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Progress with the revision of the Euratom Basic Safety Standards and consolidation with other Community legislation

Janssens, Augustin
European Commission, Directorate-General for Energy and Transport, L-2920 LUXEMBOURG

Abstract
The revision of the Euratom Basic Safety Standards (Directive 96/29/Euratom) was undertaken to allow for the new ICRP Recommendations (Publication 103) as well as to consolidate all radiation protection legislation in a single BSS Directive. In line with ICRP the new Directive will allow for the three exposure situations: planned, existing and emergency. This required significant restructuring, together with the consolidation or recast. The new Directive will fully integrate all natural radiation sources, introducing more binding requirements for NORM industries, building materials, radon in dwellings and workplaces. The protection of the environment is now within the scope of the Directive. The Directive develops the concept of a graded approach to regulatory control, so that it is commensurate to the risk and to the effectiveness of such controls. In this context also the concepts of exemption and clearance have been worked out in more detail and new consideration is being given to the harmonisation of exemption and clearance levels. Further issues that emerged from the revision process are the definition and use of constraints and reference levels, as introduced by ICRP, and the principle of justification, in particular with regard to the deliberate exposure of people for reasons other than medical (e.g., for security screening). The revision and recast process was completed in February 2010. Harmonisation with the International Standards (IAEA and co-sponsors) is vigorously pursued in view of co-sponsorship by Euratom.

1. Consolidation of the Community legislation
The Community *acquis* in radiation protection, derived from Title II, Chapter 3 of the Euratom Treaty, constitutes a comprehensive and evolutionary legislative framework, with the Basic Safety Standards Directive (EU, 1996) as principal piece of legislation, and supplemented by eight binding instruments (Directives, Regulations, Decisions in addition to non-binding Recommendations and Communications).

The Commission undertakes the simplification of its "*acquis*" of Community legislation by the codification of related acts (without modification, e.g., amendments or complementary legislation) or recasting these if necessary (e.g., allowing for different definitions). Such recast will be undertaken for the five main Directives (all except shipment of radioactive waste (EU, 2006)). The very recent Council Directive

2009/71/Euratom on nuclear safety of nuclear installations was not considered for a recast at the present stage. In addition to the Basic Safety Standards, this recast thus concerns the following Directives:

- Medical applications of ionising radiation: Directive 97/43/Euratom (EU, 1997)
- Information in case of radiological emergency: Directive 89/618/Euratom (EU, 1989)
- Protection of "outside workers": Directive 90/641/Euratom (EU, 1990)
- Control of high-activity sealed radioactive sources and orphan sources ("HASS Directive"): Directive 2003/122/Euratom (EU, 2003).

The Basic Safety Standards Directive had introduced in 1996 some new features. A specific Title VII was introduced for the regulatory control of "work activities" involving natural radiation sources. With the exception of aircrew exposure, the Directive left the responsibility for the identification of work activities (NORM industries and workplaces with high radon concentrations) with national authorities. This flexibility was needed in order to achieve consensus on the inclusion of these new features at a time when there was little experience with such matters. The experience gathered since 1996, with transposition in national legislation (due by May 2000) and with operational implementation, demonstrated a need for enhanced harmonisation. Thus a revision of the Basic Safety Standards was undertaken amongst others to strengthen and broaden the requirements on natural radiation sources.

2. Revision of the Basic Safety Standards

The Community's Group of Experts established under Article 31 of the Euratom Treaty had established a four year work programme for the revision of the Basic Safety Standards. Initially it followed a topical approach. Working Parties took on board the redrafting of requirements on natural radiation sources, on exemption and clearance, and on a graded approach to regulatory control. Specific attention was given to the requirements on Education and training as well as to the definition of the responsibilities and qualifications of the Radiation Protection Expert, the Medical Physics Experts, and Radiation Protection Officer.

2.1. Exposure Situations

The revision of the Euratom Basic Safety Standards took account of the ICRP recommendations in Publication 103 (ICRP, 2008). While these do not necessarily require major changes in regulatory requirements, the Commission undertook to structure the requirements along the concepts of planned, existing and emergency exposure situations.

The distinction between the three exposure situations proved very helpful in structuring the Standards. However, very precise definitions are needed in a regulatory context, rather than the somewhat loose descriptive formulations in ICRP Publication 103.

For instance, ICRP defines a planned exposure situation merely as one involving the planned operation of sources. Existing exposure situations relate to "sources that already exists when a decision on control has to be taken". We strongly believe that when an activity significantly affects or alters an exposure situation caused by existing sources, such as NORM (Naturally Occurring Radioactive Material) or cosmic radiation, this is a planned exposure situation. Hence NORM industries and the exposure of aircrew are planned situations and the activities can be labelled as practices.

On the other hand, NORM materials with levels of activity concentration that are common in the earth's crust should be exempted from the requirements for practices. The boundary is established through identification of those types of NORM industries that should *a priori* be managed as a practice. The concept of a threshold in activity concentration, for the application of requirements for practices, matches the concept of exemption from such requirements. The new Directive has introduced the values of 1 Bq/g for U-238/Th-232 and 10 Bq/g for K-40 taken from IAEA RS-G-1.7 (IAEA, 2004), together with a graded approach to regulatory control using dose thresholds of 1 mSv and 6 mSv per year.

Truly existing exposure situations are those for which the exposure results from where you are, rather than what you do. Radon ingress in a dwelling, from soil, is not related to any activity, so it yields in general an existing exposure situation. Any exposure at work, not necessarily resulting from the work, is however the responsibility of the employer. High levels of radon in the workplace thus should be subject to a reference level, to a threshold for the management as a planned exposure situation (which may be the same as the reference level) and to the dose limit for workers.

There are other boundaries where pragmatic choices need to be made. The production or import of commodities clearly is an activity. However, if the radioactive substances arise from an existing exposure situation, then it is more convenient to manage such commodities in the same context. Hence, building materials and contaminated food are managed under the heading, “existing exposure situations”.

An emergency exposure situation eventually leads to the existing situation of living in a contaminated area. The delineation in this case requires a management decision.

In earlier drafts of the new Directive the provisions for emergency and existing exposure situations had been laid down in specific titles. Later if was found preferable to have, for example, all aspects of occupational exposure, including emergency workers and the follow-up to accidental exposure of workers, in a single title. Hence there is a title on “justification and regulatory control of planned exposure situations”, but the chapters on the protection of workers, patients and members of the public are no longer part of an overall title on “planned exposure situations” (as is the case with the current draft of the international standards.) It was proposed to have a clear 3 x 3 matrix structure with the categories of exposure (occupational, public and medical) on the one hand, and the three exposure situations on the other hand. (see Table 1).

Table 1. New matrix structure of the Euratom BSS.

OCCUPATIONAL EXPOSURE	PUBLIC EXPOSURE	MEDICAL EXPOSURE
Planned exposure situations	Planned exposure situations	Planned exposure situations
Emergency exposure situations	Emergency exposure situations	Emergency exposure situations
Existing exposure situations	Existing exposure situations	

2.2. Emergency exposure situations

The new management scheme for emergency exposure situations builds on recent guidance of ICRP (ICRP, 2009). The old approach of an emergency plan with different *intervention levels* is replaced by a more comprehensive system:

– threat analysis;
– overall emergency management system;
– emergency response plans for identified threats;
– pre-planned strategies for the management of each postulated event.

The key difference is that each strategy should aim at keeping doses below the *reference level*, optimising the available preventive and protective actions rather than justifying each action. New Annexes list the elements to be included in the management system and in the emergency response plan.

2.3. Natural radiation sources

The Working Party of the Article 31 Group of Experts on natural radiation sources undertook in the first place the harmonisation of the identification and regulatory control of NORM-industries. The Working Party agreed on a "positive list" of types of industries that will be subject to controls in all Member States. It will be the task of the national authorities to inform the concerned industries and to make sure that they understand the radiation protection issue and take, if necessary, appropriate measures to reduce exposures within the overall Health and Safety policy of the undertaking.

The industries (those listed and such other industries as identified at national level) will be requested to investigate activity concentration levels at any point of their process. On the basis of an assessment of occupational exposures in identified industries a graded approach to regulatory control will be applied. Where doses are all below 1 mSv per year, the practice is exempted. Where doses are in the range of 1 to 6 mSv per year the only requirement is to review whether optimisation calls for further reduction of exposures, and whether the exposures remain broadly the same over many years. Since there is in general no risk of accidental exposure, there is no need for individual dosimetry or medical surveillance. In the exceptional case that doses exceed 6 mSv per year the full set of requirements for classified workers will apply.

In the same way as for practices involving artificial radionuclides, the concepts of exemption and clearance should merge (even more so, since the output of one NORM industry often is the input to another). The values proposed for this purpose in earlier Community guidance (Radiation Protection 122 part II (EC, 2000)) were 0.5 Bq/g for (U238/Th 232 and 5 Bq/g for K-40, on the basis of an exemption criterion of 300 µSv per year for natural radiation sources. The values endorsed for the sake of international harmonisation (RS-G-1.7), twice as high as in (EC, 2000), are not always suitable for clearance of residues from NORM industries. The Euratom Directive therefore establishes unambiguously that the values in RS-G-1.7 for naturally occurring radionuclides apply neither to the recycling of residues into building materials nor to situations where there is a specific risk such as groundwater contamination.

While NORM industries and the exposure of aircrew are managed as planned exposure situations, a management system for existing exposure situations applies to:

– building materials;
– radon in dwellings and public buildings (workplaces are considered either as an existing or as a planned exposure situation).

An indicative list of types of building materials considered for control in view of the emitted gamma radiation has been included in an Annex. On the basis of earlier guidance (EC, 1999), requirements for the placing on the market and use of building materials have been incorporated in the Basic Safety Standards. The activity concentration index I :

$$I = C_{Ra226}/300\ Bq/kg + C_{Th232}/200\ Bq/kg + C_{K40}/3000\ Bq/kg$$

may be translated into two classes of building materials depending on the use of the material and on whether a common reference level of 1 mSv per year (above background) would be exceeded. This is the only reference level that will be imposed through the Directive. Indeed, leaving a free choice to Member States would lead to very complex requirements to allow for free trade within the EU.

Currently, radon in dwellings is excluded from the scope of Directive 96/29/Euratom and is covered by a Commission Recommendation (EC, 1990). Recent epidemiological findings from residential studies demonstrate a lung cancer risk from indoor radon exposure at levels of the order of 100 Bq m^{-3}. ICRP is currently re-considering its earlier guidance on the dose conversion factors relating to concentrations of radon gas and its progeny in the decay chain. The ICRP Main Commission has issued a statement in November 2009 now proposing a maximum value for the reference level in dwellings of 300 Bq m^{-3}, in line also with the WHO handbook on indoor radon (WHO, 2009). The new Directive has incorporated this value for existing dwellings. The lower value for the reference level proposed by WHO, 100 Bq m^{-3}, is suitable as a long-term goal but a maximum value of 200 Bq m^{-3} for new dwellings has been maintained in the Directive.

A maximum value for the reference level for radon in workplaces has been set at 1000 Bq m^{-3}, in line with the ICRP Statement and with the current draft of the international standards. With the possible doubling of the dose conversion factor, a radon concentration of 1000 Bq m^{-3} would correspond to around 10 mSv per year, which is a high threshold for managing radon at work as planned occupational exposure and well above 6 mSv per year, used in the definition of Category A workers. It is expected that most Member States will set or maintain a reference level much lower than 1000 Bq m^{-3}.

Member States will be required to establish a national action plan which will cover radon in dwellings and in workplaces. The action plan will offer transparent information on the scope and objectives pursued at national or regional level, define the rationale for the conduct of surveys and for the delineation of radon-prone areas or other means of identification of affected buildings, and establish reference levels and building codes. An Annexe to the Directive gives an indicative list of items to be covered in the national action plans for radon.

2.4. Graded approach

The current system of regulatory control is a two-tier system: reporting of practices above exemption levels, and prior authorisation for certain categories of practices. IAEA (IAEA, 1996) had introduced a three-tier system: notification, registration and licensing. The Directive identifies which type of practices will be subject to each pillar, which general conditions need to be fulfilled and what is the content of requirements laid down upon registration or as part of a specific operating licence.

The current system for exemption of apparatus and of consumer goods relies very much on the concept of "type approval". This concept was not worked out further and there is a lack of harmonisation of conditions for type approval and corresponding decisions in the EU. A system of mutual recognition (or at least allowance for) type approvals granted in other Member States has now been introduced.

Directive 96/29 had introduced exemption values in terms of activity (Bq) and activity concentration (Bq/g). In addition, the reuse or recycling of materials with negligible levels of contamination, especially arising from dismantling, could be authorised so that the materials would be released from regulatory requirements, subject to compliance with clearance levels. The clearance levels should be established in such a way that individual doses would be below about 10 μSv (and collective doses below 1 man Sv), taking Community guidance into account. Such guidance has been adopted by the Group of Experts for specific materials such as metals (scenarios for steel, copper and aluminium), buildings and building rubble, and default values for any type of material (EC, 2000).

Meanwhile the IAEA adopted similar guidance in RS-G-1.7 (IAEA, 2004), on the basis of scenarios to a large extent inspired by those underlying RP 122 part I. The IAEA levels were not specifically developed for the purpose of clearance, but it was suggested to use them for this purpose. For the sake of international harmonisation it was decided to introduce in the Directive the RS-G-1.7 values rather than those in RP-122. A study (EC, 2009) has investigated whether the differences between the two approaches and series of values has any significance in practical terms. In general the RS-G-1.7 values are equal to or higher than those in RP 122, but the differences can rather well be explained through the scenarios and assumptions. Nevertheless, several Experts consider that the Community guidance has a better scientific basis, and they are concerned with the increase of some of the values for artificial radionuclides.

The same concentration values now apply by default both to the concepts of exemption and clearance. It has been investigated whether lowering the exemption values will affect any consumer goods placed on the market. While the EC study (EC, 2009) concluded that there would be indeed no adverse practical consequences, it also highlighted some Member States' reluctance to abandon the old numbers already incorporated in national law. In addition IAEA's transport standards committee (TRANSC) advocated keeping the existing values.

As part of the graded approach exemption from any requirements is built in at all levels of control. Specific exemption and specific exemption or clearance levels are a powerful tool in addition to the criteria for general exemption of practices from the scope of the requirements. Whenever the exempt activity concentration values laid down in Directive 96/29/Euratom, on the basis of Radiation Protection 65, would be

preserved in national legislation, these values should be used only for moderate amounts of material, as defined in legislation or as specified by the competent authority.

2.5. System of protection

The overall "system of protection" mirrors the wording used in ICRP Publication 103. The main elements of the system of protection: justification of practices, optimisation of protection and limitation of individual doses are not essentially different from those in the current BSS. More weight is given to the principle of optimisation, subject to constraints and reference levels. The bands of constraints/reference levels proposed by ICRP (0-1 mSv, 1-20 mSv, 20-100 mSv) have been introduced explicitly, including the societal criteria that ICRP listed for each band (Table 5 of Publication 103).

The concepts of justification and authorisation in planned exposure situations were brought together in one title in view of the fact that they are the two main pillars of regulatory control. Also, the more elaborate requirements for the type approval of apparatus or consumer goods relate both to justification and to authorisation.

The concept of justification is described very much in the same terms as before. The so-called "medico-legal" exposures introduced in the Medical Directive (EU, 1997) have now been clearly identified as "non-medical imaging exposures" (deliberate exposure of individuals for other than medical purposes), and have been put under appropriate regulatory control. The need for justification of such practices, in three stages as for medical exposures, and for establishing associated conditions, has been worked out, including differentiation between procedures implemented by medical staff using medical equipment and procedures implemented by non-medical staff using non-medical equipments (e.g. security screening). While, in general, the annual dose limit and corresponding constraints for public exposure should apply, exceptions should be allowed for some specific non-medical exposure procedures carried out in a medical environment (e.g. drug search within the body).

The current dose limits for practices are kept, but the annual dose limit for occupational exposure will be simply 20 mSv per year. There should be no need for averaging over 5 years, except in special circumstances specified in national legislation.

On grounds of the precautionary principle, the Directive applies the optimisation principle also, where appropriate, to keep organ doses as low as reasonably achievable. The Scientific Seminar in 2008 (EC, 2008) on emerging evidence for radiation induced circulatory diseases indicated that epidemiological evidence is accumulating on an increased risk in circulatory diseases for cumulative doses higher than 0.5 Gy low-LET radiation.

In view of the conclusion of the Scientific Seminar in 2006 (EC, 2006) on the issue of radiation induced cataract and the further review of scientific literature performed by the Group of Experts, the dose limits to the lens of the eye should be reduced. ICRP will soon issue guidance on this matter and the Commission will take this guidance into account. Furthermore, the Directive requires the set-up of adequate systems for individual monitoring of (significant) doses to the lens of the eye.

3. Categories of exposure

3.1. Occupational exposure

A specific title covers all types of occupational exposure: of workers, apprentices and students, emergency workers, workers in identified NORM industries, aircrew and space-crew.

The graded approach to arrangements for occupational exposure is made more explicit, with a threshold of 1 mSv per year. The categories A and B workers are preserved. For workers in NORM industries, as part of the graded approach and if doses are in the range 1 to 6 mSv, it is sufficient to keep the exposures under review.

Emergency workers are subject to a dose limit of 50 mSv or, for specific cases identified in national emergency plans, an appropriate reference level. In the current Directive provision was made also for "specially authorised exposures". This provision will now be applied to the exposure of space-crew.

3.2. Medical exposure

Medical exposure applies to the protection of patients, carers and comforters and volunteers in bio-medical research ("other individuals submitted to medical exposure"). There are very few changes to Directive 97/43, except the removal of "medico-legal" exposures and emphasis being given to the information to patients, to interventional procedures, diagnostic reference levels and dose indicating devices. A new feature is the introduction of accidental or "unintended" exposures.

3.3. Public exposure

There are little changes to the protection of members of the public. More precise requirements on the establishment of discharge authorisations have been introduced, as well as on the monitoring of discharges, with reference to a Commission Recommendation (EC, 2004).

3.4. Protection of the environment

The general objective of the Directive is the health protection of workers, members of the public and patients. The recast introduces complementary objectives on the control of sealed sources and on providing information to the public in the event of a radiological emergency. The health protection of the population and workers against the dangers of ionising radiation includes the protection of the human environment as a pathway from environmental sources to the exposure of man. In line with ICRP Publication 103 it is now felt that this should be complemented with specific consideration of the exposure of biota in the environment as a whole.

This extension of the scope of the Basic Safety Standards Directive will enable a better integration of the Euratom legislation with overall environmental legislation adopted under EC Treaty provisions, as well as the observance of international agreements, such as the OSPAR Convention on the protection of North-Atlantic waters, and meet the concerns of stakeholders.

While Chapter 3, "Health & Safety" of the Euratom Treaty only relates to the health protection of workers and members of the public, the policies for the protection of man and the environment should be coherent. For instance, environmental criteria as well as dose constraints should be considered for the authorisation of discharges of radioactive effluent.

Publication 108 of ICRP (ICRP, 2008) offers guidance on the definition of reference animals and plants, and the assessment of the impact of radiation on non-human species. The application of the principles of radiation protection on non-human species and ecosystems needs to be further developed however. The protection of the environment does not seem to warrant a high level of regulatory control, and the means for the demonstration of compliance should be proportionate to the expected relevance of the issue, in line with the graded approach. Also in view of the limited experience so far, the Commission envisages to leave enough time for transposition of these requirements in national law, pending the results of further research and international guidance of ICRP.

4. Prospects

The Group of Experts under Article 31 of the Euratom Treaty finalised the text of the new Directive in February 2010. The text of the Experts and their Opinion are the basis of a Commission proposal scheduled for the end of 2010. Adoption of the Commission's proposal by the Council may take another few years and, taking into account the time granted for transposition into national legislation, it may not be before 2014 that the requirements become truly effective.

Meanwhile the Commission is closely following the revision of the international Basic Safety Standards. As a result of the decision making rules in the European Union, the EC has so far never formally co-sponsored the international Standards. It is now envisaged to do so, in the same way as for the Safety Fundamentals. The aim is to harmonise as much as possible the definitions and requirements, both reflecting the ICRP Recommendations.

It should be emphasised, however, that the Euratom Standards and the international Standards will still look very different, on the one hand because the structures are not the same as well as the amount of detail in existing legislation; on the other hand because of the legally binding nature of the Euratom Standards, applicable to the 27 Member States of the European Union.

As a result of the rules of the recast procedure the current draft of the new Basic Safety Standards has in principle not introduced any requirements that had not been part, possibly in a different way, of the earlier Directives (except for the much broader requirements on natural radiation sources). In particular, no major changes have been made to the most recent Directive on High Activity Sealed Sources and orphan sources, except for the application of some of the requirements to any sealed sources, where this is considered to be good practice. The HASS Directive had introduced new safety, security and enforcement aspects, some of which have now been applied to all radiation sources. On the other hand there are still problems with orphan sources, and there have been important cases of contaminated metal being imported from third countries. Some requirements on orphan sources have therefore been strengthened, and a requirement on the notification of incidents with orphan sources or the contamination of metal has been introduced. Further international efforts are needed in this area to meet the conclusions of the Conference held in Tarragona in February 2009, striving for world-wide consensus on further legislative initiatives, in particular with regard to the restriction of trade in metal and scrap metal.

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Comparison of current clearance standards and their brief history

Koskelainen, Markku[1, 2]
[1] STUK – Radiation and Nuclear Safety Authority, FINLAND
[2] The University of Manchester, UK

Abstract

Over the last 30 years, governments and the nuclear and non-nuclear industry have funded efforts to assess the potential for tightening of materials cycles and minimisation of waste containing measurable levels of radionuclides. A number of studies have demonstrated the technical efficacy of converting various forms of radioactively contaminated materials into safe form and demonstrated that this can be achieved cost effectively and safely. However, until now clearance of materials considered safe has only occurred in small volumes, or within the nuclear industry for specific internal uses.

In the near future large amounts of radioactively contaminated and activated materials will be generated by the decommissioning of first generation nuclear power plants and the historic case by case approach will not be sufficient to handle the associated volumes. To minimise the waste arisings and encourage clearance of radioactively contaminated materials number of governments and international organisations have redrafted their regulations and guidance, allowing for a more fluent release of materials, from regulatory control.

The current approach taken by the international organisations and national authorities is risk based. It intends to provide protection to workers, public and environment alike. Although the International Atomic Energy Agency (IAEA), European Commission (EC) and United States Nuclear Regulatory Commission (USNRC) recommendations are in general agreement on the principles of how clearance should be applied there is still some way to go before clearance values are harmonised.

This study looks a the historic development of clearance standards over the last 30 years and compares the current risk based models and specific activity limits given by the IAEA, EC and the USNRC.

Introduction

Together the governments and nuclear and non-nuclear industry have tried to identify options for waste minimisation and tightening of materials cycles. Hence numbers of regulations and standards have been developed since the 1970s dealing with the de-minimis values. These approaches to exemption, exclusion and clearance are

documented in reports published by International Atomic Energy Agency (IAEA), European Commission (EC), United States Nuclear Regulatory Commission (USNRC) and many other national regulatory bodies.

Exemption, exclusion and clearance are often discussed as coincident concepts. To a degree this is true as they are concepts to exempt radioactive materials from regulation, so that the effects of radiation on the human body are not subject to any further consideration.

Of these, the concept of exclusion is fundamentally applied to the radiation from anthropogenic origin so called “natural radiation”. There are various sources of “natural radiation” in the nature, uranium in soil, radon in air and radioactive potassium in bananas. Another source of “natural radiation” are cosmic rays, which bombard us relentlessly. The global average dose received from “natural radiation” is estimated to be 2.4 mSv/a. This radioactive dose is not subject to regulation and is hence excluded from regulation. The radioactive materials that are subject to exclusion are specified in IAEA International Basic Safety Standards (BSS) for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (IAEA, 1996) and EC Basic Safety Standards (EC, 1996), as materials that are not suitable to be controlled or cannot be controlled.

There is an exception to the “natural radiation” rule: although not from anthropogenic origin radioactive fallouts on the earth surface due to nuclear tests are usually treated as exclusion, as they cannot be controlled.

The concepts of clearance and exemption, on the other hand, mean that the materials are exempt from regulation in terms of radiation protection. These concepts are possible to be applied for two kinds of materials; one not subject to regulation at the onset and the other subject to regulation at the onset but exempt afterward. Today, the former concept is termed exemption and the latter clearance.

IAEA had previously used the term of de-minimis to combine both of these concepts. In early 1980s, the term of exemption began to be used, but at this time it still included both concepts. The two concepts were first differentiated by IAEA around 1995, when both terms clearance and exemption were given in IAEA BSS, which was published in co-operation with international organizations of FAO (International Food and Agriculture Organization), ILO (International Labour Organization), WHO (World Health Organization), EC etc.

Materials requiring clearance

So what is material requiring clearance? In general it is material which is regulated, but due to low levels of radioactive materials could be exempted from regulation. From this arises another question what materials are regulated? In most developed regulatory systems regulated materials arise from utilisation of nuclear energy and radiation. The material composition and the type of contamination present will vary depending on its origin. Virtually all facilities which have been sites of nuclear activity will, at some point, become sources for radioactive materials which can be cleared. Nuclear power plants are by no means the only source of radioactive materials. For instance each step in the uranium ore processing results in uranium contaminated equipment and contaminated slag. The utilization of uranium for the production of power or weapons results in equipment contaminated not only with uranium, but also with fission and

activation products. Fuel handling, storage, and reprocessing also result in more contaminated materials. Radioactive source manufacture facilities and laboratories undertaking nuclear research are another source, and yet more radioactive materials can be expected from accelerator facilities.

Albeit that there are a number of sources for radioactive materials the commercial nuclear power plants have by far the largest arisings. Previous research and regulatory databases can be utilised to assess the material composition, type of contamination present and volumes of contaminated materials. Generally the radionuclides found in nuclear power plants differ according to reactor type. According to research radionuclides resulting from activation of iron, ^{54}Mn, ^{59}Fe, cobalt, ^{60}Co, and zinc, ^{65}Zn (ICRP, 1983) were shown to be present at similar levels in pressurized water reactors (PWR) and boiling water reactors (BWR), unlike the activation nuclides for nickel and tin. The nuclides resulting from the activation of nickel, ^{58}Co and ^{63}Ni, were found to be present at a higher level in PWR's, whereas the tin activation nuclide, ^{125}Sb, was present at higher levels in BWR's. Contamination of materials by caesium isotopes, ^{134}Cs and ^{137}Cs is higher in PWRs, while strontium isotopes ^{89}Sr and ^{90}Sr are usually present at the same level (Dyer and Bechtold, 1994). A survey of reactor parts showed that the radionuclides which accounted for 1% or more of the total activity were ^{54}Mn, ^{55}Fe, ^{60}Co, ^{65}Zn, ^{125}Sb, ^{134}Cs, and ^{137}Cs (Schlienger et al., 1996). These are the key radionuclides for all materials arising from nuclear power plants.

