a balanced decision serving both interests. A decision making process was developed based on transparency and on clear definition of the responsibilities of the authorities involved. This lead to a broadly accepted decision by the government, ensuring both the nuclear safety of the HFR and the availability of medical radioisotopes.

1. INTRODUCTION

In the 1950s and 1960s, many research reactors were built to support the development of the nuclear industry by experiments with nuclear processes and testing materials to be used in nuclear reactors. With the decreasing interest in nuclear energy in the 1980s and 1990s, the usefulness of research reactors diminished. Of the total of 668 research reactors built over the years, over 25% have been decommissioned and over 35% are out of operation and in a shutdown



FIG. 1. Status of research reactor worldwide (Sept. 2009; source: IAEA).

state (Fig. 1^1). Of the remaining 250 research reactors still in operation two thirds are more than 30 years old, which means that much care has to be taken to operate them safely.

Research reactors, designed to produce large neutron fluxes, were also applied to produce medical radioisotopes for nuclear diagnostics. At the beginning this activity was of minor importance, but in the last decade, with the expansion of nuclear medicine, the production of medical radioisotopes became more and more important.

⁹⁹Mo is used as precursor for ^{99m}Tc, which is applied in about 80% of the nuclear diagnostic procedures. To date, about 95% of this ⁹⁹Mo needed worldwide is produced in five nuclear research reactors. The National Research Universal (NRU) reactor at Chalk River in Canada produces 40% of the world production. The High Flux Reactor (HFR) in Petten, Netherlands, produces 30%. The Belgian Reactor 2 (BR2) in Mol, Belgium, the Osiris reactor in Saclay, France and the Safari 1 reactor in Pelindaba, Pretoria, South Africa, produce the

¹ Considerations on Safety Issues in the Current Situation of Medical Radioisotope Production, Panel Briefing and Discussion on Reliability of Supplies of medical Isotopes Produced in Research Reactors, Issues for Regulators; 53rd IAEA General Conference, Vienna (2009).

remaining 25%. In these reactors, targets with highly enriched uranium are irradiated to produce 99 Mo.

All five reactors are over forty years old. Since 2007, both the NRU and the HFR faced problems. A water leak was detected in the NRU reactor vessel, and in the HFR deformation and degraded thickness of the wall of the primary coolant pipe were observed. The NRU is now being repaired and is due to return to service at the end of the first calendar quarter of 2010. The HFR was restarted one year ago with extra safety precautions and will cease operation before 1 March 2010 to undergo repair.

As a result, in the last couple of years, the supply of ⁹⁹Mo has been severely affected and a similar situation is expected for the coming months. The authorities in Canada, the Netherlands, and elsewhere have been facing and will face challenging situations to ensure nuclear safety next to patient care.

This paper describes how the Dutch authorities dealt with the HFR problem and the decision making process that followed. This process lead to a balanced decision about the restart of operation at the HFR ensuring the nuclear safety of the HFR as well as the availability of medical radioisotopes.

Section 2 comprises the technical aspects and nuclear safety of the HFR case and describes the characteristics of the HFR, the deformations in the primary coolant system, the repair studies of NRG and the assessment of the KFD, and the threatening shortage in production capacity and its consequences.

Section 3 describes the decision making process that followed. This process made it possible to turn a dilemma (the choice *between* nuclear safety and isotope supply) into a broadly accepted decision, which ensures the nuclear safety of the HFR *and* the availability of medical radioisotopes.

In Section 4, the follow up developments are described after the decision to allow the restart, including the repair plan of HFR, KFD's assessment of this plan and the IAEA review.

Section 5 discusses the lessons learned from the experiences with the HFR case.

2. THE HIGH FLUX REACTOR CASE

2.1. Characteristics of the HFR

The HFR (Fig. 2) is a 45 MW(th) 'tank in pool' type reactor, similar to the Safari reactor in South Africa and the (closed) Studsvik reactor in Sweden.



FIG. 2. High Flux Reactor (HFR) in Petten, Netherlands.

The Joint Research Centre of the European Commission owns the reactor. The operator as well as the licensee is the Nuclear Research and Consultancy Group (NRG) located in Petten, Netherlands. The reactor was built in the late 1950s and has been in operation since 1961. In 1984, the reactor vessel was replaced. The reactor was not fully refurbished: most of the wiring, piping and instrumentation were not renewed.

For the last four years, the reactor fuel is low enriched uranium (LEU). The targets for producing ⁹⁹Mo are made of HEU.

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2.2. The HFR problem

The first signs of deformation and decrease of thickness of the wall in a part of the primary cooling circuit were detected during a regular in-service inspection, as required by the license, in spring 2006.

These phenomena were carefully monitored during the following maintenance outages. In June 2008, after several in-service inspections, the Dutch nuclear supervisory authority (Kernfysische Dienst, KFD) and NRG recognized the existence of a safety problem with regard to the wall of the primary coolant system, which needed further actions.

In the course of the maintenance activities during the summer outage of August 2008, no significant progress in deformation and decrease of thickness was detected. A few hours before the reactor was to be restarted, camera images showed a gas bubble jet in the 'reducer' of the bottom plug liner (Fig. 3), revealing a pinhole at one of the inward deformations of the reducer.



FIG. 3. Position of the reducer in the bottom plug liner of the HFR.

At that time both NRG and KFD assessed the safety of the reactor as not sufficiently assured. Therefore NRG decided not to restart the reactor, but rather to analyse the situation and come up with a proposal for actions and repair.

In the following months, non-destructive research of the reducer wall was performed, analysis of the released gas bubbles was attempted and possible leak paths were investigated. It is important to notice that no leakage was found, and no increased radiation level was measured in the reactor hall. Further investigation lead to the assumption that corrosion is the most probable cause, and that the bubble gas consists of hydrogen.

2.3. The repair studies

Starting in September 2008, NRG studied repair methods. Two alternative solutions were considered:

- The 'sleeve' alternative: From within the cooling circuit an aluminium sleeve would cover the damaged part. After careful investigation it was concluded in November 2008 that this alternative was not feasible, neither with rubber seals (radiation too high) nor with epoxy seals (irremovable because it sticks to the wall).
- The 'concrete' alternative: After removal of the concrete, in which the bottom plug liner is embedded (Fig. 4), the deformed part will be cut out and replaced. This alternative, remaining the only feasible one, would take at least one year to prepare and three months to carry out. This would mean that the HFR had to be put out of service for about fifteen months.

2.4. Shortage of ⁹⁹Mo production and consequences for health care

Together with the NRU reactor at Chalk River, the HFR in Petten contributes about 70% to the ⁹⁹Mo production worldwide (Fig. 5). Bearing in mind the state of the Chalk River facility at that time, loss of Petten production would have meant considerable shortage (up to 70%) of the worldwide supply of the medical isotope ⁹⁹Mo for several months in 2009. This would have also meant that healthcare quality would be severely affected and that, as a consequence, waiting lists would have increased and patients could even be deprived of proper treatment.

The Dutch medical authorities estimated that the expected shortage of radioisotopes following prolonged outage of the HFR could lead to decreased healthcare quality for several thousands of patients in the Netherlands and that



FIG. 4. View of bottom plug liner before embedding in concrete.

possibly patients could die as a consequence. These consequences of prolonged outages of the HFR were deemed undesirable by the Dutch medical authorities.

2.5. Interim solution

NRG took the initiative to propose an interim solution to the KFD and the Dutch Government. On the basis of the results of the performed analysis and considering the fact that no leakage had been found, NRG suggested to restart the HFR before repairing it for a limited period of time (one year at the most) to allow for production of ⁹⁹Mo during the preparation of the repair of the HFR. During reactor operation, extra safety precautions would be taken with respect to possible leakage paths and monitoring of leakages.

NRG based its proposal on a safety case, which was also submitted for review by a team of renowned Dutch nuclear safety experts. The conclusions of NRG supported by the experts were:



FIG. 5. World supply of ⁹⁹Mo medical isotopes.

- The overall risk as well as the core damage frequency from operating the reactor in this condition are only slightly higher than in the normal condition (without degradation of the integrity of the cooling circuit);
- The degradation is caused by a slow (corrosion) process; no sudden large leakage is expected; and
- There is enough time to allow for a safe shutdown of the reactor, according to existing procedures, in case a leakage is detected.

NRG concluded that operation of the reactor in this situation for a limited period of time would pose a limited safety issue that could be dealt with.

3. GOVERNMENTAL DECISION

The Government's decision on the proposal of NRG had to consider the level of nuclear safety (in Petten) on the one hand and the quality of patient care (worldwide) on the other.

The decision making process was divided into three steps:

- (1) Assessment of the safety level of the reactor;
- (2) Assessment of the need of radioisotopes production in the HFR;
- (3) Balance of the needs.

Each step implied a 'go/no go' decision, that is: If, at the end of step 1 the conclusion of the nuclear safety authority (KFD) would have been that the reactor was not safe, no investigation of the needs for isotope production would have taken place.

If, at the end of step 2, it would have been assessed that the reactor was not needed for isotope production, then no further action would have been taken, no decision by the government would have been required and the reactor would not have been allowed to restart.

Legal aspects

The decision to allow operation (in spite of non-compliance with the license conditions) had to be made legally sound in view of a possible court trial. Therefore a special permission document would be issued, allowing temporary operation in case of non-compliance with specific requirements of the present license. Although this document would not be a license, it in fact would have similar structure comprising a list of the considerations as the basis for the decision (the justification) and of the additional conditions to be met.

3.1. Assessment of the safety level of the reactor

The absolute requirement was that operating the HFR without repair would be "safe enough" in spite of the problems (lack of integrity) of the primary coolant system.

It was KFD's responsibility to assess the impact of the degraded wall of the primary coolant system on nuclear safety. KFD concluded first of all that operating the HFR in this condition was contradictory to the basic principle of continuous improvement of nuclear safety and that the integrity of the coolant system was not maintained. Moreover, operating the reactor in degraded conditions would be contradictory to the requirements of the license (defence in depth etc.) and, therefore, not licensable. Finally, KFD concluded that the reactor could not operate as safe as a reactor under normal conditions can and should operate.

Nevertheless, the overall conclusion of KFD was that the reactor was 'safe enough' to operate for a limited period of time provided that extra safety precautions were taken. The independent 'second opinion' of Belgium's nuclear regulator Federal Agency for Nuclear Control (FANC) confirmed KFD's conclusion.

The overall conclusion of KFD was based on the consideration that:

- No violation of limit values with regard to the overall risk (individual risk, societal risk, core damage frequency) and radiation protection were expected;
- The overall risk was only slightly increased with respect to the normal situation;
- Regular operation would not lead to higher radiation levels;
- Through an adequate and thorough monitoring of the situation, enough time and means were left to allow for a safe shutdown of the reactor without releases to the environment in case a leakage was detected.

3.2. Assessment of the need of radioisotopes production in the HFR

In addition to the assessment of the nuclear safety of the reactor, two studies were performed: the first to assess the possibility of replacing the production of medical radioisotopes in a nuclear reactor by alternative techniques, and the second to investigate the possibilities of using alternatives to radioisotopes for imaging and patient treatment. Both studies concluded that no alternatives were available, this can replace the production of isotopes in a reactor.

Further, the Dutch Government checked the availability of other research reactors to continue to take over the HFR production, as happened during the outage until then. It soon became clear that in case of prolongation of the outage of several months (in order to allow for preparation and execution of repair) that would no longer have been possible because of technical and regulatory constraints.

3.3. Balancing the needs

In this situation, where on the one hand HFR could not meet the highest (and usual) safety requirements and, on the other hand, a considerable societal interest was at stake, the decision as to whether or not to allow the HFR to restart and under which conditions had to be taken at the highest political level and not by the nuclear regulatory body.

On 12 February 2009, after comprehensive discussions concerning the balance between nuclear safety and patient care, the government decided to allow temporary operation of the HFR with additional and precautionary safety measures in order to allow the production of medical isotopes. Operation was allowed for a strictly limited period of time, until 1 March 2010. Seven ministers signed the special permission document including the extra requirements, which should be met. Two weeks later an IAEA review mission confirmed KFD's assessment, supporting the governmental decision.

4. FOLLOW-UP

Following this decision and the restart of the HFR, the reactor has been operating under strict safety precautions and conditions for almost a year.

The HFR operates in cycles: after having operated for four weeks, the reactor is put out of service for a week to allow for change of the targets and inspection. According to the requirements of the special permission, each cycle must be explicitly authorized by KFD. Before each cycle, KFD assesses whether the safety conditions for operating the reactor are fulfilled and the Ministry of Health determines whether, from a medical point of view, the need for the production of medical isotopes at HFR still exists. If, and only if, both the KFD confirms the possibility of safe operation, and the Ministry of Health confirms the necessity of isotope production, KFD authorizes the following cycle at the HFR.

So far, no leakage has been detected. However, in-service inspections show that degradation is progressing unmistakably.

Meanwhile, NRG has been preparing for the repair activities at the beginning of 2010. A mock-up bottom plug liner (Fig. 6) embedded in concrete has been built for testing and practising purposes and documents concerning detailed engineering and (nuclear) safety aspects of the repair plan were finalized by NRG.



FIG. 6. Mock-up of the bottom plug liner in concrete.

By the end of 2009, KFD completed its assessment of all NRG documents. KFD's assessment, together with the NRG documents, was reviewed by an IAEA team in the middle of January 2010. The review confirmed KFD's assessment.

According to the planning, the reactor will be put out of service before 1 March 2010 and repair will take six months. Postponement of the repair in order to continue production of medical isotopes for a longer period is not considered.

5. LESSONS LEARNED

The ageing of the research reactors for production of medical radioisotopes may in the future again lead to situations where there is a need to combine nuclear safety and healthcare. Although the Petten case has not yet come to an end (the repair work has not been done yet), the process so far has provided several useful lessons for nuclear regulation in the Netherlands:

- Decision making procedure and clear role of government and authorities.

In the Petten case, a decision making process was developed for the governmental decision, whether to allow the HFR to restart or to prohibit this and to require immediate repair. A decision was made to ensure both nuclear safety and the supply of medical radioisotopes.

The different steps in the process clearly identified and respected the role and responsibilities of the different authorities involved: the responsibility (independence) of the nuclear regulator to assess and to ensure nuclear safety, the responsibility of the medical authorities to ensure medical care and the responsibility of the government as a whole to balance the needs.

— Communication.

From the very beginning it was felt that all steps in this exceptional process should be publicly communicated on governmental websites and in press releases. In the Petten case, the website of the Ministry of Housing Spatial Planning and the Environment (www.vrom.nl) was extensively used. Press releases were announced before and issued after each governmental decision. The Petten population was invited to an information meeting. The experience from the HFR-case clearly shows that providing the public with clear information enables people to understand what is happening and increases confidence in the authorities. The open communication during the process contributed to a broad acceptance of the governmental decision.

— Transparency.

No international guidelines exist to deal with exceptional situations like this. Also, no definition exists of what, in such circumstances, could be considered 'safe enough'. However, it is doubtful whether developing international guidelines and definitions to deal with exceptional situations would be of any use at all, since each exceptional situation is unique and needs a unique approach and a unique decision making.

The experience from the HFR case clearly shows that in exceptional situations it is very important to follow two basic (golden) rules:

- (1) All considerations, calculations and assessments should be completely transparent and publicly available; and
- (2) They should be subjected to reviews of international experts.

— Facts and figures for health care.

While developing the decision making process and preparing the special governmental decision on the restart of the HFR, describing the need for medical radioisotopes in objective facts and figures became vitally important.

It appeared that the existence of objective facts and figures, which are the basis for the assessment of nuclear safety, requires similar objective information for assessing other societal interests to be taken into account.

- Ageing of research reactors.

All over the world, awareness is growing that alternatives have to be developed to fill the gaps in the supply of medical isotopes, especially when the Chalk River and Petten reactors are out of service. In Vienna, in September 2009, both OECD/NEA² and IAEA³ presented many initiatives in this area.

² DUNN LEE, J.D., NEA Activities on Medical Radioisotope Supply Issues; Panel Briefing and Discussion on Reliability of Supplies of medical Isotopes Produced in Research Reactors — Issues for Regulators; 53rd IAEA General Conference, Vienna (2009).

³ RAMAMOORTHY, N., The IAEA Support to Enhancing Reliability of Mo-99 Production and Supplies; Panel Briefing and Discussion on Reliability of Supplies of medical Isotopes Produced in Research Reactors, Issues for Regulators; 53rd IAEA General Conference, Vienna (2009).

Following an initiative of Poland, discussions have started with NRG and the Dutch regulator on the possible use of the Maria Reactor in Warsaw for the production of medical radioisotopes. Moreover, more countries are willing to modify their research reactor to irradiate uranium targets for molybdenum production. Very recently, the Delft Technical University issued a press release showing their willingness to contribute to the production of medical isotopes.

6. EPILOGUE

The Petten case was discussed in the Dutch Parliament several times. In spite of the critical attitude of the Parliament towards nuclear energy, during these discussions a very broad political support was shown towards the use of nuclear research reactors for medical use. Following these discussions and considering the fragility of the supply of medical radioisotopes and the present role of Petten, the Government sent a letter to the Parliament in October 2009 manifesting its positive attitude and the willingness to favourably consider the NRG initiative to build a new reactor (Pallas) to replace the HFR.

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THE EUROPEAN UNION NUCLEAR SAFETY DIRECTIVE: A LEGAL FRAMEWORK TO STRENGTHEN NATIONAL RESPONSIBILITIES FOR NUCLEAR SAFETY

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Presented by M. Garribba

Abstract

Nuclear safety is an absolute priority for the European Union (EU), and its importance is further heightened by the context of renewed interest in nuclear energy. A major step within the EU was achieved on 25 June 2009, when the Council adopted by unanimity of the 27 Member States, on the basis of a revised Commission proposal, the Directive establishing a Community framework for the safety of nuclear installations (Council Directive 2009/71/Euratom (OJ L 172, 2.7.2009)), with overwhelming support from both the European Parliament and the European Economic and Social Committee. This unanimity reflects the common understanding of the importance of binding nuclear safety legislation in order to reinforce the legal framework and the already strong nuclear safety culture in Europe. The fundamental principles on which the Directive is built are the national responsibility for nuclear safety and the continuous improvement of safety. The Directive builds on work that Member States have already carried out. It introduces into Community law the principles enshrined in the Safety Fundamentals of the International Atomic Energy Agency (IAEA) as well as the obligations of the International Convention on Nuclear Safety. It aims at strengthening the role and the independence of the national regulatory bodies by building on their competencies and ensuring that they have the means and the tools to fulfil their mandates. The Directive establishes a flexible approach to the continuous improvement of nuclear safety requirements and allows for flexibility in case new challenges arise. It leaves a needed appreciation margin to Member States in the practical implementation.

1. NUCLEAR SAFETY — A PRIORITY ISSUE

For a long time, nuclear safety has been an absolute priority for the European Union (EU). It is not only important for the Member States that have nuclear power plants on their territory, but also for those accommodating nuclear research reactors, as well as for neighbouring Member States.

FAROSS

Nuclear safety has been continuously addressed by the IAEA. At the 2008 General Conference, the IAEA Director General, Dr. ElBaradei, underlined that nuclear safety is of the utmost importance for every country that takes the decision to embark upon a nuclear programme. In the EU, we have been pioneers in guaranteeing the highest possible levels of nuclear safety. The EU should be an example for other countries and become a world model in assuring binding nuclear safety rules.

A solid legal framework and a strong nuclear safety culture become even more important when a growing number of countries worldwide, in very different situations, show an increased interest in the use of nuclear energy. It is therefore necessary to respond to the safety challenges posed by this renewed interest.

2. CITIZENS' AND INDUSTRY EXPECTATIONS

The nuclear issue is no longer the sole preserve of governments; it attracts the full attention of the public. The public demands to be informed and to have its voice heard. EU citizens require reassurance on the safety of nuclear installations all across Europe. It is their first demand according to the Eurobarometer surveys.¹ Most EU citizens support the enactment of Community nuclear safety legislation. Legally binding common safety requirements across the EU are therefore necessary to provide appropriate guarantees to the public.

Industry is now also a firm supporter of EU nuclear safety legislation, as reflected in the Conclusions of the second European Nuclear Energy Forum (ENEF) of May 2008.² This Forum brings together key stakeholders in a debate on the future of nuclear energy in Europe.³

Developing nuclear safety to the highest possible standard is not only Europe's responsibility but the world's, not only for our benefit but also for the benefit of future generations.

¹ Attitudes towards radioactive waste, published in June 2008: http://ec.europa.eu/public oinion/archives/ebs/ebs 297 en.pdf;

Europeans and Nuclear Safety, published in February 2007:

http://ec.europa.eu/public_opinion/archives/ebs/ebs_271_en.pdf; Radioactive waste, published in September 2005:

Radioactive waste, published in September 2005.

 $http://ec.europa.eu/public_opinion/archives/ebs_ebs_227_en.pdf.$

 $^{^2}$ http://ec.europa.eu/energy/nuclear/forum/meetings/doc/2008_05_22/2008_05_22_ conclusions_enef.pdf

 $^{^3}$ It was founded in 2007 on the initiative of the European Commission and endorsed by the 27 EU Member States.

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Healthy competition and stimulation that may stem from such an ambition should not be underestimated. By going ahead, Europe indeed stimulates similar developments by others and thus contributes to a continuous wider improvement; therefore not only our competitiveness, but also our responsibility is at stake.

3. THE NUCLEAR SAFETY DIRECTIVE

3.1. Creating common safety culture through binding legislation

Nuclear safety has been for years — and remains — a policy priority for the European Commission. Although the Commission has been consistently active in promoting nuclear safety and although EU citizens favour binding safety legislation, until the adoption of this Nuclear Safety Directive, there was no EU legislation on the safety of nuclear installations. This was difficult for the public to understand since the EU legislates in many areas affecting the daily life of citizens and industry.

The European Nuclear Safety Regulators Group (ENSREG⁴), established by the Commission in 2007⁵, contributes to achieving the Community objectives in the field of nuclear safety. It significantly boosts communication, coordination and cooperation between national regulatory authorities as well as enhanced dialogue with the Commission. In July 2009, the ENSREG presented its first activity report,⁶ with detailed recommendations for improving nuclear safety, spent fuel, radioactive waste and decommissioning arrangements.

On 26 November 2008, the Commission adopted a revised legislative proposal setting up a Community framework for nuclear safety and submitted it to the European Parliament and the Council. This revised proposal updated and replaced the 2003/2004 Commission proposal for a Directive setting out basic obligations and general principles on the safety of nuclear installations.

After months of discussions, the Council of the European Union adopted the Directive on 25 June 2009. The European Parliament⁷ and the

⁴ http://ec.europa.eu/energy/nuclear/ensreg/ensreg_en.htm

⁵ 2007/530/Euratom of 17 July 2007, OJ L 195, 27.7.2007

⁶ http://ec.europa.eu/energy/nuclear/ensreg/doc/2009_ensreg_report.pdf

⁷ European Parliament legislative resolution of 22 April 2009 on the proposal for a Council directive (Euratom) setting up a Community framework for nuclear safety (COM(2008)790final).

European Economic and Social Committee⁸ also overwhelmingly endorsed this approach.

With the adoption of this Directive, the EU is the first and only international entity to impose common nuclear safety obligations on its Members. The Directive responds to the concerns of European citizens expressed through recent Eurobarometer surveys, finally allowing a safety culture to be put in place, informing and educating the general public as well as clearly defining the responsibility of all stakeholders and ensuring transparency.

The Nuclear Safety Directive responds to continued citizens' concerns by bringing legal certainty in the EU through binding rules. Furthermore, binding legislation provides the nuclear industry in the EU with a stable and improving legal framework, ensuring equal treatment for all nuclear operators.

This shared nuclear safety culture also helps the EU to reinforce the coherence of legislative actions and policies in the international arena by speaking with one voice in the negotiations of international agreements in the nuclear field with third parties. The EU is now the first major regional nuclear actor to provide a binding legal framework on nuclear safety. Europe could thus become a real model for the rest of the world in a context of growing interest in nuclear energy.

The Directive builds on work that Member States have already carried out and introduces into Community law the IAEA Safety Fundamentals and the obligations of the International Convention on Nuclear Safety, which were both elaborated and agreed by the Member States. The real step forward is that we transform a voluntary IAEA approach related to a peer review system into a legally binding Community system, thus establishing legal certainty as well as additional rights for our citizens.

Moreover, given that a Community legal nuclear safety framework cannot be disconnected from the existing safety approaches, the Directive explicitly acknowledges the technical progress achieved by the nuclear safety regulators within the Western European Nuclear Regulators' Association (WENRA) in defining safety reference levels for power reactors and recommends Member States to rely on this process.

Finally, whereby nuclear safety should become a global concern, the EU will assist any nation willing to undertake a similar action with respect to its own citizens.

⁸ Opinion of 10 June 2009 of the European Economic and Social Committee on the proposal for a Council directive (Euratom) setting up a Community framework for nuclear safety (COM(2008)790final).

3.2. Strengthening the role of national bodies

The Directive requires Member States in particular to set up and continuously improve national nuclear safety frameworks, taking into account operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and the results of safety research.

The Directive applies to enrichment plants, nuclear fuel fabrication plants, nuclear power plants, research reactors, spent fuel storage facilities and certain storage facilities for nuclear wastes. It enhances the role and independence of national regulatory authorities, which should be functionally separated from any body or organization concerned with the promotion or utilization of nuclear energy, and invested with adequate authority in terms of human and financial resources necessary to fulfil their obligations. It also confirms that prime responsibility for nuclear safety lies with licence holders. Member States are to encourage a high level of transparency of regulatory actions, to guarantee regular independent safety assessments and to promote the availability of nuclear safety expertise. This is in full compliance with the principle of subsidiarity.

The Directive thus establishes a flexible approach to the continuous improvement of nuclear safety requirements and allows for flexibility in case new challenges arise. It leaves a needed appreciation margin to the Member States in the practical implementation.

3.3. A transparent and consultative approach

The issue of transparency has been addressed at two levels:

- By including non-nuclear EU Member States in the review and development of nuclear safety via ENSREG;
- By making Member States responsible for ensuring that EU citizens are kept informed on the status of development of nuclear safety and the regulatory process.

The Directive follows extensive consultations with stakeholders, in particular through the national regulators, brought together in the ENSREG, as well as through the ENEF, which involves a broader range of stakeholders.

Finally, in preparing this Directive, the Commission has closely worked together with the IAEA and reached agreement on important technicalities. This ensures a sound and coherent approach and, at the same time, establishes ground for a continued enhanced cooperation.

INTERNATIONAL SAFETY AND SECURITY COOPERATION

(Topical Issue 4)

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APPLICATION OF IAEA SAFETY STANDARDS AND EXPERIENCE FEEDBACK IN CHINA

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Abstract

The paper briefly presents practices in enhancing the effectiveness of the regulatory system in China. It discusses, inter alia, regulatory infrastructure, progress in nuclear energy development and nuclear technology application, the legislation system and the use of the IAEA Safety Standards for safety review. Feedback from the Chinese experience shows that the use of IAEA safety standards can help developing countries achieve and maintain a high safety level. It is recommended that the IAEA publish a complete set of safety guides within a shorter time, and keep safety standards stable for as long as possible. The IAEA should encourage general acceptance of international safety standards in Member States. Vendor countries should have a greater role in adopting these safety standards.

1. THE REGULATORY BODY IN CHINA

The National Nuclear Safety Administration (NNSA)/Ministry of Environmental Protection (MEP) is the independent regulatory body for nuclear safety and radiation safety in China. It is responsible for regulatory control of nuclear installations, radiation sources, uranium mining and milling, radioactive substance transportation, radioactive waste management and naturally occurring radioactive material (NORM).

The organizational structure of the NNSA/MEP is shown in Fig. 1.

2. DEVELOPMENT OF NUCLEAR ENERGY AND NUCLEAR TECHNOLOGY IN CHINA

2.1. Nuclear power plants

According to the national nuclear developing programme, in 2020, nuclear electricity supply capacity will reach the target of 40 GWe in operation and 18 GWe in construction, which will be 4% of the total installed capacity of all the



FIG. 1. Organizational chart of the regulatory body.

power plants at that time. The real nuclear capacity may even exceed the target of the NPP programme in 2020, possibly reaching 5%.

As at the end of 2009, mainland China had 11 nuclear power units in operation and 22 nuclear power units under construction: 14 Chinese designed standard 1000 MW(e) units, two Chinese designed 600 MW(e) units, four imported AP1000 units and two EPR units.

NNSA/MEP recently completed the integrated evaluation on 70 new sites in China. The evaluation covers the areas of nuclear safety, environmental protection, regional planning and environmental function zoning (24 indicators are evaluated). The results of the integrated evaluation of the sites are shown in Fig. 2: Category I is the best and Category IV has some limitations that need to be compensated with engineering measures.

2.2. Other nuclear installations

NNSA/MEP continues to establish and improve the regulation system for research reactors. Among the 17 in-service research reactors, nine are in operation and eight are in safe shutdown conditions. In addition, the China Experimental Fast Reactor and a medical neutron irradiator are under construction.



FIG. 2. Results of the integrated sites evaluation.

The operations of in-service installations for manufacturing, fabrication, storage and reprocessing of nuclear fuels are safe and the quality of the installations under construction is under effective control. The facilities maintain good safety records, and there is no unacceptable risk of nuclear and radiation harm to plant personnel, the public and the environment.

2.3. Radioactive waste management

Two regional disposal sites for medium to low level wastes are in pre-operation in northwest and south China. Other sites are in the planning stage. In addition, an in-depth geological disposal study on high level wastes is at an early stage. As concerns radioactive waste from nuclear technology applications, there are a total of 31 radioactive waste temporary storage sites in all provinces the country.

2.4. Radiation sources

As at the end of 2008, there were a total of 13 342 persons using a total of 106 700 radiation sources. Further, there were a total of 30 381 persons using a total of 200 000 irradiation devices.



LIU

FIG. 3. The hierarchical structure of laws, regulations and guides on nuclear safety.

2.5. National Radiation Environment Monitoring Network (first batch of monitoring points)

This Network, financed by the main pollutant reduction fund of the Central Government, has been actively used. It includes 30 automatic monitoring stations; 23 monitoring stations for nuclear installations; 70 waters monitoring points on major rivers, drinking water, underground water and seas, etc.; 318 land γ dose-rate monitoring points; 175 soil and biological sampling points; and radiation monitoring points at borders.

3. LEGISLATIVE SYSTEM

The hierarchical structure of laws, regulations and guides on nuclear safety in China is shown in Fig. 3.

3.1. The Law on Prevention and Control of Radioactive Pollution

The current state law applicable to nuclear safety field is the Law on Prevention and Control of Radioactive Pollution, which is approved by Chinese Congress and applicable to, inter alia, all regulatory activities on nuclear installations, radiation sources, uranium (thorium) mining and natural radioactivity associated mining, radioactive waste management. It provides for the general requirements on nuclear safety and radiation safety.

3.2. Regulations on safety and security

The Chinese Government has approved six regulations: the Regulation on Surveillance and Control of Civilian Nuclear Installations (1986), Regulations on Nuclear Materials Control (1989), Regulations on Nuclear Accident Emergency Responses in NPPs (1993), Regulations on Safety and Protection of Radioisotope and Irradiation Devices (2005), Regulations on Surveillance and Control of Civilian Nuclear Safety Equipment (2007) and Regulations on Surveillance and Control of Radioactive Substance Transportation (2009); the regulation on radioactive waste management is in draft form.

3.3. Department rules issued by Government agencies

Department rules on safety and security related to nuclear and radiation are issued by NNSA/MEP based on the above laws and regulations, These rules provide a more detailed explanation of the law and regulations. Licensees must follow all requirements in the Department rules. NNSA/MEP has published 22 Department rules out of a total of 36 Department rules in 11 areas (see Table 1).

Series	Areas of department rules	No. of published department rules/total
No.0	General	9/12
No.1	NPP	4/4
No.2	Research reactor	2/2
No.3	Nuclear fuel facility	1/1
No.4	Radioactive waste management	1/5
No.5	Nuclear materials	1/1
No.6	Nuclear equipment	4/5
No.7	Radioactive substance transportation	0/2
No.8	Radioisotope and irradiation devices	1/2
No.9	Uranium and thorium mining	0/1
No.10	Environmental radiation monitoring	0/1
	Published/total	22/36

TABLE 1. PUBLISHED DEPARTMENT RULES

3.4. Safety guides issued by Government agencies

Safety Guides, issued by NNSA/MEP, are explanatory or supplementary to the safety requirements in Law, Regulations and Department Ruless. In addition, they are recommendatory to the licensees.

To date, 76 out of a total of 138 Safety Guides have been issued by NNSA/MEP.

3.5. Technical safety and security documents

Safety and security technical documents for (TDs) are issued by NNSA/MEP. They are reference documents similar to the IAEA TECDOC series.

4. USE OF SAFETY STANDARDS FOR REVIEW OF NPPs

Codes and Safety Guides on the design safety of NPPs in China were established in the 1990s by referring to the IAEA Safety Standards: Design for Safety of Nuclear Power Plants (Safety Series No. 50-C-D) and the Code on the Safety of Nuclear Power Plants: Design (Safety Series No. 50-SG-D).

In 2004, NNSA issued the Code on the Safety of NPPs: Design (HAF 102), which was developed according to the IAEA Safety Standards Series, Safety of Nuclear Power Plants: Design (NS-R-1, 2000). Currently, there are 15 valid Safety Guides for design. The only differences between HAF102 (2004) and the IAEA NS-R-1 are:

- NS-R-1 (2000): "An essential objective is that the need for external intervention measures may be limited or even eliminated in technical terms."
- HAF 102 (2004): "Maintaining the requirements of off-site emergency preparedness even for advanced design of NPP and requiring that the emergency control centre in NPPs must have the capability to transfer important safety parameters to the regulator on time."
- Safety guides under HAF 102 (2004) are in the process of being revised through reference to IAEA NS-G-1. The current Safety Guides will be replaced by a new version, upon completion of a full set of new Safety Guides.

The NPPs designed by China must satisfy the requirements of Chinese nuclear safety regulations and codes. The NPPs imported from foreign countries must satisfy the requirements of nuclear safety regulations of China and vendor countries. Finally, the adopted technical standards for them should be reviewed and approved by the NNSA before import.

In China, AP1000, EPR or new designed NPPs must fully and strictly satisfy all the requirements of HAF 102 (2004). In addition, the Chinese standard NPP and existing NPPs must satisfy the principles of HAF 102 (2004) and improve design safety as much as possible, especially considering weaknesses identified during safety review and inspection in the past.

5. USE OF SAFETY STANDARDS FOR RADIOACTIVE SOURCES

China has made a political commitment to the implementation of the IAEA Code of Conduct for the safety and security of radioactive sources (2003) and the Import/Export Guidance (2005).

By adopting the IAEA standards, China issued the following: Regulation on Safety and Protection of Radioisotope and Irradiation Devices (2005), Department Rules on Licensing Radioisotope and Irradiation Devices (2006), Categorization of Radioactive Sources (2006) and Categorization of Irradiation Devices (2006).

China has clarified safety responsibility for licensees, established the inventory of sources, stored 33 000 disused sources in storage sites, established identification for each source in use, and established an Internet information system of sources. Safety measures have been taken for identified safety issues and findings. Seven training centres for radiation safety have been built and more than 3000 persons trained.

6. EXPERIENCE FEEDBACK

The IAEA sets high safety standards worldwide. Implementing these safety standards can help developing countries achieve and maintain high safety levels. These standards are accepted by the public and easily shared with the international nuclear community.

By using IAEA safety standards, NNSA has established Chinese nuclear safety regulations since its foundation in 1984. Law and regulations related to safety and security are adapted to China's context, but refer to the IAEA fundamental safety principles. Furthermore, most Chinese technical department rules refer to the IAEA safety requirements. However, administrative department rules are adapted to China's context. Most Chinese safety guides refer to the IAEA safety guides.

We recommend that the IAEA publish a full set of safety guides in a shorter timeframe, and ensure that safety standards remain stable for as long as possible, since the legislative processes of Member States need time for adopting them. The IAEA should also promote the general acceptance of international safety standards in Member States. Vendor countries should play a great role in adopting the IAEA safety standards.

GLOBAL, REGIONAL OR THEMATIC NETWORKS FOR REGULATORS

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Abstract

The Moscow Conference in 2006 highlighted the importance of information networks and databases for nuclear safety and security regulatory activities and recommended broader use and sharing of nuclear safety information and knowledge. Today, the World Wide Web contains enormous amounts of valuable safety and security information. In this paper, that part of the worldwide web that contains nuclear safety and security information is called the 'Global Nuclear Safety and Security Network' (GNSSN). While this network supports many nuclear regulatory activities quite well, the effectiveness can further be enhanced. To this end, the IAEA and its Member States, supported by the G8 Nuclear Safety and Security Group, are now launching a web-based Portal, called RegNet (Portal) that will offer regulators a more effective direct access to authorized nuclear safety and security information. The RegNet-Portal builds on existing regional networks such as the Asian Nuclear Safety Network (ANSN), on thematic networks such as the Convention on Nuclear Safety (CNS) web site or the Incident Reporting System (IRS) as well as on information available at sources of international organizations/bodies and their member states. The structure for RegNet has been deduced from today's system of resources and instruments that are used in international regulatory cooperation to achieve high levels of safety and security worldwide, i.e. from the "Global Nuclear Safety and Security Regime" (GNSSR). The concept of the RegNet-Portal is to establish and maintain common interfaces for direct access to respective information of Member States or International Organizations through (hyper) links to their web sites. The responsibility for the content of these web sites remains completely with the owners. The RegNet-Portal will now become operational. It will include systematic access to existing regional and thematic networks. Special attention will be given to information sharing on IRRS missions, generic safety issues and country nuclear regulatory profiles. Participation in RegNet will contribute to both enhanced sharing of safety and security information as well as to harmonizing safety approaches.