History of clearance standards

Since the early 1980's IAEA have demonstrated an interest in the clearance of materials, when they established the basic principles, which underlie the current approach in their safety series document 89 (IAEA, 1988a). In 1996 IAEA further defined the issue of clearance when they published their first interim report on the recommended clearance limits (IAEA, 1996). In 2004 IAEA revised these clearance limits, which now include 1650 radionuclides (IAEA, 2004).

From 1996 EC has developed the idea of clearance further from the early 1980s attempts, when they were assessing the possibilities of recycling radioactive material and published a number of reports dealing with the issue. These reports address the issue for specific cases concerning a number of fields where radioactive material is generated. There is also a specific EC radiation protection report, RP-89, dealing with the radioactive scrap metal (EC, 1998).

The most recent EC report in 2002 EC RP-122 gives the specific clearance limits for 197 radionuclides, which could be present in any type of contaminated material (EC, 2002). These clearance limits added, modified and eliminated radionuclides compared with the previous EC clearance limits published in 1996 (EC, 1996).

The decision to apply the clearance criteria in the EC countries remains the responsibility of the competent authorities in the Member States, and they can have their own clearance values where appropriate. The guidance on clearance in RP-89, different from other EC guidance, has a caveat for a less stringent clearance limits allowing for slightly radioactive metal scrap, components and equipment from nuclear fuel cycle installations to be authorised for clearance to the public domain whenever recycling within the nuclear industry is not appropriate subject to meeting the clearance criteria (EC, 1998).

US Atomic Energy Commission (AEC), the predecessor of the USNRC, has since 1940's considered slightly contaminated materials, but the original 1957 rule for the protection against radiation did not include specific values for clearance of slightly contaminated materials. An amendment was later added which allowed the regulator to grant a licensee a permission to release materials on a case by case basis. During the 1970's USNRC began the process to set uniform standards for clearance of materials from regulatory control. These efforts have continued through the 1980's and 1990's (USNRC, 1999). The latest effort came in 2003 where the technical document declared that materials with low concentrations of radioactivity can be cleared and de-regulated (USNRC, 2003).

The final 2003 technical document NUREG 1640 includes specific activity limits for 115 radionuclides and a detailed discussion of the methodology used to estimate the resulting annual doses USNRC, 2003), which are given as a justification for the clearance limits. However, currently these clearance limits are only used for case by case clearance decisions.

According to these international and national policies clearance is seen as a logical and well-based scientific concept with the potential for avoiding unnecessary regulation. While number of studies have made it clear that clearance is justified and that its adoption is important for development of nuclear power and utilisation of radiation, the various clearance standards and conflicting research have alienated people from the decision making process making it more difficult to find acceptance for clearance.

The current developments in clearance standards seem to indicate, that harmonisation of clearance values is finally moving forward as two of the major safety standards collections have indicated that they are trying to harmonise their clearance values. The current indication is that IAEA will be implementing the clearance values given in R.SG-1.7 in their new BSS with EC following suite in their new BSS (Janssens 2009).

Comparison of current clearance standards

Current clearance standards do not agree well when it comes to the specific activity limits set for specific radionuclides. When comparing the IAEA, EC and USNRC documents there are significant differences for majority of the radionuclides listed; 1650, 197 and 115 respectively.

Comparison of the key radionuclides is presented in tabulated format in table 1, and in a graphical form in figure 1.

Table 1. Comparison of clearance values for key radionuclides.

Radionuclide	USNRC (Bq/g)	IAEA (Bq/g)	EU (Bq/g)
H-3	526	100	100
C-14	313	1	10
K-40	2,94	-	1
Mn-53	11400	100	1000
Mn-54	0,63	0,1	0,1
Fe-55	21700	1000	100
Co-60	0,19	0,1	0,1
Ni-63	21300	100	100
Sr-90	17,50	1	1
Mo-93	270	10	10
Tc-99	6,25	1	1
I-129	0,05	0,01	0,1
Cs-137	0,63	0,1	1
Ir-192	0,91	1	0,1

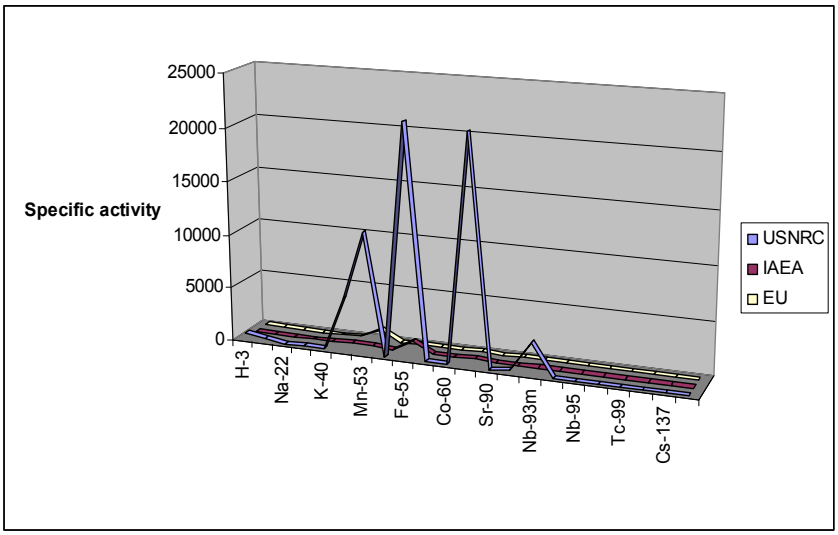

Fig. 1. Graphical comparison of clearance limits for key radionuclides.

Although the specific activity limits in the IAEA, EC and USNRC documents are not in agreement, they do agree on the principles of how clearance should be applied. The comparison of the content of these documents is given in table 2.

Table 2. Comparison of content of clearance standards.

	NUREG 1640	RS-G-1.7	EC RP 122
Waste material	All materials	All materials	Many kinds of materials
Nuclides	115	1650	197
Amount of material	Large	Large	Large
Disposition scenarios	Typical exposure scenarios for all materials	Typical exposure scenarios for all materials	Enveloping scenarios
Application constraints	No constraint on the origin and the type of materials	No constraint on the origin and the type of materials	No constraint on the origin and the type of materials
Standard dose	10 μSv/a	10 μSv/a	10 μSv/a

In all the documents the specific activity limits are based on the idea of negligible risk to the individual. All three standards have based their approach on the ICRP recommendation, that a dose of 10 μSv/a, which is 1% of the recommended public annual dose of 1 mSv, is negligible. By comparison, this means that the annual dose of 10 μSv is less than 0,5% of the natural radiation dose even in areas of very low background (~2 mSv/a) (UN, 2000), and less than 0,2% of the annual radiation dose in Finland (Muikku et al., 2007).

In the spirit of the concept of exclusion, clearance levels should be set at such levels that the resulting doses are small enough to be compared with doses from "natural radiation" so that the risk to the public health is so small it can be neglected.

Development of scenarios and dose evaluation

The clearance values in the current IAEA document RS-G-1.7 are derived numerically using 10 μSv/a for credible scenarios, 1 mSv/y for scenarios with low probabilities, and 1 manSv for the collective dose as the standard doses. The details of those derivations are shown in IAEA Safety Report Series No. 44 (IAEA 2004b).

In order to derive clearance levels, dose evaluations were performed by setting up required parameters for every pathway to be evaluated for the scenarios. Table 3 show evaluation pathways assumed for RS-G-1.7 clearance values.

Table 3. Evaluation pathways assumed by the IAEA.

Scenario	Group	Exposure path	Specific nuclides
Worker of repositories and other end-point facilities	Worker	External, inhalation and ingestion	^{239}PU and ^{241}Am (ingestion)
Worker of melting facilities	Worker	External, inhalation and ingestion	
Other workers (driver etc.)	Worker	External	
Peripheral residents of repositories or other facilities	Child	Inhalation and ingestion	^{3}H, ^{36}Cl, ^{41}Ca, ^{59}Ni, ^{63}Ni, ^{90}Sr, ^{99}Tc (ingestion)
Peripheral residents of repositories or other end-point facilities	Adult	Inhalation and ingestion	^{3}H, ^{36}Cl, ^{41}Ca, ^{59}Ni, ^{63}Ni, ^{90}Sr, ^{99}Tc (ingestion)
Peripheral residents of melting facilities	Child	Inhalation	
Residents of the house built with the contaminated materials	Adult	External	^{54}Mn, ^{60}Co, ^{65}Zn, ^{94}Nb, ^{134}Cs, ^{137}Cs, ^{152}Eu,^{154}Eu (external)
Peripheral residents of public facilities built with the contaminated materials	Child	External, inhalation and ingestion	
Residents consuming contaminated river fish and well water	Child	Ingestion	^{14}C, ^{129}I (ingestion)
Residents consuming contaminated river fish and well water	Adult	Ingestion	^{14}C, ^{129}I (ingestion)

The differences in the chemical and physical behaviour of radionuclides to be evaluated results in different doses for each nuclide at a given concentration, and hence each parameter is conservatively set up to include various postulated events. According to the dose-evaluation results for all evaluation pathways the clearance value is the minimum radionuclide concentration which is equal to the standard dose under any of the postulated events.

Table 3 also gives the major radionuclides which are critical for each of the pathways. Namely, it demonstrates that critical pathways are external exposure for gamma emitters (i.e.^{60}Co and ^{137}Cs), oral ingestion of beta emitters such as ^{90}Sr, and inhalation ingestion of alpha emitters such as ^{241}Am.

Concept of Limited Clearance

In accordance to the concept of clearance; materials, which are cleared are not subject to further regulation, but, as described in the development of EC clearance standards a concept of less stringent "limited" clearance exists, which provides more lax limits, and provides further conditions on the method of clearance or destination of cleared materials. This concept of "limited" clearance is also termed as "specific" clearance or "conditional" clearance.

As described earlier, the clearance level is usually set as the lowest concentration delivering the standard dose for the assumed exposure pathways. Therefore, if the assumed exposure pathways can be limited by imposing conditions on the implementation of clearance, the number of exposure pathways for the scenario evaluation will be reduced, and for the standard dose higher radionuclide concentration

levels can be accepted. Similarly, if the amount of the materials for clearance is smaller, the clearance value will become higher.

As the USNRC did not gain acceptance for their Clearance approach outline in NUREG 1640 they are currently releasing materials under previous rules following the concept of "limited" clearance. There are also a number of other countries where this type of clearance approach has been incorporated into the legal regulations, such as Finland (STUK, 2008) and Germany (Sefzig, 2009).

Obstacles to clearance

Many countries face significant obstacles in adopting and applying clearance standards. The obstacles have been identified in a technical report published by the IAEA. The report deals with recycling of metals, but all of these factors could become obstacles for radioactive materials clearance aswell. Some of the factors are specific to a facility or a country and others are international (IAEA, 1988 b). In the context of clearance of metals these are:

- The availability of regulatory criteria giving activity levels for clearance and alternatives to applying the clearance levels
- The availability of technology and facilities to recycle the metals
- The availability of instrumentation to measure regulatory clearance levels and quality assurance programs to assure compliance with the criteria.
- The effect that recycling of materials will have on the extension of natural resources
- The economic implications including cost of decontamination, waste disposal, market value of recycled materials.
- The socio-political attitudes in the affected country or industry regarding the recycling/reuse of materials or components.

Of these factors the first is a legislative issue, which is for the governments to decide. The next two are technological issues, which are much dependant on the country's infrastructure. The fourth is an international issue with stakeholder implications regarding sustainable development and conservation of natural resources. The second to last factor is a country specific issue with international economic dimensions. The last factor is a country specific issue which is strongly affected by stakeholder attitudes. In a modern western society it is unlikely that these first two factors would be significant obstacles to radioactive scrap metal recycling as readily available standards exist and there are ongoing operations around the world.

The third factor is a potential obstacle due to detector technology and associated cost implications, but these are discussed in detail in scientific publications and international guidance (Lubenau and Yusko, 1998, Clouvas et al., 2005).

Fourth issue is an international issue with strong stakeholder implications. However, in the current atmosphere of environmental conservation the considerate use of raw materials can be advantageous to radioactive scrap metal recycling if the stakeholders can be convinced of the safety of operations and the quality of the final product.

The fifth factor can become a hindrance if consumers do not accept the use of trace radioactive scrap metal in recycled metals, however the cost implications are

unlikely to be an issue if burial cost avoidance is added to the financial calculations. The issue of cost benefit analyses is addressed by a number of scientific and articles and reports as well as national research (Menon et al., 1990, Hill et al., 1996, Yuracko et al., 1996, Rivera et al., 1996, Andreani and Bailo, 2000), the feasibility has also been demonstrated by the operational plants around the world.

The last factor can be, and it is the most serious obstacles to scrap metal recycling. To date a number of stakeholder involvement processes have been undertaken to convince the public of the benefits and safety of radioactive scrap metal recycling, but these stakeholder processes have not been successful in alleviating the concerns of the stakeholders and there is no free market for cleared radioactive scrap metal in the world.

Conclusions

Clearance regulation is provided to ensure the safety of the general public and the environment, and to ensure, that no one suffers health hazards from regulated radioactive materials. To a degree the numerous studies undertaken in developing the current clearance standards have demonstrated that it can be done safely and cost effectively, but the fact remains that significan differences are present in the clearance values eventhough they are working with the same standard dose of 10 µSv/a. This is mainly due to different approximations used in the exposure scenarios from which the limits have been derived.

This inconsistency makes it more difficult for regulators to convince stakeholders of the safety concerns associated with recycling of low activity scrap metal, and it would be more desirable to have consistent standards for materials rather than state of the art science.

With the indications coming from the IAEA and EC that they will be harmonising their clearance standards there seems to be some hope that in the future harmonisation for clearance values can be achieved, but this is still a long way away considering the effort that has been put into researching clearance standards and how jealously the assumptions behind clearance standards are discussed in the international environment. However if harmonised clearance standards can be agreed upon, it is more likely that the industries dealing with cleared materials would be more willing to include cleared materials in international trade.

According to IAEA clearance is: “a logical and well based scientific concept with the potential for avoiding costly and unnecessary regulation”, and clearance of materials is demonstrated to be achievable through licensed operations around the world, but making it acceptable requires careful work from the international organisations and governments in justifying clearance and thorough stakeholder engagement and involvement at policy, strategy and facility levels.

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Current situation with application of new ICRP system of radiological protection in the Russian Federation: regulation and optimization issues

Shandala, Nataliya[1]; Kiselev, Mikhail[2]
[1] Burnasyan Federal Medical Biophysical Centre, Moscow, RUSSIAN FEDERATION
[2] Federal Medical-Biological Agency, Moscow, RUSSIAN FEDERATION

Abstract
The current Russian basic regulative document, Radiation Safety Standards, needs updating, which must be carried out in accordance with common international practice. In the light of issuing of new ICRP principal recommendations in 2007, review of the IAEA Basic Safety Standards is in progress. In compliance with the national practice, the IAEA member states implement the Basic Safety Standards in a form of national systems of laws, norms and rules. In fact, the current national radiation safety standards can be updated in Russia only after new IAEA standards issuing. Nevertheless, even today, we must take the contemporary principles of development of the radiation safety system postulated in the ICRP recommendations into account. There are no stricter hygienic regulations in ICRP Publication 103 in comparison with those established in Russia, but there are some new conceptual provisions and concepts in it. The paper deals with the frame of national system of radiation safety regulation. Application of optimization and dose constraints in the course of Russian NPP operation is the specific case and its relevance is stressed in terms of future development of nuclear power engineering. Using the nuclear legacy regulation as an example, an importance of application of new exposure situations from ICRP Publication 103 has been shown.

Introduction
Radiation safety regulation consists of:

- Science based knowledge of ionizing radiation effects under development of the United Nations Scientific Committee on the Effects of Atomic Radiation;
- Conceptual model of the human safety and effective control of radiation sources and technologies being generated by the International Commission on Radiological Protection (ICRP);
- Legislative and regulative support of radiation protection and safety for different modes of nuclear energy using and another activity connected with radiation exposure to the human, being developed by the IAEA.

Development or change of each component has resulted in the necessity of the regulation system revision and its adequate submission at the international and national

levels. The International Basic Safety Standards (BSS) have always followed the establishment of new ICRP recommendations. For example, the fundamental ICRP recommendations of 1990 issued as Publication 60 were the basis of the revised BSS, published in 1996. Then, in 1999, the Russian national radiation safety standards were developed.

The current Russian fundamental regulatory document – Radiation Safety Standards (NRB, 2009) – requires necessary revision, which must be carried out according to the established world practice. As it is well-known, issuing of the new ICRP fundamental recommendations in 2007 (ICRP, 2007), caused the revision of the IAEA BSS revision (IAEA, 2010). However, just before the official publication of new BSS, we must take into account the up-to-date principles of the radiation safety development as they are postulated in the ICRP recommendations, in our everyday practice.

Regulation of radiation safety and protection in Russia: regulatory bodies, legislative acts and regulative documents

In addition to operators directly responsible for radiological protection in Russia, as it is well known, there are some regulatory bodies, whose functions include regulation, licensing of the appropriate activity and its supervision, fig. 1.

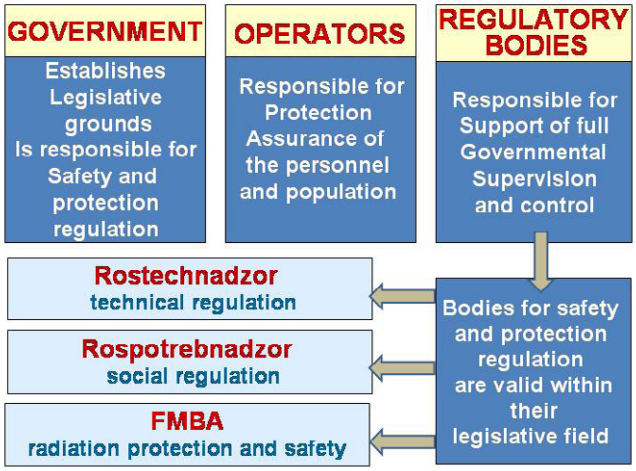

Fig. 1. State regulation of radiological protection in the Russian Federation.

According to the current Russian legislation, the Federal Medical-Biological Agency (FMBA of Russia) is responsible for medical and sanitary support as well as for the state sanitary epidemiological supervision. It covers organizations in some industrial branches with especially hazardous work conditions and the population of some Russian territories according to the list approved by the RF Government. This list includes all radiation hazardous facilities all over Russia (more than 400 facilities). One of the FMBA's principle functions is the state regulatory supervision of safety during nuclear energy using.

At that, some these functions are implemented through the system of the state sanitary and epidemiological regulation, to the extent that approval of the documents developed by the RF State Chief Medical Officer and their following registration in the

RF Ministry of Justice. Such regulations and sanitary rules are obligatory for observation by operators. Over recent 5 years, experts from the FMBA of Russia have developed more than 100 scientific and technical regulatory documents on radiation protection of nuclear workers and the public. 20 of such documents are ascribed to the category of sanitary rules and registered in the RF Ministry of Justice. They include sanitary rules for design and operation of nuclear power plants, including floating ones; regulations for surveillance of radiation safety during overall decommissioning/dismantlement of nuclear submarines; and the requirements for the Russian ports during enter and moorage of ships equipped with nuclear powered installations etc.

Principles of legislative regulation are postulated in laws and directives of the Government of the Russian Federation. National system of radiological protection and radiation safety assurance in the Russian Federation is based on two principal documents: Radiation Safety Standards (NRB, 2009) and Main Sanitary Rules for Radiation Safety and Protection (OSPORB, 1999). Figure 2 shows hierarchical frame of regulative and methodical documents as an example of radiological protection regulation of the personnel and population as applicable for the facilities of the State Atomic Energy Corporation "Rosatom".

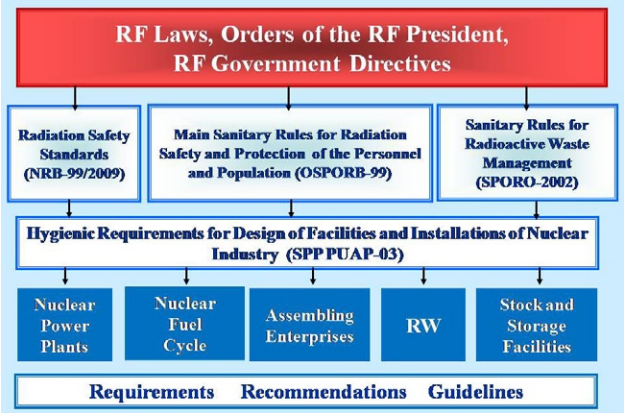

Fig. 2. Normative and methodic support of radiological protection of the personnel and population from the "Rosatom" facilities.

The legislative and regulative background established over the recent decade supports safe operation of nuclear facilities. However, its practical application revealed some problems as well. In the regulative documents, there are difficult questions to be solved connected with operation of the national nuclear industry, such as:

- remediation of sites contaminated due to past nuclear activity and "uranium legacy";
- decommissioning of nuclear energy using facilities or justification of prolonged operational time of functioning facilities;
- radioactive waste management;
- assurance of effective emergency response;
- difficulties in adequate application of the optimization principle.

The mentioned problems can partially be solved on the base of issued ICRP principal recommendations - Publication 103.

Impact of the new system of the radiological protection on development of radiation safety and protection system in Russia

It is necessary to note that regardless the fact that the final BSS version is not finished so far, the principal Russian regulative document - Russian Radiation Safety Standards (NRB, 2009) has already been revised and is in force since 1 September 2009. Its amendment is due to not only Publication 103 issuing. Such kind of amendments is dictated by the termination of the ten-year operational time.

New version of the Russian Radiation Safety Standards keeps the previous structure. 300 different amendments have been made in total and the following in particular, up-to-date detriment adjusted nominal risk coefficients for stochastic effects after exposure to radiation at low dose rate have been given. In the section «Limitation of natural exposure» in addition to regulation of the construction raw materials, the finished production manufactured on its base has been added together with the mineral raw materials. Regulation of chemical fertilizers and agro-chemicals has been amended. In assessment of drinking water radiation safety the supplement says that regulation is made by adults, and intervention levels for the particular radionuclides are given as a special annex. In the section «Limitation of medical exposure», the criterion on discharge of the patient from the hospital after treatment with radiation sources is amended.

It should be noted that not all provisions of new ICRP system found their reflection in the revised document.

In Russia, the main actual task is to explain, how new ICRP conception of Publication 103 can be effectively and successfully applied in the regulation practice. The following new provisions of the radiation safety and protection system can be important for Russia:

- refusion of “practice and intervention” conception and its replacement by three types of exposure situation: planned, existing and emergency;
- introduction of dose constraint and reference levels for each exposure situation depending upon the category of individuals exposed;
- use of “representative individual” concept instead “critical group”;
- establishing of the eco-centric principle of radiation protection of non-human species and environment.

Some changes of the radiological protection system will cover the following issues as well review of weighting factors for relative radio-sensitivity of organs and tissues, selective use of collective dose value, etc.

Regardless of mentioned changes, together with the above new provisions of the radiological protection system, fundamental revision of current national NRB system is not assumed. Figure 3 illustrates evolution or dynamics of dose limit change in the ICRP documents and in the Russian documents regulated radiation safety, respectively. So, regarding to the professional exposure in planned situation, ICRP continues to advise to present dose limit as 20 mSv a^{-1} effective dose. The public exposure in planned exposure situation is either unchanged: ICRP continues to advise 1 mSv a^{-1} dose limit.

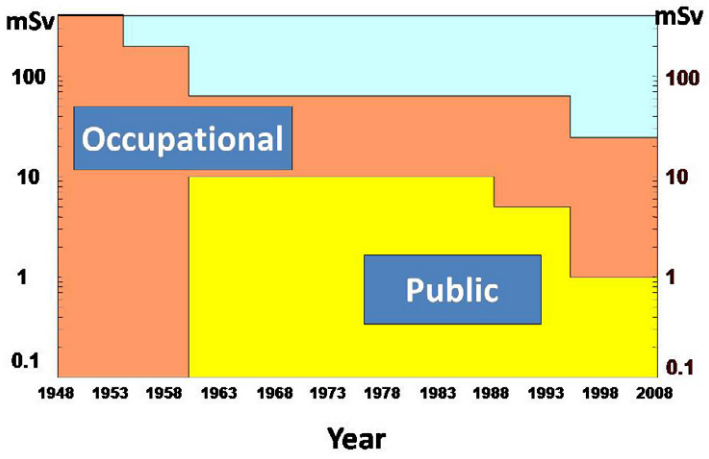

Fig. 3. Evolution of individual dose limits.

Thus, even before issuing of new IAEA international safety standards instead those in use today, it is already evident that national NRB will be the subject of evolutional amendments relating to «reconstruction» of the conceptual background of the radiological protection system, as well as change of digital values of dose coefficients.

In the nearest time, hard work should be performed on introduction of new recommendations into the national system for radiation protection and safety assurance. Therefore, after official issuing of ICRP Publication 103 in Russian, wide discussion is necessary both of the Russian terminology from the "Glossary" section and the whole text translated. Application of new conceptions and terms in the system of regulations must be weighted and one should avoid their formal application. When improving national regulative documents, one should analyze carefully national experience and take into account the up-to-date social and economic circumstances in Russia. The priority of changes from ICRP Publication 103 is to be specified to select those relating to the most important problem in nuclear industry.

Radiological protection optimization in the course of the Russian NPP operation

Information materials on the Russian NPPs operation are being demonstrated as a positive example of good practice of adequate application of the radiological protection optimization principle. In the regulative documents concerning this problem, the dose quote of 25% public dose limit, i.e., 0.25 mSv a^{-1} is written and observed over more than 10 years (SP AS, 2003). The dose quote in the national regulation assumes or is similar to dose constraint in the planned exposure situation. The current NPP 0.25 mSv a^{-1} dose quote value corresponds to the ICRP recommendations for dose constraint (of 0.3 mSv a^{-1}) established in the course of optimization of public radiological protection against existing or potential radiation source. This dose quote also corresponds to practice of other states, where nuclear power engineering is under development.

For the functioning Russian NPP, 250 μSv a^{-1} quote for the public dose is established, while for NPP under design and construction this value is 100 μSv a^{-1}. These quotes are being established for total public exposure due to radioactive gas-

aerosol atmospheric discharges and liquid effluents in surface water reservoirs for NPP as a whole, regardless the amount of energy units on the industrial site. Table 1 shows the quote values for the public exposure originated from radiation factors (discharges and effluents) under route operation of the Russian NPPs.

Table 1. Quotes for the public exposure originated from discharges and effluents under route operation of the Russian NPPs, μSv per year.

Radiation factor	Functioning NPP	NPP under design or construction
Gas-aerosol effluents	200	50
Liquid discharges	50	50
Ttal	250	100

According to the regulatory document (SP AS, 2003), the approach is proposed for identification of permissible radionuclide releases into atmosphere based on the optimization principle and on the acceptable risk conception, when the lower border of the risk optimization area for the single radiation source (NPP, in this case) is assumed to be 10^{-6} a^{-1} (that corresponds to annual effective dose of about 10 μSv a^{-1}). For lower values, public doses are not to be reduced, i.e., we mean here application of additional radiation protection. The quote value is considered as upper border of potential public exposure due to radiation factors in the course of optimization of such public protection under condition of route (normal) NPP operation. Figure 4 illustrates the general ides of such approach.