1. INTRODUCTION

The first IAEA International Conference in this area, Effective Nuclear Regulatory Systems: Facing Safety and Security Challenges, was held in Moscow in February–March 2006. The objective of the conference was to give senior regulators the opportunity to discuss ways of improving the effectiveness of nuclear safety, radiation safety and security regulation as a whole for the benefit of the global community.

The summary and conclusions of the Conference were written by the Conference's President, Lawrence Williams. One of these conclusions is related to global, regional and thematic networking of regulators:

"The Conference recognized the establishment and broader use of information networks and databases to enable regulatory bodies to have prompt access to the most current developments in areas of interest".

"The Conference noted the increasing development of information and knowledge management networks to enhance the regulation of nuclear safety and security." [1]

That part of the World Wide Web which contains nuclear safety and security information is now called the 'Global Nuclear Safety and Security Network' (GNSSN). This GNSSN contains enormous amounts of valuable safety and security information, often distributed over many sites that are organized in different ways. Identification and use of this information, especially with regard to assuring quality and validity requires major efforts. On the other hand, establishing and maintaining all individual web sites is also a major burden. This leads to the question of what can be done further to support nuclear regulators by enabling more effective and efficient use of the GNSSN in performing regulatory functions.

The approach presented and launched today is the Portal of a Multinational Network among Regulators (RegNet-Portal), which is hosted by the IAEA. The structure and content of the portal will be further developed at the IAEA together with Member States and other international organizations. The added value of the Portal is the common framework for an easier and effective access and use of safety and security related information and knowledge, enhanced transparency and promotion of harmonization

The RegNet-Portal must not duplicate information. As much use as possible should be made of already existing open and secured web sites of Member States and organizations involved in nuclear safety and security regulation.

Lead roles in developing the RegNet-Portal for enhanced use of the GNSSN were played in particular by the G8 Nuclear Safety and Security Group (NSSG) and the IAEA.

The Heiligendamm G8 Summit Report (June 2007) stated that the NSSG would "support the further enhancement of the evolving web-based systems and networks for information exchange and co-operation in nuclear safety matters, as implementation of nuclear conventions, co-operation on safety standards, and harmonization of safety approaches, exchange of operational experience and resolution of generic nuclear safety issues." [2]

The IAEA hosted a consultants meeting in August 2007 in Vienna, to review the current status and trends of nuclear safety networks, and to identify opportunities for better using the synergies among the networks to continuously enhance nuclear safety. For this meeting, a list of safety networks and information resources was compiled by the IAEA and amended by Member States [3].

Specific issues of global regulatory networking were addressed in technical meetings such as the Technical Meeting on Global Cooperation on Generic Safety Issues for Nuclear Power Plants and Measures for their Resolution, which was held in Bonn in December 2007. The meeting reached a common understanding of a GNSSN-Portal for:

- Cooperation and sharing of information on current safety issues;
- Addressing significant findings from operational experience feedback, safety investigations, and research;
- Maintaining and improving knowledge on safety and security matters.

It is concluded that the existing GNSSN essentially has the main elements in place today. But its efficiency and effectiveness for international cooperation on assuring and improving safety and security could be enhanced by pursuing some concerted efforts, related to its contents and to their processing and integration, and to the adaptation of such systems to the changing requirements of the international user community.

Progress has been achieved: The RegNet-Portal, as a key part of the GNSSN for nuclear safety and security regulators, has been established with the cooperation of Member States and the IAEA staff and with continuous support by other international organizations and multilateral cooperation such as by the G8 NSSG. The RegNet-Portal is hosted by the IAEA and will be operational in a test mode early next year.

The RegNet-Portal:
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- Is based on the concept of the Global Nuclear Safety and Security Regime;
- Uses guidance and recommendations of INSAG-21: Strengthening the Global Nuclear Safety and Security Regime" [4];
- Is established by advanced IT collaboration and content management software for global sharing of information and knowledge from existing nuclear safety and security networks;
- Is flexible to be further extended and adapted to future needs.

The GNSSN and RegNet-Portals offer a new dimension for international regulatory cooperation and for strengthening the effectiveness of the Global Nuclear Safety and Security Regime.

2. OBJECTIVE OF THE PAPER

The RegNet-Portal operation will be launched by the IAEA early next year. In this context this paper has the following objectives:

- To present the concept of the RegNet-Portal;
- To refer to existing regional and thematic networks;
- To demonstrate the advantages and potential of RegNet;
- To explain the multilevel concept for the RegNet-Portal;
- To invite national nuclear safety regulators worldwide to actively participate in RegNet and to support its further development.

3. CONCEPT AND FRAMEWORK FOR NETWORKING IN A GLOBAL CONTEXT

3.1. Global Nuclear Safety and Security Regime (GNSSR)

The Global Nuclear Safety and Security Regime (GNSSR) (Fig. 1) is understood here as the institutional, legal and technical framework for ensuring safety and security of nuclear facilities and activities throughout the world. The GNSSR — as other international regimes — is based on a wide range of national and international actors to achieve shared goals while preserving and complimenting the sovereignty, authority and ultimate responsibilities of States. Within each State, the primary responsibility for nuclear and radiation safety and security rests with the operator, the industry or the users of nuclear and radiation technologies. The relevant actors also include non-governmental and intergovernmental organizations, experts' communities and civil society. The shared

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FIG. 1. The Global Nuclear Safety and Security Regime (GNSSR).

objective of the GNSSR is to lead to a world where the operation of nuclear facilities and the performance of nuclear and radiation activities is safe and secure.

The GNSSR is based on four principal elements:

- (1) The need to ensure strong national infrastructures and a global experts' community;
- (2) The widespread subscription to legally binding and non-binding international instruments such as the conventions and the codes of conduct;
- (3) A comprehensive suite of nuclear safety standards and security guidance that embodies good practices as a reference point to the high level of safety and security required for all nuclear activities;
- (4) A suite of international safety reviews and services, based on the safety standards as well as international security missions based on security guidance.

At the foundation of this global regime are strong national infrastructures. The key factors for the effectiveness of the global regime that have been in place since the mid-1990s are the international legal instruments, such as *Conventions* and *Codes of Conduct*. These elements work together in synergy with international safety standards, security guidance, peer reviews and appraisal as well as knowledge networks to support and further strengthen existing national and regional infrastructures.

Any country that wants to start a nuclear power plant programme needs to commit itself to become an active participant in the GNSSR.

The effectiveness of the GNSSR depends on its overall framework of principles, norms, rules and decision making procedures as well as related institutional, legal and technical resources. The GNSSR becomes effective through its actors and their interactions. Most of the participating actors are operating sites in the World Wide Web. In addition, more and more GNSSR activities and interactions are making use of the Internet.

Regimes must be learning systems to be effective. This Conference is a very important contributor to further enhance the GNSSR. Many elements of the GNSSR were developed and implemented in the past as strategic responses to emerging safety and security challenges, two examples of which are the Nuclear Conventions and the systematic updating and extension of the IAEA safety standards that were initiated in the late 1980s as a response to the Chernobyl accident.

Both the learning process for enhancing the GNSSR as well as the interactions and processes under the global regime are supported by the World Wide Web. Important examples are the web based systems for operational feedback such as INES, IRS or FINAS or the web support for the verification process under the nuclear conventions.

3.2. Global Nuclear Safety and Security Network (GNSSN)

That part of the World Wide Web that contains nuclear and radiation information — Global Nuclear Safety and Security Network (GNSSN) — contains tremendous amounts of more or less important information. Sometimes the information is qualified, sometimes just wrong. The GNSSN is in principle very valuable to support regulators. But on the other hand, there is too much information and it is too widespread to be handled effectively.

To make better use of the possibilities of the GNSSN, some regional or thematic networks have been developed in the past and are now operated by specific communities.

Examples of regional networks are the Asian Nuclear Safety Network (ANSN) (Fig. 2), the Latin American Forum of Nuclear and Radiological Regulatory Organizations (FORO) or, more recently, the Forum of Nuclear Regulatory Bodies in Africa (FNRBA).

Examples of thematic networks are the web sites of the nuclear conventions such as the CNS web site (Fig. 3), the World Nuclear Association (WNA), NucNet, the International Decommissioning Network (IDN) or the web based systems for sharing operational experience, such as INES, IRS, and FINAS.



FIG. 2. Example of regional networks — Asian Nuclear Safety Network.

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FIG. 3. Example of a secured thematic network — Convention on Nuclear Safety.

This paper presents a portal approach for integrating such activities and for further enhancing the practical use of the GNSSN for regulatory activities.

3.3. Portal approach to the Global Nuclear Safety and Security Network

The concept of the GNSSR has been used to define the overall framework and the key elements for the IT based Portal to the GNSSN. The GNSSN Portal will be hosted at the IAEA using the GNSSR framework and its main constituents. One important part, which has now been developed by the IAEA and some Member States, is the Portal for the Multinational Network among Nuclear Safety and Security Regulators — the **RegNet-Portal**.

The structure of the GNSSN-Portal and its content are based on an approach developed in INSAG-21, Strengthening the Global Nuclear Safety Regime. INSAG has developed a schematic picture of the Global Nuclear Safety Regime that can be expanded to also cover security aspects. This schematic picture has been amended by a few elements to support the definition and establishment of the GNSSN Portal.

Figure 4 shows three types of key factors contributing to the effectiveness of the GNSSR: first, national and international actors or participants (stake-holders and their networks), second, information resources and instruments and third, interactions.

The following three types of factors determine the structure and operation of the GNSSN Portal:

- National and international actors or participants operate information systems, in particular public or protected/secured web sites, as well as regional or multinational networks. Such systems and sites are designed and operated to comply with respective responsibilities, requirements and activities of the owner;
- Information resources and instruments that have been agreed legally or voluntarily — among respective actors or participants. Such resources or instruments are regularly reviewed and further developed or amended as appropriate. Related documentation and processes today are more and more web based. Such web sites are operated by the dedicated 'operator' or 'owner' of the resource or instrument;
- Interactions among actors and participants are performed in a more or less formalized manner, based on mutual agreements or individual actions.



FIG. 4. Key elements for the entry page of the Portal for the Global Nuclear Safety and Security Network.

3.4. Multilevel Concept for the GNSSN Portal

The overall GNSSR and the main activities at the IAEA are agreed by the policy organs and laid down in the IAEA programme and budget. This is a commonly agreed framework. But the different information resources and networks of other actors differ considerably in structure and content. Sites of national regulatory bodies for example have to be designed and operated for specific needs in the given national context.

It would be neither practicable nor useful to try to develop a common structure for the web sites of actors or participants of the global regime or to establish one global system that contains the content of all *different* actors and participants. It would also not be useful to duplicate the content in an additional global system.

The approach used instead is a Portal for sharing information and knowledge on the established common framework with contributor sites and 'interface' pages that enable direct and structured access to the specific information of member countries or of international actors. The basic idea is to establish the portal on a server hosted by the IAEA, while the nuclear safety and security content is provided and maintained under the responsibility of the respective actor. Therefore, the GNSSN Portal is organized by a step by step approach to the relevant content of the GNSSN as part of the World Wide Web. These steps are organized by the following five levels:

- 0: Home page of the GNSSN Portal including reference to the global regime GNSSR;
- 1: Home pages of a multinational network among specific groups of stakeholders, such as the Homepage of the Regulatory Network — RegNet-Portal;
- 2: Contributor sites of actors;
- 3: Interface pages of actors with uniform approaches for navigation and retrieval of specific classes/groups of content for each actor;
- 4: Direct links to the actor's content in the World Wide Web.

The content in the five levels of the GNSSN Portal shall be as lean as possible and shall be focused on main activities that are important for the effectiveness of the global regime.

One view of the top level is the GNSSN Portal home page based on the concept of the GNSSR as established and further developed with the Member States at the IAEA. This page provides direct access to official GNSSR information and resources available at the IAEA (see Fig. 1).

Another view of this GNSSN top level is amended by a more detailed picture based on INSAG-21 describing the elements of the global regime and their interactions in more detail (Fig. 4). This picture can be used for direct access to web based resources of national and international stakeholders and their networks.

The next GNSSN Portal level (Level 1) consists of the home pages for the specific portals for actors of the GNSSR. This paper will focus on the Portal for the Multinational Network among nuclear safety and security regulators, the RegNet-Portal.

3.5. Multilevel concept for the RegNet-Portal

The RegNet-Portal is the portal for international regulatory cooperation under the GNSSR.



FIG. 5. RegNet in relation to GNSSN and to corresponding contributors sites.

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The	RegNet-P	ortal is	organized	in	four	level	s:

1: RegNet-Portal home page	Home page of a multinational network among nuclear regulatory bodies — Overview and direct access to current international activities and interactions important for regulatory effectiveness
2: Contributor sites of actors under the actor's sites — common structure	Overview following an agreed common structure to the contributions of the participating actors — countries, international organizations, bodies — with direct access through links
3: Interface pages — with uniform approaches for navigation and retrieval of specific classes/groups of content for each actor	Executive Summary for specific information from the actor and its activities
4: Links to content in the World Wide Web	Up to date links to safety and security information of the actor.

All four levels are hosted on a server at the IAEA. Level 1 is maintained by the IAEA in close cooperation with the Member States. Levels 2 to 4 are established and maintained under the responsibility of each actor. The content in the four RegNet-Portal levels shall be as lean as possible and shall be limited to what is necessary to find access to what the contributors have posted on their web sites.



FIG. 6. Multilevel concept for the RegNet-Portal.

The following guiding principles to strengthen regulatory effectiveness in the global context have already been formulated in August 2007:

- Ultimate responsibility for the content and quality remains with the respective providers of the information and network operators (process owners);
- Process owners recognize that they are part of a broader community of networks;
- Continuous efforts are made by process owners to make the network visible and conducive to international cooperation;
- There is a striving for common solutions, using best practices and advanced technologies, and for optimal use of resources;
- Agreed upon commitments are adhered to;
- The sustainability and continuous improvement are ensured.

It was agreed to focus the development of the RegNet-Portal first on:

- IRRS mission and other reviews and appraisals organized by the IAEA;
- Operational feedback systems;
- Generic safety issues (GSI).

3.6. Information sharing and collaboration for IRRS missions

The example of the IRRS is used to describe the layout and function of the level 2 and 3 elements of the RegNet-Portal in more detail.

General information on IRRS missions is available on the IAEA home page. This web site is static and gives no current information on ongoing IRRS activities. Some additional information on IRRS missions may be found using internet search tools on web sites of some regulatory bodies.

There is common understanding that there should be an easier and more comprehensive overview and access to IRRS activities, reports, methods and lessons learned.

To achieve this, RegNet contains an IAEA contributor site with all generic information on organizing and performing IRRS missions including background, history and schedules. Country specific information will be made available through the RegNet-Portal. Countries that want to participate can post an IRRS interface page within the RegNet country area for their country. The interface page should be a short, one web page overview of the country's IRRS activities with links to web sites owned by that country where further information is available.

It is up to each participating country to decide, which information shall be made available within the RegNet-Portal and within its own systems. Information can be made publicly available or it can also be exchanged on protected sites.

4. SUMMARY AND CONCLUSIONS

4.1. Significant development of regulatory and thematic networks and of the comprehensive RegNet-Portal

During the past three years, the conclusions of the Moscow conference in 2006 regarding the "increasing development of information and knowledge management networks to enhance the regulation of nuclear safety and security" have successfully been addressed. The development of regional networks and thematic networks has made significant progress.

A comprehensive approach for web based international cooperation of nuclear safety and security regulators has been designed and developed. The **RegNet-Portal** will become operational early next year.

The portal is hosted by the IAEA and uses state of the art information technology for content management and collaboration. The portal can be used



FIG. 7. Screen shot of the IRRS site.

interactively by the participating regulators, international organizations and other bodies.

The further development should be based on a common statute and a steering committee. Experience from the regional networks will be used.

Resources have already been made available by national and international actors to enable further progress.

4.2. Priority areas for future applications and developments

The RegNet-Portal has significant potentials for improving organizational and administrative activities in international regulatory cooperation such as:

- Shared workspaces for collaboration;

Enhanced exchange and cooperation between the growing number of regional networks;

- Cooperation platform for countries embarking on nuclear power;
- Enhanced access to and use of:
 - meeting schedules and related documentation,
 - standards and reports;
- Global Nuclear Safety and Security Directory Global Nuclear Safety and Security 'Yellow Pages'.

Priority areas for the further thematic developments are:

- Entry pages of country contributor sites with Country Nuclear Regulatory Profiles following the revised GS-R-1 and other information important for nuclear regulatory cooperation;
- IRRS Platform and platforms for other reviews and appraisals such as OSART, EPREV, IPPAS;
- Web based platforms for operational experience feedback systems.

The added value shall be achieved by enhanced information and knowledge sharing between the different actors by using common contributors' sites and interface pages with agreed structures.

The portal approach and technology chosen can easily be adapted to future needs.

4.3. Need for commitment and leadership of the top management

The IAEA standard GS-R-3 requires that information and knowledge are managed as a resource. The promotion of global sharing safety and security information and knowledge is most important for the effectiveness of nuclear regulatory systems.

RegNet has been designed and has to be further developed for this objective. Further progress requires commitment and continuous support from the top management level and senior regulators.

All regulatory bodies are invited to join in the development of the RegNet-Portal and to participate in sharing information and knowledge.

The overall objective is that at the next IAEA International Conference on Effective Nuclear Regulatory Systems in about three years, further progress with web based regulatory cooperation, and in particular with the RegNet-Portal, can be reported.

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EXPERIENCE WITH LEGALLY BINDING AND NON-BINDING INTERNATIONAL NUCLEAR INSTRUMENTS

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Abstract

Over the past several decades, a range of international legal instruments — both binding and non-binding — have been developed to address issues concerning the safety and security of nuclear and other radioactive materials and associated facilities. The following instruments and documents will be discussed as most directly relevant to the development and enhancement of a global nuclear safety and security regime: the Convention on the Physical Protection of Nuclear Material and its 2005 Amendment; the Convention on Nuclear Safety; the Convention on Early Notification of a Nuclear Accident; Convention on Assistance in the Event of a Nuclear Accident; the Joint Convention on the Safety of Spent Nuclear Fuel and Radioactive Waste Management; the International Convention for the Suppression of Nuclear Terrorism; United Nations Security Council Resolution 1540 (2004); Code of Conduct on the Safety of Research Reactors; Code of Conduct on the Safety and Security of Radioactive Sources and Guidance on Import and Export of Radioactive Sources; and the IAEA Nuclear Security Series. Implementation of these instruments is primarily the responsibility of the States that have either adhered to them or made a political commitment to apply them in implementing their national nuclear programmes. Given the widespread diversity among States in levels of nuclear development, as well as differing legal, economic, industrial, social, scientific and technical practices and conditions, assessing the overall experience with these instruments poses significant challenges. However, most of the relevant instruments contain provisions for periodic reviews by their States parties to assess implementation. For some instruments that do not explicitly include a review mechanism, review procedures have been established through agreement of the parties or interested States. These periodic reviews confirm that both binding and non-binding nuclear instruments and documents have provided a basis for increased harmonization of State practice in dealing with issues of nuclear safety and security, as well as encouraging mutual assistance and cooperation in enhancing regulatory approaches to protect people and the environment.

1. INTRODUCTION

Over the past several decades, a range of international instruments — both binding and non-binding — have been developed to address issues concerning the safety and security of nuclear and other radioactive materials and associated

facilities. Given the limitations of the length this paper, it is important to clarify which "instruments" will be discussed in this paper and the many other documents in the nuclear field that cannot be covered. For purposes of this analysis, an "international nuclear instrument" is defined as a document related to the uses of ionizing radiation in the form of a commitment by a number of States to apply its terms as a matter of legal obligation (treaties,¹ conventions, agreements) or political determination (voluntary codes of conduct). This definition excludes the many important safety standards documents (and more recent Security Series documents) developed under the aegis of the IAEA.² The omission of these guidance documents should not be interpreted as suggesting that they are less significant for enhancing nuclear safety and security. On the contrary, they describe the essential specific measures and more detailed recommendations that States can use in meeting the more general provisions typically contained in international "instruments". The focus of this paper is on how the legal and policy commitments in such instruments have been implemented to enhance nuclear safety and security.

'Experience' is another term that needs some explanation. Given the recognized responsibility of individual States for ensuring the safety and security of their nuclear programmes, nuclear instruments are primarily implemented through the actions of national authorities. Thus, the experience of individual States in interpreting and applying these instruments and documents is probably most relevant in assessing their effectiveness. However, given the large number of States utilizing ionizing radiation for peaceful purposes and the wide differences in their national nuclear programmes, this paper cannot meaningfully include a State-by-State review of national implementation. Nevertheless, most of the instruments discussed here provide that the Parties will conduct periodic reviews, with the aim of reaching a collective judgment on how well an instrument is being implemented.³ This paper will primarily focus on this collective review 'experience', referencing national experience where practicable.

¹ The authoritative Vienna Convention on the Law of Treaties defines a 'treaty' as "an international agreement concluded between States in written form and governed by international law, whether embodies in a single instrument or in two or more related instruments and whatever its particular designation." See Article 2.1(a).

² Also, given the focus of this conference on safety and security, this paper will not deal with other important instruments, such as those addressing nuclear proliferation, arms control or civil liability for nuclear damage.

³ See my discussion of such review mechanisms in STOIBER, C., "The Review Conference Mechanism in Nuclear Law: Issues and Opportunities", Nucl. Law Bull. No. 83 (2009) 5–27.

The binding international instruments discussed here include:

- The Convention on the Physical Protection of Nuclear Material and its 2005 Amendment;
- The Convention on Nuclear Safety;
- The Convention on Early Notification of a Nuclear Accident;
- The Convention on Assistance in the Event of a Nuclear Accident;
- The Joint Convention on the Safety of Spent Nuclear Fuel and Radioactive Waste Management;
- The International Convention for the Suppression of Nuclear Terrorism;
- United Nations Security Council Resolution 1540 (2004).

Of the numerous non-binding guidance documents developed under the aegis of the IAEA, the following will be discussed:

- The Code of Conduct on the Safety of Research Reactors;
- The Code of Conduct on the Safety and Security of Radioactive Sources and Guidance on the Import and Export of Radioactive Sources;
- The IAEA Nuclear Security Series.

2. CONVENTION ON THE PHYSICAL PROTECTION OF NUCLEAR MATERIAL

The Convention on the Physical Protection of Nuclear Material (CPPNM)⁴ was negotiated in the late 1970s and was opened for signature in March 1980. However, some seven years passed before the 21 required instruments of ratification, approval, acceptance or accession were received to permit entry into force under Article 19.1. The Convention's review provision states that "[a] conference of States Parties shall be convened by the depositary five years after the entry into force of this Convention to review implementation of the Convention and its adequacy as concerns the preamble, the whole of the operative part and the annexes in light of the then prevailing situation" (See Article 16.2⁵).

The first Review Conference mandated under Article 16 was held in September 1992 and a further Conference on Physical protection in November 1997. At the second conference and in meetings of the IAEA Board of Governors

⁴ IAEA document INFCIRC/274/Rev 1, May 1980, entered into force 1987.

⁵ The 2005 Amendment to the CPPNM reproduces this provision, but with conferences every five years to commence after entry into force of the Amendment.

and General Conference, it was decided that although the CPPNM had made a significant contribution to enhancing physical protection of nuclear material worldwide, certain weaknesses in the regime made it desirable to amend the Convention. Beginning in 1999, an open-ended working group convened by the IAEA Director General considered possible amendments. Major terrorist events in 2001 also gave political impetus to this effort, and the Amendment to the CPPNM was adopted at a diplomatic conference in July 2005. The Amendment aims to: enhance the Convention regime by extending its scope to all domestic activities and facilities utilizing nuclear materials; cover acts of sabotage; codify 12 fundamental principles of physical protection; clarify definitions; and to add punishable acts. Article 20.2 requires that two thirds of CPPNM States Parties must approve an amendment for it to enter into force. At the time this paper was written, 142 States had become Parties to the CPPNM, meaning that 95 Parties would be needed to approve an amendment. Given that only 32 States had approved the amendment during the four and a half years since it was approved, its entry into force is likely to be long delayed. Also, since the CPPNM does not contain an article on provisional application prior to entry into force, States lack a clear legal mechanism for advancing the effective application of the amendment.

Finally, as will be discussed in connection with the recent Convention on Suppression of Acts of Nuclear Terrorism, the CPPNM's scope is limited to nuclear material as defined in Article 1(a).⁶ This scope limits the Convention's effectiveness in combating nuclear terrorism using other radioactive materials, for example, in so-called radiation dispersal devices (RDDs) or 'dirty bombs').

3. CONVENTION ON EARLY NOTIFICATION OF A NUCLEAR ACCIDENT AND CONVENTION ON ASSISTANCE IN THE EVENT OF A NUCLEAR ACCIDENT OR RADIOLOGICAL EMERGENCY

In a process unprecedented for most international instruments, these two companion conventions were negotiated very rapidly in response to the 1986 reactor accident at Chernobyl in the former Soviet Union (now Ukraine). Together, they establish a legal framework for providing early notification⁷ and

⁶ Nuclear material includes plutonium (with certain exceptions, U-233) and uranium enriched in the isotope-235 or in the isotope-233

⁷ Convention on Early Notification of a Nuclear Accident, INFCIRC/335 (18 November 1986) (hereinafter Early Notification Convention).

assistance in the case of a nuclear accident⁸. They have both been accepted by a large number of States: 105 Parties and 70 signatories for the Notification Convention and 103 parties and 66 signatories for the Assistance Convention. Neither instrument explicitly contains a provision mandating periodic reviews by the Parties. However, the equivalent of such a mechanism has been established recently under the auspices of the IAEA through the conventions.⁹ The adoption of this mechanism illustrates how international legal instruments and arrangements can evolve to meet the needs of their Parties, while avoiding the instrument. Four meetings of the competent authorities have been conducted¹⁰ and a National Competent Authority Coordinating Group created to facilitate cooperation and help implementation of an Action Plan approved by the IAEA Board of Governors.¹¹

4. CONVENTION ON NUCLEAR SAFETY

The Convention on Nuclear Safety (hereinafter CNS)¹² was negotiated between 1991 and 1994 as a somewhat delayed response to nuclear power reactor accidents at Three Mile Island in the United States of America in 1979 and Chernobyl in 1986.¹³ One impetus for the negotiation was the fact that, following

⁸ Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, IAEA document INFCIRC/336 (18 November 1986) (hereinafter Assistance Convention).

 $^{^{9}}$ See Article 7 of the Early Notification Convention and Article 4 of the Assistance Convention.

¹⁰ In June 2001, July 2003, July 2005 and July 2007.

¹¹ Information on the process under the Early Notification and Assistance Conventions may be found on the IAEA website at www-ns.iaea.org/conventions/emergency.htm.

¹² The IAEA document INFCIRC/449, 5 July 1994, which entered into force 24 October 1996. See also, 33 International Legal Materials, p. 1514 (1994).

¹³ Detailed analysis of the CNS is available in the following articles: JANKOWITSCH, O., The Convention on Nuclear Safety, Nucl. Law Bull. No. 54 (1994) 9; REYNERS, La Convention de 1994 sur la sûreté nucléaire, 99 Revue Générale de droit international public (1995), p. 605; STOIBER, C., "International Convention on Nuclear Safety: National reporting as the key to effective implementation", HORBACH N, ed., Contemporary Developments in Nuclear Energy Law: Harmonising Legislation, in CEEC/NIS (1999) 97; HANDL, The IAEA Nuclear Safety Conventions: An Example of Successful 'Treaty Management'?, Nucl. Law Bull. No. 72 (2004) 7; RAUTENBACH, J., TONHAUSER, W., WETHERALL, A., Overview of the International Legal Framework Governing the Safe and Peaceful Uses of Nuclear Energy: Some Practical Steps, NEA No. 6146, OECD, Paris (2006) 7.

the break-up of the former Soviet Union, a number of Newly Independent States were now responsible for operating and regulating inherited nuclear facilities of Soviet design. This raised concerns about ensuring that the safety of these facilities under new national legal and regulatory arrangements. Article 1 of the CNS states its three main objectives as follows:

- I. To achieve and maintain a high level of nuclear safety worldwide through the enhancement of national measures and international co-operation including, where appropriate, safety-related technical cooperation;
- II. To establish and maintain effective defenses in nuclear installations against potential radiological hazards in order to protect individuals, society and the environment from harmful effects of ionizing radiation from such installations;
- III. To prevent accidents with radiological consequences and to mitigate such consequences should they occur.

The Convention covers land based civil nuclear power plants.¹⁴ At the time this paper was prepared, the CNS had 66 States Parties (notably including all States currently operating nuclear power reactors) and 65 signatories. The CNS has been characterized as an 'incentive' convention, rather than a 'regulatory' or 'sanctions' instrument. Under this approach, the Parties rely on periodic peer review meetings to assess the effectiveness of implementation, rather than adopt other types of regulatory or compliance mechanisms. Article 21.3 of the CNS provides that "The Contracting Parties shall hold meetings (hereinafter referred to as 'review meetings') for the purpose of reviewing the reports submitted pursuant to Article 5...."

Since its entry into force in 1996, four triennial review meetings have been held — in 1999, 2002, 2005 and 2008. Over this decade, the organizational and procedural structure of the CNS process has been enriched through the promulgation of several key documents, including: guidelines on the review process,¹⁵ guidelines on national reports¹⁶ and rules of procedure.¹⁷

The substantive review of implementation at CNS review meetings is conducted in country groups with diverse membership. The Summary Report of

¹⁴ See definition of 'nuclear installations' in Article 2(i).

¹⁵ Guidelines Regarding the Review Process under the Convention on Nuclear Safety, INFCIRC/571/Rev.3, IAEA Vienna (11 January 2007).

¹⁶ Guidelines regarding National Reports under the Convention on Nuclear Safety, INFCIRC/572/Rev.2, IAEA, Vienna (2 September 2002).

¹⁷ Convention on Nuclear Safety: Rules of Procedure and Financial Rules, INFCIRC/573/Rev.3, IAEA, Vienna (11 January 2007).

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the Fourth Review Meeting¹⁸ held 14–25 April 2008 reported a high degree of compliance with its provisions. Several areas were identified for special attention, including: legislative and regulatory framework; independence of the regulatory body; safety management and safety culture; staffing and competence; probabilistic safety assessment; periodic safety review; ageing management and life extension; emergency management; and new nuclear power plants (NPPs).

5. JOINT CONVENTION ON THE SAFETY OF SPENT NUCLEAR FUEL AND RADIOACTIVE WASTE MANAGEMENT

A companion instrument to the CNS,¹⁹ the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (hereinafter the Joint Convention), was negotiated between 1995 and 1997, and entered into force on 18 June 2001.²⁰ As of the date of this paper, the Joint Convention has 52 States Parties and 42 signatories. The provision from the review conference on the Joint Convention states: "The Contracting Parties shall hold meetings for the purpose of reviewing the reports submitted pursuant to Article 32." Joint Convention, Article 30.1 states: "At each review meeting the interval between review meetings not exceeding three years," Joint Convention, Article 30.2.i.

The Parties have conducted three review meetings — in 2003, 2006 and May 2009.²¹ As with the CNS, the Joint Convention Parties have developed a number of documents to guide the work at meetings.²²

The Joint Convention review meetings have identified areas where significant progress has been made, particularly in the establishment of holistic

¹⁸ See CNS/RM/2008/6 FINAL at the IAEA's web site under 'Conventions'.

¹⁹ See CNS preambular para. viii, which affirmed the need to promptly begin the development of a convention on the safety of radioactive waste management.

²⁰ A discussion of the negotiation of the Joint Convention and its basic provisions is contained in TONHAUSER, W., JANKOWITSCH, O., The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, Nucl. Law Bull. **60** (1997).

²¹ See the Summary Reports of the three meetings in documents JC/RM.106/Final Version (14 November 2003) and JC/RM.2/03/Rev. 1 (24 May 2006) available on the IAEA documents web site.

²² See Rules of Procedure and Financial Rules for the Joint Convention in the IAEA document INFCIRC/602/Rev.2 (24 January 2006) and Guidelines Regarding the Review Process in the IAEA document INFCIRC/603/Rev.3 (18 July 2008).

waste management policies that includes decommissioning and management of legacy waste. Challenges have also been identified over the long term, such as the management of spent fuel, the disposal of high-level radioactive waste and the need to find suitable disposal options for all types of radioactive waste.

6. INTERNATIONAL CONVENTION FOR THE SUPPRESSION OF NUCLEAR TERRORISM

The Nuclear Terrorism Convention, or NTC, was adopted by the United Nations General Assembly on 13 April 2005 and entered into force on 7 July 2007. It currently has 54 parties. Initially proposed by the Russian Federation in 1997,²³ it was developed primarily to remedy perceived weaknesses in the existing international legal framework for combating nuclear terrorism. In particular, it was intended to fill certain gaps in the CPPNM, namely, to provide for an effective response to acts of nuclear terrorism, rather than merely to provide physical protection measures and to extend the coverage of such measures to acts involving radioactive materials beyond nuclear material.

The basic structure of the NTC parallels the CPPNM and contains the following elements:

- Offences established by the Convention;
- Matters not affected by the Convention;
- Criminalization of NTC offences under national law;
- Measures to ensure that offenses are not justified on grounds of political, philosophical, ideological, racial, ethnic, religious, or other similar nature and to ensure that penalties are consistent with their grave nature;
- National measures to prevent and counter preparations for the commission of offenses;
- Exchange of information and coordinating measures to detect, prevent, suppress and investigate offenses;
- Protection of confidential information,
- Competent authorities and liaison points;
- Measures to protect radioactive material;
- Establishment of jurisdiction over offenses;
- Investigation of offenses;
- Ensure presence of alleged offenders for prosecution or extradition;

²³ See original draft issued as United Nations Doc. A/AC.252/L.3 and Corr. 1 and 2. For debate held: Document A/53/37 pp. 2–4, Chapter III Summary of general debate.

- Treatment of alleged offenders;
- Prosecution or extradition;
- Extradition and establishment of extraditable offenses;
- Assistance with investigations, criminal proceedings or extradition;
- Ensuring that extradition or mutual legal assistance is not avoided on grounds of 'political offense';
- Treatment of detained persons whose presence is sought for investigation or prosecution of offenses;
- Measures to control and protect radioactive material, devices or facilities after commission of an offense;
- Information on prosecutions;
- Consultations on implementation.

Unlike the other binding instruments discussed in this paper, the NTC does not contain a provision for review meetings of its Parties. As of the writing of this paper, no incidents covered by the Convention have been reported by its Parties. A number of activities relevant to implementing the NTC (as well as the other 15 conventions promulgated under United Nations auspices to combat terrorism) are being conducted by the United Nations Office of Drugs and Crime (UNODC) through its Terrorism Prevention Branch in Vienna. In cooperation with the IAEA, the UNODC has developed model legislation implementing the NTC, in addition to other anti-terrorism instruments.

7. UNITED NATIONS SECURITY COUNCIL RESOLUTION 1540 (2004)

In April 2004, the United Nations Security Council adopted Resolution 1540 concerning weapons of mass destruction. The Resolution was adopted pursuant to the Council's authority under Chapter VII of the United Nations Charter to address threats to international peace and security. Thus, its provisions are mandatory for all United Nations Member States. The Council decided that:

- All States shall take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing appropriate controls over related materials and to this end shall:
 - (a) Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport;
 - (b) Develop and maintain appropriate effective physical protection measures;

- (c) Develop and maintain appropriate effective border controls and law enforcement efforts to detect, deter, prevent and combat, including through international cooperation when necessary, the illicit trafficking and brokering in such items in accordance with their national legal authorities and legislation and consistent with international law;
- (d) Establish, develop, review and maintain appropriate effective national export and trans-shipment controls over such items, including appropriate laws and regulations to control export, transit, transshipment and re-export and controls on providing funds and services related to such export and trans-shipment such as establishing end-user controls; and establishing and enforcing appropriate criminal or civil penalties for violations of such export control laws and regulations.

The United Nations Security Council has created a Committee to monitor implementation of the resolution, including receiving national reports mandated by the resolution. The 1540 Committee has also developed a legislative database of national laws relevant to its obligations.

8. CODE OF CONDUCT ON THE SAFETY OF RESEARCH REACTORS

At the suggestion of the Chair of the IAEA's International Nuclear Safety Advisory Group (INSAG), an initiative under the Agency's auspices resulted in development of a non-binding Code of Conduct on the Safety of Research Reactors adopted by the IAEA General Conference in 2004.²⁴ The concept of a review meeting for the Code of Conduct was advanced at a meeting of the CNS, where the parties adopted a resolution requesting the IAEA Director General to convene meetings of Member States "to discuss how to best assure the effective application of the 'Code of Conduct on the Safety of Research Reactors'."²⁵ An open-ended meeting for this purpose was conducted in Vienna in December 2005, where the participants adopted a recommendation that periodic meetings should be organized to discuss topics related to the Code, exchange experience

²⁴ See RAUTENBACH, J., TONHAUSER, W., WETHERALL, A., op. cit., footnote 10, pp. 13–14.