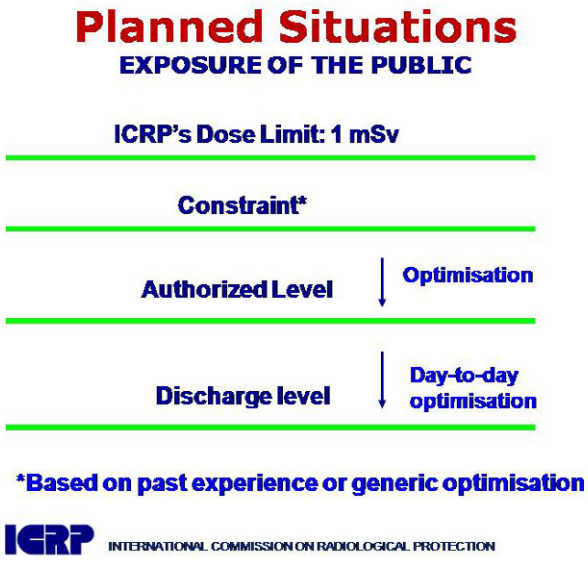

Fig. 4. Radiation protection optimization of the public living nearby the NPP.

Thus, permissible radionuclide releases due to the NPP operation result from optimization approach based on the "benefit-harm" analysis. Here, numerical values of permissible releases vary over the range between the upper and lower borders of

optimization and they are not derived levels of dose quotes for the single radiation source (MG, 2004). When establishing the permissible annual releases of radioactive gases and aerosols into atmosphere, the fact was taken into account that noble radioactive gases made the main contribution (more than 98%) into the public dose under route of NPP operation. These are: argon, krypton, xenon and radionuclides ^{131}I, ^{60}Co, ^{134}Cs, ^{137}Cs (^{24}Na –for fast neutron type reactors, BN-600). Limitation and control of other radionuclide activities being detected in the NPP discharges seems to be unreasonable because of their trivial contribution into dose. Table 2 includes values of annual permissible discharges of radionuclides for the NPP equipped with different reactors taking into account ratios of the nuclide activities in such discharge and conditions of the discharge (heights of ventilation pipes).

Table 2. Annual permissible releases of radioactive gases and aerosols from the NPP into atmosphere.

Radionuclide, dimension	T3 with RMBK	T3 with WWR and BN
Noble gases, TBq*	3700	690
^{131}I (gaseous + aerosol forms), GBq**	93	18
^{60}Co, GBq	2.5	7.4
^{134}Cs, GBq	1.4	0.9
^{137}Cs, GBq	4.0	2.0
Note: * 1 TBq = 10^{12} Bq = 27 Ci; ** 1 GBq = 10^{9} Bq = 27 mCi		

The above mentioned permissible discharges are those of minimum significance and they observance guarantees that the public dose during rout operation mode will not be higher 10 μSv per year. Taking into account doses, which are the upper border of optimization, maximum permissible discharges are established for the functioning NPPs at the level of 20 permissible discharges, while for the NPP under design and construction – at the level of 5 permissible discharges. Values of maximum permissible discharges for all NPPs are 5 times higher than the permissible discharge.

If real release (discharge/effluent) from the NPP is lower than maximum permissible values, but higher than the permissible ones, then it is recognized that radiation impact of the NPP on the public and environment does not comply with the optimization principle. This is evidence of the manufacture culture violation and is to be considered with the purpose to eliminate the excess revealed. Excess of maximum permissible discharges or effluents is forbidden under route operation mode of the NPP, because this is violation of the sanitary norms and rules and can justify the suspension of the NPP operation.

Real releases from the Russian NPPs are not higher than 20% of permissible releases. Releases during power unit closures are much higher than those during normal operation at the stable power level (noble (inert) radioactive gases – up to 40%, ^{131}I – up to 70% of gross annual releases). At stable powers of the power units, measurement of the NPP release activities is of illustrative nature because of their low values.

Discharges and effluents due to the NPP operation at the level of about 100% of the permissible releases are undoubtedly acceptable; effective public doses confirm this

fact for the population living at the NPP vicinity (Shandala N. et al., 2007). Table 3 includes doses to the public on the example of Volgodonsk NPP.

Table 3. Individual effective public doses at the supervision area of the Volgodon NPP, mSv a^{-1}.

Regions of the supervised area	Years of surveillance				
	2004	2005	2006	2007	2008
Cymlyansky	0.02	0.012	0.021	0.06	0.08
Volgodonsk city	0.015	0.01	0.09	0.017	0.019
Dubovsky	0.09	0.02	0.015	0.013	0.005
Zimovnikovsky	0.012	0.014	0.011	0.01	0.004

Thus, real discharges and effluents originated from the NPP operation are optimized and their reduction is not economically justified. The task is to keep the reached level of atmospheric effluents and discharges into water media, especially in the light of ambitious plans of nuclear power engineering development in Russia.

Optimization and regulation of the Russian nuclear legacy

Optimization of radiological protection in Russia is also important issue in remediation of nuclear legacy of sites and facilities of ex-USSR. Routine operations and discharges from radiation hazardous facilities do not contribute substantially to the public exposure and do not result in any significant consequences for health. In contrast, some legacy radioactive contaminations due to radiological accidents and emergency situations (Techa River, 1949; Kyshtim, 1957; Chernobyl, 1986) resulted in radiation doses to some population groups that significantly exceeded the permissible levels, Table 4 (Balonov M., 2008).

Table 4. Public exposure due to man-made radionuclide releases.

Source	Time period	Significant Nuclides	Mean dose (mGy, mSv)
Global fallout	1950 – 2020	^{137}Cs, ^{90}Sr, ^{131}I, ^{14}C, ^{3}H	1.1
Techa River, PA "Mayak", Russia	1949 – 2020	^{90}Sr, ^{89}Sr, ^{137}Cs, etc.	50-2000
Chernobyl, USSR	1986 – 2056	^{131}I, ^{134}Cs, ^{137}Cs, ^{90}Sr	Up to 500; Thyroid – up to $10 \cdot 10^3$

Emergency exposure led to adverse health effects, such as, radiation sickness and a long-term increase in the incidence of cancer in the residents of the affected areas. The research institutions under the FMBA of Russia study consequences of contamination of Techa River, Southern Urals, due to both unauthorized radioactive discharges from the PA "Mayak" at the later 1940s and the accident at the "Mayak" in 1957. Following some radiological accidents, significant detriment of human health and environment has been observed. Consequences of defense activity are rather considerable for environmental safety at the sites of nuclear submarine allocation. Such kind of activity resulted in large amounts of the spent nuclear fuel and radioactive waste accumulated at the sites of temporary storage in the Russian Northwest and Far East.

What kinds of problems do arise in optimization context in case of existing exposure? Let us consider them on example the nuclear legacy regulation. The main Russian regulative document (NRB, 2009) presents the guidance (intervention criteria) with respect to the radioactively contaminated areas as a reference Appendix 5. Nevertheless, there is no comprehensive guidance for the existing exposure situation. The optimized protective and remedial measures are recommended at annual dose over the range 1 – 20 mSv; at dose >20 mSv, residence at the territory is forbidden. Prima facie, quite good general compliance with the ICRP Publication 103 is evident; however, application of the lower boundary (1 mSv/year) for the large-scale situation (Chernobyl, Kyshtym, Techa) seems to be inadequate. This can be explained by the Chernobyl Law adopted on the rise of democracy at the early 1990s and by wrong use of the dose limit in case of emergency and existing exposure situations (Shandala N. et al., 2009).

According to the ICRP Publication 103 (ICRP, 2007), environmental remediation can be considered as an existing exposure situation: exposure already exists, when decision is to be made on radiation protection. This kind of exposure situation includes prolonged exposure due to excess radiation background, after radiation accidents, following previous radiation substance handling (including nuclear weapon manufacturing and tests, peaceful nuclear explosions etc.). In many respects, consequences of the Chernobyl accident resulted in generation of such independent exposure situation. The previous ICRP Publication 82 (ICRP, 1999) and the IAEA documents (WS-R-3, WS-G-3.1) recommended the following principal provisions with respect to the remediation situation:

- Dose limits cannot be used, because they cannot be observed in each case.
- Criteria for the human protection – justification and optimization of intervention.
- Generalized criterion of non-intervention – non-exceeding annual effective dose to the public due to all environmental sources (including background) is 10 mSv. Intervention may be grounded above this level.

To develop the above mentioned provisions, the ICRP Publication 103 refuses the "intervention" concept and introduces the reference dose or risk level. The reference level is such level, above which radiation exposure is impermissible, and so optimized protective measures are to be taken, including those at dose below the reference level. The regulatory body establishes the reference level for the specific or typical situation. In case of the existing exposure situation, the reference level of annual effective dose within the range from 1 mSv to 20 mSv is proposed to be established. Higher levels are proposed to be applied in more large-scale situations.

Thus, in addition to review of actual Russian regulatory document (here we mean reasonability of introduction of three exposure situations instead practice and intervention available now), some special criteria of the environmental remediation are to be developed.

Conclusions

1. The ICRP Publication 103 has been translated into Russian.
2. There are no stricter hygienic regulations in ICRP Publication 103 in comparison with those established in Russia, but there are some new conceptual provisions and concepts in it.

3. The safety levels reached due to the optimization principle application in the field of radiation safety and protection at the Russian NPPs and at the areas of their potential impact on the public and environment can be recognized as quite good.
4. The actual Russian radiation protection system is not arranged enough in its documentation basis and differs from the international one, in particular, in inadequate application of dose limit for the planned exposure situations (1 mSv/year) under conditions of emergency and existing exposure situations. Introduction of three exposure situations in the Russian regulation can improve this situation.
5. Recommendations are as follows: 1) To introduce a chapter on radiation protection of the public in the existing (prolonged) exposure situation into the national radiation safety standards and put it in harmony with the international radiation protection system; 2) To promote development of the international connections on studying of good experience in the radiation protection is necessary.

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Stakeholder Involvement in Medical Practices – Report of the Heads of European Radiation Control Authorities HERCA

Levebvre, G.[1]; Kettunen, E.[2]; Godet, J.-L.[3]; Olerud, H. M.[4]; Sánchez, M.[5]; Trueb, Ph. R.[6]; Griebel, J.[7]; Stoop, P.[8]; Clarijs, T.[1]

[1] Federal Agency for Nuclear Control, Brussels, BELGIUM;
[2] Radiation and Nuclear Safety Authority, Helsinki, FINLAND;
[3] Aurorité de Sûreté Nucléaire, Paris, FRANCE;
[4] Norwegian Radiation Protection Authority, Osteras, NORWAY;
[5] Consejo de Seguridad Nuclear, Madrid, SPAIN;
[6] Federal Office of Public Health, Bern, SWITZERLAND;
[7] Bundesamt für Strahlenschutz, Neuherberg, GERMANY;
[8] National Institute for Public Health and the Environment, Bilthoven, NETHERLANDS

Abstract

A working group of HERCA has reviewed a large variety of examples of stakeholder involvements in medical practices which have already been performed in the member states and in addition looked at possible stakeholder involvements for the future, where a leading role of the national radiation protection authority is needed. The authorities should take the lead to bring stakeholders together to solve today's challenge in a concerted manner. These challenges appear where different professional groups work together on new technologies and/or new processes. Examples can be found in radiation therapy (image guided radiotherapy, dealing with accidents), in nuclear medicine (PET/SPECT-CT), in radiology (going digital, patient dose optimization), screening, the complex of problems through self referral and many others.

Introduction

In diagnostic radiology radiation is used to form an image of a plane or volume, or in nuclear medicine to visualize the function of an organ, and the radiation dose to the patient is just an unwanted side effect. In radiation therapy radiation as such is used to control cancer growth for cure or palliation. We have seen a tremendous technological development both in diagnostic and therapeutic applications of radiation. This growth and development is mainly of great benefit to the patients as individuals and to the society as a whole, but it also causes a strong increase of medical radiation exposure of the population which is of concert for radiation protection reasons. Only a close collaboration between all the stakeholders will allow this dose increase to be understood and kept under control.

Material and methods

The Heads of the European Radiation Control Authorities HERCA have first met in 2007 to discuss the common problems in radiation protection in Europe. 22 member states of the European Union and Norway and Switzerland identified the key issues which needed to be worked on. 5 main topics have been chosen to be looked at more closely in therefore created working groups. The task of Working Group 5 was to analyse the situation of stakeholder involvement in medical practices and give recommendations to national radiation protection authorities of how to identify the relevant stakeholders and how to proceed in involving them in radiation protection issues.

Results

The working group has reviewed a large variety of examples of stakeholder involvements which have already been performed in the member states (see Annex A) and in addition had look on possible stakeholder involvements for the future, where a leading role of the national radiation protection authority is needed.

The participating experts from HERCA member states have discussed the role of the authority in the involvement of stakeholders, have tried to identify relevant parties and to make some recommendations and to give examples of stakeholder involvement.

Definition and identification of stakeholders in medical practices

A stakeholder is someone who is (or should be) entitled to have an interest in radiation protection in medicine. To give a better overview, stakeholders are split into three groups *Justification, Optimization* and *General*.

Justification	• Medical doctors, medical societies and associations • Patients, patient organizations • Legislator
Optimization	• Medical doctors, medical physicists, technicians, other medical staff • Manufacturers and suppliers, staff undertaking installation and maintenance • Hospital directors
General	• Patients and their relatives • Patient ombudsman • members of the public • Insurance and social security • Legislator and health authorities

In the group *Justification* the stakeholders are involved in the process before a prescription has been issued by the medical doctor. Subsequently in the group *Optimization*, the stakeholders are carrying out the procedure.

The overall goals of stakeholders involvement

The national authorities competent in the field of in radiation protection should take the lead in bringing the different stakeholders together (stakeholder platform), analyzing the different interests and needs (stakeholder analysis) and motivate them to participate actively in optimizing medical radiation exposure (stakeholder participation).

The goals, which should be achieved by this process, are summarized in the following table:

Justification	• Specialized Medical doctors in charge of radiotherapy, radiology, nuclear medicine, etc are aware of the principle of justification (ICRP Publication 103 ….) • Specialists and generalists use the guidelines "good practices" (Guide du bon usage, Orientierungshilfe, EU referral criteria RP 118…) • Medical doctors and dentists (generalist) are aware of the justification of radiological examination • Patients are informed of the risks and the benefits of the procedure
Optimization	For the application of the principle of optimization, medical doctors in charge of radiotherapy, radiology and nuclear medicine, physicists and technicians are in charge of : • State-of-the-art technical equipment, quality assurance and maintenance • Optimized procedure for the realization of the examination (i.e. diagnostic reference levels, handbooks of good practice…) • Regularly trained staff • Defined responsibilities in the process (rights and duties) • Resources for radiation protection in all radiological procedures • Feedback culture (safety information system, continuous improvement, self auditing….)
General	• Manufacturers care about radiation protection • Awareness and knowledge in radiation protection (public, patients …) • Well-accepted authorities, who inform, coach and train all users…. • organizations preparing standards are taking care of radiation protection

Discussion

There is no doubt that important benefits can result from interactions between stakeholders and regulatory authorities.

These interactions can vary significantly from one situation to another. Their importance, intensity, purpose and expected outcome depend on well-known factors (benefits, detriments, risks – real as well as perceived). Associated circumstances (e.g. sense of urgency, potential crisis situation, current political engagements of governments) also affect the interactions, as well as socio-economical factors (e.g. need for improved business conditions). In addition, the expertise and resources available to the authorities, as well as the potential need for improved regulatory framework, play a role on the interactions with the stakeholders.

The purposes and expected outcomes of the involvement can be any of these: information exchange, development of tools (books, guidelines, training), advice and expertise, recommendations, legal texts and instruments, direct or indirect involvement in decision making as well as in activities related to authorization and control, prevention of incidents and accidents, preparedness, and response.

The WG agrees with the recommendations concerning stakeholder involvement formulated during the 10th European ALARA Network Workshop:

"Regulatory bodies have an important role to play in facilitating stakeholder involvement, and are encouraged to establish mechanisms for communicating with relevant parties and encouraging their participation. This may for example include seminars, consultation exercises, public meetings, internet forums, etc."

- Stakeholders should be consulted as widely as possible, whenever acceptable (there may be security related restrictions for some types of interactions) and manageable. Authorities should try to be clear on the purpose of the involvement and on the output expected from the interaction (transparency).
- Authorities should try whenever possible to build structural mechanisms for consultation with stakeholders.

One could find several kinds of roles for radiation protection authority when working with stakeholders and getting their involvement to reach an appropriate level of safety. Roles could be for example:

1. Forerunner

The national authorities competent in the field of in radiation protection should initiate, co-ordinate and monitor safety related research and development. The results of the research will support its regulatory functions and also stakeholders in using justified and optimized methods and equipment and to apply and adopt optimized work procedures.

The Radiation protection authority could promote research projects where stakeholders are partners in trying to achieve common goal. The authority could suggest ideas for topics to be investigated and initiate and motivate research projects which will be performed by research groups, universities and research institutions as well. Also small scale studies together with educational institutes and students are valuable.

Especially in the medical sector the opinion leaders are in universities, major hospitals, and educational institutes and in specialized research institutes. Co-operation with these stakeholders will provide a solid base for further work in radiation protection and will grant credibility for radiation protection authority in further actions.

Specialists of the Radiation protection authority should participate in international congresses to get understanding of the newest applications of ionizing radiation.

One has to investigate the needs of education and training together with the users of radiation in discussions and meetings with different kind of specialists and organizations. Surveys together with educational organizations of the needs are valuable as well. Based on this information Radiation protection authority could propose further education for radiation users at universities and training institutions.

2. Rule maker

According to IAEA GR-S-1 "In order to fulfil its statutory obligations, the Regulatory authority shall define policies, safety principles and associated criteria as a basis for regulatory actions". To get commitment from stakeholders for the regulation it is useful to prepare basic regulations using consultation with stakeholders. Sometimes pre-stage in preparing regulation is to perform preliminary study or research project to get better understanding of the status quo. Here you could involve some key stakeholders in the work. The results of the projects could serve as basic information for the foundation of the regulation.

Many times it is practical to invite experts from professional societies to join in to the working groups to prepare specific regulatory documents. Furthermore it is important to call for comments from all involved stakeholders on the drafts of the documents and take these opinions into account in the final version, if appropriate from the point of view of radiation protection.

3. Advisor

Radiation protection authority shall provide guidance to the operator on developing and presenting safety assessments or any other required safety related information. This is according to the IAEA GS-R-1. It is important to make surveys which kind of guidance is needed by license holders and specialists in the field. This is also to get a better mutual understanding of the common goals in radiation protection and to prepare proper guidance. When preparing such guidance and information it is useful to prepare guidance together with the specialists working in actual practices.

4. Communicator

Radiation protection authority shall introduce the regulation and guides for all radiation users (organizations, experts) and involved parties. All radiation users should have information on new regulations and guides soonest possible. Good practice is to mail this information based on the registers of the stakeholders if any. Good service for stake-holders is to provide all kind of general information on radiation protection for stakeholders on the www-pages of the authority.

An effective method is to organize regular discussions and meetings on current topics with different specialists and organizations.

How to communicate risk is a particular challenge, it should be prepared with other stake holders like medical doctor organizations, hospital directors, patient organizations, press bodies. Communicate the risk in advance (booklet), communicate the risk after an incident/accident (info unit important). In some cases (e.g. contamination, permanent source implants), communication should not be limited to explaining what the risk is, but should allow people to contribute to radiation protection (how to behave in order to limit exposure of oneself and/or others and/or environment).

5. Supervisor

Radiation protection authority should have high reputation in its work. To reach this goal authority should have competent experts in all applications of radiation practices with good understanding of radiation protection. The authority should inform all stakeholders of its activities transparently to get a well known status among users of radiation. When recognized status is reached the supervisory work will be more effective and stakeholders will be cooperative to reach optimal radiation protection.

6. Connection to other Health authorities

Radiation protection authority should have a strong connection to health authorities; they are a very important stakeholder. Health authorities obviously have responsibilities for all aspects of health care provision; while the radiation protection authorities have selected duties. There are many different national approaches. In some countries the health authorities are giving expert advice on radiobiology, where in others the

competence is within the radiation protection authority. In some countries the responsibility for staff protection and patient protection may be in different authorities.

Where is the justification question set in the national regulatory framework; In the RP legislation, or in a more generic legislation? For example, are other health authorities involved in the justification question? For example breast screening program in Finland, the justification question is judged in a medical – ethical trial.

Examples of areas where other health authorities are involved in addition to the radiation protection authority:

- Justification
- Patient safety
- How patient data are stored, frequency of examinations and treatments, dose data, and other information needed for surveys
- Financing
- Following up of epidemiological data
- International standards

7. Network creator

Information transfer between stakeholders is an important part of a learning process in radiation protection. Users of radiation can learn good practices from each other and also learn from the mistakes of other stakeholders. Radiation protection authority could activate this information transfer by creating discussion forums for example in regular meetings with target groups. Discussion forums on web pages might be useful as well. Data banks of incidents and accidents could be created and made available through the network.

8. Trainer

Radiation protection authority could act as a trainer of trainers on special topics. In this meaning one could educate and train some opinion leaders of stakeholders who can distribute the information on radiation effects, radiation protection and regulation and guides among other specialists.

9. Role to verify and improve radiation protection

Radiation protection authority should verify from time to time the situation at the particular point of time for example by making surveys with stakeholder groups on special topics related to radiation protection. The results of such verification offer useful material to create fruitful discussion with stakeholders in the meetings to improve the process of radiation protection.

Conclusions

The progressively but steadily increasing exposure to ionizing radiation associated with medical applications should be specifically addressed. The lack of awareness of the general public and some medical professions in relation to medical exposures needs to be addressed. Consultations with all stakeholders (medical devices manufacturers, medical staff, hospital managers, structures involved in the organization of national health systems, patients) should be organized in order to address this complex problem and try to find appropriate solutions.

Concerning medical devices, consultations with manufacturers and suppliers should be established to address the radiation protection issue directly at the source. Additionally, a discussion (on a national or international level), allowing better understanding and more transparency concerning the EC specifications for medical devices, should be initiated with the responsible EC structure.

Consultations concerning the notification of medical events and conditions for reporting those events to the medical community and the public should be further developed (medical staff, hospital managers, structures involved in the organization of national health systems, patients).

Health detriment and radiation protection management

Schneider, Thierry; Lochard, Jacques; Vaillant, Ludovic
CEPN, FRANCE

Abstract

Introduced in 1977 by ICRP, the concept of health detriment is a complex construction based on scientific information and on expert judgement. It gives an estimate of the total harm to health to individuals and their descendants as a result of an exposure to radiation, assuming a linear-non-threshold dose-effect relationship. It allows to compare risks induced by different types of radiation exposure situations and to put into perspective with other health risks.

Understanding its meaning is not straightforward, even for experts. It is in fact necessary to analyse its components and associated value judgements, and their evolution to catch this meaning. In addition, the application of this concept for different exposure situations is still a matter of debates in the radiation protection community. For instance: Does it represent a potential number of health effects for an exposed population? Does it give an estimate of the probability of occurrence of a radiation-induced effect for an individual?

The aim of this presentation is to recall the basis of this concept and its evolution and to discuss the key stakes regarding its usefulness in the radiation protection system. For instance, for occupational exposures, although the radiation detriment is no more the central indicator for establishing exposure limits, it is still quite useful to compare the risk associated with these limits with the levels of risk associated with exposure to different carcinogens and with occupational injuries. In addition, it is a key element for addressing the probability of causation for occupational diseases associated with ionizing radiation. Its use is also a matter of debate regarding radioactive waste management or environmental exposures, for which the main concern refers to exposure of future generations and large populations. Nevertheless, this concept is useful in this domain for assessing the level of protection on the basis of the current radiological protection criteria.

Norwegian strategy to fulfil the OSPAR Radioactive Substances Strategy objectives

Natvig, Henning; Nilsen, Mette
Norwegian Radiation Protection Authority, NORWAY

Abstract

At the 1998 Ministerial meeting of the OSPAR Commission, the Contracting Parties agreed to a strategy with regard to radioactive substances, the OSPAR Radioactive Substances Strategy (RSS). It states that the ultimate aim is: substantial and progressive reductions in discharges and to achieve concentrations in the environment near background values for naturally occurring radioactive substances and close to zero for artificial radioactive substances by 2020. Several of the Contracting Parties are far from meeting the 2020 objective. The oil and gas industry represent a substantial part of the TENORM-discharges to the North-East-Atlantic. A substantial part of the discharges come from the Norwegian sector. The Norwegian Radiation Protection Authority (NRPA) regulates the oil and gas industry on the Norwegian sector. NRPA uses a variety of means to contribute to fulfil the RSS objectives by 2020. NRPA collaborate with the competent authorities from the other oil and gas producing countries in the North Sea area to work towards a more harmonized regulation. The Norwegian zero discharge goal for the oil and gas industries has been extended to contain radioactivity, it is also recommended to perform a new assessment of injection of produced water on the two offshore platforms with the highest discharges of radioactive substances. We work towards a strengthened regulation of radioactive waste and discharges by a closer collaboration with the Norwegian Climate and Pollution Agency (former Norwegian Pollution Control Authority). As part of this work the legislation is currently under revision, and a new regulation based on the Pollution Control act is proposed. It is important to continue and develop the national monitoring programme of the industry, as well as investigate possible cleaning technologies and initiate cooperation between industry, regulators and researchers. Norway has at present special focus on TENORM. One of the first repositories for final storage of TENORM waste from the oil and gas industry was commissioned in 2008.

Introduction

Radioactive substances are used or found in several research institutions, hospitals and industries in Norway and on the Norwegian Continental Shelf. Some of these are well known such as the oil and gas industry on the Continental Shelf and in the research reactors at Kjeller and in Halden, the latest is part of an OECD project called OECD

Halden Reactor Proctect, as well as the use in medical diagnostic and therapy in hospitals. In addition NRPA has started a mapping of other industries where there can be discharges of radioactive substances with waste water or generating of radioactive waste of any category as part of the production. The discharges from the oil and gas installations on the Continental Shelf are far the largest radioactive discharges in Norway.

OSPAR

The OSPAR Convention for the Protection of the Marine Environment of the North East Atlantic was agreed in 1992. Countries that either have a North East Atlantic coast or discharge into the OSPAR maritime area via their rivers are Contracting Parties to the Convention. The North Sea including Skagerak, the Norwegian Sea and the Barents Sea are all within the area covered by the Convention. Totally 15 countries and the EU commission have ratified the Convention.

At the 1998 Ministerial meeting of the OSPAR Commission, the Contracting Parties agreed a strategy with regard to radioactive substances (see Box 1).

Box 1: OSPAR Radioactive Substances Strategy (RSS)*

Overall objective:
To prevent pollution of the maritime area, as defined under the Convention, from ionising radiation, through progressive and substantial reductions of discharges, emissions and losses of radioactive substances. The ultimate aim is to achieve concentrations in the environment near background values for naturally accruing radioactive substances and close to zero for artificial radioactive substances. In achieving this objective, the following issues should, inter alia, be taken into account:

- legitimate uses of the sea
- technical feasibility
- radiological impacts to man and biota

Intermediate objective (2020)
By the year 2020, the OSPAR Commission will ensure that the discharges, emissions and losses of radioactive substances are reduced to levels where the additional concentrations in the marine environment above historical levels, resulting from such discharges, emissions and losses, are close to zero.

* Radioactive Substance Strategy of the OSPAR Commission for the Protection of the Marine Environment of the North East Atlantic, 1998.

Norwegian Environmental Policy and Goals

In the Report No 21 (2004 – 2005) to the Storting "The Government's Environmental Policy and the State of the Environment in Norway" one of the national goals says that discharges of radioactive materials from Norwegian sources shall be limited to levels that do not have an adverse effect on the natural environment.

The Report No 8 (2005 – 2006) to the Storting "Integrated Management of the Marine Environment of the Barents Sea and the Sea Areas off Lofoten Islands" states that the targets for limiting inputs and concentrations of radioactive substances in the Barents-Lofoten area are.

> *The environmental concentrations of hazardous and radioactive substances will not exceed the background levels for naturally occurring substances and will be close to zero for man made synthetic substances. Releases and inputs of hazardous or radioactive substances from activity in the area will not cause these levels to exceed.*

In the "Integrated Management of the Marine Environment of the Norwegian Sea", Report No 37 (2008 – 2009) to the Storting is an analogous target is expressed.

With regard to radioactive substances are the goal expressed in these two Reports to the Storting more or less identical with the objective of the OSPAR Strategy. In the report to the Storting 26 (2006 – 2007) "The Government's Environmental Policy and the State of the Environment in Norway" it is referred to the Norwegian obligation to OSPAR, expressed as.

> *As a member of OSPAR Norway have the obligation to prevent pollution of the maritime area from ionising radiation through progressive and substantial reductions of discharges. The goal is that the level of naturally occurring radioactive substances shall be close to the background levels. Norway shall as part in OSPAR before 2020 secure that the discharges of radioactive substances be reduced to levels that contribute to concentrations in the environment beyond historical levels as a result of such discharges are near to zero.*

In the same Report to the Storting the Norwegian government also states that there should be a mapping of discharges, supplies and levels of radioactive materials in the Norwegian Coastal Current and the nearest maritime areas from both oil and gas activities and other sources, and that a need for strengthening of the knowledge of the consequences of the discharges were needed.

Norwegians efforts to reducing the discharges

Acts and regulations

The Norwegian radiation Protection Authority (NRPA) is the competent national authority in the field of radiation protection and nuclear safety in Norway. The NRPA administers two acts along with associated regulations:

- Act of Nuclear Energy Activities (No. 28 of 12 May 1972)
- Act of Radiation Protection and Use of Radiation (No. 36 of 12 May 2000)

- Regulations No.568 of 9 May 2003 on Application of the Act on Radiation Protection and Use of Radiation on Svalbard and Jan Mayen
- Regulation No 1362 of 21 November on Radiation Protection and Use of Radiation (Radiation Protection Regulations)

In addition the NRPA's preparedness mandate is laid down in a Royal Decree of 17 February 2006

When the Norwegian radiation protection legislation was revised at the end of the 1990s, resulting in the Radiation Protection Act of 2000, it was built to a large extent on the prevailing international recommendations. The main focus of radiation protection has traditionally been the protection of man from harmful radiation doses, which also was the main focus in the Radiation Protection Law. However, the Radiation Protection Act also embodied increased environmental awareness of radiation by including the environment in the purpose of the law alongside the goal of preventing the harmful effects of radiation on human health. The Radiation Protection Regulations, adopted pursuant to the Radiation Protection Act, went into effect in 2004. It has special provisions concerning radioactive emissions and waste. Even though the regulations are limited it includes requirements for approval of emissions of radioactive substances, waste facilities, and the export and import of radioactive waste. The Ministry of the Environment was authorised to function as the administrative appeal body under these provisions in 2006.

In recent years, an increased awareness of radiation as an environmental problem has gradually grown both in the international co-operation in the radiation area and in Norway. With respect to the relation between humans and environmental protection, the presumption has long been that as long as people are protected, then the environment is protected. An expression of this prevailing perception is given in the recommendations from International organisations like the Commission on Radiological Protection (ICRP), the International Atomic Energy Agency (IAEA) and the Nuclear Energy Agency (NEA). Corresponding perceptions are also found in EU documents.

As a part of the work of strengthening the radiation protection administration for the external environment, the Norwegian Radiation Protection Authority, Climate and Pollution Agency, the Ministry of Health and Care Services and the Ministry of the Environment have performed a review of the challenges of regulation of radioactive substances in the environment and the roles of the current bodies of regulations. There is a need for a more comprehensive set of regulations than the present regulations on protection of the environment. To meet these challenges a new radiation protection regulation is put forward. The regulation will be under and pursuance of Pollution Control Act. This regulation will result in a regulation of radioactive pollution will be based upon fundamental environmental principles such as prevention and the precautionary principle, the polluter pays and the best possible technologies. This new regulation is proposed to be put into force 1 January 2011.

The zero discharge project

The objective of zero discharges to sea of potentially environmentally hazardous substances from the petroleum activities was established in the Report No. 58 (1997 – 98) to the Storting "Environmental policy for a sustainable development". Based on the petroleum activities' substantial and increasing discharges to sea, the authorities identified a need to formulate a strategic, general objective that could contribute to reducing the discharges beyond that which followed from national and international objectives for reduction of oil and chemical discharges

In the Report No.26 (2006-2007) to the Storting the Norwegian Government announced that in 2009 evaluation of the progress of this project and whether further measures were needed to ensure that the zero discharge targets were achieved for oil and naturally-occurring substances discharged with produced water from the offshore petroleum industry. The Government also wanted to evaluate the need of efforts to reduce the discharges of naturally occurring radioactive materials (TENORM) from the petroleum industry.

To establish a basis to answer this questions the Climate and Pollution Agency and the Norwegian Petroleum Directorate were asked by the Norwegian Ministry of Environment and the Norwegian Ministry of Oil and Energy in 2008 to an evaluation of the above mentioned tasks. This was carried out in cooperation with the Norwegian Radiation Protection Authority. Data prognosis of discharges from the oil and gas installations on the Norwegian Continental shelf were collected from the companies together with estimates of costs for injection of produced water as an alternative to discharges. In addition an evaluation of technical ways to accomplish the injection and The influence of the marine environment of the discharges with special focus on the most vulnerably areas in the North Sea and the Norwegian Sea was also considered together with an evaluation of technical challenges of injection of produced water.

So far no harmful influence on living species in the marine environment can directly be related to discharges of radioactive substances with produced water on the Norwegian Continental Shelf. There is a need for more knowledge of long time effects. It is, however, known that radioactive substances have similar properties and potential environment-related harmful effects such as heavy metals and other environmental toxins.

The concentrations of radioactive substances in produced water can vary considerably between the field and these together with the great variation in the volume of produced water discharged will result in a great variation of the amount of radioactive materials discharged from the fields. The two installations Troll B and Troll C in the northern part of the North Sea are among the installations with the highest discharges of produced water. There is also relative high concentration of radioactive substances in the water discharged from these installations resulting in large discharge of radioactive materials from this field, see figure 1. The discharged radioactive substances from the Troll field count for about 40 % of the total Norwegian discharges.

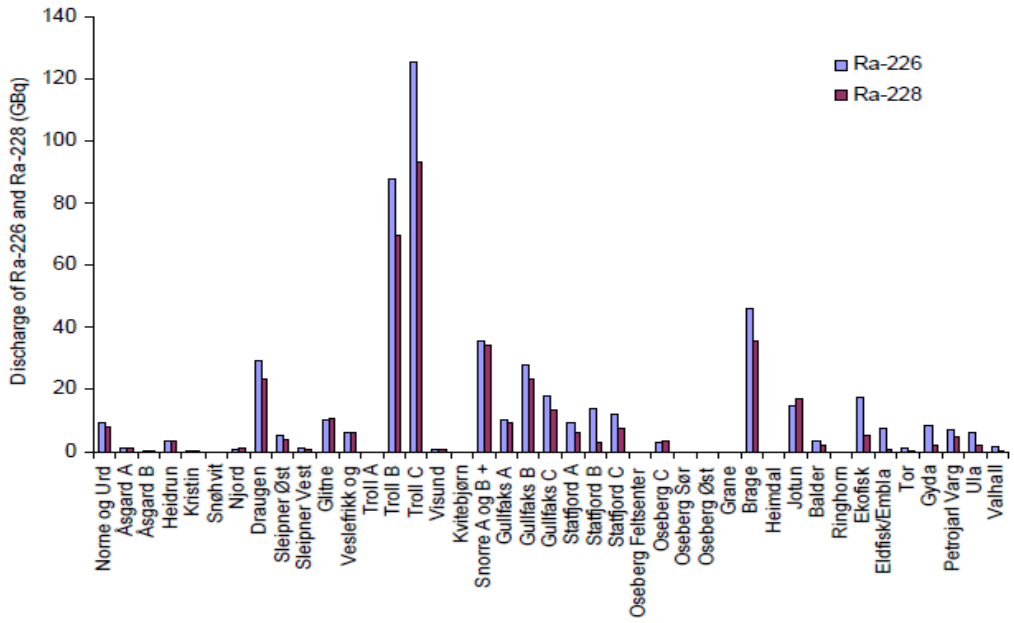

Fig. 1. Estimated discharged activity of ^{226}Ra and ^{228}Ra from Norwegian oil and gas fields in 2007 (NRPA 2009).

Based on the above mentioned evaluations two advices regarding radioactivity in the zero discharge project were given to the Ministry of Environment:

- to include radioactivity (TENORM) in the zero discharges target
- carry out new evaluations of the possibility of injection of produced water from the Troll B and C platforms due to the large amount discharged

Reporting

All activities that hold a permit to discharge radioactive substances to the environment have an obligation to report on the discharges from the activities every year. The reports should include information of the complete discharges of the various nuclides that have been discharges and also the concentration of the nuclides. For land based activities the recipient to which the discharges take place be described too. A description of how the use of best available technology is implemented as well as treatment of radioactive materials before discharges, to reduce the concentration of radioactive substances, should also be included.

Monitoring

National Programme

The Norwegian Radiation Protection Authority has since 1999 had a program for monitoring of radioactivity in the marine environment, both in coastal areas and the open sea (Radioactivity in the Marine Environment, RAME). Samples of seawater, sediments and biota are collected every third year in the North Sea including Skagerak, The Norwegian Sea and the Barents Sea. That is samples are collected from one of the areas each year. In addition samples are collected at permanent coastal stations, at Bear Island, Hopen and Svalbard, and in selected Norwegian fjords. The samples are

analysed for both naturally occurring radioactive substances like radium and for some dedicated substances from earlier tests of nuclear weapons in the 1950ies and –60ies, from the accident of Chernobyl and discharges from the reprocessing facility at Sellafield in UK and Cap de La Hauge in France.

In addition the Climate and Pollution Agency is coordinating a task to establish a long-term monitoring programme for the Norwegian maritime areas. The main purpose of this programme is:

- Calculation of the entry of environmental harmful substances including radioactive materials from various sources, divided in up to 12 regions
- Calculation of transport and concentration of these substances in the marine area
- Monitoring of environmental harmful substances in biota and sediments

Monitoring around oil and gas installations on the Norwegian Continental Shelf

The oil and gas companies operating on the Norwegian Continental Shelf have an obligation to carry out monitoring of the water column and the sediments in the neighbourhood of their installations. This monitoring shall give an overview of the environmental conditions and map the development and trends in the environment around the oil and gas installations. The Norwegian Shelf is divided in several regions, see figure 2. Surveys of taking sediment samples is carried out in each region every third year. For the water column the monitoring consist of two parts; condition monitoring in which samples of fish are analysed every third year, and the other part which is being developed is an effect study and the frequency of monitoring near by the different installations is not yet decided. In addition to demonstrate trends the results are the basis for expectations for future developments. In the later years the monitoring programme has included analyses of sediment samples for radioactivity for a few stations.

A process to develop the monitoring of radioactivity around the oil and gas installations has to been started and for 2010 the number of stations where sediment samples will be taken is expanded compared with the previous years.

The results from the monitoring will, among other things, be used for:

- evaluation of the risk for environmental damage and ecological effects
- verification of models for calculating the environmental risk as a function of existing and expected discharge from the offshore industry.
- verification of laboratory based research

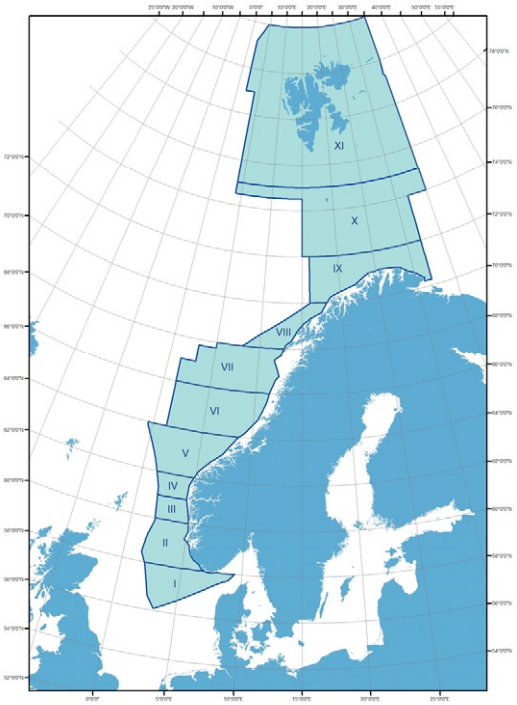

Fig 2. Overview of regions for monitoring of sediments on the Norwegian Continental Shelf.

Regulation of discharges

Generally

All approvals/permissions issued to companies who discharge radioactive substances instruct the companies to examine all their procedures and routines carefully to identify any measure to reduce their discharges of radioactive substances. The results of such an examination should be reported to NRPA within a certain deadline.

NRPA should carry out a total review of all approvals/permissions to secure that the discharges limits are in according to the existing discharges and that they does not open up for significant increase in the future.

If relevant, request for environmental monitoring is a part of the approvals/ permissions, and the results of this monitoring shall be reported to NRPA within a certain deadline.

All approvals/permissions to discharges should contain requests for use of best available technology, to avoid discharges if possible or keep the discharges as low as possible.

Research nuclear reactors

The company responsible for the two Norwegian research reactors (IFE) should be requested to carry out risk analysis of the discharges for both the facility in Halden and at Kjeller. As a part of new discharge permits IFE has to evaluate potential measures to reduce the discharges and by that reduce the radiation doses to the public as well as the environment. In a new discharge permit discharge limits based on the activity of the various nuclides has to be established. As the only Norwegian company IFE have

discharge limits given in dose limits, other companies have discharge limits given in nuclide activity.

Oil and gas industry

New fields shall, as a general rule, be developed with the objective of zero discharges of produced water containing radioactive substances under normal operations. For new fields that are developed with a tie in to existing installations discharges of produced water should only be allowed under normal operation if it is needed of serious safety, technical economic or environmental reasons.

On fields in production where injection of produced water is a existing solution it is important that the amount of produced water is kept at the prevailing level or is increased if there is no serious technical, safety, environmental or economical reasons for reducing or stop the injection.

Development of technology for reduce the content of radioactivity in the produced water has to be carried out in a cooperation of operating companies on the Norwegian Continental Shelf, the suppliers of purify technology and research institutions.

Hospitals, universities and research institutions

A joint evaluation of all discharges of radioactive substances from these kinds of institutions to map doses to people and the environment should be carried out. Based on the results of such an evaluation the requirement of further measures to reduce the discharges should be developed.

Waste management

All waste management companies should have a permit with requirements that contribute to as low discharges or other kind of radioactive pollution from the activities as possible. The new regulation mentioned earlier describes procedures for how to handle waste containing radioactive materials with various content of activity. For radioactive waste with origin offshore that have concentrations above certain limits should be sent to a special repository for final disposal. Also for waste with lower activity there are requirements for handling and final disposal.

Mapping of discharge from other sources

NRPA has started several projects to map any discharges or other kinds of radioactive pollution from mines other kinds of industry which may lead to radioactive pollution These projects form a basis for further development of regulations of radioactive waste management and discharge.

Auditing

Inspections and auditing are important to verify that the companies or other institutions that have approvals/permits for discharges or handling radioactive waste from NRPA are operating in conformity with the regulations and permits. These activities should be carried out in accordance to a yearly established plan.

References

NRPA, 2009. Radioactivity in the Marine Environment 2007. Results from the Norwegian National Monitoring Programme (RAME). StrålevernRapport 2009:15. Østerås: Norwegian Radiation Protection Authority.

The Integrated Management System – to ensure an overall safety

Ham, Ulla; Lorenz, Bernd
GNS – Gesellschaft für Nuklear-Service mbH, GERMANY

Abstract

GNS (**G**esellschaft für **N**uklear-**S**ervice mbH) as a subsidiary company of the German utilities E.ON, RWE, EnBW and Vattenfall is charged with ensuring the radioactive waste management for their nuclear facilities. Moreover GNS also provides its products and services to foreign customers.

"Safety first" – this is the key note of our vision to ensure sustainable radioactive waste management, meaning first of all the protection of people and the environment.

For this reason GNS has implemented an integrated management system strictly based on the requirements of the IAEA Safety Requirements GS-R-3 "The Management System for Facilities and Activities" /1/ in early 2009.

The management system integrates safety, health, environment protection, security, quality and also economic elements.

Our company policy including the respective guidelines reflects the top-ranking of a strong safety culture within our management system.

An adequate organisational structure and the process organisation needed to fulfil the purpose of our company have been implemented always keeping in mind the meeting of the safety requirements. Continuous improvement of the organisation and processes is guaranteed, especially regarding the further development of our safety culture.

The paper presented in this abstract is to demonstrate in which way an integrated management system, strictly following the requirements of the above mentioned IAEA Safety Requirements, has been developed and implemented. The structure and the daily working of such an integrated system will be illustrated, benefits and advantages will be presented as well as the experiences gained up to the moment. But also challenges that appeared when developing such an integrated system with the emphasis on "safety first" will be addressed.

Introduction

GNS (**G**esellschaft für **N**uklear-**S**ervice mbH) as a subsidiary company of the German utilities E.ON, RWE, EnBW and Vattenfall is charged with ensuring the radioactive waste management for their nuclear facilities. The activities range from the planning, design, manufacturing and services in the field of radioactive waste and nuclear casks to

the handling, transport and interim storage of flasks/casks for irradiated fuel as well as the decommissioning/dismantling of nuclear plants or the preparation of final storage. Moreover GNS also provides its products and services to foreign customers.

All these activities are governed by GNS' vision

"as a centre of expertise of the German energy supply companies, to sustainably ensure nuclear waste management while maintaining the highest safety standards at competitive terms".

This vision has been specified by the company's policy taking into account nuclear safety and radiation protection, health and safety, quality and environment factors as well as by the related principles, the very first being "we are aware of our responsibility for safe and reliable waste management". It is supported by the "Code of Conduct" accepted by the management and the employees.

Irrespective of this voluntary commitment GNS also has to satisfy legal requirements, technical rules and standards, requirements defined in licences and approvals all intending to keep safety objectives as e. g. shielding, leak tightness, under criticality, prevention of release of radioactive substances and so to protect men and environment from adverse effects of radioactivity.

But – how to meet these requirements in day-to-day business? Could an adapted management system help? And if yes, what type of management system should it be?

Material and methods

Why an Integrated Management System?

An adapted management system has to provide an instrument to achieve a company's vision and objectives. It defines the organisational structure as well as the process organisation needed to fulfil the company's tasks and the respective requirements. It has to conform to the specific and accepted management rules and standards. It has to integrate already existing procedures and systems or modify them, where necessary, as the already existing quality management system and environmental system, both being accepted for a long time by third parties. And it has to be suitable for day-to-day business.

So GNS decided for the implementation of a – process related - **I**ntegrated **M**anagement **S**ystem (IMS) strictly following the requirements of GS-R-3 /1/ taking into account the requirements of radiation and environmental protection, occupational health and safety, quality control and cost-effectiveness in the planning, design and management of projects and processes. The IMS "covers all specifications, regulations and organisational aids that are provided within the company to manage the relevant tasks for the success of the company under controlled conditions and to control and improve the achievement of objectives" (KTA 1402 /2/). The IMS focuses on the processes that are important to the company.

But – which are the processes important to the company?

Process identification

In co-operation with the management board GNS processes have been identified, the ones classified as being the most important to the company's success as defined in the

vision and the policy have then be divided up into management processes, main processes, supporting processes and "other processes".

Management processes are those necessary for the overall regulation of the company and are primarily dedicated directly to the Management Board.

The main processes cover all activities to fulfil the essential tasks in relation to the customers and to a decisive extent determine the economic performance of GNS and the importance of the company for the shareholders in accordance to GNS' vision and policy.

Supporting processes are necessary to achieve the goals of the main processes. The supporting processes provide the prerequisites for the working of the main processes or define procedures which apply to all processes in the same way.

"Other processes" focus on procedures and workflows for other overall elements of the IMS.

Organisation structure to ensure an Integrated Management System

The organisation structure of GNS always follows the essential tasks in relation to the customers and so the main processes. Where necessary the organisation structure has been adapted to other relevant processes within the context of establishing the IMS and therefore focussing on the different interested parties. Persons with special responsibility for elements or processes within the IMS have been authorised.

Documentation of the Integrated Management System

The structure and the processing of the IMS in principle have been described in the IMS Manual /3/. Details are fixed in supplementary documentation.

Results

The processes identified as the most important are shown in figure 1.

The requirements originating from the elements of the IMS (as there are radiation protection and nuclear safety, environmental protection, occupational health and safety, quality and cost-effectiveness) as well as the requirements and the satisfaction of the interested parties (customers as well as shareholders, authorities and experts, employees, suppliers and sub-contractors, members of society) basically determine GNS' processes.

The structure of the processes shown in figure 1 are described in detail in further process visualisations and completed by descriptions or instructions, where necessary. Stipulations are documented to guarantee the keeping of the requirements originating from the different aspects of the IMS. All documents are made available to all employees by an adequate database. The structure of the IMS documentation is shown in figure 2. This figure also demonstrates the correlation between the company's policy or external influences (legal requirements, licences, approvals etc.) and the management system of GNS.

The IMS as means to keep the company's policy and principles has been discussed and communicated to the management and the employees.

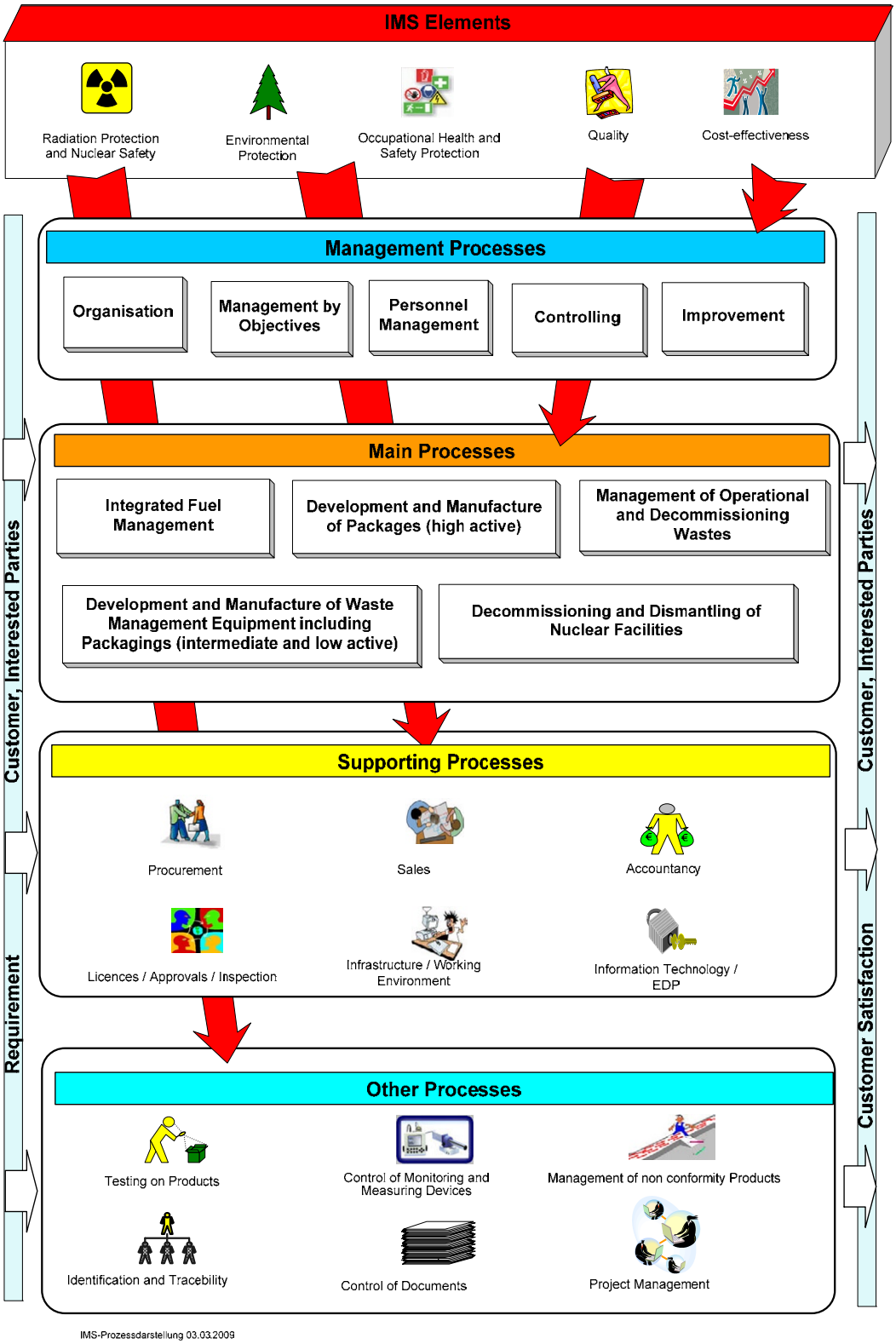

Fig. 1. Process Model of the Integrated Management System.