²⁵ See DEITRICH, "The Open-ended Meeting on Effective Application of the Code of Conduct on the Safety of Research Reactors", a PowerPoint presentation at www.-ansn.iaea/org/Documents/apmd/asia288p3.pdf; and LOY, "Implementation of the Code of Conduct on the Safety of Research Reactors", Effective Nuclear Regulatory System: Facing Safety and Security Challenges (Proc. Int. Conf. Moscow, 2006), IAEA, Vienna (2006) 129–135.

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and lessons learned, including best practices and assistance to overcome any identified difficulties. The meeting also supported the convening of regional meetings to share experience with implementing the Code. Presentations at these regional meetings indicate that systematic self-assessments of research reactor safety are increasingly performed. Further, many Member States have developed laws, regulations, regulatory practices and operating practices implementing the Code's recommendations. Some regional meetings have also conducted group exercises on self-assessment of application of the Code.

9. CODE OF CONDUCT ON THE SAFETY AND SECURITY OF RADIOACTIVE SOURCES

Another important recent instrument in the field of nuclear safety and security is the Code of Conduct on the Safety and Security of Radioactive Sources²⁶ and its associated Guidance on the Import and Export of Radioactive Sources.²⁷ Although the Code and Guidance are not legally binding, they represent an important codification of basic principles that States should apply to ensure the safe and secure management of radioactive sources, some of which can pose significant risks if improperly handled or diverted from authorized uses. At the time this paper was written, some 95 States had expressed a political commitment to apply the Code in letters to the IAEA Director General.

The Code of Conduct does not include a specific provision mandating review meetings; however, a de facto review meeting mechanism has been established. The need for such a mechanism was highlighted during debates at the IAEA's International Conference on the Security of Radioactive Sources convened in March 2003 in Vienna. This was followed by a similar call for enhanced information exchange in an Action Plan for the Safety and Security of Radioactive Sources approved by the IAEA Board of Governors in August of 2003.²⁸ As part of this Action Plan, another review of issues in this area was conducted at the International Conference on the Safety and Security of Radioactive Sources in Bordeaux, France, on 27 June to 1 July 2005. The findings of the Bordeaux Conference cover a wide scope of topics, including assessment and recommendations in the following: the Code of Conduct; import and export controls; dealing with the legacy of past activities; sustainability and

²⁶ IAEA document IAEA/CODEOC/2004.

²⁷ IAEA document IAEA/CODEOC/IMP-EXP/2005.

²⁸ See IAEA document GOV/2003/47-GC(47)/7 of 4 August 2003.

continuity of control; illicit trafficking and inadvertent movement; emergency management; and the outlook for the future.²⁹

In 2006, an open-ended meeting was convened under the auspices of the IAEA to consider whether and how to structure a process for information exchange that could help States applying the Code and Guidance better implement their provisions.³⁰ The participants decided to establish triennial Open-Ended Meetings of Technical and Legal Experts for Sharing of Information as to States' Implementation of the Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance on the Import and Export of Radioactive Sources. The first of these meetings was held in June 2007 and another is planned for the spring of 2010. The review process is substantially less formal than that adopted under the CNS or Joint Convention, with national reports being optional and the written question and response procedure omitted.

10. IAEA NUCLEAR SECURITY SERIES

Unlike the subject of safety standards, the IAEA Statute does not contain a provision mandating the development of the IAEA security standards. However, as a result of recent decisions by the IAEA Board of Governors and General Conference, the IAEA is conducting expanded activities related to security under its triennial Nuclear Security Plans.³¹ Pursuant to these plans, the IAEA Secretariat has been coordinating the development of a range of security guidance documents to parallel the long standing IAEA Safety Standards Series. As of mid-2007, at least 14 documents in this Nuclear Security Series have either been published, approved for publication, or are in advanced stages of development; The documents related to illicit trafficking that have already been published or approved for publication include:

²⁹ The Findings of the President of the Conference are available at www-ns.iaea.org/meetings/rw.../bordeaux-france2005.htm

³⁰ A useful discussion of this development may be found in MCINTOSH, S., "Implementation of the Code of Conduct on the Safety and Security of Radioactive Sources", June 2007 Information Exchange Meeting, Nuclear Inter Jura 2007 Proceedings, Int. Nucl. Law Assoc. (2007) 589–594.

³¹ At the time this paper was written, the NSP for 2006–2009 was in the final stages of implementation and a new NSP for 2010–2013 had been approved by the IAEA policy making organs.

- No. 1. Technical and Functional Specifications for Border Monitoring Equipment;
- -No. 2. Nuclear Forensics Support;
- No. 3. Monitoring for Radioactive Material in International Mail Transported by Public Postal Operators;
- --- No. 4. Engineering Safety Aspects of the Protection of Nuclear Power Plants against Sabotage;
- -No. 5. Identification of Radioactive Sources and Devices;
- No. 6. Combating Illicit Trafficking in Nuclear and Other Radioactive Material;
- No. 7. Nuclear Security Culture;
- No. 8. Preventive and Protective Measures Against Insider Threats;
- No. 9. Security in the Transport of Radioactive Material;
- No. 10. Development, Use and Maintenance of the Design Basis Threat;
- No. 11. Security of Radioactive Sources.

Other documents in the IAEA Nuclear Security Series in preparation include:

- Protection Against Sabotage;
- Radioactive Waste Security;
- Nuclear Security at Major Public Events;
- Nuclear Security Guidance in the Design, Siting and Construction of New Reactors.

It is beyond the scope of this paper to provide a detailed review of these documents. However, these non-binding documents provide important guidance for development of national legal and regulatory framework for nuclear security.

11. CONCLUSIONS

On the basis of the rather general survey set forth in this paper, some few basic conclusions may be offered on the experience States, international organizations and relevant stakeholders have had in implementing these binding and non-binding instruments for nuclear safety and security. These conclusions will be discussed under five headings.

11.1. Review meetings as a basis for systematic review

During the past decade, the practice of conducting review meetings of the Parties to various binding instruments and non-binding guidance documents has become a regular feature of the international nuclear landscape. Although the experience under the various instruments has been mixed, it is fair to say that these regular exchanges have helped States using ionizing radiation for peaceful purposes to harmonize their national approaches for ensuring the safety and security of the technology. At the very least, these meetings require the national authorities to conduct some form of self-assessment based on the provisions of the relevant instruments. The most appropriate format and process for implementing a particular instrument or document will vary depending on its legal character and subject matter. However, it is clear that there are cross-cutting lessons to be learned among and between the various instruments. A useful activity at the various review meetings or during preparatory consultations among parties would be to consider such cross-cutting lessons, including whether arrangements used for one instrument could enhance experience with another. Of the many such issues, the following seem most relevant:

- National reporting format and procedures;
- Scheduling and frequency of meetings;
- Preparatory and inter-sessional work;
- Official participation;
- Industry participation;
- Participation by non-governmental organizations and the public;
- Structure and procedures of sub-groups and subsidiary bodies;
- Financing of the meeting, resources and assistance;
- Decision making processes (consensus, unanimity, voting);
- Selection and role of leadership of the meeting;
- Role of the Meeting Secretariat;
- Role of the IAEA and other international bodies;
- Verification and compliance issues;
- Final documents, conclusions and recommendations.

Many of these issues will have already been addressed in rules of procedure or financial rules of the various regimes. However, revisiting them on a periodic and systematic basis — including reference to other regimes — can assist the parties in the progressive development and more effective use of these mechanisms.

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11.2. Harmonization of national legal and regulatory frameworks

For most of the instruments and documents discussed in this paper, effective implementation depends on the actions of national authorities and users of the technology. As would be expected, this wideranging set of instruments, addressing different subjects, and with different legal status can be difficult to implement in a consistent and harmonized manner. However, nuclear technology has a recognized global character due to many factors, including inter alia, multinational business arrangements, environmental considerations, (including pressures to reduce global warming), and the international threat of nuclear terrorism. Measures undertaken pursuant to the various instrument and documents must give priority attention to how States can more effectively adopt consistent national frameworks for implementation. Some options include:

- Seeking agreement on agreed interpretation of the provisions of instruments at review meetings;
- Developing model legislation or regulations implementing an instrument;
- Providing assistance to States needing such assistance (through bilateral, regional or IAEA programmes);
- Encouraging voluntary assessment activities by the IAEA or other relevant bodies;
- Considering amendments or protocols to instruments where inconsistencies or conflicting provisions have caused difficulties.

These options are only the most obvious of many activities that could lead to greater harmonization of national measures. Several of them are discussed further below.

11.3. Need for assistance and resources — human, technical and financial

For many States, particularly those embarking on new nuclear programmes or entering into expanded programmes, assistance will be critical to their ability to meet the obligations or guidance contained in the instruments and documents discussed in this paper. States with established and successful nuclear programmes have taken decades to educate and train relevant technical personnel, often at substantial expense. Putting into place the regulatory arrangements necessary for safety and security can also be a time-consuming and costly process. Developing States will not be able to meet the obligations of relevant conventions or implement relevant guidance documents without outside support, including training, equipment and instrumentation and financial resources. In a period of economic difficulty, finding such resources will impose challenges to the global nuclear community.

The review meetings and other activities conducted in relation to the various international instruments provide an opportunity for assessing the needs of States for cooperation and assistance. Such meetings and activities provide a form of useful assistance and guidance. However, participation in the review processes can become a significant burden for States with modest resources and small regulatory bodies or user organizations. Consideration should be given to how to improve the review process for certain instruments to permit more effective participation by States with limited resources. Joint meetings concerning related instruments (for example, the Early Notification and Assistance Conventions) have been used to a limited extent. Further opportunities for coordinated meetings should be explored. Ways should also be explored to reduce the burden of participation by expanded use of electronic communications and simplified reporting procedures. Regional meetings have been used for some instruments and should be considered for others to reduce the expense of participation. Options for providing assistance in implementing the various instruments should be on the agenda of review meetings as a priority matter.

11.4. Role of the IAEA and other international bodies and initiatives

As the United Nations system organization primarily responsible for coordinating activities related to the safety and security of the peaceful uses of nuclear energy and other forms of ionizing radiation, it is not surprising that the IAEA has played a central role in implementing the various international instruments and documents discussed in this paper. Indeed, several of the instruments have been developed under IAEA auspices. The drafters of most of the binding international instruments have relied on IAEA standards documents and other publications as the basis for codifying requirements and procedures in the safety and security field. This process of translating so-called 'soft law' into 'hard law' has become a common feature in the field of international nuclear law in general.

As will be noted below, IAEA voluntary assessment missions have also become an important mechanism for assessment of implementation of the various instruments and documents. These missions and other IAEA assistance activities are critical for States lacking economic and technical resources in developing the necessary framework to conduct peaceful nuclear activities in a safe and secure manner. The reports of these assessment meetings are also an important resource for demonstrating compliance with the various instruments at the periodic review meetings of the parties.

Some of the instruments, such as the Early Notification and Assistance Conventions, mandate a specific role for the IAEA in implementing their provisions. However, because the Agency is not a party to most of the instruments, defining its proper role is a matter to be determined by its Parties.³² The past decade has witnessed a trend in expanding the role of the IAEA in activities related to the various instruments. This role increasingly extends beyond merely convening and providing services for a meeting or managing relevant documentation. This expanding role is likely to continue in the future, but is dependent on the willingness of the IAEA Member States and major donors to provide adequate resources for the Agency's activities.

11.5. Compliance and dispute resolution

Experience with the various binding and non-binding nuclear instruments highlights a basic difference between international and domestic legal and regulatory systems with regard to compliance, enforcement and dispute resolution. International nuclear instruments do not ordinarily include clear provisions and procedures for verifying and enforcing compliance with their obligations or commitments, or resolving disputes among the parties. This is a fundamental distinction of the power of sovereign States to compel or prohibit certain actions of persons or legal entities under their jurisdiction and control and to resolve disputes through formal administrative or judicial means. Periodic review conferences have become a substitute for a compliance regime.³³ For most instruments, this 'soft enforcement' role has generally been viewed as ineffective.³⁴

The first aspect of the compliance issue is how States Parties to an instrument can verify that other Parties are meeting their obligations. As stated, with some exceptions, verification or dispute resolution measures are absent from most nuclear instruments. In any case, the generality of some of the requirements in nuclear instruments would make it difficult to develop meaningful 'metrics' for measuring compliance.³⁵ Further, there is little interest in identifying or creating international regulatory bodies to conduct verification activities and enforce

³² Whatever role the Parties seek for the IAEA must be agreed to by the Agency's policy making organs.

³³ Some might argue that verification and enforcement may be irrelevant for 'incentive' conventions such as the CNS and Joint Convention.

³⁴ This deficiency has been most widely discussed regarding non-proliferation instruments. See, for example, SQUASSONI, NPT Compliance: Issues and Views, Congressional Research Service Report for Congress (26 April 2005) at http://www.au.af.mil/au/awc/awcgate/crs/rs22125.pdf.

³⁵ For example, what agreed measures could be adopted under the Joint Convention to verify compliance with the Article 20.2 obligation that contracting parties "ensure the effective independence of the regulatory functions from other functions"?

compliance. In some areas related to radiation protection, nuclear safety and security, and general regulatory organization and implementation, the IAEA has successfully conducted voluntary missions to assess whether measures implemented in Member States are consistent with relevant international instruments and the IAEA standards and guidance documents. However, converting such missions into verification inspections would probably be unacceptable to many States, as they are considered too costly or too intrusive into the responsibilities of national regulatory bodies.

A second aspect of compliance is determining what actions should be taken in response if a State Party is determined to be violating the terms of an instrument. No nuclear law instrument provides specific sanctions or other penalties for non-compliance. Indeed, sanctions measures have been deliberately omitted from 'incentive' instruments as inappropriate in the context of their review processes. The only mechanisms available are reference to the United Nations Security Council for action under Chapter VII of the Charter regarding threats to or breaches of the peace, or to the IAEA for violations of safeguards obligations. An option for enforcing compliance that does not appear practical is termination or suspension of the operation of an instrument as a consequence of its material breach. Article 60.2 of the Vienna Convention on the Law of Treaties sets forth the procedures applicable to multilateral instruments. First, it may be difficult to establish that a breach is 'material'.³⁶ Termination normally requires unanimity of the other parties, basically impossible for instruments with very large adherence. But more importantly, the basic goals of nuclear safety and security instruments argue against termination as a compliance measure. Such a step would only free a State Party accused of violating an instrument from the need to comply with its important objectives. Thus, it is unrealistic to expect review meetings of multilateral instruments to take concrete and effective measures to verify and enforce compliance. However, such meetings do focus on compliance issues to some extent. This attention to how Parties are fulfilling their commitments can enhance implementation. Discussion of problems with compliance in a peer review setting has been shown to constitute a meaningful inducement for improved performance. However, it must be recognized that the 'incentive' character of these meetings is not well adapted to implementing a rigorous compliance process.

³⁶ See Vienna Convention Article 60.3, defining 'material breach' as a repudiation of the treaty or violation of a provision essential to the accomplishment of the object or purpose of the treaty.

EXCHANGES IN THE INTERNATIONAL REGULATION OF NUCLEAR ENERGY: PRACTICES AND ELEMENTS FOR IMPROVEMENT

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OPENING REMARKS

I should first like to thank the International Atomic Energy Agency for this opportunity to reflect on the importance of international cooperation in the regulation of nuclear energy. This is based on my complete conviction that international cooperation and the exchange of experiences and good practices in this area constitute a guarantee of safety and should therefore be seen as an essential tool for the reinforcement of regulatory practices.

INTRODUCTION

International relations in the regulation of nuclear safety and radiological protection are an excellent tool for cooperation between different countries and provide numerous benefits. On the one hand, they provide each individual country with ways of improving its own institutional system, while on the other hand, allowing us to carry out activities jointly with other countries. This serves to improve the international regulatory system overall and has obvious repercussions on the safety and welfare of all the countries involved.

We are undoubtedly witnessing a new era of structural changes in international society that need to be addressed through international cooperation and international relations. We are seeing increasing globalization opening up new challenges and demands requiring new solutions. The increasing number of interconnections in the system means that any disturbance tends to propagate more easily, as a result of which uncertainty has become a striking characteristic of our time and our societies.

In the world of nuclear energy, social and psychological interconnections are particularly significant, and in fact — and in the words of the IAEA — any incident occurring anywhere in the world has an impact on all countries. In addition to its physical implications, this impact may affect public opinion regarding the reliability of using this energy source.

We should be taking advantage of this interconnection to create synergies contributing to the improvement and reinforcement of cooperation and of our regulatory practices and providing an environment favouring trust and cooperation in the peaceful use of nuclear energy.

Cooperation among countries in a globalized environment, and specifically as regards the use of nuclear energy and ionizing radiations, involves governments, international organizations and regulatory bodies alike, since we are the framework supporting the actions implemented to guarantee safety in the use of nuclear energy. The mechanisms required to accomplish this are essentially the adoption of international safety standards and the exchange of technology and learning through the standard application of good regulatory practices.

INSTRUMENTS AND MECHANISMS AVAILABLE TO THE GOVERNMENTS FOR INTERNATIONAL COLLABORATION IN THE FIELD OF NUCLEAR ENERGY

In referring to the instruments or mechanisms available to the international community to guarantee and reinforce safety, I feel that it would be logical to begin with international conventions.

International conventions are one of the best instruments for cooperation and exchange available to governments since they entail the explicit commitment of the countries adhering to them to comply with the objectives specifically set out. Consequently, they constitute the most important official expression of the overseas policy of the States, they are the standards that shape international law, they are universal in their pretensions and they are motivating rather than penalising in their approach. For this reason it is necessary to encourage all countries to ratify the international conventions.

In this respect, the Convention on Nuclear Safety is a mechanism for multilateral cooperation, which means that the different countries accept the application of fundamental principles of safety to their nuclear facilities via their regulatory authorities. This Convention recognizes that nuclear safety is a State responsibility and sets out as an objective the spreading of an effective culture of nuclear safety throughout the entire international community.

To date, 64 countries have ratified or joined the Convention since it was approved in 1994. Spain's ratification took place in 1995 and the Convention now includes all member States with operating nuclear power plants.

Ratifying and adhering to the Convention is obviously the first step, but the work to be carried out subsequently by the States, through their regulatory authorities, in order to ensure the continued safety of their nuclear facilities is also fundamentally important. This means actively collaborating in the exchange of

good practices, information and operating experience with other countries, accomplished through peer reviews.

International commitments in relation to nuclear safety are undoubtedly strengthened through these meetings, during which we share experiences and subject our regulatory practices to comments from our peers.

In keeping with the above, Spain has ratified the main international conventions on nuclear safety and radiological protection:

- Convention on Nuclear Safety;

- Joint Convention on the Management of Irradiated Fuel and Radioactive Waste;
- Convention on the Prompt Notification of Nuclear Accidents;
- Convention on Mutual Assistance in Response to Nuclear Accidents and Radiological Emergencies;
- Convention on the Security of Nuclear Materials.

Participation in these conventions has allowed Spain to improve its regulatory practices. The request made by our government to host the Integrated Regulatory Review Service (IRRS) mission arose precisely as a result of a recommendation received in the wake of the second report of the Convention on Nuclear Safety.