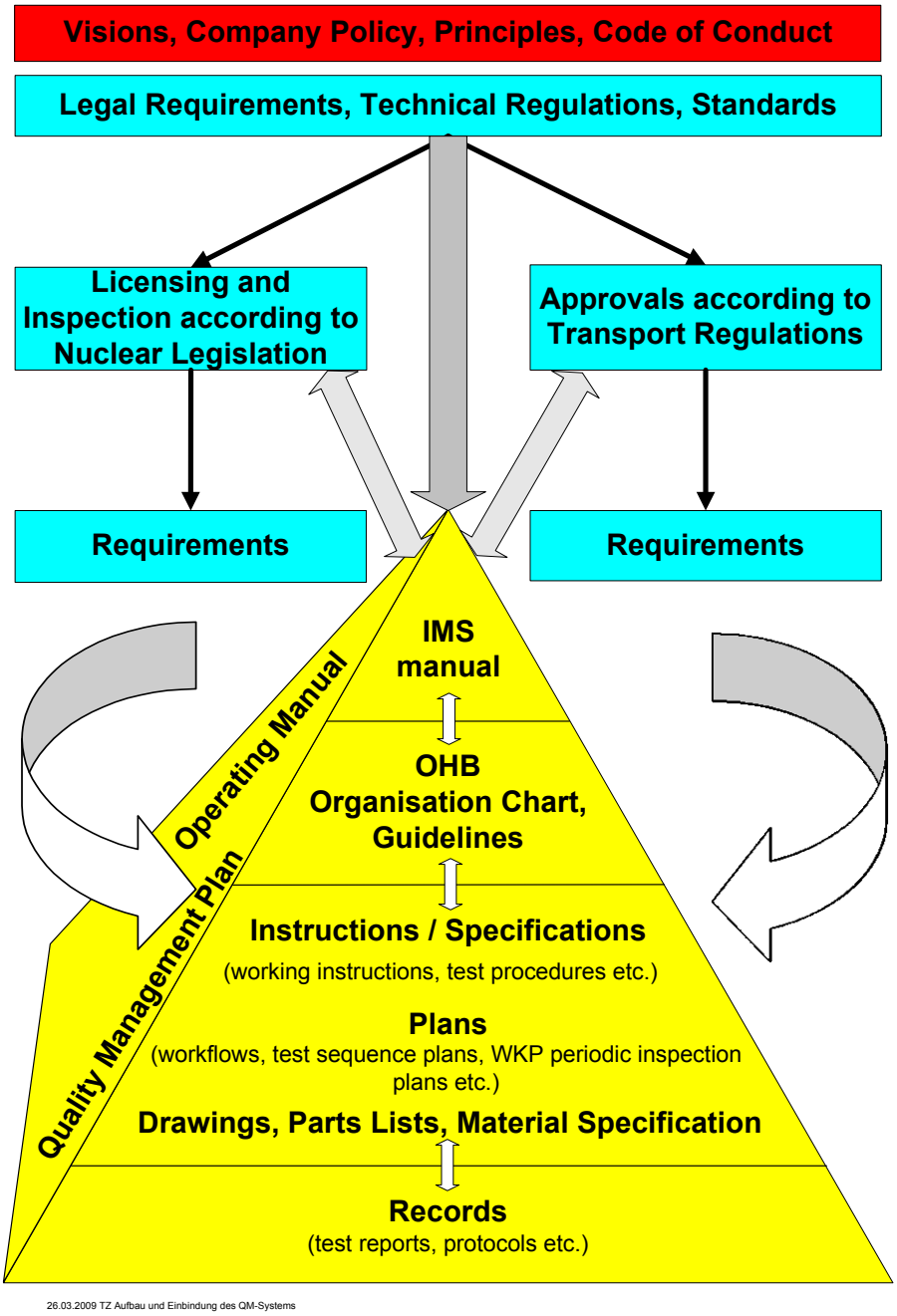

Fig. 2. Structure and Integration of the Management System.

Discussion

What did change regarding the day-to-day business when introducing the integrated management system as presented before?

The IMS is the result of an appropriate combination and continuous development of already existing systems (the quality or environment management system). The principles of the functioning of these systems, proven for a long time, have been adopted and, where necessary, modified according to experiences made. Only the factors systematically to be taken into account when planning, designing and managing

processes and projects have been extended according to the company's policy and principles. This fact has supported a high acceptance of the IMS by the management and the employees.

Benefits and advantages of an IMS are highly detectable. The integration of all relevant aspects into the internal procedures has made clear the correlations between them. It has led to a higher sensitivity of the employees for the different requirements and their responsibility for fulfilling them within the frame of their process and project activities. This has also led to a continuous assessment and improvement of the implemented processes and so the management system. Moreover all organisational structures within GNS that could be concerned by a project or a process are involved in the respective planning, designing and managing.

Systematically taking into account all factors that may influence a process, a product or a project also lead to a higher legal certainty with regard to the legal requirements, standards and rules to be kept.

But – how to decide in case of contradictory requirements that originate from the different factors, e. g. aspects of cost-effectiveness versus those of environment protection requirements? The interests have to be balanced, but safety shall never be compromised. The optimum solution has to be found while fulfilling the legal requirements or such coming from licences or approvals. Due to the long lasting experience and practise with operating nuclear facilities or performing activities with radioactive material this spirit was already there in the whole company and its deliberately expression in the IMS Manual was not new for the staff.

Conclusions

The implementation of an integrated management system focussing on the processes important for the company with regard to its policy and principles has been successful. It has been accepted by the management and the employees. Nevertheless continuous sensitisation for as well as discussion and assessment of the needs of such a system as well as of the single factors is required and realised. So it will be and is integral part of continuous improvement.

Regarding the parts of quality management and environment management the IMS has already been accepted as appropriate system by the certification body. The IMS has also been accepted as an adequate system to manage safety (as synonym for quality within the nuclear industry) by third parties as authorities.

References

/1/ GS-R-003; IAEA, Safety Requirements, Management System for Facilities and Activities, Vienna, 2006

/2/ KTA 1402 (Draft Safety Standard in Preparation); KTA, Management System for the Operation for Nuclear Facilities, November 2007

/3/ IMS-Manual – GNS, Manual on GNS' Integrated Management System, Rev. 0, April 2009

Possible implications of new Basic Safety Standards – a Swedish viewpoint

Hellström, Gunilla; Lund, Ingemar
Swedish Radiation Safety Authority, SE-171 16 Stockholm, SWEDEN

Abstract

The 2007 Recommendations of the International Commission on Radiological Protection (ICRP) [1] formally replaced their earlier 1990 Recommendations. The International Atomic Energy Agency and the European Commission presently update and review their *Basic Safety Standards* (BSS) [2, 3] within their frameworks, jurisdiction and international roles. The Swedish regulatory system will be influenced and steered by these emerging documents, especially by the Euratom BSS since these are binding for the Member States. With the proposals existing as of spring 2010 as starting point, we offer our view on the possible implications the new Standards will have on the radiation safety regulations of Sweden.

Introduction

Both the *International BSS* and the *Euratom BSS Directive* relate to the health protection of patients, workers and the public from the dangers of ionising radiation. The standards apply to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation.

The new *Standards* reflect changes introduced in ICRP 2007 main recommendations:

- Updating the radiation detriment based on latest scientific information of the biology and radiation exposure,
- Moving from a process-based protection approach (practices, interventions) to a situation-based approach, basing the system on type of exposure situations (planned, emergency, existing),
- Emphasis on the use of optimisation and dose constraints/reference values in all exposure situations, and
- More focus on the protection of the environment, developing a framework to demonstrate the radiological protection of the environment.

The fundamental principles of radiological protection: *Justification, Optimisation, Application of dose limits*; and the Commission's *dose limits* for effective dose and equivalent dose from all regulated sources in planned exposure situations are kept.

Furthermore, the new *Standards* reflect the societal needs, experience feed-back, and value judgements which have led to inclusion or updates of:

- Requirements on national/regional education, training, and competence,
- Security issues and concerns influence threat analysis and the national emergency planning,
- The justification and treatment of non-medical imaging,
- Regulation of planned or existing exposure situations involving naturally occurring radioactive materials (NORM) and radon in dwellings and workplaces.

Influence on Swedish legislation and regulations

In the following a non-exhaustive treatment of the possible influence of the *Standards* in Sweden is given. Focus is on the Euratom BSS Directive since it is binding for the EU member states.

Exposure Situations

The use of the three exposure situations to identify and determine the appropriate protection needs will influence the present legislation. The control of *planned exposure situations* (includes *practices*) is since earlier well developed and justification and optimisation were required in the Swedish regulation. The new concepts with existing and emergency exposure situations with different approaches to justification and the use of reference levels in the optimisation of protection must be reflected in new legislation. The choice between planned exposure situations and existing exposure situations is not always obvious for all activities which must be taken into account.

Optimisation of the protection and safety in new exposure situations.

For *emergency exposure situations* and *existing exposure situations*, optimisation shall be used to enhance protection. In practice, existing regulations and procedures for emergency preparedness, management of radon exposure and others, classified as existing exposures, will be reviewed. For emergency preparedness this will involve the planning phase (*optimised protection options* related to different events) or decision-making in emergency situations (release of contaminated land, radiation doses to public and emergency workers, etc.). In *existing exposure situations*, protective measures shall be optimised and not merely result in exposure levels below an action value. *Reference values* will have to be developed if they do not already exist. For *existing exposure situations*, any changes in regulatory approach will in Sweden often involve several authorities.

Graded Approach

Especially the *Euratom BSS Directive* now put emphasis on *a graded approach*. The protective measures should be more commensurate with the actual risk estimates. Though for many practices the Swedish authority uses a graded approach in licensing and supervision, it is more of praxis than based on legal documents. This means that a larger diversity of possible legislative and regulatory means must be introduced. In Sweden, the radiation protection legislation will have to introduce the concepts of notification and registration, the existing options of licensing or not licensing are not

sufficient. Furthermore, the actual requirements must be proportional; the regulatory body must develop regulations and/or license conditions with a larger degree of versatility. The need for prioritising of practices and sources suitable for registration is obvious and also to more frequently exempt activities or products from control. The proposed general clearance levels are expected to be complemented by authorised release from practices based on the criteria for clearance given in the BSS.

Education and Qualified Experts

Education and good knowledge of sciences and the existing radiation protection philosophy is needed in radiation protection work. Sweden has, as an example, good education in radiation physics. Most of these students become medical physicists and a high number of these are employed in Swedish hospitals but some are employed as qualified experts in the nuclear industry or research institutions. The SSM has issued *general advices* in its Code of Status on suitable educations and competence for operational staff at nuclear facilities and for qualified radiation protection experts. Regulations exist connected to education for the medical and the nuclear sector as well as in many more specific activities (e.g. radiography). However, a general overview of existing advice and regulations must be done and in some cases more specific requirements could be needed. The Euratom BSS directive is now more precise in defining the concepts and tasks of *radiation protection experts* and *radiation protection officers* and this must be accounted for and amendments in regulations introduced as necessary. Another factor that makes education and training important is the on-going generational change at the licensees as well as at the authority.

Regulation of NORM

What earlier was specified as *work practices* in the existing *Euratom BSS Directive*, will now, after the member states have performed national investigations of the needs for regulation and control, require regulation. In many areas, such as radon in residences and work places, Sweden is since many years prepared with regulations. In other areas, changes in legislation and regulations are foreseen. The SSM is for the moment preparing regulations on how NORM material emerging in constructional projects (roads, buildings, tunnels etc…) should be handled if the quantities are smaller than 100 tonnes per year. Further regulatory activities are to be expected; one issue is how the requirement on how optimisation under *reference levels,* is ensured for such *existing exposure situations*.

Justification

An issue of major importance is the justification of activities involving radiation protection. The justification process in the medical field (overall justification of methods and justification of the individual examination, qualifications and responsibilities of referring medical practitioner, radiological medical practitioner) is an unceasing source of importance. The justification of consumer products (e.g. use of smoke detectors) is also a relevant topic and an even more "hot topic" is the justification of non-medical imaging in relation with legal or insurance purposes, theft detection, security or anti-smuggling purposes. The two *Basic Safety Standards* have different approaches to these issues but the common denominator is that such activities,

should they occur, must be justified and regulated according to national praxis. The *idea* is to allow for justified use of non-medical imaging however applying strict regulation. How to deal with these complex situations should be further analysed and dealt with, purpose for purpose, situation for situation.

Conclusions

Sweden is well prepared for implementing the new requirements as formulated in the international radiation protection standards, especially the Euratom BSS Directive. Nevertheless quite some work will be needed to review and amend the existing legislation and regulatory framework. Emphasis will have to be put on the new requirements of optimisation in all exposure situations, applying a graded approach and the requirements of education and radiation protection experts. Regarding NORM, some regulations exist but more is foreseen. Finally, we would like to underline that the issue of justification needs emphasising, both in medical as well as in non-medical imaging.

References

[1] ICRP Publication 103, *The 2007 Recommendations of the International Commission on Radiological Protection,* Annals of the ICRP, Volume 37, Nos. 2-4, 2007

[2] Draft European Basic Safety Standards Directive, Version 24 February 2010

[3] International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Draft 3.0, January 2010

IEC standards for measurement of environmental radiation

Voytchev, Miroslav[1]; Chiaro, Peter[2]
[1] IRSN/DSU/SERAC/BIREN, FRANCE
[2] Oak Ridge National Laboratory, USA

Abstract
This paper presents the IEC/SC 45B "Radiation Protection Instrumentation" and its 15 standards for measurement of environmental radiation that have been published or that are under development or revision. Two types of standards are considered: general standards for environmental measurement instrumentation and standards for airborne radioactivity measurements. The first type covers gamma radiation ratemeters for environmental monitoring (IEC 61017-1&2), equipment for monitoring of radionuclides in liquid effluents and surface waters (IEC 60861), mobile instrumentation for the measurement of photon and neutron radiation in the environment (IEC 62438) and in-situ photon spectrometry systems using a germanium detector (IEC 61275). The second types concerns equipment for continuous monitoring of radioactivity in gaseous effluents (IEC 60761 series), monitoring equipment of atmospheric radioactive iodines (IEC 61171) and radioactive aerosols (IEC 6117) in the environment, radon compensation for radioactive aerosol monitors (IEC 61578) and equipment for monitoring radioactive noble gases (IEC 62302) and airborne tritium (IEC 62303).

Introduction
Different international organizations (ICRP, ICRU, IAEA, ISO, IEC…) develop standards, recommendations, reports or other international documents concerning radiation protection and particularly for measurement of environmental radiation. This paper will present IEC, its Sub Committee 45B "Radiation protection instrumentation" and the scopes of the 15 international standards that IEC/SC 45B has developed for measurement of environmental radiation.

IEC/TC 45/SC 45B
The International Electrotechnical Commission (IEC) was founded in 1906 and is the leading global organization that prepares and publishes international standards for all electrical, electronic and related technologies. These standards serve as basis for national standardization, as references when drafting international tenders and contracts, and for conformity evaluation of instrumentation.

A total of 76 countries are now participating in the IEC family (56 members and 20 affiliates from developing countries). Each country participates through its national committee.

There are 179 Technical Committees (TC) and Subcommittees (SC), and more than 700 working groups (WG) that carry out the standardization work for IEC. The working groups are composed of representatives from all over the world who are experts in their own field and who are members of research and testing laboratories, regulatory agencies, academia, manufacturers, and user organizations.

Technical Committee 45 "Nuclear instrumentation" addresses standard development for instrumentation specific to nuclear applications. Its Sub Committee 45B "Radiation protection instrumentation" covers all the fields of radiation protection instrumentation for measurements under normal and accident conditions of external and internal individual exposure, to workers, the public and in the workplace and environment.

SC 45B has more than 200 experts from 22 participating and 12 observer countries. There are currently 47 publications in force and 14 projects are in development. The SC has liaisons with IAEA, ISO, ICRP and other organizations. Its standards are considered by CENELEC for adoption as European ones.

SC 45B currently has the following active working groups:

- B5: Measurement of environmental radiation;
- B8: Pocket active electronic dose equivalent and dose equivalent rate monitors;
- B9: Installed equipment for radiation and activity monitoring in nuclear facilities;
- B10: Radon and radon decay products measuring instruments;
- B14: Passive integrating dosimetry systems for monitoring of external radiation;
- B15: Illicit trafficking control instrumentation;

SC 45B, through its WGs B5 and B13, was charged with the development of international standards for environmental measurement instrumentation. WG B13 "Measurements of Airborne Radioactivity" was recently disbanded and its activity was transferred to WG B5.

General standards for environmental measurement instrumentation

The general standards for measurement of environmental radiation are developed within WG B5.

IEC 61017 "Portable, transportable or installed X or gamma radiation ratemeters for environmental monitoring"

The first standard to be considered is IEC 61017 "Portable, transportable or installed X or gamma radiation ratemeters for environmental monitoring" published in 1991. This standard has two parts: part 1 "Ratemeters" and Part 2 "Integrating assemblies". Being rather old, a revision of this standard is expected to start in 2010. Both parts will be combined into one standard covering transportable and installed assemblies. Portable (rate) meters are already covered by IEC 60846-1 (2009) developed within WG B8.

IEC 61017 is applicable to portable, transportable or installed assemblies intended to measure environmental air kerma rates from 30 nGy h^{-1} to 10 μGy h^{-1} due to X or gamma radiation of energy between at least 50 keV and 1.5 MeV. If the assembly is to be used to measure air kerma rates in the area surrounding a nuclear reactor producing 6 MeV photons it will be necessary to determine the response at that energy.

For the purpose of radiation protection these assemblies comprise at least a detection sub-assembly (e.g., ionization chamber, GM counter tube, scintillation detector, etc.), a measuring sub-assembly including a display device, which may be connected together either rigidly or by means of a flexible cable or incorporated into a single assembly. The installed assembly may also comprise a continuous recorder (e.g., chart or magnetic cassette recorder or telemetry equipment). The requirements of this standard are also applicable to assemblies that use integration of the ionization current, count-rate, etc. to enable a mean air kerma rate to be indicated or determined.

This standard does not apply to thermoluminescence dosemetry systems or other passive integrating devices and it does not provide for the measurement of beta radiation.

IEC 60861 "Equipment for monitoring of radionuclides in liquid effluents and surface waters"

IEC 60861 Ed. 2 (2006) defines technical requirements for equipment used for monitoring of alpha, beta or gamma emitting radionuclides in liquid effluents and surface waters, provides some general guidance as to the possible detection capability of such equipment and indicates when and where its uses may be practicable.

This standard is applicable to equipment for continuous monitoring of the activity in liquid effluents which could be released in the environment during normal operations and in environmental waters.

It is applicable to water monitors intended to measure the volumetric activity or count rate due to radionuclides in the liquid and its variation with time and to actuate an alarm when a limit value of volumetric activity or count rate in water is exceeded.

IEC 60861 does not apply to equipment specifically for use in accident conditions that may require additional capabilities.

This standard is restricted to equipment for continuous monitoring of gross alpha or gross beta of maximum energy higher than 150 keV or gamma activity in liquid effluent streams and environmental waters. It does not deal with sample extraction and laboratory analysis.

The second edition of this standard from 2006 cancels and replaces the first edition published in 1983 and the first edition of IEC 61311 published in 1995. This edition, with respect to the previous edition, takes into account the main technological evolutions, notably the feasibility of continuous monitoring of alpha radioactivity in liquids and tests for electromagnetic compatibility.

IEC 62438 "Mobile instrumentation for the measurement of photon and neutron radiation in the environment"

IEC 62438 (2010) is applicable to mobile radiation detection systems used for the detection, quantification and identification of photon and/or neutron emitters in the environment. This includes point and distributed radiation sources.

In general, mobile instrumentation systems for nuclear radiation measurements in the environment are comprised of detectors, detector signal processors, position sensing devices, on-board data recording, operational monitoring, and real time display/alarm capabilities. In addition, advanced systems may provide data streams that can be transmitted by telemetry to operation centres.

This standard cancels and replaces IEC 61134, issued in 1992. The scope of IEC 61134 was restricted to exploration for geological deposits of potassium, uranium and thorium. IEC 62438 incorporates the range of currently available detector technologies and incorporates neutron monitoring. This standard also relates to a wide range of mobile platform applications including environmental, emergency response, security, in addition to geological.

IEC 61275 "Measurement of discrete radionuclides in the environment - In-situ photon spectrometry system using a germanium detector"

IEC 61275 (1997) is applicable to a portable or transportable photon spectrometry assembly using a high purity germanium (HPGe) detector to survey in situ, generally at 1 m above ground level, areas in the environment for discrete radionuclides. Such equipment is used to make rapid assessments of activity levels and corresponding free air exposure rates from photon emitting radionuclides. Measurement results may be used to develop guidance for subsequent follow on action including radiological assessments, sampling and monitoring programmes.

This standard does not apply to mobile measurement systems that are covered by IEC 62438.

IEC 61275 is currently in revision on CD level with expected publication in 2012.

Standards concerning the measurements of airborne radioactivity

These standards have been developed for many years within WG B13 of SC 45B before this working group was merged with WG B5.

IEC 60761 series "Equipment for continuous monitoring of radioactivity in gaseous effluents"

IEC 60761 Ed. 2 published in 2002 consists of the following parts, under the general title "Equipment for continuous monitoring of radioactivity in gaseous effluents":

- Part 1: General requirements
- Part 2: Specific requirements for radioactive aerosol monitors including transuranic aerosols
- Part 3: Specific requirements for radioactive noble gas monitors
- Part 4: Specific requirements for radioactive iodine monitors
- Part 5: Specific requirements for tritium monitors

IEC 60761-1 defines acceptable forms of such monitoring, provides general guidance as to the possible range of measurement and capability of such equipment as may be envisaged, and indicates when and where its uses may be practicable. This standard is applicable to equipment for continuous monitoring of radioactivity in gaseous effluents during normal operations and during anticipated operational occurrences. IEC 60761-1 does not apply to equipment specifically for use in accident conditions. Such equipment may require additional capabilities. This standard is

restricted to equipment for continuously monitoring radioactivity in gaseous effluent. It does not deal with sample extraction and laboratory analysis.

IEC 60761-2 is applicable to equipment intended for simultaneous, delayed or discrete sequential measurement of aerosols in gaseous effluents discharged into the environment. It is applicable to equipment designed to fulfil the following functions:

- the measurement of the volumetric activity of the aerosols in gaseous effluents and/or the released total activity of aerosols ;
- the actuation of an alarm signal when either a predetermined volumetric activity or a predetermined total released activity of aerosols is exceeded.

This equipment is intended for measurement over a wide range of activity, including very small quantities in the presence of a much larger natural background. The daughters of ^{222}Rn (radon) and ^{220}Rn (thoron) are naturally occurring aerosols contributing to the natural background. The discrimination against natural activity can be an important problem when monitoring low level activity. In order to provide more and better information, complementary or retrospective laboratory analysis of the filters after collection may be performed.

IEC 60761-3 is applicable to equipment intended for simultaneous, delayed or discrete sequential measurement of radioactive noble gas in gaseous effluents discharged into the environment. It is applicable to radioactive noble gas effluent monitors intended to fulfil the following functions:

- the measurement of the volumetric activity of radioactive gases in the gaseous effluents at the discharge point and its variation with time;
- the actuation of an alarm when a predetermined volumetric activity or a predetermined total released radioactivity is exceeded;
- the determination of the gas activity discharged over a given period and/or information on the composition of a mixture of different gases in the discharge.

Radon is a natural radioactive noble gas. Its measurement is not included in this standard. The presence of radon, or its decay products, may interfere with the measurement of other (artificial) radioactive gases.

IEC 60761-4 is applicable to equipment intended for the simultaneous, delayed or discrete sequential measurement of radioactive iodine in all forms. When the effluent is sampled for measurement, iodine bound on aerosols is generally collected on a pre-filter which should be analyzed separately in a laboratory to provide a complete measurement.

It is applicable to equipment designed to fulfil the following functions:

- the measurement of the volumetric activity of iodine and compounds of radioactive iodine in gaseous effluents or of the released iodine total activity;
- the actuation of an alarm signal when either a predetermined concentration or a predetermined total released activity due to iodine or its compounds is exceeded.

This equipment is intended for measurement over a wide range of activity in the presence of other radionuclides in the gaseous effluent, including naturally occurring radioactive nuclides. Discrimination against other radionuclides can be important in measuring low levels of radioactive iodine.

This standard considers both the use of iodine collection media such as activated charcoal and the direct measurement of iodine in stacks or ventilation ducts.

IEC 60761-5 is applicable to equipment intended for the simultaneous, delayed or discrete sequential measurement of tritium in any gaseous form in gaseous effluents discharged into the environment. It is applicable to equipment designed to measure the concentration of tritium in the gaseous effluents at the discharge point and its variation with time and actuate an alarm when a predetermined volumetric activity or a predetermined total released radioactivity is exceeded. The equipment may also be used for the determination of the tritium activity discharge over a given period.

IEC 61171 "Monitoring equipment - Atmospheric radioactive iodines in the environment"

IEC 61171 (1992) is applicable to equipment intended for transportable or installed use for monitoring, as a function of time, airborne radioactive iodines (e.g., ^{131}I, ^{125}I) in the environment (outside of buildings or facilities, at heights typically from one to a few meters above the surface) of a nuclear facility during normal operations, during anticipated operational occurrences or during accident conditions. For the purpose of this standard, monitoring includes the continuous sample collection with, if it is required, the capability to automatically initiate sampling.

This standard does not include equipment intended for monitoring radioactivity associated with gaseous effluents (at the stack). This type of equipment is covered in IEC 60761-1 through IEC 60761-5. This standard does not include monitoring for ^{129}I.

Specific chemical species of radioactive iodines may be selectively collected by specialized sampling equipment according to the requirements specified by agreement between manufacturer and user. Such samples should be in the form appropriate for laboratory analysis. The radioactive iodines may be gaseous, vapour or in aerosol form. IEC 61171 is restricted to equipment for monitoring radioactive iodines in the atmosphere and does not address sample extraction and subsequent laboratory analysis. This standard does not specify tests with atmospheric radioactive nuclides.

IEC 61172 "Monitoring equipment - Radioactive aerosols in the environment"

IEC 61172 (1992) is applicable to transportable or installed equipment for continuous monitoring of radioactive aerosol in the environment for both normal and accident conditions. For the purpose of this standard, monitoring includes the continuous sample collection with, if desired, the capability to automatically initiate sampling. In particular the standard is applicable to equipments designed to fulfil the following functions:

- determination of the activity per unit volume of radionuclides in the form of aerosols, either per unit time together with the variations as a function of time, or integrated over a longer time period, e.g., 24 h and measurement of the volume sampled.
- actuation of an alarm signal when either a predetermined high concentration or a predetermined time integrated concentration of an aerosol activity is exceeded.

The aerosol monitoring can be made both by continuous measurements during sampling and by measurement after collection of the sample. In the measurement after collection, the sample is removed from the air sampler and analysed in a laboratory. This procedure of measurement has to be followed in special cases such as the activity

assessment of specific radionuclides and is not within the scope of this standard. The continuous method of measurement is the more widely used and consists in collecting the radioactive samples by drawing air through a filter and measuring the aerosol activity accumulated on it with a detector which is close to the filter. The filters are suitably chosen and periodically changed according to the conditions of use. In some cases automatic filter sequences are used to avoid the build-up of radioactivity or excess of dust on the filter. Also the type of detectors depends on the various conditions such as the type of radiation, its energy and the level of activity.