MULTILATERAL COLLABORATION

In referring to Spain's experience of the IRRS mission, I should like to touch on another fundamental mechanism in international collaboration that undoubtedly contributes to improving the regulatory system. I refer to multilateral collaboration between the Regulatory Authorities.

The leading exponents of this multilateral collaboration in the world of nuclear energy are the IAEA and the Nuclear Energy Agency (NEA) of the Organisation for Economic Co-operation and Development (OECD/NEA). In both these organizations, the decision by a country to cooperate is voluntary and is taken by the government through the regulatory authorities.

THE IAEA

The IAEA has been working on the peaceful use of nuclear energy since 1957, the year in which it held its first General Conference, acting as the

backbone of regulation of this energy source at the world level and bringing about a true harmonization of regulatory practices.

The objective is to achieve the involvement and collaboration of all the Member States in improving the safety of activities relating to nuclear energy. Numerous mechanisms are available in this respect, including the development of standards, the training of less experienced countries, and peer reviews; particularly significant among these are the missions for the analysis of operational safety (Operational Safety Review Team, OSART) and the missions for the assessment and review of regulatory activities (IRRS). The active collaboration and involvement of all the Member States in these activities is a fundamental condition for achieving these objectives.

Integrated Regulatory Review Service (IRRS) missions

In 2005, the IAEA initiated a project for the integration of the different instruments used to examine the regulatory systems of the Member States. Prior to this date, the IAEA had already carried out reviews relating to specific objectives, covering the infrastructure and regulatory systems associated with nuclear safety (International Regulatory Review Team, IRRT), radiological protection and the control of radioactive sources (RaSSIA), transport (TRANSAS) and security (International Physical Protection Advisory Service, IPPAS).

The goal of the new system, known as the IRRS, is to cover and integrate all aspects of the operation of the regulatory bodies in relation to nuclear safety and radiological protection in order to improve efficiency, standardize international practices and share operating, organizational and legislative experiences.

Integrated Regulatory Review Service (IRRS) mission to Spain

Please allow me now to refer briefly to the significance of the IRRS Mission carried out by the IAEA with respect to the Spanish regulatory authority.

At the Spanish regulatory authority, we considered that an IAEA assessment of this type was without any doubt the best way to analyse our procedures and detect any aspects that might be improved, with a view to ensuring better compliance with our assigned functions.

The IRRS missions, which may vary in their scope, are not obligatory and in all cases are carried out in response to requests by the government or national authorities. The Nuclear Safety Council of Spain (CSN) decided that its review should be the first complete and integral assessment including the issue of security.

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The IRRS missions are not audits or inspections, but rather a mechanism for review, evaluation and the sharing of ideas and experiences with our peers. The objective is not to award a score, but rather to contribute to improving efficiency and regulatory practices. Furthermore, the improvement is not only for the body reviewed, but for all the peers, since we can and should all learn from the good practices observed through this exchange of ideas and apply the lessons within our respective organizations.

The cultural mix of the teams undertaking the missions is also highly enriching. The Spanish IRRS was carried out by a team led by the President of the Swiss Regulatory Authority, Ulrich Schmocker, and made up of 24 people from 15 countries, in addition to members of the staff of the IAEA itself.

The results have served to identify good practices that might serve as an opportunity for learning by other countries. We have also identified areas where we can and should improve in order to comply with our mission to oversee nuclear safety and radiological protection in our country.

In addition to the IAEA, there are other regulatory environments in which membership is an economic or regional issue.

OECD NUCLEAR ENERGY AGENCY

As I have already pointed out, the OECD/NEA is the other body promoting multilateral relations in the field of nuclear energy. Numerous projects and initiatives that it would be impossible for any single country to address alone are carried out via this Agency. The objective in all cases is cooperation, the exchange of information and the harmonization of regulatory practices.

THE EUROPEAN UNION

The efforts in cooperation and harmonization made by the European Union (EU) deserve mention. In this case, cooperation springs from our condition as EU member countries, but we should certainly underline the efforts made to standardize the regulation of nuclear energy in all the countries that make up the EU.

A Directive has recently been approved establishing a community framework covering the nuclear safety of all European nuclear power plants. Clearly, this Directive has not emerged from a vacuum. Within the European framework, the member States have been working for some time on the harmonization of regulatory practices in the field of nuclear safety through the European Atomic Energy Community (EURATOM) and the Western European Nuclear
Regulators' Association (WENRA). However, while recognizing this, the Directive assumes the need to harmonize regulatory practices, establishing a solid safety culture at the nuclear facilities and strengthening the role and independence of the national regulatory authorities in order to maintain and promote continuous improvement with regard to nuclear safety and its regulation. These objectives may be achieved only through cooperation and the joint efforts of the different countries and regulatory bodies.

REGULATORS' ASSOCIATIONS

Regulatory authority associations and forums have been created for the exchange of information and knowledge and the sharing of experiences and practices with other organizations across the world. These serve to develop common strategies and to establish links for improving regulation policies to the extent possible at the international level.

The three most relevant associations in which Spain participates are the International Nuclear Regulators Association (INRA), WENRA and the Latin American Forum of Nuclear and Radiological Regulators.

Western European Nuclear Regulators Association (WENRA)

As you are all aware, WENRA was set up to establish a regional forum allowing for the exchange of information and experiences in relation to nuclear safety and to develop mechanisms for the standardization of regulatory practices among the countries located within this specific geographical area.

The objective is to develop a common strategy on nuclear safety. WENRA's work has served to assess nuclear regulation in the countries that have joined the EU over the years, and to establish the terms of reference that have made a common European regulation possible.

International Nuclear Regulators Association (INRA)

INRA is another forum where those ultimately responsible for the regulatory authorities of the member countries are able to develop an open and constructive dialogue on issues of common interest for improving nuclear safety in our respective countries.

Latin American Forum of Nuclear and Radiological Regulators

Finally, I should like to mention the Latin American Forum of Nuclear and Radiological Regulators (FORO). The main objective of FORO is to promote a high level of safety in all practices using radioactive materials or nuclear substances in this region, encouraging the exchange of information and experiences among its members. Another objective is to set up a knowledge network among the Latin American countries in order to maintain strict standards in nuclear safety, at the level of those proposed by the IAEA.

Spain has a high level of commitment to FORO. Our common language and cultural links facilitate the transfer of know-how through the sharing of our regulatory practices.

Within FORO we jointly undertake a technical programme in which certain issues receive priority attention, such as the radiological protection of patients, the safe management of radioactive sources, the safety of radioactive facilities and nuclear safety and security.

For Spain, contributing to the development of this regional knowledge network in relation to nuclear safety and radiological protection, using the standards of the international organizations as a reference, is a priority task. In this respect, the technical programme aimed at the areas considered a priority in the region, and to which I have referred previously, has been designed and is being carried out within the framework of a programme outside the IAEA budget, funded initially by my country.

FORO is currently a unique example of sustainable international cooperation in which the member countries provide funds depending on their respective economic capacities, since the leitmotif is the establishment of a nuclear and radiological safety culture and the harmonization of regulation in the region.

BILATERAL COLLABORATION

In addition to multilateral cooperation, the regulatory authorities also have bilateral collaboration available to them.

Advantage should be taken of this area to share practices, experiences and technical knowledge in a closer knit and more practical manner, through periodic contacts helping us to consolidate a demanding and continuously improving regulatory activity.

To illustrate with practical examples, my country has undertaken exchanges with other countries as a result of the bilateral relations that we are describing.

- For example, with the United States of America, France and Germany, Spain has developed specific standards for application at nuclear power plants whose technology originates in these countries;
- With France, we have developed a system of regulatory practices through two-way inspections, with CSN technicians participating in French inspections and vice versa;
- CSN provided assistance to draft the Law establishing the Ukrainian Regulatory Body, which is independent;
- The development of the Spanish regulatory model, and more recently, the Integrated Plant Supervision System (SISC), via our bilateral relationship with the United States.

I should like to briefly describe the way in which this technology exchange was accomplished.

Integrated Plant Supervision System (SISC)

In 2000, the CSN studied the best regulatory practices of various countries. Following an analysis of these four supervision models, the decision was taken to adopt the US model, known as the Reactor Oversight Process (ROP), adapted to the characteristics of the Spanish nuclear fleet.

The SISC is complex but highly efficient as regards progress in guaranteeing the safety that we owe the general public. There is a large number of parameters to be taken into account, and SISC's contribution consists precisely in integrating all this information in order to optimize and systematize the supervision of nuclear power plants.

With a view to increasing transparency and improving communications with the public, the results of the SISC are published on the Council's institutional website.

Experience shows that this is a good mechanism, not only for supervision but also for ensuring transparency when reporting on and communicating the performance of the Spanish nuclear fleet to the general public. There are many barriers that have to be broken in order to increase awareness among those involved that rigorous information must necessarily be a priority.

As is well known, nuclear energy is a field that depends enormously on public opinion. This requires us as regulatory authorities to ensure the maximum possible transparency, not only because it is a legal requirement, but also because transparency undoubtedly increases trust in our performance.

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CLOSING REMARKS

In closing, I would like to underline a few points that I consider to be of key importance as regards improving exchange within the framework of international cooperation.

First, we have seen the need for this international collaboration, based on the result of cooperation among all those involved, either on the initiative, of the governments or of the regulatory bodies.

However, this cooperation must be active, that is, the institutions in charge of overseeing nuclear safety in the different countries should participate actively and proactively. While participating is important, it is just as important to be collaborative, and be willing to exchange experiences, and to be evaluated by our peers.

I consider the role of the IAEA as a vital catalyst and enabler of such cooperation. This international conference is a good example of this. For this reason, all countries should adhere as closely as possible to the safety standards set out by the IAEA, thereby generating an environment favourable to trust and cooperation. It is very important that this also include those countries that are about to embark on nuclear programmes. Collaboration and good communication among all is fundamentally important for the establishment of regulatory bases capable of guaranteeing safety. As we have seen, the mechanisms and instruments are available and within everyone's reach, and there is also the full availability and support of the IAEA.

Cooperation is much more than mere social coordination. Cooperation means working together in accordance with rules and methods recognized and accepted by all as the elements regulating our activities. We all know that safety and security are national responsibilities, but also that any fault may have consequences beyond the frontiers of a given country, affecting safety and trust everywhere in the world.

Consequently, we should take the fullest advantage of the opportunities offered by the structures and mechanisms that we have all jointly implemented. In this respect, we find ourselves immersed in a social contract in which our activities are based on equality and reciprocity, understood not in altruistic terms, but from the awareness that this benefits all those concerned.

There should be no room for complacency. As regulators, none of us can or should lower our guard. We must be permanently on the alert, improving our regulatory practices, collaborating actively and ensuring that knowledge is shared by all. There are no positions of strength when we cooperate, and that is precisely our strength.

This requires efforts by the regulatory authorities, efforts that should be channelled towards increasing transparency in two directions: on the one hand, towards our own countries — we know that transparency is the basis for trust, that we cannot turn our backs on public opinion, and that for this reason, we have to make greater efforts in communication; and on the other, transparency also with respect to the international community, in the awareness that the consolidation of a safety culture at the world level is to the benefit of all.

Equally important is the need for the regulatory authorities to work within a framework of independence, an independence that should be formal and set out in legal instruments but at the same time real and effective.

I would like to finish by thanking the IAEA for its work, for its role as an enabler of harmony and a driver of actions, allowing for mutual learning and ongoing improvement of the safety culture in the use of nuclear energy.

INTERNATIONAL LESSONS LEARNED FROM NATIONAL INTERNATIONAL REGULATORY REVIEW TEAM MISSIONS

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Abstract

The IAEA has built on its two well established peer review services, International Regulatory Review Team (IRRT) and Radioactive Sources Infrastructure Appraisal (RaSSIA) missions to develop what is now a comprehensive Integrated Regulatory Review Service (IRRS). In the case of IRRT/IRRS, the recipients benefiting from such peer reviews have changed from being mainly developing regulatory bodies in need of advice and support, to established regulatory bodies that have come to understand the needs for continuous improvement and how peer reviews assist in this process. Additionally, there is also now a need to further develop the IRRS process to assist countries planning to start new nuclear programmes. While considerable international learning has taken place through feedback at the Convention on Nuclear Safety review meetings, from individuals disseminating experience gained in their own countries and, more recently, from information and experience derived from IAEA workshops following a number of IRRS missions, there is still room for enhancing the opportunities for the international community to learn from IRRS missions. The biggest hurdle facing the development and implementation of the IRRS programme more widely now appears to be the limitations on resources, both within the IAEA and in Member State regulatory bodies, to provide support for both the review missions and subsequent learning workshops. Innovative ways of addressing these difficulties need to be developed. These may include: using regional enhanced self-assessment activities; sharing more widely the results of selfassessments and review missions, for example, through the evolving International Regulatory Network; improving the consistency and thereby the wider applicability of review reports; and providing focused assistance programmes to countries developing new nuclear programmes. All of these should continue to take place within an international programme monitored and coordinated by the IAEA.

1. INTRODUCTION

In the 20 years or so since the IAEA first launched an embryonic regulatory peer review service, the need for, and appreciation of the benefits of, such reviews have altered considerably. What was originally conceived as a vehicle for

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the information and support of regulatory bodies in need of advice and support, has been transformed into an internationally accepted service that, in addition to its original remit, assists the continuous improvement of established regulatory bodies, as well as informing potential regulatory bodies in countries new to nuclear programmes.

This change has been engendered by an increasing understanding of the global nature of the hazard and an improved network of global communication enabling the sharing of knowledge, experience and lessons learned. With the widened remit of the original International Regulatory Review Team (IRRT) and Radiation Safety and Security of Radioactive Sources Infrastructure Appraisal (RaSSIA) missions into the Integrated Regulatory Review Service (IRRS), the opportunity for mature, developing and new regulatory bodies to benefit are all addressed. Additionally, the IRRS mission provides an ideal international vehicle to enable regulatory bodies to demonstrate openness and transparency through information sharing, communications and international cooperation.

There is a growing level of international learning from regulatory review missions through such opportunities as the Convention on Nuclear Safety, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and IAEA workshops dedicated to the IRRS programme.

While the format and direction of these IAEA services to regulatory bodies have changed since their inception, the overall effect and appreciation of their implementation has grown extensively. Most regulatory bodies now recognize the benefits of peer reviews. As an example, European Union Member States have cooperated to incorporate the IRRS concept of international peer review into the 2009 Nuclear Safety Directive.

It is not the objective of this paper to explain the IAEA regulatory peer review service — they are best placed to do that — but rather, to illuminate the various benefits of such peer reviews as perceived by one member of one Member State.

2. HISTORY

In the late 1980s, the IAEA, the European Commission (EC) and a significant number of international senior regulators perceived the need for a structured system of support to regulatory bodies through a peer review process. The IAEA had already piloted this concept on an ad hoc basis, but a more formalized approach was required; a programme for such review mission was thus initiated early in the 1990s. The Guidelines, for what were then called IRRT missions, were developed at this time to provide guidance for all participants in

the mission, in particular the participating experts, in an attempt to ensure the consistency and comprehensiveness of the regulatory review while complementing the expertise of the IRRT reviewers. Following some trials of the guidance concepts, initially with Romania and then separately with the cooperation of the EC, the IAEA IRRT Guidelines were formally issued in April 1993.

Between 1992 and 2004, the IAEA led full-scope missions (where all IRRT modules were addressed) to 12 countries, two of which also had additional reduced scope missions (where selected modules, relevant to the Member State, were addressed); reduced scope missions to a further three countries and 11 follow-up missions. This was a mission load of 28 over 11 years, which, after a slow start, peaked in one year at seven missions. These missions compared (insofar as this was possible) the nuclear regulatory practices in a Member State with existing international consensus guidelines and good practices elsewhere. The bases for each review were formed by the IAEA Safety Standards Series publications, particularly the Requirements on Legal and Governmental Infrastructure and associated Guides, supplemented by the expertise of the IRRT reviewers themselves. The outcome of each mission was a national report identifying a number of Recommendations and Suggestions for the regulatory body to enhance its capabilities in line with the IAEA Safety Standards. The reports also identified good practices for wider dissemination and as a model for improvement by other regulatory bodies.

In 2004, the IAEA established a programme of RaSSIA missions that were designed to provide the IAEA and Member States with a means for assessing progress and effectiveness in establishing a national regulatory infrastructure for radiation safety and security of radioactive sources. Twenty-one missions, mainly to countries without a nuclear power programme, were carried out in 2004, and a further 30 missions in 2005. As a result, a comprehensive and effective programme of control of radiation sources was enabled.

Between 2004 and 2006, the IAEA transformed the IRRT programme and combined it with the RaSSIA programme to develop what has become the Integrated Regulatory Review Service (IRRS). The IRRS is intended to strengthen and enhance the effectiveness of a Member State's regulatory infrastructure in nuclear, radiation, radioactive waste and transport safety and security of radioactive sources, while recognizing the ultimate responsibility of each State to ensure the safety of these facilities and activities. In addition to the IRRT approach of reviewing regulatory practices and technical issues, the IRRS review also offers the opportunity to discuss policy issues affecting nuclear safety. Another fundamental change from the IRRT is that the missions are led by a senior regulator and not by the IAEA.

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Since 2006, the IAEA has facilitated 12 missions ranging from full scope to various levels of reduced scope. A number of these missions have been to countries with established regulatory bodies that have not previously received an IRRT or RaSSIA mission.

3. LEARNING OPPORTUNITIES

Each IRRS mission provides all of the participants, including the regulatory body being reviewed, the reviewers, and the IAEA, with learning opportunities that can be disseminated to the international regulatory community.

3.1. Recipient Member State

As intended, the most powerful learning from an IRRS mission is enjoyed by the Member State regulatory body receiving the mission. The learning process starts with the regulatory body carrying out the prerequisite self-assessment. This self-assessment, a structured review within IRRS programme guidance, forces the regulatory body to examine and report on its organization and arrangements against the criteria of the IAEA Safety Standards. It is also carried out by the people who best understand the strengths and weaknesses of the regulatory body — its own staff. Difficulties may arise when staff do not fully understand the requirements and implications of the IAEA safety standards, but gaining that level of understanding is in itself a step towards organizational learning.

The output of such a self-assessment is a report and a programme of work that the regulatory body considers internally as necessary to improve to meet the IAEA standards. This is a key primary level of self-understanding, without which subsequent learning is not truly effective. Both the report and the programme of work become key components of the advance reference material made available to the subsequent IRRS review team.

Since not all organizations truly appreciate and take cognizance of the depth of understanding available internally, subsequent programmes of work may not be progressed with the appropriate level of commitment that they deserve. This is where a further strength of the IRRS comes into play. The review mission itself is composed of a number of senior experts, internationally diverse, who bring their experience to bear on the recipient regulatory body. This focuses attention, albeit over a very compressed time span, on the issues raised by the self-assessment, new issues identified during the mission, and progress with the programme of work. The subsequent published independent mission report can then provide a forceful driver for continuous improvement and provide additional leverage to secure additional resources for the regulatory body, whether internally or externally.