The discrimination against natural radioactivity (such as airborne radon and thoron daughters) can be an important problem in monitoring low-level radioactivity in air especially with transuranic elements.

IEC 61578 "Effectiveness of radon compensation for radioactive aerosol monitors including transuranic aerosols "

IEC 61578 "Calibration and verification of the effectiveness of radon compensation for alpha and/or beta aerosol measuring instruments - Test methods" was published in 1997 but is currently in revision on CD stage with a new title "Effectiveness of radon compensation for radioactive aerosol monitors including transuranic aerosols".

This standard is applicable to type test methods which allow calibration and measurement of the effectiveness of radon decay product compensation for radioactive aerosol monitors. IEC 61578 in his 2nd edition defines aerosol characteristics used in these tests and applies the following test methods permitting the measurement of:

- the sensitivity of the monitor relative to alpha and/or beta defined man-made aerosols,
- the reference response of the monitor relative to alpha and/or beta defined man-made aerosols,
- the response of the monitor relative to radon decay product aerosols,
- the effectiveness of radon compensation,
- the response of the monitor relative to a mixture of aerosols constituted by natural and man-made radioactive emitters.

IEC 62302 "Equipment for sampling and monitoring radioactive noble gases"

IEC 62302 (2007) directly compliments IEC 60761-1 and IEC 60761-3. This international standard is applicable to equipment used for sampling and continuous measurement of radioactive noble gases in the workplace, in gaseous effluents discharged into the environment as well as in the environment itself. Monitoring by definition is the process of continuous and real-time measurement. The processes of sampling or taking samples for retrospective laboratory analysis are included in this standard.

IEC 60761-3 that will be complimented by IEC 62302, is applicable to installing portable and transportable equipment for sampling and monitoring radioactive noble gases, only in gaseous effluents, while IEC 62302 expands coverage to include monitoring all possible locations where radioactive noble gases could present a radiological hazard. The equipment is designed to be operational during normal operation conditions as well as under emergency conditions, both during and following an accident. Depending on the nature of the emergency conditions it may be necessary

to install specially designed equipment for normal operational conditions and other equipment for emergency conditions.

IEC 62303 "Equipment for monitoring airborne tritium"

IEC 62303 (2008) is applicable to equipment used for sampling and continuous measurement of tritium in the workplace, in gaseous effluents discharged into the environment as well as in the environment itself and it is applicable to installed, portable and transportable equipment.

The object of this international standard is to establish mandatory general requirements and to present examples of acceptable methods and equipment for continuously monitoring and/or sampling airborne tritium. IEC 60761-5 which is complemented by IEC 62303, is applicable to equipment for sampling and monitoring tritium only in gaseous effluents, while IEC 62303 expands coverage to include monitoring all possible locations where tritium could present a radiological hazard. The equipment is designed to be in operation during normal operation conditions as well as under emergency conditions, both during and following an accident. Depending of the emergency conditions, it might be necessary to install specially designed equipment for normal operation conditions and other equipment for emergency conditions.

IEC 62303 is applicable to tritium samplers and tritium monitors intended to provide the following functions:

- measurement of the volumetric activity of tritium and its variation with time in the workplace, in gaseous effluents at the discharge point and in the environment;
- actuation of an alarm when a predetermined volumetric tritium activity or tritium concentration or a predetermined total activity of released tritium is exceeded;
- determination of the total tritium activity discharged over a given time;
- sampling and analysis of air or gas containing tritium.

Conclusions

The object of the presented standards is to establish performance requirements, to give examples of acceptable test methods and to specify the general characteristics, general testing procedures, radiological, mechanical, electrical and environmental characteristics of the equipment.

IEC/SC 45B with its 15 published international standards greatly contributes for the high quality of existing instrumentation for measurement of environmental radiation. Compliance with such standard requirements provides the manufacturers with internationally acceptable specifications and the device users with assurance of the rigorous quality and accuracy of the measurements.

Experts from all countries are welcome to contribute to the IEC work (the national committees should be contacted for registration). The next SC 45B meeting will be in October 2010 in Seattle (US).

Acknowledgements

The authors wish to thank all convenors and experts of IEC/SC 45B WG B5 and B13 for their contributions during the preparation of presented standards. They are also thankful to the IEC Central Office staff.

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Investigation radiation hygienic monitoring in the Russian NPP vicinity

Shandala, N.; Kiselev, S.; Novikova, N.; Seregin, V.; Filonova, A.; Semenova, M.; Isaev, D.
Burnasyan Federal Medical Biophysical Centre, Moscow, RUSSIA

Abstract

Investigation monitoring in the NPP vicinity includes radiation hygienic monitoring and population health monitoring. Radiation hygienic monitoring is the system of the comprehensive and dynamic surveillance including the long-term continuous control of radiation hygienic situation parameters and doses of residents in the near-by areas of NPP. In the reference points of the NPP surveillance area and in the comparison area, the specialized rules are elaborated. These rules include the types of environmental media, scope and periodicity of sampling, methodological and technical requirements, etc. Two approaches are used for population health assessment: epidemiological and cohort. Medical demography characteristics are based upon indices of the birth rate, general malignant neoplasm mortality, and infant and childhood mortality. Morbidity is used as quantitative and qualitative index of the population health.

The radiation hygienic situation in NPP surveillance areas is generally satisfactory and stable. The individual population risk for all radiation sources in surveillance areas of three examined NPPs is $(2.5\text{-}3.1)\cdot10^{-4}$ cases per year. The individual risk related to the NPP operation is $0.4\cdot10^{-12}$ (Volgodonsk NPP) to $3.2\cdot10^{-8}$ (Novovoronezh NPP) cases per year. Thus, this risk is hundreds and even million times lower if compared to unconditional acceptable risk – $1\cdot10^{-6}$. The assessment of the health baseline as well as in the comparison areas was elaborated applying data of state medical statistics within more than ten years. The peculiar attention was attracted to the malignant neoplasm morbidity, their incidence rate and dynamics. The developed comprehensive investigation monitoring in the NPP vicinity should be the necessary part of the nationwide system of the public radiation protection regulation under nuclear renaissance, because it provides the opportunity to get the modern objective assessment of the NPP impact in the environment and population health.

Introduction

The basic social requirement for the atomic power is the provision of convincible evidences of the safety warrantees of both the plant operation personnel and residents of the NPP affected area. Since the USSR atomic industry start-up, the Burnasyan Federal Medical Biophysical Centre (before 2008 – Institute of Biophysics) of the Federal Medical Biological Agency of Russian Federation was the leading institution

responsible for the medical issues of the industry. One of basic activities of the Burnasyan Federal Medical Biophysical Centre is the scientific support of the radiation protection of the public.

The analysis of medical effects of the Chernobyl accident has obviously demonstrated the high importance of the establishing so-called "zero" baseline of the population health. Such information is necessary to evaluate possible medical effect of many year operation of atomic facilities and to clarify the scale of the health impact. Such assessments require vast comprehensive hygienic studies within the long period of time. Thus, the necessity to organize the rigorous social hygienic monitoring (SHM) in the NPP vicinity is occurred, which is the system of state surveillance, analysis, assessment, and prognosis of the population health and habituated environment as well as the correlation of the population health versus the habituated environment factor exposure. According to the Russian Federation Law on Sanitary and epidemiological well-being of the population, SHM is the major mechanism to regulate this well-being. The SHM implementation is of specific significance, taking into account special document regulates this work and attributes it not only to sanitary and epidemiological authorities and institutions, but also to other ministries and agencies [1]. Present SHM system presumes the development of the unified system of collection, management, and assessment of the information regarding the environmental contamination and population health indices.

The purpose of the present paper is to describe methodology and current status of SHM results obtained in the NPP vicinity. SHM includes radiation hygienic monitoring and population health monitoring.

Ideology & methodology of the research

The main stages of SHM in the NPP vicinity are as follows:

- Conducting of background "zero" examination of public health and radiation hygienic situation before the NPP start-up;
- Dynamic monitoring of important parameters of public health and hygienic parameters (including radiation factor) during the whole NPP operation period;
- Comparison of observed changes of public health and environment against "background" values;
- Observation of changes of public health within 5-10 years after decommissioning NPP or reactor units.

Following eight SHM directions are included for the NPP vicinity:

1. Radiation hygienic situation specifications and population doses
2. Medical demography features of the populations
3. Population morbidity analysis
4. Reproductive health status
5. Endemic diseases
6. Children health status
7. Societal psycho-physiological status of the population and mass media relations
8. Monitoring data bank development.

The scientific ideology of the this research is investigation radiation hygienic monitoring (RHM), which is the system of the comprehensive and dynamic surveillance

including the long-term continuous control of radiation hygienic situation parameters and doses of residents in the near-by areas of NPP and other radiation facilities of the first category [2].

The obvious question on the differences between research RHM and radiation control elaborated by different agencies and organizations is occurred. It is clear that radiation situation monitoring in the NPP surveillance area is elaborated by the NPP operator and designer, hydrometeorology service, and sanitary and epidemiological surveillance service. Results of such control attributed to the agency responsibility as well as elaborated under the radiation hygienic certification of territories have some disadvantages. These disadvantages include the rare application of radiochemical techniques, low periodicity of examinations, insignificant number of comparison points, and, in some cases, the absence of the comparison area and significant change of the list of objects subjected to the control. Finally, the radiation factor is not considered together with other non-radiation environmental factors affecting the human and the ranking of these factors is not provided. Unfortunately, low levels of radiation hygienic parameters are not recorded in practice. The indicated disadvantages of the practical radiation monitoring can be corrected by the implementation the detailed investigation RHM.

To elaborate RHM in the reference points of the NPP surveillance area and in the comparison area, the specialized rules are elaborated. These rules include the types of environmental objects, scope and periodicity of sampling, methodological and technical requirements, and inter-relations of interested parties. Table 1 provides a number of aspects of elaborated RHM rules on the sampling and examined parameters of the radiation hygienic situation in the NPP vicinity. RHM rules (environment section) presume the usage of NPP surveillance network data obtained by State Hydrometeorology Committee and Automated System of Radiation Situation Control as well as the original own data [3].

Table 1. Periodicity of sampling and examined parameters in the control points of the NPP surveillance area (routine operation) and in the comparison area.

Supervision object	Periodicity of information receipt	Parameters	Value dimensionality to be measured
Environment			
Gamma background in the area	Random inspection (weekly)	Exposure dose rate of external γ radiation in the area	μR/h
		Effective dose rate of external γ radiation	mSv/y
Atmospheric air (aerosol content in surface air)	Daily, monthly	ß-radioactivity, ^{90}Sr, ^{137}Cs, ^{134}Cs. Content of inert radioactive gases, ^{131}I, ^{60}Co	Bq/m^3
Density of radioactive fallout	Monthly	Total ß-radioactivity, ^{90}Sr, ^{137}Cs, ^{131}I	Bq/m^2/month
Soil	Annually	Total ß-radioactivity, ^{90}Sr, ^{137}Cs, ^{40}K	Bq/kg, kBq/m^2
Gramma grasses or natural growth	Annually (during period of vegetation)	Total ß-radioactivity, ^{90}Sr, ^{137}Cs, ^{40}K, ^{131}I	Bq/kg

Table 1. Continued.

Supervision object	Periodicity of information receipt	Parameters	Value dimensionality to be measured
Environment			
Water of open ponds including water reservoir-cooler	Two times a year (random inspection)	Total α- and ß-radioactivity, ^{90}Sr, ^{137}Cs. In water reservoir-cooler: ^{131}I, ^{60}Co, ^{90}Sr	Bq/l
Underground sources of water (using observation wells)	Monthly (random inspection)	Total α- and ß-radioactivity, ^{90}Sr, ^{137}Cs, ^{3}H	Bq/l
Drinking water (using draw well and water supply systems)	Quarterly	Total α- and ß-radioactivity, ^{90}Sr, ^{137}Cs	Bq/kg
Water-plants and sea-floor sediments of open ponds	Annually (random inspection)	^{90}Sr, ^{137}Cs, ^{40}K in water-plants – total ß-radioactivity	Bq/kg
Foodstuffs of local manufacture			
Bread or bread flour	Annually	^{90}Sr, ^{137}Cs	Bq/kg
Grain (wheat)	Annually	^{90}Sr, ^{137}Cs	Bq/kg
Milk	Two times a year (in summer and in winter)	^{90}Sr, ^{137}Cs, ^{131}I	Bq/l
Meat (pork, beef, mutton)	Annually	^{90}Sr, ^{137}Cs	Bq/kg
Poultry meat	Two times a year	^{90}Sr, ^{137}Cs	Bq/kg
Freshwater fish (river and lake ones)	Annually	^{90}Sr, ^{137}Cs	Bq/kg
Potatoes	Annually (during harvesting)	^{90}Sr, ^{137}Cs	Bq/kg
Edible roots (beet, carrot)	Annually (during harvesting)	^{90}Sr, ^{137}Cs	Bq/kg
Vegetables (cucumbers, tomatoes, onion, cabbage)	Annually (during harvesting)	^{90}Sr, ^{137}Cs	Bq/kg
Gourds (melon, water-melons)	Annually (during harvesting)	^{90}Sr, ^{137}Cs	Bq/kg
Food pot-herbs and leaf vegetables	Two times a year (during period of vegetation)	^{90}Sr, ^{137}Cs, ^{131}I	Bq/kg
Garden fruits and berries (at places of harvest)	Annually (during harvesting)	^{90}Sr, ^{137}Cs	Bq/kg

When choosing the comparison area, following circumstances should be taken into account:

a) hygienic characteristics similarity:
   - soil and sub-soil type;
   - plant species;
   - chemical content of water in superficial reservoirs and underground waters;
   - conditions of foodstuff production;
   - burdens of natural and (or) global fallout radionuclides.

b) the positioning outside the radiation facility affecting area;

c) medical assistance peculiarities (number of specialized medical doctors and availability of medical equipment etc.).

We would like to address population health monitoring, which requires the scientific justification of index selection and population health assessment criteria. These criteria should correspond to the following conditions:

- Applicability for the population assessment;
- Correspondence to the long-term observation tasks, namely, the simplicity, the applicability for the large number of individual examinations, reliable quantification, and objective qualitative characteristics;
- Future possibility for the assessment of possible NPP radiation impact in population health.

Two approaches are used for population health assessment: epidemiological approach based upon the health evaluation via medical statistics data and cohort clinical approach to include health assessments via detailed examination of critical population groups and critical body systems.

Medical demography characteristics are based upon indices of the birth rate, general malignant neoplasm mortality, infant and childhood mortality.

Morbidity is used as quantitative and qualitative index of the population health to assess the dissemination and structure of major diseases in the population of the NPP vicinity. To evaluate health status, medical statistics data are applied and dynamic indices within many years are analyzed.

The index reflecting the population health as a whole is the reproductive health. Reproductive health changes are most specific to the unfavorable factor impact in human health. Basic parameters of the reproductive health are as follows:

a) obstetric and gynecological status (rate and character of the pregnancy termination, gynecological and oncological morbidity)

b) reproduction function state (spontaneous abortions, still birth, early neonatal mortality) and newborn condition (morbidity, inherited developmental defects, etc.).

The child organism at growth and development phase is specific to the peculiar sensitivity, so the children under the radiation risk compose the population critical group. In the framework of the elaborated children health monitoring, statistical data on pediatric assistance are used as well as the detailed clinical examination results in some groups of children.

The “baseline” data on leukemia and thyroid morbidity are essential for the comprehensive assessment of NPP vicinity resident health to use these data as the reference for the following radiation exposure effects. Thyroid examinations presume

endocrinologist evaluation and ultrasound imaging to obtain sizes and echo structure as well as the iodine deficiency assessment via urinalysis.

Material and methods

The investigation monitoring been implemented in a number of Russian NPPs including Kalinin, Volgodonsk and Novovoronezh NPPs. When implementing monitoring the following tasks were elaborated:

1. The dynamic acquisition of necessary, sufficient, and confident information on controllable radiation parameters of the environment and on radionuclide burdens in foodstuff and water.
2. Investigation of the foodstuff consumption.
3. Assessment of the external and internal exposure doses in population.
4. Revealing current changes of radiation hygienic situation and prognosis of possible consequences in the population.
5. Providing the information for the managerial decision making to keep radiation doses as low as reasonably achievable.
6. Providing the information for local authorities and local centers of State Sanitary and Epidemiological Surveillance on radiation hygienic situation in the surveyed territory.
7. Forming the databases on the examined parameters.
8. Providing the information for local residents of the NPP vicinity.

More than 670 environmental and foodstuff samples in 48 settlements positioned both in the surveillance areas and in the comparison areas, in cooling ponds and other water reservoirs of the NPP vicinity was investigated (Table 2).

Table 2. The amount of investigations, which were carried out nearby NPPs.

NPP	Quantity of points	Number of proof samples		
		Foodstuffs	Drinking water	Other objects of environment
Volgodonsk	22	270	26	24
Kalinin	15	151	29	20
Novovoronezh	11	98	22	12
	48	519	77	56

Results of the Investigation Monitoring

The comparison to the current standards is also provided. The radiation hygienic situation in NPP surveillance areas is generally satisfactory and stable:

- Outdoors gamma dose rate is in the range of background fluctuations for such territories;
- ^{90}Sr and ^{137}Cs specific activity in outdoor water reservoirs is in the range of radionuclide content in water reservoirs of the Central Russia;
- ^{90}Sr and ^{137}Cs burdens in drinking water is below intervention levels for 135 and almost 300 times, respectively; total alpha and beta activity is below permissible levels;

– ^{90}Sr and ^{137}Cs burdens in foodstuff products and drinking water are 100-1000 times below permissible levels;
– ^{90}Sr and ^{137}Cs burdens in foodstuff products and drinking water (NPP surveillance areas) are similar to these in other regions of the country.

Table 3 provides total doses in NPP vicinity residents due to all sources of ionizing radiation. As it follows from Table 3, the natural background irradiation results to 69-71 % of total effective dose from all sources. The dose impact of global fallout and NPP exposure is 0.2-0.3% in the vicinity of Volgodonsk, Kalinin and Novovoronezh NPPs [4].

Table 3. Total effective doses in the population in the NPP vicinity, mSv/year.

Component of dose, mSv/y	Volgodonsk NPP	Kalinin NPP	Novovoro-nezh NPP	Assessment criteria
^{137}Cs and ^{90}Sr man-caused background	0,007	0,0079	0,010	Russia – 0.022 world – 0.007
NPP	0,0000006	0,00044	0,0017	0.01
Natural sources	2,4	2,9	2,3	2.4
Medical sources	1,0	1,3	1,2	Russia – 1.0 world – 0.4
Sum of all sources	3,4	4,2	3,5	Russia – 3.5 world – 2.8

The assessment of the health baseline in the vicinity of NPPs as well as in the comparison areas was elaborated within more than ten years. The peculiar attention was attracted to the malignant neoplasm morbidity, its incidence rate and dynamics. Specifying children health and the morbidity structure is estimated. Data obtained did not show any significant terms of worse health state of adults and children.

At present time, the radiation hygienic monitoring in the NPP vicinity can provide the radiation risk assessment (Table 4). The individual population risk for all radiation sources in surveillance areas of three examined NPPs is $(2.5\text{-}3.1)\cdot10^{-4}$ cases per year. The individual risk related to the NPP operation is $0.4\cdot10^{-12}$ (Volgodonsk NPP) to $3.2\cdot10^{-8}$ (Novovoronezh NPP) cases per year. Thus, this risk is hundreds and even million times lower if compared to uncondtional acceptable risk – $1\cdot10^{-6}$.

Table 4. Individual life span risk of stochastic effects in residents of the NPP surveillance area, year^{-1}.

Risk due to all the sources	Risk due to NPP operation (R_{NPP})	UAR/ R_{NPP}
Volgodonsk NPP		
$2,5\cdot10^{-4}$	$4,0\cdot10^{-13}$	2,5 million times
Kalinin NPP		
$3,1\cdot10^{-4}$	$6,6\cdot10^{-9}$	150 times
Novovoronezh NPP		
$2,6\cdot10^{-4}$	$3,2\cdot10^{-8}$	30 times

Conclusion

The developed comprehensive investigation monitoring in the NPP vicinity (a) should be the necessary part of the nationwide system of social hygienic monitoring, (b) provides the opportunity to get the modern objective assessment of the NPP impact in the environment and population health, and (c) can be widespread to other radiation facilities in this country.

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Radio-ecological criteria and norms during remediation of the nuclear legacy facilities in the Russian Northwest

Shandala, Nataliya[1]; Seregin, Vladimir[1]; Sneve, Malgorzata[2];
Titov, Alexey[1]; Akhromeev, Sergey[1]
[1] Burnasyan Federal Medical Biophysical Centre, RUSSIA
[2] Norwegian Radiation Protection Authority, NORWAY

Abstract
Remediation of the sites for temporary storage (STS) of the Spent Nuclear Fuel (SNF) and Radioactive Waste (RW) is one of the most important challenges for the Russian Northwest region. The prime task is to develop radiation environmental regulations on justification of radiation safety assurance during remedial operations at the STS. According to legislative and normative acts of the Russian Federation regulating management of radioactively contaminated territories after identification of the site contamination level at the radiation facility, one of three decisions can be made: conservation of the site; renovation of the site and buildings (brown lawn);unlimited use of the site (greenfield).The criteria and regulations for the SNF and RW STS facilities and site have been developed, which are suitable for each remediation option. At the same time, the environmental models have been taken into account; reference levels have been developed expressed in radiation parameter units, which could be measured during radiation control and monitoring: surface beta and alpha contamination of the STS buildings, gamma dose rate, radionuclide specific activity in soil, annul activity concentration of ground water, radionuclide contents in hydrobionts.

Introduction
Two technical bases of the Northern Fleet were created in the Russian Northwest in the 1960s 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 since been re-categorized as sites of temporary storage (STS).

Remediation of sites and facilities of the STS of SNF and RW in Andreeva bay and Gremikha village on the Kola Peninsula is one of regulatory functions of the Federal medical-biological agency (FMBA of Russia). The work has involved the Russian Federation Burnasyan Federal Medical Biophysical Centre, which is technical support organization of the FMBA of Russia. In thus work took part the Norwegian

Radiation Protection Authority (NRPA) in frame of the Norwegian government's Plan of Action to improve radiation and nuclear safety in northwest Russia.

Main tasks within the FMBA – NRPA cooperation consist of:

- Independent detailed analysis of the radiation situation at and near the STSs.
- Radiological threat assessment to determine priority issues for regulatory attention.
- Radiological control and monitoring of the environmental conditions.
- Development of a regulatory documentation system ensuring radiation protection observance of workers and the public, including radiation-hygienic criteria and standards of rehabilitation of contaminated territories.

In order to obtain comprehensive information with respect to current radiation circumstances at STS (independent from regulatory point of view), radiation-hygienic monitoring of STS facilities has been carried out.

Material and methods

Over 2005-2008, more than 180 samples of environmental media, local foods and drinking water were collected in Andreeva Bay and Gremikha village expeditions; moreover, personal dose monitoring was implemented. Gamma-spectrometry and radiochemical methods were applied in sample measurements.

Characterization of SevRAO facilities in Andreeva Bay and Gremikha

The STS Andreeva Bay is located on Kola Peninsula in the Barents Sea coastal strip (Motovsky gulf, west bank of Zapadnaya Litsa bay). The nearby settlements are: Bolshaya Lopatka (2.4 km); Nerpitchie village (1.8 km); Zaozersk city (8 km). The population is 15 700, the majority of which are military estates. The facility holds about $1.3 \cdot 10^{17}$ Bq of SNF and $6{,}0 \cdot 10^{14}$ Bq of RW.

The STS Gremikha is located on Kola Peninsula in Chervyanaya Bay of the Barents Sea. The nearby settlements are: Gremikha village (0.7 km from the site) and Ostrovnoy city (1.2 km). The population is 3500 (mainly, former soldieries and their families). The facility holds about $1.3 \cdot 10^{16}$ Bq of SNF and about $3.3 \cdot 10^{13}$ Bq of RW.

Up to now, a large amount of SNF contained in 88 unloaded cores, as well as 17558 tons of solid radioactive wastes and 3042 tons of liquid radioactive wastes have been accumulated in Andreeva Bay and Gremikha.

Specification of areas within the STS territory

With the purpose of radiation protection of workers and the public, the following areas are specified on-site and around the STS site:

- Controlled access area (CAA) – SNF and RW store facilities are situated here and radiation-hazardous operations are performed here too;
- Uncontrolled (free access) area (UA) – Facilities intended for work supplying in CAA;
- Health protection zone (HPZ) – This is an area of administrative and technical provision of the STS;
- Supervised area (SA) – This is an area surrounding the STS, where radiological monitoring is carried out to guarantee radiation safety and protection for the public.

The member of the public must not stay within the first three areas.

Radiation situation on-site the STS in Andreeva Bay

The accomplished examinations showed that gamma dose rates within the STS territory varied over a wide range: in CAA - from 0.2 to 140 μSv/h-1; in UA - from 0.2 to 12 kBq·kg-1; in HPZ - from 0.1 to 0.2 kBq·kg-1. Within SA, gamma dose rates varies from 0.063 to 0.14 μSv/h-1 with an average value of 0.12 μSv/h-1, which does not differ from the levels typical for the territories of Northwest Russia and in the Murmansk region, in particular. The results of selective personal dose monitoring show that external exposure gamma rates of the public and workers of group B (individuals who are not working directly with the sources of ionizing radiation, but who, due to their working place location, can be exposed to radiation) due to natural and man-made sources of ionizing radiation are, respectively, equal to 0.8 and 0.9 mSv/y. Internal public radiation doses associated with intake of radionuclides with food are 14 μSv·y-1. The total effective radiation doses to the public living in the STS's SA of Andreeva Bay(due to natural and man-made radionuclides) are estimated to be approximately 0.8 – 0.9 mSv·y-1, that is not more than the actual norms.

The highest level radioactive contamination of soil on-site induced by man-made radionuclides is observed in the area of the old technological pier and around some SNF store facilities, where ^{137}Cs specific activity reaches 5.7 107 Bq·kg-1, and that of ^{90}Sr is 5.7 106 Bq·kg-1. ^{137}Cs and ^{90}Sr concentrations in soil within HPZ and SA is at the background level typical for "clean" Russian Northern areas and does not exceed 36 Bq/kg and 4 Bq/kg, respectively.

Radiation situation on-site the STS in Gremikha

Gamma dose rate within CAA varies from 0.2 to 500 μSv·h-1 (maximum values are 4 times more than those in Andreeva bay); in UA – from 0.2 to 12 μSv·h-1 and levels within approximately 80% of the territory do not exceed 5 μSv·h-1. In HPZ and SA (in Ostrovnoy and Gremikha) it varies from 0.09 to 0.2 μSv·h-1, i.e., within fluctuation limits of natural background of this region. The results of selective personal monitoring of the people living and working (workers group B) due to natural and man-made sources of ionizing radiation in the STS area show that the external exposure gamma dose rates are 0.7 mSv·year-1(for public) and 0.9 mSv·y-1 (for worker group B). Internal public radiation doses due to intake of ^{137}Cs and ^{90}Sr with food are approximately 14 μSv·y-1, which is significantly lower than acceptable levels.