Other recipient benefits include the accessibility of a team of experts to discuss and advise on national policy issues and concerns in the light of their wider experience and in terms of international good practice. It is also an excellent opportunity for establishing a network of contacts and potentially sympathetic understanding and assistance in future capacity building programmes. For countries with an established regulatory body, this is a strong aid to continuous improvement, and for countries new to the nuclear programme, a significant opportunity to learn from others and get it right the first time.

Example of how IRRS missions benefit the United Kingdom

In 2005, the United Kingdom announced a review of its energy policy. Subsequently, the Health and Safety Executive (HSE) was asked to contribute an expert report to include an assessment of the health and safety risks associated with a new generation of nuclear power stations and in the event of nuclear build, the potential role of pre-licensing assessments of candidate designs. In this context, and at short notice, the UK Government invited a modular IRRS mission, focusing on the topic areas of organization, authorization, and review and assessment. and to review how the HSE proposed to conduct the appraisal of reactor designs in advance of specific proposals for new build.

The IAEA's mission report was extremely helpful in informing the Government's review of its energy policy. The mission was also one of the first to demonstrate that the IRRS process could be successfully deployed in countries with major nuclear programmes and to confirm that the modular approach is an effective way of reviewing practices in such countries.

In 2009, the UK invited a second modular IRRS mission to review progress since the first mission and recent regulatory developments, together with the regulation of, and inspection and enforcement programme for, nuclear power plants and fuel cycle facilities, and the emergency preparedness and response arrangements. In addition, in light of the UK Government's decision to move the nuclear regulatory body to a more autonomous 'statutory corporation', to provide it with more freedom and independence to better meet the challenges of a changing nuclear industry, the IRRS team were also asked to review the proposed transition arrangements.

The IRRS report commended some of the existing regulatory practices and identified further areas where they felt regulatory effectiveness could be improved. The reviewers also closed out many of the findings from the 2006 IRRS mission. In addition, they provided positive and constructive contributions to inform the process of transition to a statutory corporation and provided a

timely reminder to maintain focus on current safety responsibilities while this transition took place.

3.2. Participating experts

The second group that benefits directly from the IRRS process is the participating experts themselves. To participate effectively, they need to reacquaint themselves with the IAEA Safety Standards prior to the mission, to ensure that they are applying the correct criteria when formulating their views. They also need to become acquainted in some detail with the legislative, organizational and operational arrangements of a country other than their own. It is these disciplines, in addition to the individual skills and experience that the expert has already gained, that ensure an effective input by all of the team members to the mission process. This, in turn, leads to a wide sharing of international good practices, not only with the recipient regulatory body, but also between experts participating in the mission.

The participating experts therefore benefit by: consolidating their knowledge and understanding of international safety standards; exchanging best practices, which can be shared in their own country; and developing a network of regulatory contacts for potential subsequent information sharing.

3.3. The IAEA

The IAEA is not an intended direct beneficiary of information gained during IRRS missions, nor does it perceive itself as such; however, it does use the knowledge and insights gained in the reviews to form an overview of issues affecting regulatory bodies internationally. The IAEA is then in a unique position to compile this learning with data from other review missions, international meetings, workshops and conferences in order to provide a synopsis of issues of international regulatory concern for consideration at international fora such as the Convention on Nuclear Safety. This compiled and refined oversight provides invaluable feedback to assist the continuous improvement of the international safety standards and inform the development and future actions of regulatory bodies worldwide.

3.4. International regulatory community

Such understanding by the IAEA, particularly of the need to disseminate learning more widely has led directly to the implementation of regular international workshops to discuss feedback from IRRS missions. This enables regulatory bodies — whether established or in development, and whether

recipients of IRRS missions or not — to be involved in and exposed to the key learning issues arising from IRRS missions. This process leads to a wider pool of regulators exposed to the benefits from and learning opportunities provided by IRRS missions. It also serves to emphasize the need for adherence to international safety standards, which themselves need to be continuously reviewed and enhanced as international experience and learning is taken into account. It also serves to emphasize the benefits of being outward rather than inward looking when developing national safety standards and arrangements.

Example of regional learning

In adopting a common legal framework for nuclear safety, EU Member States took close account of the benefits of IAEA IRRS review missions, and cooperated to incorporate the concept into the 2009 Nuclear Safety Directive. This demonstrates an understanding of the ability of IRRS review missions to strengthen and enhance national regulatory frameworks in order to provide an opportunity to exchange professional experience and to share lessons learned and good practices in an open and cooperative spirit through advice by peers.

The implementation of the programme of regulatory body self-assessment and international peer reviews, required by the Directive, is currently under discussion between the Agency and the EC to integrate the whole process, as far as is practicable, within the IRRS programme.

4. WAY AHEAD

It is well accepted that, in order for the IRRS process to be fully effective, there must be wide international learning from the missions, regardless of which or how many modules are reviewed, and that this goes beyond the participants in the mission. As no process, however well conceived and implemented, can afford to stand still and rest on its reputation, there needs to be serious efforts made to remove potential constraints on the IRRS programme to enable it to continue to flourish.

One of the biggest hurdles facing the wider development and implementation of the IRRS programme appears to be the limitations on resources — both within the IAEA and in Member State regulatory bodies — to provide support for both the review missions and subsequent learning workshops. Innovative ways of addressing these difficulties need to be considered.

To the Agency's credit, it has long recognized some of the constraints and has taken steps to address them. One good example is the development of a web based global nuclear safety and security network, within which an International

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Regulatory Network is planned, which will include areas for IRRS generic safety issues. A further step could be to encourage Member States to include the findings, and subsequent improvement programmes, from their self-assessments onto this database.

Another positive step is the development and launch by the IAEA this year of the Integrated Nuclear Infrastructure Review (INIR) service to provide peer review of Member States' development towards nuclear power, within which modular IRRS missions can be provided to peer review regulatory body activities for countries in the early stages of new nuclear programmes. This step begins to address international concerns on how to identify and meet the needs of such 'new' regulatory bodies.

Nonetheless, there could be value in the IAEA exploring the benefits of some further alternative approaches that, for example, may include the use of regional processes to provide enhanced self-assessment activities, and taking steps to improve the consistency and thereby wider applicability of review reports.

Other aspects that may benefit from consideration, as resources allow, could be the harmonization of IRRS assessment questionnaires with current standards, the encouragement of targeted or modular missions, and improved guidance on the use of good practices. Finally yet most importantly, is the need to provide the necessary resources to the IAEA and within Member States to progress and implement IRRS programmes.

5. CONCLUSIONS

The establishment and implementation of the IAEA IRRS programme provides an unparalleled opportunity for nuclear safety regulatory bodies worldwide to benefit from a structured peer review process, which guides the recipient towards a system of continuous safety improvement in line with international good practices.

The international learning from IRRS missions takes place at several levels, the most significant being through the self-assessment and subsequent review of the regulatory body. This learning is then more widely shared through the reviewing experts taking good practices back to their own countries; by the IAEA compiling and sharing wider issues through international fora such as Conventions; and through the international workshops organized by the IAEA to specifically discuss and learn from the IRRS review missions.

For the IRRS programme to develop in breadth and strength, the Agency needs to explore all of the various methods for achieving its purpose, and for the programme to be resourced appropriately at all levels, both nationally and internationally. The need to find innovative ways forward remains a key concern, as the resource issue will always be a constraint and the need for continuous improvement will always be with us. Whatever options are explored and progressed, they need to continue to take place within an international programme monitored and coordinated by the IAEA.

NOTE

The contents of this paper represent the opinions of the author and should not be attributed to either the UK Health and Safety Executive Nuclear Directorate or the IAEA.

PRACTICAL ISSUES IN FACING THE REGULATORY CHALLENGE OF ENHANCING SAFETY CULTURE IN LEGACY SITE REHABILITATION

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Abstract

The paper discusses the management of the nuclear legacy in the Russian Northwest region in particular, the remediation of facilities, and related spent fuel and radioactive waste management, at the former Shore Technical Bases at Andreeva Bay and Gremikha Village. New regulatory guidance documents have been developed, which are necessary due to the special abnormal situation at these sites, and also due to the transition from military to civilian regulatory supervision and the evolving regulatory system in the Russian Federation. Also discussed is the ongoing work in 2009 on the, development of the radio-ecological basis for identifying radiation supervision area boundaries and a system of recommended dose constraints and derived control levels. Unconditional guarantee of long-term radioecological protection serves as the basis for criteria development. Non-exceedance of these dose constraints and control levels implies compliance with radiological protection objectives related to the residual contamination.

1. INTRODUCTION

In the 1960s, two technical bases of the Northern Fleet were created in the Russian Northwest region at Andreeva Bay in the Kola Peninsula and Gremikha village on the coast of the Barents Sea. They maintained nuclear submarines, performing receipt and storage of radioactive waste (RW) and spent nuclear fuel (SNF). No further waste was received after 1985 and the technical bases have

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since been re-categorized as sites of temporary storage (STSs). After two decades, the Treaty on the Non-proliferation of Nuclear Weapons called for functional decommissioning of a large number of nuclear submarines within a relatively short period, from the late 1980s to the early 1990s. This gave rise to increased attention from the international community to the circumstances in the Russian Northwest region.

The Norwegian Radiation Protection Authority (NRPA) and the Federal Medical-Biological Agency (FMBA) of the Russian Federation have a collaboration programme that forms part of the Norwegian Government's Plan of Action to improve radiation and nuclear safety in the Russian Northwest region. The main focus of the cooperation projects is concerned with regulatory supervision of the management of the nuclear legacy in the Russian Northwest region, in particular the remediation of facilities and sites of temporary storage (STS) and related spent fuel and radioactive waste management. The work has involved major technical inputs from the Russian Federation Burnasyan Federal Medical Biophysical Centre, as well as review and advice on international recommendations and good practice in other countries provided by other technical support organizations.

As one goal of remediation is putting STS into ecologically safe conditions, an elaboration of quantitative radiation-hygiene criteria and norms (requirements for radioecological situation) for STS site and facility end-state conditions is urgent. This paper focuses on work carried out to characterize the STS radioecologically and the development of criteria for remediation of the territory of the STS.

2. RESULTS OF RADIATION SITUATION ASSESSMENT AT SITES OF TEMPORARY STORAGE IN ANDREEVA BAY AND GREMIKHA

When developing remediation criteria and norms, the current radiation situation at STSs was taken into consideration as well as the predicted radiation situation that might exist during SNF and RW removal.

In 2005–2009, more than 500 samples of environmental media, local foods and drinking water were collected in Andreeva bay and Gremikha village expeditions; moreover, additional ambient dose rate monitoring was implemented. Gamma-spectrometry and radiochemical methods were applied for sample measurements. The obtained results served as a basis for calculating the current doses to workers and the public, and for the prognostic assessment of future doses.

Gamma dose rates were recorded from background level up to 142 $\mu Sv/h$ in Andreeva Bay STS and up to 8500 $\mu Sv/h$ in Gremikha STS. Maximum levels

were observed near radiation-hazardous facilities, where the gamma dose rate is due to radiation from contaminated soil and from radioactive substances inside the storage facilities.

At the territory of STS industrial sites, man-made contamination of the soil surface with ¹³⁷Cs and ⁹⁰Sr is observed, exceeding local background values by a factor of up to 100 times or more. Levels of soil contamination with ¹³⁷Cs are four to 20 times greater than those of ⁹⁰Sr. The territory of industrial sites of Gremikha STS are also contaminated with ⁶⁰Co (9.7×10^2 – 2.3×10^5 Bq/kg), ¹⁵²Eu (3.3×10^2 – 7.5×10^5 Bq/kg) and ¹⁵⁴Eu (2.2×10^2 – 7.5×10^5 Bq/kg). Within the Andreeva Bay STS, contamination of the soil was detected at depths as deep as 15.6 m.

The concentration of ¹³⁷Cs in bottom sediments of the coastal strip at STS in Andreeva Bay is 100 Bq/kg near the mouth of the former brook and 36 Bq/kg behind the health protection zone barrier. The health protection zone is an area of administrative and technical provision of the STS. The concentration of ⁹⁰Sr in the same bottom sediment samples is 36.6 and 2 Bq/kg, respectively. Locally, the concentrations of ¹³⁷Cs and ⁹⁰Sr in seaweed moderately exceed background values for ¹³⁷Cs and are more than 50 times the background values for ⁹⁰Sr. However, off-site, the seaweed contamination is small, similar to background values. However, when assessing the dynamics of radioactive seaweeds contamination, some tendency is observed of ⁹⁰Sr accumulation in sea vegetation due to releases of STS activity.

Environmental radiation monitoring demonstrated significant exceeding (in comparison with typical background values) of ¹³⁷Cs and ⁹⁰Sr contents at local parts of the coastal strip of STS health protection zone in seawater, seaweeds, bottom sediments, vegetation and soil. Results of radionuclide sorption examination in soil and underground water allow to assume the presence of effective migration from contaminated areas via groundwater, causing radioactive material inflow into offshore marine waters. Bearing in mind the possibility of further contamination of the STS area, a dynamic surveillance is needed of the radiation situation during both routine activity and SNF and RW removal.

The on-site measurements suggest that remediation work will have to be planned so as to take account of the on-site contamination in two ways. First, the activity levels will present external and internal irradiation hazards to remediation workers. Second, the SNF removal work must be planned so as not to disturb and hence release significant contamination from the sites.

According to the radiation monitoring of catches in the STS off-shore marine environment, the concentration in fish is in the range 0.7–13 Bq/kg for ⁹⁰Sr and 0.4–35 Bq/kg for ¹³⁷Cs, being significantly lower than actual Russian accepted radiation contamination levels. With the aim of radiation exposure

restriction during large scale STS remedial work, FMBA of the Russian Federation established a public radiation dose quota of 100 μ Sv/a due to effluents and 30 μ Sv/a due to radioactive discharges.

3. NORMS OF REMEDIATION

Remediation criteria and norms defining requirements for radiation protection of workers and the public, and limits of environmental contamination were developed for three main options: conservation (monitoring and controlling current situation), conversion (partial or overall renovation) and liquidation (to green-field unrestricted use), in the form of:

- Dose limits and dose constraints for workers during remediation operations;
- Dose limits and dose constraints for the public during remediation operations and after they are completed;
- Levels of radioactive superficial contamination of workshops and on equipment inside them;
- Concentration of radionuclides in marine media, including fish;
- Concentration of radionuclides in underground waters on-site STS.

The STS in Andreeva Bay is not likely to be used for direct purpose in the future. The planned operations are associated with preparations and removal of SNF and RW from the territory with subsequent liquidation or conservation of the buildings and other constructions, and decontamination of the territory. We assume that at STS in Gremikha, in addition to environmental rehabilitation operations, the remediation and reconstruction of the infrastructure for unloading and following interim storage of NS core reactors with liquid-metal coolant is required.

The Federal Medical-Biological Agency of the Russian Federation has approved norms for the main options of the STS remediation, based directly on the output from the NRPA-FMBA collaboration programme. They have been developed on the basis of actual Russian laws and standards and taking account of the unusual radiation situation existing currently at the STS. The norms were developed in terms of contemporary international recommendations and experience in the field of contaminated area remediation in other countries.

4. CONCLUSION

The work carried out is an important step forward in the improvement of regulation of radiation and nuclear safety during STSs operations. Current output has included the following regulatory guidance and documents:

- Initial Threat Assessment for the situation at STSs, identifying priority issues for regulatory supervision;
- Guidance: 'Criteria and norms on remediation of sites and facilities contaminated with man-made radionuclides';
- Guidance: 'Hygienic requirements for personnel and public radiation safety guaranteeing at the stage of designing the work with SNF and RW at STSs';
- Guidance: 'Arrangement of the environmental radiation monitoring in the operational area of the STSs',
- Guidance: 'Personal dose monitoring of occupational exposure';
- Guidance: 'Arrangement of environmental radiation monitoring in the operational area of the STS'.

The environmental radiation monitoring findings served as a basis for setting up an associated databank. The environmental measurement results have been plotted on an electronic map of the site. Further work in progress in 2009 will lead to the development of a full geographic information system. This will allow to calculate the main indices for the simulation and prognosis of the radioecological situation (as identified in Section 3), in order to enhance radiation safety supervision.

CLOSING SESSION

Report of the Conference President¹ The Honorable Gregory B. Jaczko Conference President Chairman, United States Nuclear Regulatory Commission, Washington, D.C., United States of America

BACKGROUND TO THE CONFERENCE

The second international conference on Effective Regulatory Systems was held in Cape Town, South Africa, between 14 and 18 December 2009 as a follow up to the earlier conference on the same subject held in Moscow in 2006. The purpose of this conference was to stress the importance of a strong, effective global nuclear safety and security regime, and the responsibility that all nuclear regulators, operating organizations and vendors have in maintaining it. Conferences like this are a vital part of the global effort for senior nuclear safety and security regulators to review issues important to the global nuclear regulatory community, focused on the important role regulators play in safety and security. A regulatory system is effective when it ensures that a high level of safety, security and safeguards is being maintained by licensees/operating organizations; when it takes appropriate actions to prevent the degradation of safety and security, when it takes actions to promote safety and security improvements; when it performs its regulatory functions in an independent, transparent, timely and efficient way and it strives for the continuous improvement of itself and the industry.

The conference reviewed achievements since the first conference in Moscow and also addressed current and future challenges. Since the 2006 Moscow conference, the nuclear industry and regulatory bodies continue to face challenges: the need to maintain focus on the safety and security of existing nuclear facilities in a rapidly changing world; the renewed and expanding global interest in the use of nuclear energy for electricity generation; the continued importance of maintaining high levels of safety and security for the world's

¹ The views and recommendations expressed here are those of the President of the Conference and the participants, and do not necessarily represent those of the IAEA.

operating nuclear power plants; the need for safety and security to be well coordinated; the increased global use of radioactive materials; the need to ensure a strong safety and security culture, and the need to pay due attention to radiation protection and research reactors, which are also challenges for the regulators.

This conference took stock of a three decade long effort by Member States, the IAEA and other international organizations to strengthen the safety and security of the use of nuclear and radioactive materials through strong national infrastructures and consistent international dialogue. This regime has been established as a cooperative mechanism to share principles, norms, rules and decision making procedures to achieve shared goals in nuclear safety and security while preserving and complementing the sovereignty, authority and ultimate responsibilities of States.

CONFERENCE OBJECTIVES

The objectives of this were to review and assess the effectiveness of the global nuclear safety and security regime, and to propose specific actions to further enhance it in areas such as:

- Establishing and maintaining independent and effective national regulatory systems, given the challenges of:
 - Launching new nuclear power programmes;
 - Undertaking new builds after a long time interval in those countries with existing nuclear power programmes;
 - Addressing the increase in radioactive materials and radiation applications;
- Prioritizing and addressing emerging issues concerning multinational and national responsibility for nuclear safety and security;
- Fostering effective international cooperation among regulators for the sharing of regulatory knowledge, practices and information.