Within the industrial site, man-made contamination is observed in top-soil due to ^{137}Cs, ^{90}Sr and, in small concentrations, ^{60}Co, ^{152}Eu, and ^{154}Eu. In SA (including Gremikha and Ostrovnoy), ^{137}Cs and ^{90}Sr contents in soil are mainly within background level (1 – 50 Bq·kg-1). In some cases, at local parts outside the settlements, observed levels exceed background values by up to 100 Bq·kg-1 by ^{137}Cs.

Results of radiation situation assessment at STS in Andreeva bay and Gremikha

Radiation monitoring of the environmental media showed considerable exceeding of typical background values of ^{137}Cs and ^{90}Sr radionuclide concentrations (in the SSZ coastal strip) in seaweeds, bottom sediments and vegetation. An exceeding is also observed in some cases in the STS SA environmental media in comparison with background values. Preliminary results of sorption experiments of radionuclides on

local soil and ground waters suggest that radionuclide migration from highly contaminated areas on site, via groundwater flow pathways, is possible. This leads to permanent entry of radioactive substances into the off-shore marine environment.

According to radiation monitoring of catches in the STS off-shore marine environment, the concentration of ^{90}Sr and ^{137}Cs in fish is in the range 0.7 - 13 Bq·kg-1 for ^{90}Sr and 0.4 – 35 Bq·kg-1 for ^{137}Cs, respectively, being significantly lower than actual Russian accepted radiation contamination levels. With the purpose of radiation exposure restriction during large-scale STS remedial work, FMBA established a public radiation dose quota; this quota is 100 µSv·y-1 due to effluents and 30 µSv·y-1 due to radioactive substance discharges (table 1).

Table 1. Public radiation dose quota due to effluents and to radioactive substance discharges under conditions of STS facility normal operation.

Sources of exposure	Quota, µSv·y-1
Gas-aerosol discharges	100
Intake with seafood	300
Reserve for unregistered sources	200

Conclusions

Environmental radiation monitoring demonstrated significant excess (in comparison with typical background values) of ^{137}Cs and ^{90}Sr contents at local parts of the coastal strip of the STS health protection zone in seawater, seaweeds, bottom sediments, vegetation and soil.

Results of radionuclide sorption examination in soil and ground water permit to assume the presence of effective migration from contaminated areas via groundwater, causing radioactive inflow into offshore marine waters. Having in mind a possibility of further contamination of the STS area, dynamic surveillance is needed of the radiation situation both at routine activity, and at SNF and RW removal [2].

The described work carried out under joint FMBA and NRPA Project, devoted to regulation of the public radiation and nuclear safety during STSs operations, current output has included the following documents:

– InitialThreat Assessment for the situation at STS sites.
– Guidance “Criteria and norms on remediation of STS 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”.

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Quality management system of in-vivo measurement (IVM) lab at Karlsruhe Institute of Technology (KIT) – accreditation and experience

Breustedt, Bastian; Mohr, Ute; Biegard, Nicole; Cordes Gabriele
Institute for Radiation Research, Karlsruhe Institute of Technology, D-76021 Karlsruhe, GERMANY
(contact: bastian.breustedt@kit.edu)

Abstract
The in-vivo monitoring lab (IVM) at Karlsruhe Institute of Technology operates one whole body counter and three partial body counters. IVM is an approved lab for individual monitoring for incorporation according to German regulation. In 2007 a web based quality management system has been set up and all the method and procedures used at IVM have been described in a set of documents. Several document classes are (e.g. standard operation procedures SOP) are used for this. For each class of document a template satisfying the formal requirements is used. In 2007 several internal audits were used for fine-tuning the system before an external audit, which finally granted accreditation to the IVM, was held. The system is kept flexible and can thus be easily adapted to new situations (e.g. organisational changes). Only a sparse amount of the work time needs to be spent to maintain the running system. It also leaves enough freedom in the daily routine work at IVM and found acceptance by the employees, quickly. After two years of working with the quality management we can say it was worth the trouble and time required in setting it up.

Introduction
The in-vivo monitoring laboratory (IVM) at Karlsruhe Institute of Technology (KIT) operates one whole body counter with NaI(Tl) detectors in a stretcher geometry and three partial body counting systems, two with Phoswich and one with HPGe-detectors. Routine monitoring and special measurements of workers at the KIT campus north (either staff of KIT, or of external companies located at the campus) and for external customers are done at IVM. The laboratory is used in scientific studies, e.g. studies on caesium content of the population, and in education and training of students and radiation protection workers. IVM is an approved lab for individual monitoring by direct assessment of incorporated radionuclides according to German regulation. One of the requirements for the approval is an poof of competence via accreditation on ISO/IEC Standard 17025. A quality management system (QMS), which was successfully audited and granted accreditation, has been set up at IVM in 2007.

Material and methods

The quality management system (QMS) is based on ISO9001 certified system of the central safety department. All issues dealing with management requirements (i.e. chapter 4 of ISO 17025) are met by this system. The IVM team added documentation of the routine work and the quality assurance procedures in the lab meeting the technical requirements (i.e. chapter 5 of ISO 17025).

A web based quality management software (CAS Teamworks 2010) is used for handling and controlling of all relevant documents and the workflow for all the steps of document issuing and approval. Employees can log in to the system from their workplaces simply via a web browser. Using an online system ensures that everyone is working with the same revision of a given document. Thus "errors" caused by invalid or expired documentation are minimised. In principle one should work only with the electronic documentation and avoid printing the documents. The latter is not forbidden, but hardcopies are valid only if the revision number on the hardcopies and the revision number in the electronic system are identical. For each controlled document the roles of editor, examiner, approver and the persons that need to acknowledge the final document need to be assigned. In the document properties displayed in the system action links for each step of the document control workflow are provided. The persons involved are informed by the system's messaging interface or via an email with a link to the document in the QMS, when their duty is due. The final approval for the release of a document is given by the quality management representative and a process owner of the procedure involved. This assures a final check of the document and ensures that the system is kept consistent.

Table 1. Main Document Classes in the Quality management system.

Class		Content
QMH	Quality Management Manual (Qualitätsmanagementhandbuch)	Description of formal organization, quality objectives and procedures
MB	Description of Method used (Methodenbeschreibung)	Description of non-standardized methods used in the laboratory
VVP	Protocol of verification of validation of methods (Verifizierungs- und Validierungsprotokoll)	Description of verification and validation of methods used
VA	Generic Procedures (Verfahrensanweisung)	Description of general processes and workflow
SAA	Standard Operating Procedure (Standardarbeitsanleitung)	Operations are described step by step
HMS	Specification of tools and materials (Hilfsmittelspezifikation)	Only tools and materials used in the methods are specified
QA	Reporting Forms (Qualitätsaufzeichnung)	Standardized Reporting Forms for perseverative reporting

Several classes of documents are used in the quality management system, an overview of the most important ones is given in table 1. Central document of the quality management system is a quality management manual (QMH) which provides information of the duties and the formal organization of the institution described (e.g.

ISF or IVM), as well as the quality objectives and policy. The generic processes used are described in process instructions (VAA), more detailed instructions are provided in standard operating procedures (SAA). The tools and materials used in the processes are described in specification sheets (HMS) only if they need to be calibrated or are relevant for the quality of the process or of its product. Templates satisfying all formal requirements of ISO 17025 are provided for each class of documents. Each document is derived from these templates and given a unique ID of the type "Class Lab Number" e.g. "SAA IVM 100" and a meaningful title. Using this ID the documents can easily refer to others and thereby link procedures during a workflow.

The generic principles of our measurements were described in three documents as non-standardized methods:

- Determination of incorporated radionuclides by gamma spectroscopy in the whole body counter
- Determination of incorporated radionuclides by gamma spectroscopy in the partial body counter with Phoswich detector.
- Determination of incorporated radionuclides by gamma spectroscopy in the partial body counter with germanium detectors

The general information and the scientific background of the techniques used in the laboratory is provided in separate documents (MB). These descriptions were required because no reference document (e.g. an ISO standard) on in-vivo monitoring techniques are available. Scientific publications (IAEA 1996, ICRU 2003) were the basis for these documents. Based on past experience and successful participation in intercomparison exercises these methods were verified and validated. This has been documented in a VVP-document.

The full workflow from customer enquiry to final billing including measurement and reporting has been described in a generic procedure (VAA IVM 003). A translated flowchart as provided in this document is shown in figure 1. Two other generic procedures describe the principal workflow for measurements and dose assessments. Detailed step by step descriptions for the single parts of these workflows are given in standard operating procedures, which are linked by their document IDs in the generic procedures. The single documents are focussed on (small) steps of the work (e.g. daily quality assurance measurement), thus only small adoptions of the documentation are required when changes in parts of the procedures are made. The minimum requirements which need to be fulfilled before an enquiry is accepted are described in a standard operation procedure. A counselling interview with a customer is conducted to check these requirements prior to the first measurement ordered. Two documents describe the application of the reference procedure for internal dose assessments as reported in German regulation. All other laboratory (e.g. quality assurance of the balances in the lab) and administrative work (e.g. invoicing, archiving, …) is described in separate SAA documents. An overview of all quality assurance procedures and their frequencies (e.g. daily, weekly, ….) is provided in a document of the quality manual. There all the according standard operating procedures and reporting forms are linked by their document ID. This document provides an overview of the QA procedures at the lab. If

changes in on of these procedures are made, only the according SOP (SAA) documents for this special procedure needs to be adapted.

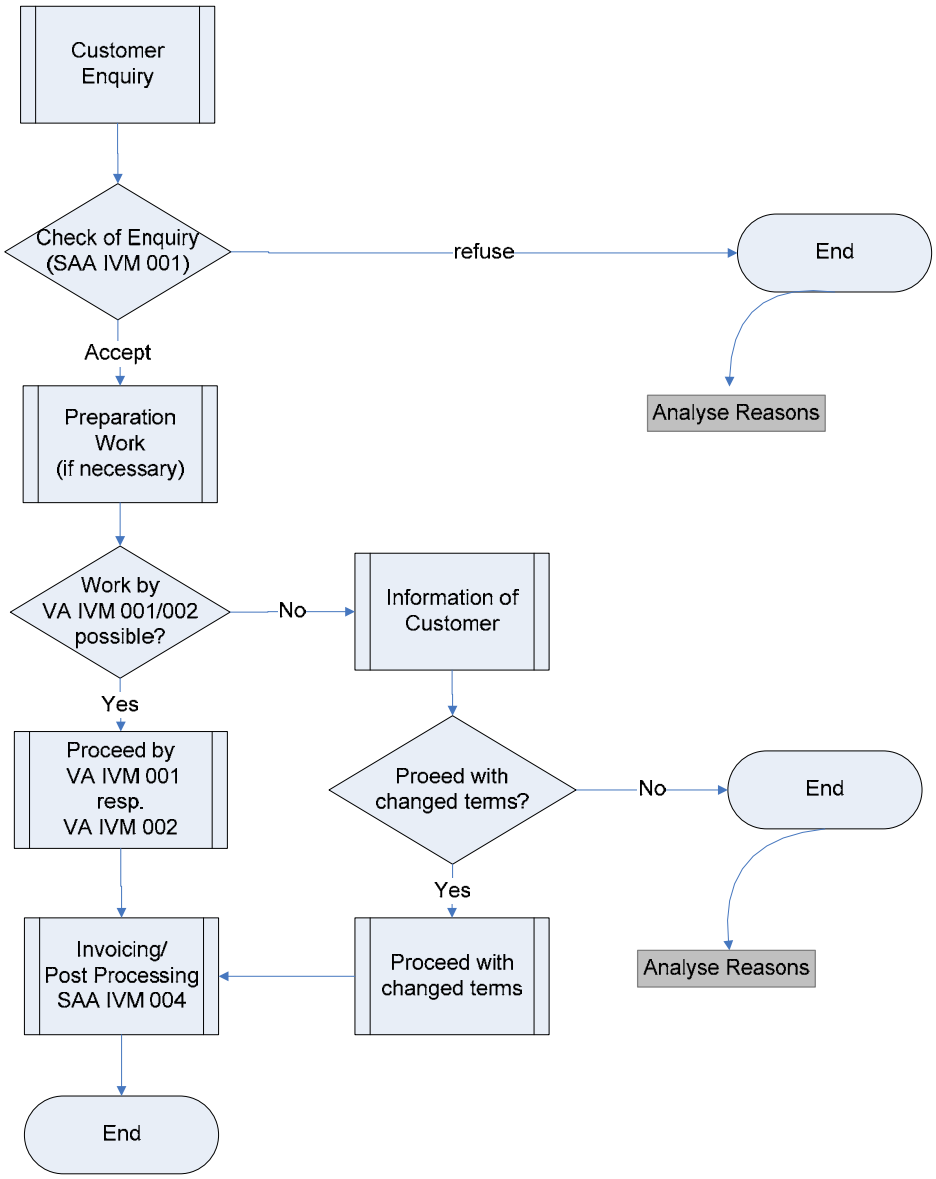

Figure 1. A translation of the flowchart for the generic procedure from customer enquiry to final billing. A short description an the ID of the document providing detailed procedures is given in the VA document.

The whole system including the generic ISO 9001 parts and special documentation of IVM has been set up flexible and could easily be adopted to new situations, like recent organizational changes (e.g. the founding of a new Institute for Radiation Research at KIT to which the IVM was then assigned). Here only minor changes in the existing documentation were needed to adapt the whole system to the new situation.

Conclusions

All the mechanisms required in ISO 17025 chapter 4 are met by the ISO 9001 certified quality management system our accreditation is based on. Thus we "only" needed to add our laboratory specific parts to the system. The experiences from the accreditation of the spectrometry lab in 2006 saved lots of time and discussions to be spent on very basic issues, like e.g. the handling of electronic data. We carefully reviewed and improved our processes during planning and writing the documentation. All processes in the lab are now well documented, the former hidden experiences of the staff are now "publicly" available and are assured against getting lost over time. The quality management documentation now serves as a manual of the work in the laboratory and is under constant review. The discussions and explanations to our quality management team, which was non-expert in the field of in-vivo monitoring, were helpful in putting everything in clear words. Thus our final documentation became more comprehensible for people without in-depth knowledge of the laboratory. The materials developed for the QMS is also used for the education and training of new personnel e.g. the students of Karlsruhe university of cooperative education, who do parts of their practical studies in radiation protection at the in-vivo monitoring laboratory (IVM).

After more than two years of working with the quality management we can say it was worth the trouble and time required in setting it up and gave an overall benefit for the lab. Only a sparse amount of the work time needs to be spent to maintain the running system. It also leaves enough freedom in the daily routine work at IVM and found acceptance by the employees, quickly.

Acknowledgement

Support by the quality management team of HS (now KSM) and the staff of the spectrometry lab is gratefully acknowledged.

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Setting up of a Molecular Imaging Unit in biomedical research centres

Escudero, Rocio[1]; Mulero, Francisca[2]; López, Germán[3]; Pérez, Jorge[4]
[1] Centro Nacional de Investigaciones Cardiovasculares, Madrid. SPAIN
[2] Centro Nacional de Investigaciones Oncológicas, Madrid. SPAIN
[3] Globalpet, Madrid. SPAIN
[4] Lab Safety Consulting, Madrid. SPAIN

Abstract

Molecular imaging techniques have become important tools for the clinical diagnosis of several diseases. These techniques are today in a highly mature state in the clinical field and are now being rapidly developed for use in biomedical (preclinical) research. Among currently available techniques are those allowing acquisition of high resolution anatomical images (CT, MRI), while others offer high sensitivity physiological/ molecular imaging (PET, SPECT, optical). However, used separately each technique offers limited information, and therefore the emphasis of imaging applications for research is on multimodal imaging, wherein images from different techniques are combined to yield an image of high resolution and sensitivity.

Although the use of radioactive isotopes in biomedical research is declining overall, their use in molecular imaging techniques is increasing. Currently, the most developed molecular imaging technique in research, and the most significant from the perspective of radiation protection (RP), is the microPET, combined with anatomical imaging, mainly by CT. In order to set up this technique (or others, such as SPECT) in a biomedical research centre, the RP requirements associated with the handling of high energy gamma sources (PET) and X rays (CT) must be met (equipment, shielding, dosimetry, waste management, training, etc.). These measures also need to be evaluated and adjusted to meet the specific requirements of research centres in terms of biosafety, animal health and welfare, etc. This situation thus complicates RP in this kind of facility.

The aim of this study is to briefly describe the most important imaging techniques and their application in biomedical research, and to present an example of the setting up of a unit or laboratory specialized in these techniques in centres dedicated to pure biomedical research (not associated with a healthcare centre).

This study has been conducted by specialists from the RP and molecular imaging fields.

Introduction

Biomedical research addresses increasingly complex problems related to the biochemical processes that occur in living organisms. As in clinical research, medical imaging techniques are excellent tools to study these processes. A molecular image can be defined as a visual representation, characterization, and quantification of biological processes at the cellular and subcellular levels within living organisms without disturbing the system under study. It has been demonstrated that the visualization and quantification of the function of certain organs of laboratory animals by means of molecular images is a very important tool in the study of human diseases, and also for the discovery and development of new drugs and biochemical probes. As a consequence, animal models are being developed on a translational scale for the generation and the development of tools suitable for the diagnosis and/or treatment of this type of diseases.

Molecular Imaging Techniques with implications for radiation protection

Different Molecular Imaging techniques are combined in this single discipline with a common aim: to change the way in which biological research is carried out. Techniques such as, among others, PET, single photon emission computed tomography (SPECT), digital autoradiography, magnetic resonance (MR), MR with spectroscopy, bioluminescence, fluorescence, and echography, are under constant development. Lately, considerable effort has been directed towards the development of these non-invasive high-resolution imaging techniques for their use in small animals. These miniature systems are not an unnecessary fashionable trend, since they have a better resolution and are generally cheaper than their counterparts for clinical use; several systems can be placed in one laboratory and can be shared among different disciplines. Nevertheless, there are still challenges that need to be solved, such as: trying to obtain an image of a mouse that weighs 30 g and compare it with that of a human who weighs 70 kg, differences in size and volume, the spatial resolution necessary to collect useful anatomical and/or functional data, and the time needed to obtain the images (1). In small animal research the main goal is to obtain the maximum signal possible using the minimum amount of molecular probe, and to locate this signal as precisely as possible in terms of temporal and spatial resolution, using a single system that is able to produce a three-dimensional image that simultaneously presents anatomical and functional information (2). Below, we will evaluate each of the imaging techniques that have major repercussions for radiation protection.

Positron Emission Tomography (MicroPET)

By means of PET the metabolic route can be visualized that a given molecule follows after its incorporation into the organism, generally by means of intravenous administration of a radiolabelled drug. Various biological molecules are labelled with positron-emitting isotopes and follow their normal metabolic route, moving to the sites where they are metabolized (2). Throughout their course, and also from the sites were they are stored and eliminated, they emit a radioactive signal that can be detected from the outside. Detection is done by means of a positron camera or a PET camera. At present, the basic radiolabelled drug used in this technique is fluorodeoxyglucose

(FDG), a glucose analogue labelled with Fluorine-18 (Figure 1). This tracer is relatively unspecific and, although it allows to locate and to study in detail the uptake of the molecule in tissues with high glucose consumption (heart, brain, tumours), deposits may also be produced in other sites that are not of interest, such as points of inflammation. Nevertheless, FDG can be obtained commercially very easily. The use of PET is limited by a poor access to other types of radiolabelled drugs specific for other applications (synthesis of proteins and nucleic acids, hypoxia, immunoPET, etc.); even though such drugs have been developed or are being developed, access to them is difficult if one does not possess a cyclotron or does not have one nearby. Drugs radiolabelled with other isotopes (Ga-68, Cu-64, I-124) are also being developed. At the moment the main applications of PET, both in research and in the clinic, are oncology for localizing and monitoring tumours, and cardiology and neurology for the detection of specific pathologies.

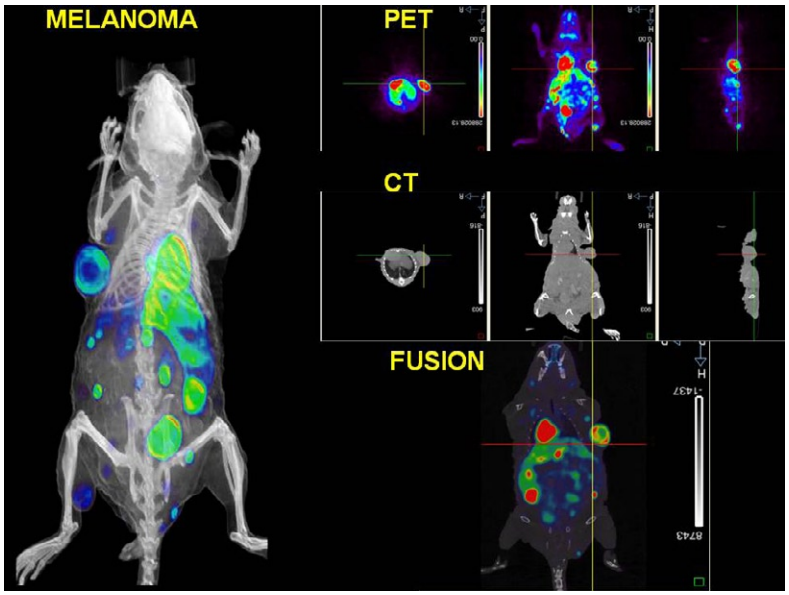

Fig. 1. Image of a study of a transgenic mouse with metastasized melanoma using PET, CT, and a fusion of both. Multiple F18-FDG deposits corresponding to metastases are observed.

Single photon emission computed tomography (MicroSPECT)

SPECT is a technique that is analogous to PET. The difference resides in the type of isotope used, which in the case of SPECT are single photon gamma emitters. Labelling, administration, and acquisition are similar to those for PET, but in this case the technique offers a lower resolution and sensitivity. However, there is a greater variety of tracers and isotopes, since most radiolabelled drugs used for SPECT are obtained using a Tc99m generator, with a longer half life and allowing to work *in situ*. SPECT is applied to the same cases as PET, and in addition for the control of renal and osteoarticular function, but since there is a greater number of approved radiolabelled drugs available, the field of application extends to a larger number of benign pathologies and functional studies.

Computerised Tomography (MicroCT)

The images of computerised tomography are based on the different absorption by tissues when X-rays pass through them. CT is not a technique that provides information at the cellular or molecular level *per se*, and therefore it is not considered a molecular imaging technique. Nevertheless, this technique is of great importance for the anatomical location of functional images (PET and SPECT) and for their reconstruction. This is even more so if one takes into account that the molecular probes are increasingly specific. The radiation deposited in the experimental animals is not insignificant (0.6 Gy/scan, corresponding to 5% of the LD50 in mice), which limits obtaining images in series (3).

Model for applying Molecular Imaging techniques in biomedical research centres

In this part of the paper we will develop a model for the design and management of working with imaging techniques in a research centre not associated with clinical facilities. What is indicated under each point is an option that the authors consider appropriate to be in operation or in phase of development in real centres.

Radioactive Facility

The development of the imaging techniques mentioned above (PET, CT) implies the handling of non-sealed radioactive isotopes and the use of equipment emitting ionizing radiation (RX), which is why, according to the Spanish legislation, it is necessary to have a radioactive facility (RF) authorized by the competent authorities.

In Spain many biological research centres follow a similar RF model. The model includes a central laboratory and authorized areas in the research laboratories. It is a model designed for the use of non-sealed sources both *in vitro* and *in vivo*, although depending on the type of centre and activity it may include equipment emitting ionizing radiation (irradiators, diffractors, imaging equipment, etc.). According to this model, there is a central laboratory designed for the manipulation of high activities (limits of activity per essay from 10 to 30 mCi, depending on the type of isotope) or high-risk isotopes (volatile iodides, high energy gamma emitters). This laboratory is also used for the management and control of the RF and contains the central radioactive waste depots. The RF further includes authorized areas in the research laboratories. These are small areas in each laboratory that requires it, and are specifically placed and equipped for the exclusive handling of limited activities of radioactive isotopes (between 0.5 and 2 mCi per assay, depending on the isotope). In addition to these we may also find areas where emitting equipment is stored; these areas are set up according to the requirements of the equipment (access control, shields, etc.). The Molecular Imaging Unit (MIU) is considered as another authorized area, to which the appropriate measures of control and protection are applied, based on the types of isotopes handled and the techniques developed. The research centres normally have personnel specifically assigned to the management and control of the facility, with an official license (for operation or supervision) granted by the competent authority.

Central Laboratory of the Radioactive Facility

As mentioned before, this laboratory is especially equipped for the development of techniques that imply the handling of high activities or high-risk isotopes. The laboratory should be classified as a controlled area with radiation and contamination hazards. It must have access control and control of atmospheric pressure (negative pressure), as well as activated carbon filtration of all air extracted from the laboratory.

The laboratory has both the basic laboratory equipment and all the necessary means of protection for the development of the established techniques (fixed and movable shields, containers, containment equipment, detectors, emergency devices, etc.).

Since the radioactive waste deposits are included in it, in this laboratory the whole spectrum of registration, preparation, and elimination of radioactive waste or waste material with radioactive contents is realised.

With respect to imaging techniques, in this laboratory the control and registration of the incoming commercial radioactive material is carried out by personnel in charge of Radiation Protection management, and the labelling of tracers is done in situ; these activities are developed by research personnel with specific training in Radiation Protection.

The laboratory has the necessary specific protection equipment to carry out the indicated activities. It must have manipulation cells, movable shields, shielded containers, general laboratory equipment, materials that enable the proper course of action in emergency situations, etc. For manipulation cells, one can opt for mixed and shielded biosafety cabinets. These are conventional biosafety cabinets that have been modified by adding activated carbon filters and the necessary shielding in the outer and frontal panels. They allow working under sterile conditions, and at the same time they protect the operator from radioactive gases or vapours, as well as of aerosols contaminated with pathogenic biological agents that may be used in the research.

This model is being successfully used in various centres.

Molecular Imaging Unit

As mentioned before, a research centre that wants to develop this type of techniques must have a Unit specialized in molecular imaging. The MIU must provide the research groups with the latest imaging techniques. This unit must be in charge of the preparation of the doses, administration to the animals, obtaining the images, and their analysis. It must therefore have specifically trained personnel. Because of the nature of the work done, this unit must be intimately linked to the Animal Facility, ideally being located close to this facility. The unit must also have specific facilities both for handling the animals, which must form part of the Animal Facility, and for the analysis of the images, which should be outside the facility but close to it.

Design of the facility for handling radioactive material and animals

Normally, one starts out with a defined space that must be adapted to the requirements of this type of techniques. Especially with PET isotopes, it is more efficient in economic terms to take advantage of the distances instead of using thicker shields as a means of protection against radiation, or to place the different areas next to low occupation spaces, such as corridors, technical areas, etc. Of course, one should also

consider the isotopes to be used and the activities to be manipulated; the latter depends on the study model, since large animals usually require higher activities.