OPENING SESSION

The Opening Session comprised two parts.

Opening addresses

The opening addresses outlined the importance of international cooperation among nuclear regulatory bodies for effective nuclear safety and

security regulation at the national and international level. This role is particularly important given the increased interest in nuclear power worldwide, related, in part, to an enhanced focus on climate change. In this context, mature regulatory bodies should consider support for new countries, better control of radioactive sources, and enhancement of international cooperation for the global nuclear safety and security regime, including application of international legal instruments, knowledge networks, safety standards and security guidance. Regulators should also focus on developing an open, transparent process with appropriate mechanisms for interacting with the public. In addition, regulators should take steps to ensure they have sufficient resources to address an increasing volume of work in the coming years.

The presentations highlighted the role and responsibility of governments for global adherence to international instruments relevant to nuclear safety and security, in establishing and maintaining the legal and governmental infrastructure for nuclear safety and security; the role of an effective regulator at national and international levels, the expectations of society and the role of international organizations for assuring an effective global nuclear safety and security regime.

It was emphasized that while safety performance indicators have shown steady improvement over the last two decades, it is necessary to avoid complacency and to continuously improve and strengthen the existing global nuclear safety and security regime so that the use of nuclear technologies can be introduced or expanded in a safe and credible manner to meet the world's needs for human well-being, environmental protection, growth and development. Furthermore, nuclear regulation is a global responsibility, and the conference should be seen as an opportunity to implement concrete proposals for actions.

Keynote Panel: Addressing Needs and Challenges in Global Nuclear Safety and Security. What are the Priorities?

The Keynote Panel presented and debated policy and technical issues in nuclear safety and security that benefit from international cooperation between governments, regulatory bodies and international organizations. The panellists addressed the following points:

— An effective regulatory programme is a prerequisite to any nuclear programme. Regulatory programmes, including adequate capacity building mechanisms, are essential components of the national safety and security infrastructure.

- The more globalized and dynamically changing world involves new technologies and shifts in the working environment. This requires new strategies for regulators and harmonization of regulatory approaches, where appropriate.
- Competence of the regulatory body staff is essential. Competence needs to be developed and maintained through effective capacity building, including education and training programmes.
- Sharing of experiences and lessons learned among regulatory bodies for effective nuclear regulatory systems are very valuable. Regulatory peer reviews, knowledge networks and review meetings of international instruments are highly effective tools for promoting the sharing of experience and mutual learning.
- Ageing of plants need to be considered from the beginning in the development or expansion of nuclear power programmes.
- Knowledge networking to share experience and lessons learned and to build a common safety and security culture are key elements for capacity building and safety and security infrastructure. The Asian Nuclear Safety Network, the Ibero American Network for Regulators (FORO) and the recently created forum of nuclear regulatory bodies in Africa were mentioned as examples.
- Current regional and international cooperation efforts contribute to safety and security improvements; however, better coordination would enhance their effectiveness. In this context, the vital role of the IAEA was emphasized.
- Regulators and operating organizations should share and learn from operating experiences and seek to identify and use best practices for the improvement of their regulatory systems.

TOPICAL ISSUE 1: EMERGING REGULATORY CHALLENGES

This session addressed the challenges associated with regulating new and existing nuclear power programmes and radiation applications. This includes maintaining a high level of safety and security in existing nuclear power programmes, launching new nuclear power programmes; undertaking new reactor builds after a long time gap in the countries with existing nuclear power programmes; establishing national strategies for waste management and decommissioning; regulating medical activities and the mining industry; and addressing the threat of nuclear and radiological terrorism, and strengthening related assessment and response activities. The conference noted the following points:

- The need for regulators and operating organizations to avoid complacency, to strive for continuous improvement, to share operating experiences and use best practices.
- The importance of having a sufficient number of well trained and experienced regulators and the potential need for additional IAEA safety standards and security guidance on training issues.
- The important role of regional and international organizations in maintaining and ensuring the global nuclear safety and security regime. Safety and security both involve a broad group of stakeholders, such as regulators, operating organizations, vendors, non-governmental organizations (NGOs), law enforcement agencies, etc.
- Regional approaches are important and are needed to bring together regulators and other organizations to share and facilitate mutual learning. The new Forum of African Regulatory Bodies was raised as a good example.
- More countries are considering safety and security in a more coordinated, synergistic and integrated manner, when appropriate.
- The need for international organizations and associations to work together to foster harmonization of approaches to safety and security, operations, regulations, and training.
- The need to address the challenges related to the changing nuclear power environment, the evolving security situation and the growing numbers of countries interested in nuclear power and new builds.
- The need for countries embarking on nuclear power to become party to and effectively implement international instruments related to nuclear safety and security, and to develop national legal frameworks and clear regulatory direction and guidance.
- The need for effective transparency with respect to the public.
- The need to utilize both technical and human measures to ensure safety. The discussion focused on the management of these measures and the need for increasing technical measures in the design of new reactors.
- That waste management and decommissioning of facilities remain important challenges for existing nuclear power programmes and that countries embarking on new nuclear power programmes should consider these issues at the very beginning of their national planning process.
- The importance of regulating the mining industry, in particular in developing countries for sustainable protection of workers, population and the environment.
- The importance of regulating medical facilities to prevent accidents and unnecessary exposure of patients and workers, while allowing for effective patient diagnosis and treatment procedures.

- The importance of openness and transparency of regulatory programmes through IAEA safety and security peer reviews, such as Integrated Regulatory Review Service (IRRS) missions and advisory services to build public confidence in national regulatory programmes.
- The importance of a robust safety infrastructure and proper consideration of ageing of existing facilities in the current context of countries embarking on nuclear power or expanded nuclear programmes.

TOPICAL ISSUE 2: REGULATORY INDEPENDENCE AND EFFECTIVENESS

This session continued discussions on key elements and attributes of effective regulatory independence and proposed means by which effective independence of national regulators could be advanced. The session also focused on issues related to establishing, maintaining, measuring and continuously improving regulatory effectiveness, openness and transparency, stakeholder involvement and self-assessment peer review missions, competence and knowledge management. The conference noted the following points:

- Independence of the regulatory body is important for all regulators. The understanding and interpretation of regulatory independence has evolved since the introduction of the Convention on Nuclear Safety. An updated definition is needed that takes into account the need for independence from undue political and economic influences; sufficient human and financial resources, staff competence, and availability of in-house or external technical support organizations, transparency and international cooperation. It was also emphasized that independence does not imply isolation.
- International interest in strengthening independence was demonstrated with examples such as improvements to the IAEA safety standards, in particular GS-R-1 revisions, the new European Directive on Nuclear Safety, and the interest of some regulators to involve foreign senior regulators or technical support organizations (TSOs) for advice in making their own decisions.
- Independence of the regulatory body is particularly important when difficult regulatory decisions need to be made such as in the case of the fragile production of radioisotopes in research reactors for medical applications.
- Improving regulatory effectiveness is also connected with the leadership needed to achieve a high level of safety. Leadership is necessary to provide transparent, open and effective communications to licensees to maintain their focus on safety.

- Regulatory approaches are different from country to country; however, the overarching safety objectives to protect people, society and environment are common. Harmonization of regulatory approaches will contribute to improve common understanding.
- In regulatory decision making, regulators need to constantly balance many factors. These factors include safety, security, safeguards and public accountability.
- Openness and transparency are fundamental elements to achieve stakeholder confidence. However, there are needs to protect certain sensitive and classified information. Nevertheless, the policy and criteria for protection of such information should be properly communicated to stakeholders.
- Regulators must be fully responsible for their own judgments and decisions, even when based on TSO work. They should be able to analyse and make use of the work done by TSO in support of their regulatory activities. Further discussions regarding the role of TSOs and the support they provide to regulatory bodies will take place during an international conference in Tokyo, Japan, in October 2010.

TOPICAL ISSUE 3: IMPACT OF MULTINATIONAL ACTIVITIES ON THE NATIONAL RESPONSIBILITY FOR NUCLEAR SAFETY AND SECURITY

This session addressed regulatory oversight of multinational activities, interface between nuclear safety and nuclear security, safety and security culture, industry challenges in working in a multinational environment, production and international distribution of radioactive sources and medical isotopes and the European Union nuclear safety directive as a legal framework to strengthen national responsibilities for nuclear safety. The conference noted the following points:

- In recent years, national regulators have started an active co-operation at the bilateral, multinational and international level by regulatory forums, senior regulators meetings and the implementation of IAEA IRRS missions, to respond to the challenges coming from the globalization of the nuclear business, the new comers and to the expected nuclear new build in many countries.
- International cooperation and coordination activities and mechanisms are essential. Regulators should continue working together to harmonize requirements and approaches between countries. Regulators should consider establishing dedicated forums to exchange information on safety

and radiation control matters. Global and regional networks should be established and maintained, where possible, to include regulators, operating organizations, vendors and other stakeholders.

- Human factors are essential in maintaining a high level of nuclear safety and security worldwide. Regulators should consider promoting continuous improvements to reach and maintain the highest levels of safety and security culture.
- Consistent and comprehensive bases and rationales for regulatory decisions are necessary. Transparency of the regulatory process and good communication with stakeholders is of vital importance to help their understanding of the situation. IAEA safety standards can be used to support regulatory decisions.
- The transfer of knowledge and experience from countries with mature regulators to those embarking nuclear power is essential. It is necessary that the new entrants develop their own strategy and plans for building their regulatory body and for gaining the necessary knowledge to develop their capacity. Coordination and cooperation activities from the IAEA and bilateral or multilateral support are vitally important, but they cannot replace the responsibility of the regulatory body of the country embarking on nuclear power.

TOPICAL ISSUE 4: INTERNATIONAL SAFETY AND SECURITY COOPERATION

This session addressed the application of the IAEA safety standards, security guidance and operational experience; the use of global and regional knowledge networks; experience with legally binding and non-binding international instruments; international regulatory feedback systems; lessons learned from national IRRS missions; and integration of safety supervision across different types of legacy sites in all stages of remediation. The conference noted the following points:

— There is a need to strengthen regional and global regulatory forums and networks to improve regional cooperation and knowledge management, to share the results of regulatory self-assessments and peer reviews, and to disseminate lessons learned to create better opportunities for improving the regulatory performance. Regional networks have been successfully established in Asia, Europe, Ibero-America and Africa to strengthen the global nuclear safety and security regime.

- There is an extensive use of IAEA safety standards by regulators to develop and update their regulatory system to achieve and maintain a high level of safety. Adapting and adopting IAEA safety standards in accordance with national arrangements are becoming a more common practice.
- Feedback from the application of IAEA safety standards by regulators and industry is important for amendments and necessary updates. The time for developing and updating standards should be in proper relation to the review cycle of standards. The updating of standards should give due consideration to consequences for countries using such standards for their national legal systems as well as for operators.
- Significant progress has been made in the past years on developing and enhancing regional regulatory networks. Web site portals for global networking are being developed including the Convention on Nuclear Safety web site.
- Regulatory portals and thematic regulatory networks, such as the Regulatory Network (RegNet), are considered to be useful tools for international regulatory cooperation. These tools are also useful in support of IAEA peer reviews and advisory services.
- Binding and non-binding international instruments are increasingly being adopted to help States harmonize their national approaches and gain insights on how to address common issues. Significant issues regarding the interpretation and application of these instruments should continue to be routinely assessed to improve the effectiveness of the review meeting process. Also the incentive 'peer review' approach embodied in the instruments should continue to be developed to encourage effective implementation by States Parties.
- For many States, particularly those embarking on new nuclear programmes, assistance from States with established programmes and greater resources will be necessary to help ensure global safety and security.
- The IRRS programme is a unique worldwide opportunity for continuous improvement and harmonization of the regulatory systems through a structured self-assessment and peer review process. IRRS missions provide benefits at the national, regional and international level, as well as to those participating in them.
- International cooperation and support from IAEA needs to include regulatory supervision of decommissioning and license termination so as to avoid the creation of new legacy sites. Regulatory experience from countries that are already meeting nuclear legacy site challenges can support this international effort. Regulatory authorities from countries are exercising supervision over existing nuclear legacy sites are encouraged to

share and gain advantage from international cooperation activities on this issue.

CLOSING SESSION

The Closing Session comprised two parts:

Panel Discussion — Actions to Enhance the Global Nuclear Safety and Security Regime

This Closing Panel Discussion was based on the results and conclusions of the various sessions and was the capstone of the week's activities. The discussion also addressed the challenges identified during the conference to develop the convergent views on actions for enhancing the effectiveness of the global nuclear safety and security regime.

The main expectations of the Conference can be summarized as follows:

- (1) The Regulatory Cooperation and Coordination Initiative for the safe introduction and expansion of nuclear power programmes;
- (2) Long term management of radioactive sources from cradle to grave;
- (3) Capacity building and human resource development;
- (4) Regulatory effectiveness and independence;
- (5) Safety and security synergy and coordination;
- (6) Regulatory supervision of legacy sites and remediation.

SUMMARY AND CONCLUSIONS OF THE CONFERENCE

The second part of the concluding session was the presentation by the President of the Conference of the summary and conclusions of the Conference including visions, strategies and actions for the future as well as issues for consideration by governments, regulatory bodies and international organizations.

The conference concluded that the following issues and actions should be addressed by the relevant stakeholders.

Issues for consideration by governments

— Governments should ensure that national regulatory bodies have sufficient financial and human resources to establish staffing plans and training programmes to effectively discharge their functions and responsibilities.

- Countries should contribute to global and regional networks and knowledge sharing mechanisms such as the global nuclear safety and security network (GNSSN) and RegNet. The IAEA will report the status of participation for these portals in its annual report.
- Countries embarking on nuclear power should become party to and effectively implement relevant international nuclear safety and security instruments. IAEA safety standards and security guidance are important tools to assist these countries in developing their national regulatory infrastructure for nuclear safety and security.
- Countries building new nuclear facilities should consider waste management and decommissioning of facilities from the very beginning of any national plans for new nuclear programmes.
- The concept of independence and transparency of the regulatory body should be further developed at the next review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2011 to reach a common understanding and to agree on new definitions. The concept should not only address effective separation of regulatory functions from promotional functions and protection against undue influences but also ensure a balanced approach taking all aspects relevant for regulatory decision making into account.
- Countries embarking on nuclear power should develop their own strategy and plans for building their regulatory body and for gaining the necessary knowledge and develop their capacity building, using IAEA support and bilateral or multilateral support.
- Countries should consider that high demand for IRRS missions worldwide requires significant IAEA resources. Countries should recognize that the success of safety reviews depends on the participation of the best senior experts from Member States. Countries should make all necessary efforts to involve their best regulators in these reviews.
- Countries should work bilaterally and multilaterally with the IAEA and other international organizations to identify and promulgate nuclear security best practices through workshops and guidelines.

Issues for consideration by regulatory bodies

— Regulatory bodies should establish means and measures that are appropriate for their national programmes to prevent complacency and to foster continuous improvement of safety and security practices (e.g. safety day, regular dialogue between regulators, operating organizations and other relevant stakeholders).

- Regulators should establish dedicated forums to exchange information on safety and radiation control matters.
- Regulatory bodies should further strengthen transparency with respect to the public.
- Regulatory bodies should exercise their leadership to keep all stakeholders focused on meeting the safety and security objectives and to promote a strong safety and security culture, with particular emphasis on human factors.
- Regulatory bodies should further harmonize their regulatory approaches and requirements, with due consideration of national arrangements and national safety policies to improve understanding, minimize regulatory uncertainties, and facilitate regulatory decision making processes.
- Regulatory Bodies should acquire and maintain the necessary competence and knowledge to ensure their own decision making capabilities and independence from any advice from TSOs they may receive. This topic should be discussed in the technical support organization conference in Tokyo in October 2010.
- Regulatory bodies should continue their active co-operation to respond to the challenges coming from the internationalization of the nuclear business and to the expected nuclear new build in many countries, e.g. through cooperation in the Multinational Design Evaluation Programme.
- Regulators need to find new and effective approaches to address the changing environment affecting nuclear issues.
- Regulators should contribute to an international inventory of so-called 'orphan research reactors' worldwide, in order to minimize safety, security and non-proliferation risks.

Issues for future international cooperation

- The IAEA, other international organizations and Member States should enhance the coordination and cooperation in human resources development and education and training.
- All national and international organizations responsible for safety and security should strengthen synergies and coordination.
- Governments and regulatory bodies should harmonize approaches to safety, security, operations, regulations and training. International organizations and associations, such as the IAEA, the European Union, WHO, OECD/Nuclear Energy Agency, ICPO–Interpol, World Customs Organization, World Association of Nuclear Operators, World Institute for Nuclear Security, World Nuclear Association, vendors and operating organizations can help in this effort.

- The IAEA should work with WHO to better define respective roles and responsibilities of the nuclear safety regulator and the authorities in charge of the safety of medical devices.
- The IAEA and Member States should strengthen regional regulatory forums and networks to share regional cooperation, knowledge management, self-assessments of the regulatory system and international lessons learned to create better opportunities for improving the regulatory performance.
- The IAEA should publish safety standards and security guidelines in an appropriate time frame and should try to keep the standards and guides as stable as possible.
- Guidance on developing regulatory standards for legacy sites should be developed. The IAEA and Member States should develop and strengthen the platform for sharing experience and information on regulatory challenges at legacy sites. This topic should be addressed within the framework of the international Forum for Regulatory Supervision of Legacy Sites.

Issues for consideration by stakeholders

- Operating organizations, regulators and associations should establish better methods for sharing experience feedback. Actions should be taken to use experience feedback to enhance safety and security by implementing improvements from lessons learned.
- Countries, international organizations and regulators should keep in mind that while new builds represent a significant challenge, due attention must be paid to existing nuclear power plants, radiation control and research reactors.

CONCLUSION

The Conference thanked the Government of South Africa for hosting this 2nd International Conference on Effective Nuclear Regulatory Systems. It requested the IAEA, together with the other international organizations, to implement the action items for international cooperation resulting from this conference. The Conference valued this forum and agreed that the head regulators should meet again within three years to review the progress arising from the findings of this conference.
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In 2006, the IAEA convened the first international conference on effective nuclear regulatory systems, in Moscow. This conference brought together senior nuclear safety, radiation safety and security regulators from around the world to discuss how to improve regulatory effectiveness to ensure protection of the public and the environment. At that meeting, senior regulators decided that a forum dedicated to discussing regulatory effectiveness was needed every three years. Accordingly, the IAEA organized this second conference, in Cape Town in December 2009, which focused on further enhancing the global nuclear safety and security regime, and proposed future actions to further enhance it. These proceedings include: a summary; the opening and closing speeches; the invited papers and the President's summary. A CD-ROM, which is attached to the back of this publication, contains the contributed papers and presentations.

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