In this space we must establish a room for the imaging equipment, which must fulfil the installation and environmental requirements for operation of the equipment (temperature, humidity, maximum incline, electric power, etc.), and also the requirements for handling animals: space for an anaesthesia table, gas provision, etc. Preferably adjacent to it, there should be a control room from which both the specimen and the equipment can be seen. Close to this area of the facility, to avoid transfers over long distances, a room must be located where the animals are injected and where they will stay during the incorporation of the tracer, and to which they are returned and where they will remain until it can be considered safe to manipulate and house them with the rest of the animals. Normally, this area requires the most shielding of the entire facility and must provide sufficient space for the amount of studies to be done. This is the area with the highest contamination hazard because of the injection procedure and the animal excrements. To avoid transfers of radioactive material over long distances, it is also advisable to locate close to the injection room the area for dose preparation, where the radioactive material from the providing laboratories is received and divided into single doses. The floor of the laboratory must be able to sustain the weight of the of radiation protection material that will be installed in it, which usually is around 1000 kg/m2. Optionally, depending on the characteristics of the isotopes to be used, it may be necessary to have an area for the temporary storage of waste, possibly including animal carcasses until they have decayed. If only PET isotopes are used, storing for 24-48 hrs in wastebaskets may be sufficient. When (e.g. Ge-Ga) generators are used, it will be necessary to have a greater storage capacity.

As a general norm, air of these areas should not be recirculated to the rest of the facility, and the needs of the animals must determine the quality of the air supplied to these areas. All surfaces of the areas described above must be finished in such a way that they allow easy cleaning and decontamination.

Equipment

The area of animal manipulation will have to contain the necessary equipment for the development of these techniques. Below we will list the most important equipment to consider.

- Imaging equipment: select according to the technique to be used. The ideal is to use an integrated multimodal PET/CT or SPECT/CT equipment. At the moment integrated or associated PET/NMR equipment is being developed. The type of studies will determine to a large extent the type of technique and therefore the type of equipment.
- Anaesthesia Table: sized according to the type of study animal.
- Leaded screen for handling the animals, especially rodents. It has to be made in such a way that it can be easily decontaminated.
- Manipulation cell / lead castle: easily decontaminatable, with access for hands and material, shields adapted to the activities to manipulate (30-50 mm Pb is usually sufficient), with an adequate system of air circulation and filtration if the type of isotope to be manipulated requires it, and sufficient illumination. It is very

recommendable to include a properly shielded housing for the ionization chamber of the activimeter.

- Activimeter: appropriate for the isotopes to be used and in the range of the activities handled in the laboratory.
- Radiation Monitor: with a probe sensitive to the levels of design of the facility, typically from 0.1uSv/h to 20 mSv/h
- Contamination Monitor: with a probe suitable for the emission of the isotopes of the facility and with a surface not less than 100cm2.
- Wastebaskets or furnishings for temporary waste storage: easily decontaminatable and with sufficient capacity for the amount of material to be used.

Work norms

For working with PET/SPECT isotopes and the radiation emitting equipment, the general norms for working with radioactive isotopes apply. These include norms regarding the operator: personal protection (gloves, lab coat, etc.), abiding by the norms of hygiene, use of appropriate shields, correct use of the dosimeter, etc.; norms regarding the work area: signposting, order and cleanliness, containment, monitoring, access control, etc.; and norms regarding the surroundings: contamination and radiation monitoring and correct waste management.

Specific norms for PET/SPECT isotopes must also be applied, such as the use of specific movable shields (screens, dose dispenser, syringe protectors, etc.) or the use of means for increasing the distance between source and hands (forceps). Of special importance for labelling animals with PET/SPECT is prior cold training, to carry out the tasks in as little time as possible. Labelled animals must be housed in suitably shielded areas during a period of not less than 24 hours (this can be modified depending on the characteristics of the isotopes used) to allow the isotopes to decay before incorporating the animals again into the colony of the Animal Facility.

To guarantee the correct fulfilment of the norms and hence the protection of the operators, operational monitoring of the facility must be done by means of periodic inspections of control of the fulfilment of the operational norms, both in the central laboratory and in the authorized areas, including the MIU. These inspections include monitoring of contamination, waste management, appropriate conditions of order and cleanliness, filling in of the registers, correct maintenance of the specific monitors, etc. These inspections are carried out by the personnel in charge of the management of Radiation Protection.

Personnel. Functions and classification

The personnel implied in the manipulation of PET isotopes and radiation emitting equipment is as follows (references to degrees and licenses refer to what is established in the Spanish legislation):

- Personnel in charge of Radiation Protection management: Made up of the Responsible of the RF (Supervisor in charge or Head of Radiation Protection), and a team of assigned technicians, all holding an operator license in the application field of the RF at issue. These personnel will be in charge of the reception and registration of the commercial radioactive material and the operations of monitoring and control of the RF.

- Molecular Imaging Unit: Made up of a Person in charge holding a Supervisor license and a team of technicians with operator licenses, all in the field of application of the RF at issue. These personnel will be in charge of the development of the different imaging techniques that involve treating animals with radioactive material or handling radiation emitting equipment, including labelling the animals, the acquisition of images, and their subsequent analysis. This will be the only personnel authorized to carry out this type of techniques.
- Research Personnel: They will carry out the techniques of labelling experimental tracers with PET or SPECT isotopes. Depending on the activities and isotopes handled, they may or may not need to hold an operator license in the field of application of the RF at issue.

As a general norm, all exposed personnel will be considered as exposed workers of category B (according to the Spanish legislation), since it is improbable that they will receive doses above 6 mSv or 3/10 of specific limits in a calendar year. Depending on the animals handled and the doses administered, workers who carry out functions of dispensing and administering radiolabelled drugs may be classified as occupationally exposed personnel of Category A (who may receive doses above 6 mSv or 3/10 of specific limits in a calendar year).

Training

Besides knowledge acquired in training courses for operators or supervisors of Radioactive Facilities, all personnel involved in handling PET or SPECT isotopes must receive specific in-house training. This training will consist of giving different seminars in which information will be included on the general safety norms for working in a laboratory, the handling of radioactive PET/SPECT isotopes (radiological hazard, use of shields, detectors, etc.), operation, and the Emergency Plan of the RF. The personnel of the Imaging Unit dedicated to labelling the animals will receive additional training in handling research animals. These personnel must also first do practical and specific training, developing the techniques of animal handling under the same conditions as when using radioactive material, for example using portable shields (screens, syringe protectors).

Dosimetry

Dosimetry of occupationally exposed personnel of Category A and B must be done by means of individual dosimeters. In our case, we use thermoluminescence dosimeters. The whole body dose must be controlled during the entire working day by means of lapel dosimeters. For the personnel who directly handle the radioactive isotopes, the hand dose must also be controlled by means of ring dosimeters. After an accident an additional control by means of internal dosimetry must be done.

The aim is to keep the doses received by the personnel who handle the animals and the vials or syringes with radiolabelled drugs as low as possible. In the case of handling small animals, whole body dose levels can be obtained that are similar to those of the other exposed workers in research, normally below the public dose (1 mSv/year). Hand doses can be kept at very low levels (100 times below the established annual limit, 500 mSv/year). When working with large animals it is tried to obtain dose levels that are less than those received by the personnel who apply these techniques in the

clinical setting, since the doses used for large animals are of the same order as those applied to humans.

Working with research animals. Small and large animals.

Animals used as experimental models for research are, generally, rat, mouse, rabbit, and pig. Mice are the first species of choice in the scientific community for imaging studies. Nevertheless, the study of certain pathologies in mice limits the translation to humans. However, the ease with which genome can be manipulated, the possibility to work with large sample sizes, and the reduced costs make them an ideal species for study. On the other hand, the ease with which they can be handled, the low need for space, and the relatively low doses of radiolabelled drugs they receive in studies simplify the management in radiation protection regarding shielding, housing of the labelled animals, and waste management. In contrast, the use of large animals entails the inoculation of high activities of radiolabelled drugs, to which the difficulty of handling the animal is added, which will have to be anaesthetised and gavaged for the possible collection of contaminated urine (15% of the radiolabelled drug) after injection. Administration of radiolabelled drugs, both to small and to large animals, is best done with the animal under anaesthesia and using appropriate means of protection like shields, or using systems to restrain the animal to reduce the risk of self-inoculation. After the imaging study, there must be a shielded space reserved in the radioactive facility to house the animals until their decay. This module, with peripheral shielding and preferably with individual cells in which movable shields (screen type) must be installed, must have an adequate system for the containment of urine/excrements/ potentially contaminated bedding. Special mention must be made of the handling of urine, which is the major vehicle of elimination of radioactive material. Therefore, a containment system must be implemented adjusted to the volumes and activities used, such as containment tanks or deposits.

Discussion

Molecular imaging techniques are a new and very useful approach in biomedical research. Nevertheless, a technique that is useful for all fields of biomedical research does not exist. The technique must be selected that adjusts best to the needs of each type of disease studied. Multimodality in molecular imaging is the present and the future of these techniques in research and in the clinic. The use of hybrid equipment simplifies and accelerates image analysis and obtaining results.

The use of PET isotopes implies an increased risk with respect to the isotopes used most commonly in research, since it involves handling isotopes with higher energies and higher activities than the ones generally used in research. This becomes even more significant if research is done on large animals, where the doses used are similar to those used in humans. Keeping the doses low is achieved by an appropriate design and application of movable shields, as well as by the specific work norms. Hand doses can also be maintained at very low levels (approximately 100 times less than the annual limits for extremities) by using specific movable shields, by increasing the distance from the source, by avoiding direct handling of the source, and by using accessories (e.g. forceps for the handling of vials) whenever possible. In our case, the facilities for working with large animals (pigs) are in the phase of design and

construction, so that we do not have results of the dosimetry of this type of work. The objective is to obtain dose values below those of people working in clinical facilities, using the means indicated above adapted to the type of animal used.

To obtain these results, specific prior "cold" training is vital. For the selection of technicians who are going to do the animal labelling, priority must be given to previous experience in the manipulation of experimental animals, which could be complemented with the appropriate training in radiation protection. Handling laboratory animals and administering drugs to them demand special skills to obtain optimal results (injection in the minimum time possible with the smallest number of attempts and the greatest safety for the operator), that can only be achieved through training and experience. To this the difficulty is added to conduct these operations using specific shielding (syringe protectors). Therefore, the optimal situation would be to have a person with experience in animal manipulation who has sufficient time for prior training in the use of such shieldings. In Spain, training in radiation protection has been regulated for a long time, and it is therefore much more developed than training in animal handling. For this reason it is deemed that it is faster and easier to acquire an extensive and detailed training in radiation protection that complements the experience in animal handling.

Conclusions

At present, PET/CT is the molecular imaging technique that is developed furthest in research, with a greater projection and offering results of higher quality, although other techniques are being developed for specific applications, such as SPECT/CT or PET/MRI.

According to our experience, in the work with small research animals (mice), as far as the dosimetry of the personnel who handle these isotopes is concerned, it is possible to obtain whole body dose levels (lapel dosimetry) similar to the other researchers, which are very much below the annual dose limits of exposed workers and normally close to the public dose levels. Hand dose levels very much below the established annual limits for extremities can also be obtained.

Prior cold training and the selection of personnel are vital to attain the goal of the safe use of these isotopes and to maintain the doses low. It has been observed that it is preferable to prioritize previous experience and training in animal handling, which is then complemented with training in Radiation Protection. Working with large animals complicates the design considerably, and therefore all systems affected must be studied carefully to establish the most appropriate measures to take (shields, housing, control of effluents, etc.) in each case.

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Testing of sealed radioactive sources at BAM

Rolle, Annette; Neumeyer, Tino; Droste, Bernhard
Federal Institute for Materials Research and Testing (BAM), GERMANY

Abstract
Requirements and test programs for sealed radioactive sources are specified in international standards for safety in transport and in use.

Sealed sources which are approved as special form radioactive material according to the Transport Regulations, IAEA Safety Standards TS-R-1, must be able to withstand mechanical (9 m drop, percussion and bending) and thermal (800°C heat) tests without loss of radioactive content.

The International Standard ISO 2919 provides a set of tests which classifies the sources for their safety in use. Performance tests specified in this standard are temperature (high and low), external pressure, impact, vibration and puncture tests. Each test can be applied at different levels of intensity depending on typical usage.

As a criterion of pass or fail, leakage testing has to be done after each test.

The poster gives an overview of BAM's comprehensive test equipment and experience in testing sealed radioactive sources.

Introduction
Requirements and test programs for safety evaluation of sealed radioactive sources are specified in international safety standards for transport and for use. BAM is the competent authority for approvals for special form radioactive material and for type testing of devices with inserted radioactive sources and possesses a comprehensive test equipment and experience in testing for many years./1/

Regulations and standards for testing

Transport regulations
Special form radioactive material is defined in IAEA –Regulations TS-R-1 /2/ as an in-dispersible solid material or a sealed capsule containing radioactive material. The design must be able to withstand severe mechanical and thermal tests without undue loss or dispersal of radioactive content. As a consequence the predicted hazards after a severe accident are minimised and the transport of a greater activity in a Type A - package is permitted. Tests specified in Para 705-709 of TS-R-1 are

– impact test
– percussion test
– bending test
– heat test

A different specimen may be used for each test. As a criterion of pass or fail, leakage testing according to ISO 9978 has to be done.

Regulations for use

The International Standard ISO 2919 /3/ provides a set of tests which classifies the sealed source for their safety in use. Performance tests specified in this standard are

- temperature test (high and low),
- external pressure test
- impact test
- vibration test
- puncture test
- bending test.

Each test can be applied at different levels of intensity depending on typical usage (Table 1). The criterion for passing or failing is also the leak-tightness.

Table 1. List of test conditions (ISO 2919:1999).

Table 2 — Classification of sealed source performance (5 digits)

Test	Class						
	1	2	3	4	5	6	X
Temperature	No test	– 40 °C (20 min) + 80 °C (1 h)	– 40 °C (20 min) + 180 °C (1 h)	– 40 °C (20 min) + 400 °C (1 h) and thermal shock to 20 °C	– 40 °C (20 min) + 600 °C (1 h) and thermal shock to 20 °C	– 40 °C (20 min) + 800 °C (1 h) and thermal shock to 20 °C	Special test
External pressure	No test	25 kPa absolute to atmospheric	25 kPa absolute to 2 MPa absolute	25 kPa absolute to 7 MPa absolute	25 kPa absolute to 70 MPa absolute	25 kPa absolute to 170 MPa absolute	Special test
Impact	No test	50 g from 1 m or equivalent imparted energy	200 g from 1 m or equivalent imparted energy	2 kg from 1 m or equivalent imparted energy	5 kg from 1 m or equivalent imparted energy	20 kg from 1 m or equivalent imparted energy	Special test
Vibration	No test	3 times 10 min 25 to 500 Hz at 49 m/s² (5 g_n) 1)	3 times 10 min 25 to 50 Hz at 49 m/s² (5 g_n) 1) and 50 to 90 Hz at 0,635 mm amplitude peak to peak and 90 to 500 Hz at 98 m/s² (10 g_n) 1)	3 times 30 min 25 to 80 Hz at 1,5 mm amplitude peak to peak and 80 to 2 000 Hz at 196 m/s² (20 g_n) 1)	Not used	Not used	Special test
Puncture	No test	1 g from 1 m or equivalent imparted energy	10 g from 1 m or equivalent imparted energy	50 g from 1 m or equivalent imparted energy	300 g from 1 m or equivalent imparted energy	1 kg from 1 m or equivalent imparted energy	Special test

1) Acceleration maximum amplitude

Specimens that comprise special form radioactive material may be subjected alternatively to ISO 2919 tests if these are the more severe ones. The ISO 2919 temperature class 6- test with 1 h at 800°C is in any case more severe than the IAEA TS-R-1 heat test with 10 min at 800°C. Special form radioactive material with a small mass may be except from 9 m drop impact. Capsule designs with a mass less than 200 g may be alternatively subjected to the ISO 2919 impact class 4- test, and for designs with a mass less than 500 g the impact class 5- test may be equally acceptable.

Test methods, equipment and experience

BAM cannot test radioactive samples. All tests have to be done with dummy sealed sources, i.e. the source capsule has the same design, same manufacturing methods and is made from exactly the same material as those of the sealed source that it represents, but containing, in place of radioactive material, a substance resembling it as closely as practical achievable in physical and chemical properties.

Impact test (9 m drop)

For impact test of special form radioactive material the specimen should be dropped from a height of 9 m onto a flat unyielding target so as to suffer maximum damage. Because a definite angle of impact could be important for the damage result BAM use a magnetic release device for a momentum free drop. A high-speed camera (image frequency 5.400/s, 1024x1024 pixel) is used to keep track of the impact position.

Impact test 1 m, percussion test, puncture test

For impact and puncture test according to ISO 2919 and for percussion test according to the IAEA regulations for special form radioactive material the same equipment is used by BAM. (Fig.1)

This test device has also a magnetic release system to assure a momentum free drop, and is suitable for hammer masses up to 5 kg. Impact tests with higher hammer masses are performed at the 9 m drop facility.

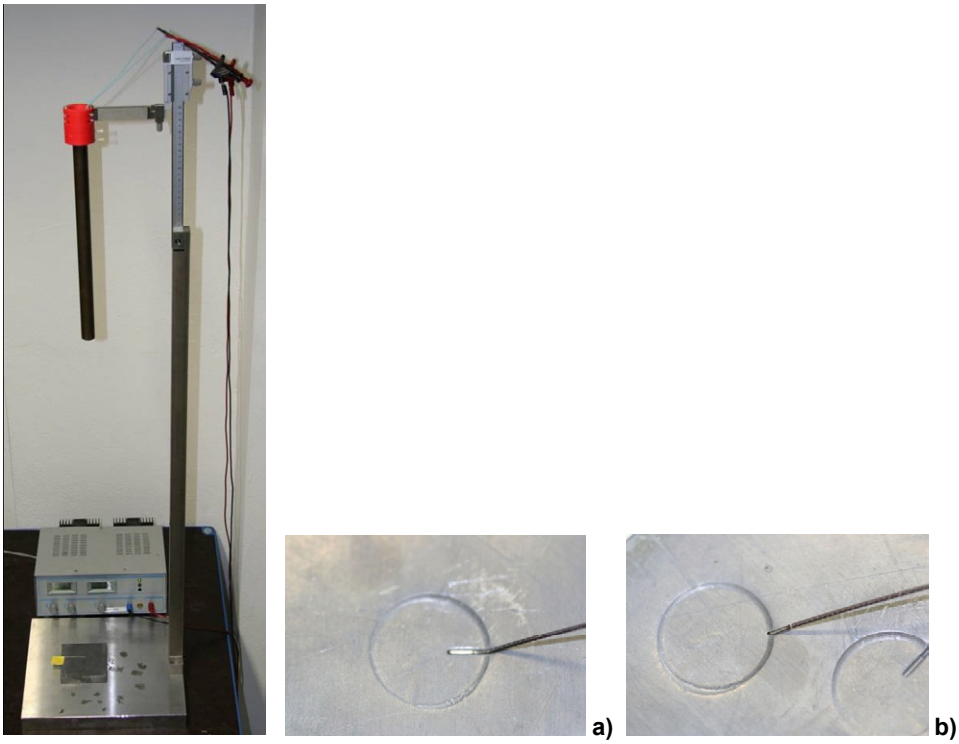
Most of the different steel hammers for the tests in different classes (Table 1) are available (Fig.2).

For percussion test with special form designs the specimen shall be placed on a sheet of lead and struck by a steel bar of 1.4 kg from a height of 1 m. A fresh flat surface of lead shall be used for each impact. The bar shall strike the specimen so as to cause maximum damage.

As an example, in case of small welded Ir-192 sources used for the brachy therapy the bar should strike the weld-seam with its rounded edge to cause maximal bending stress by pressing the source only partly into the soft lead (Fig. 1 b).

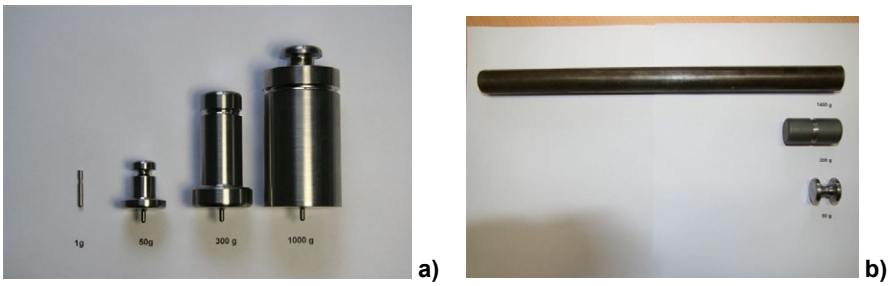
For ISO 2919 impact test class 4 the specimen is placed on a steel anvil with a mass of at least 20 kg, and is struck by a hammer of 2 kg from a height of 1 m. In most cases strains are much higher than in case of the IAEA percussion test, were an only 1.4 kg hammer drives the specimen in the soft lead sheet, excepting cases with additional bending stress as described above. Beside the striking position, also the form of simulated content can have an influence on damage results. For example Ir-192 sources could be filled with one long iridium wire or several shorter iridium-cylinders. Under impact the edges of the cylinders can partly push trough the thin capsule wall.

Steel hammers for puncture test bear a fixed pin with a diameter of 3 mm and a height of 6 mm and can also be attached at the magnetic release device .The mass depends on the test-class and varies between 1 g and 1 kg. If source design has more than one vulnerable area, tests have to be carried out on each of them.



a) b)

Fig. 1. Percussion test on a Ir-192 source for brachy therapy (1.4 kg from 1 m on a sheet of lead) with different impact positions a) less damage , maximum bending stress in the flexible wire; b) maximum bending stress in weld seam of the source.



a) b)

Fig. 2. Examples for steel hammers for a) puncture and b) impact or percussion test.

Temperature tests

An approval for special form radioactive material requires a heat test in air at a temperature of 800°C for 10 min.

Temperature tests according to ISO 2919 include a high–temperature test at temperatures of 80 to 800°C for 1h and a low-temperature test to -40°C for 20 min. The class 6 test (-40°C for 20 min, 800°C for 1 h) as an adequate alternative to the IAEA heat test (800°C for 10 min) is often employed by BAM.

BAM uses for upper temperature test a furnace with a capacity of 10 kW for a maximum temperature of 1200°C to be reached in 2.5 h. Attention should be paid to positioning the specimen in the middle of the furnace and to fitting the thermocouple directly on the specimen surface. In case of designs with a low-melting content, for

example distance pieces made of aluminium, an eutectic reaction can happen and can cause a damage of the capsule material and in worst a leakage.

A climate chamber (-80°C until 190°C) is used for low temperature test.

Bending test

Bending tests shall apply only for long, slender sources. IAEA regulations require this for sources with both a minimum length of 100 mm and a length to minimum width ratio of not less than 10. The free end of a rigidly damped specimen has to be struck by a 1.4 kg steel bar. BAM uses a common clamping tool for fixing the specimen and a tripod to adjust the drop height.

Bending tests according to ISO 2919 shall apply to sealed sources having a length to minimum width ratio of 15 or greater. Test procedure is different from this described above. BAM has up to now never carried out this ISO bending test.

Vibration test

BAM features an electro-dynamic shaker with up to 26 kN peak force and frequencies of 5-2000 Hz with acceleration and force control for performing the vibration test according to ISO 2919. Up to now none of the tested sealed sources have shown any signs of damage after these tests done by BAM. Often applicants abstain from this test.

External pressure test

A hydraulic power unit with a maximum operating pressure of 345 MPa , operating medium water, is used for the external pressure test, therewith BAM is able to carry out also tests up to 170 MPa .

Leakage test as criterion for pass or fail

Compliance with all mechanical and thermal tests has to be determined by the ability of the sealed source to maintain its leak-tightness after each test performed.

BAM uses non –radioactive procedures based on a relationship between volumetric leakage rates and loss of radioactive material with test procedures according to the International Standard ISO 9978 /4/.

A volumetric leakage test is only applicable if there is a minimum void within the capsule (Table 2). In particular in the field of medicine sources become smaller and the need for application of volumetric leak test methods with very small void increases.

BAM possesses comprehensive equipment for performing various kinds of helium tests, vacuum bubble and nitrogen bubble tests.

Table 2. Minimum void in capsule for different volumetric leak test methods.

Leak test method	Minimum void in capsule [mm³]
Vacuum bubble	
- glycol or isopropyl alcohol	10
- water	40
- Pressurized bubble with isopropyl alcohol	10
Liquid nitrogen bubble	2
Helium pressurization	10

Conclusions

The International Standards ISO 2919 and the IAEA Safety Standard TS-R-1 provide a set of mechanical and temperature tests for assessing the safety of sealed radioactive sources in transport and use. BAM possesses comprehensive knowledge, experience and equipment for performing nearly all of these tests.

Since BAM is the competent authority for approval of special form radioactive material tests according to the IAEA regulations have always the priority. But depending for their work load test labs are always ready to carry out also the classification tests according to ISO 2919. About four weeks after incoming of specimens, a test program for one source design can be finished in general.

BAM actively works in further development of test methods and regulations and its' representatives take part in national and international working groups and boards dealing with this topic.

References

/1/ Rolle,A,Droste,B.Safety during whole life time: important aspect in safety assessment of sealed radioactive sources. Packaging, Transport, Storage & Security of Radioactive Material 2008; Vol 19 (No 3):151-154

/2/ Regulations for the Safe transport of Radioactive material, 2005 Edition, International Atomic Energy Agency (IAEA) No. TS-R-1

/3/ International Standard ISO 2919:1999, Radiation protection- Sealed radioactive sources-General requirements and classification

/4/ International Standard ISO 9978:1992, Radiation protection-Sealed radioactive sources-Leakage test methods

Radiological criteria's for patients discharge following a radionuclide therapy or brachytherapy with implanted sealed radionuclide sources

Balonov, Mikhail; Golikov, Vjacheslav; Zvonova, Irina
Research Institute of Radiation Hygiene, RUSSIAN FEDERATION

Abstract

Dose criteria for limitation of exposure incurred by persons helping the patients or living with patients discharged from hospitals following radionuclide therapy or brachytherapy with implanted sealed radionuclide sources have been proposed for national Russian regulation. By means of a conservative dosimetry model, the values of operational radiological criteria for patient discharge from hospital are substantiated basing on the standards of permissible effective dose for population – 1 mSv and for persons helping the patient or living with him – 5 mSv. Two sets of whole body activity for radionuclides I-125, I-131, Sm-153 and Re-188 used in Russia for therapy, as well as dose rate near patient body were received. The smallest one was included in the new Russian Standards for Radiation Safety (SRS-99/2009). Observance of suggested criteria will ensure radiation safety of people in near environment (family, close friends et al.) of the discharged patient.