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# D2.11 – Identifying research needs and R&D priorities supporting the implementation of BSS (2)

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## Abstract

The aim of Task 2.7 of CONCERT was to look for research and innovation needs that might help the transposition and implementation of Council Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation and provide input to joint programming of integrative research actions. To achieve our aims we organised a workshop and participated in meetings involving the European Commission and national authorities, regulators as well as Technical Support Organizations (TSOs).

The Workshop was organised during the ICRP/Radiation Protection Week meeting in Paris, France at October 10, 2017 to conclude Task2.7 related problems and unravel national needs. Twenty-three participants attended the workshop including Task 2.7 members, CONCERT, MELODI, EURADOS, NERIS, EURAMED, ALLIANCE leaders, as well as ICRP and EU representatives. During the workshop we discussed the most burning research needs of BSS implementations and tried to uncover further necessary research directions to improve the scientific background of radiation protection.

The latter point was the main aim of an Article 31 group organised meeting on the epigenetic effect of ionising radiation. A few Task 2.7 members actively participated on this event.

Task 2.7 members were also actively involved in European Union organised RISKAUDIT and MESTRA meetings to help the implementation of the new EURATOM directives.

Finally, we can summarise those fields that needs active research on the radiation protection fields as follows: The effects of protracted exposure and low dose effects; Mechanism of low dose effects; Organ-specific and age and sex differences in tissue radiation sensitivity; The role of genetic differences in individual radiosensitivity; 5. Effects other than cancer and genetic effects and their contribution to detriment; 6. Relating exposure, doses and effects in predicting viability of non-human biota; Reliability of dose estimates; Dosimetry and protection methods in medicine; Ethical and social dimensions in radiation protection

## 1. Scope of Task 2.7

The Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom determines the new safety standards in radiation protection and radiation safety for the member states of the European Union. The member states should implement these new standards to national laws by February 5, 2018. This implementation is obligatory for the member states.

The Council Directive 2013/59/Euratom was based on ICRP recommendations published in ICRP 103 bulletin. The recommendations of ICRP took into account the recent scientific data on radiation protection issues. It is obvious however, that we need more research data to support the implementation process and to help the continuous development of radiation protection.

In Task 2.7: Research and innovation supporting the implementation of the revised European Basic Safety Standards of Work Package 2 the CONCERT project aimed to pay attention to the communication of knowledge from research and innovation conducted within CONCERT and outside that might lay down the scientific basis for the revised European Basic Safety Standards, in order to help those who are involved in the transposition and implementation of these Basic Safety Standards, which will require changes in national regulations and practices.

The key planned activities were

- Organizing meetings with EC and national authorities, regulators and Technical Support Organizations (TSOs) to explain the scientific basis of the BSS and to consult on research and innovation needs related to the revision of BSS and its implementation in member states
- Identifying research needs at national level and identifying priorities for European R&D
- Providing input to Joint Programming of integrative research actions (WP3)

The following CONCERT participants contributed to Task 2.7: OKI (task leader), STUK, UEF, IRSN, BfS, VUJE, ISS, RIVM, IMROH, UT;

## 2. Achievements

### 2.1. Participating in meetings involving EC and national authorities, regulators and Technical Support Organizations (TSOs)

#### 2.1.1. Contact with the Article 31 group

The Article 31 - group of experts advises the Commission on all relevant issues related to radiation protection. Obviously they were the advisor of the Commission in preparing the basic standards on radiation protection. To keep contact with the Article 31 group Task 2.7 members attended the EU Scientific Seminar 2017: Epigenetic effects – potential impact on radiation protection, in Luxemburg on October 11, 2017. The meeting was basically organised by the Article 31 group and intended to stress the importance of epigenetic research for further developments on radiation protection. The following presentations were delivered on the topic:

1.	<b>Objectives of the seminar</b> <i>Patrick Smeesters, on behalf of the Article 31 WP RIHSS</i>
2.	<b>General introduction to epigenetics</b> <i>Anna Friedl</i>
3.	<b>Introduction to epigenetic effects and ionising radiation</b> <i>Munira Kadhim</i>
4.	<b>Trans-generational effects</b> <i>Yuri E. Dubrova</i>
5.	<b>Non coding RNAs: a new mechanism to regulate sensitivity to ionizing radiation?</b> <i>Michèle Martin</i>
6.	<b>Round table discussion: Policy implications and research needs</b> <i>Moderator: Anna Friedl</i> <i>Round table: Speakers, Simon Bouffler, Leon Mullenders, Abderrafi Benotmane</i>

CONCERT Task 2.7 was represented by the following members at the meeting: G. Sáfrány, Fieke Dekkers, M. Markkanen

### *2.1.2. Meetings with EC and national authorities, regulators and Technical Support Organizations*

#### Contacts to national authorities

To be involved in the implementation process of the 59/2013 EURATOM directive it is very important to make contacts with national authorities, important stakeholders and participate in events workshops that deal with and help the implementation. Most of the CONCERTS participants (for instance BSF, STUK, etc.) are working, as a national authority. Others are closely linked as a technical support organization (for instance IRSN, OKI, NCRRP, etc.) to national authorities. These organizations are routinely involved in the implementation process and are participating in national meetings/discussions. CONCERT participant OKI was heavily involved in the BSS transplantation in Hungary on the medical and radon fields. They prepared the draft of the Hungarian decree on the medical field and also prepared the National Radon Action Plan. During this process they always stressed the importance of continuous research on these fields.

#### Meetings involving the European Commission

The European Commission (EC) is organising activities to prepare, accompany, and monitor the transposition of the Directive. The aim is to evaluate the Member States strategies and plans for transposition, and to facilitate discussion amongst Member States, candidate countries and EFTA states - with a view to identifying problematic areas, exchange of experience, identifying good practices and resolution of issues. The EC conduct surveys, and organise general and topical workshops in order to provide an open and transparent platform for exchanges and discussions. The work related to this will be performed by RISKAUDIT.

RISKAUDIT is a consortium composed of the French, German and Belgian technical support organisations, i.e. the Institut de Radioprotection et de Sûreté Nucléaire (IRSN) and the Gesellschaft für Anlagen- und Reaktorsicherheit (GRS). It provides consultancy services in the field of nuclear safety and protection of the environment. Yann Billarand from IRSN is the contact point between RISKAUDIT and CONCERT Task 2.7. CONCERT members such as OKI, STUK, PHE, etc. actively participated on the final RISKAUDIT workshops entitled “Enhancing Radiation Protection in the European Union” held in Brussels, Belgium, through 27-28 June, 2017.

The meeting was divided into 3 sections: Session 1: Status of the project: Summary and Evaluation; Session 2: Perspectives on Open Issues; Session 3: Status of implementation by the Member States; Examples of implementation (near) completion.

The conclusion of the meeting was that most of the Member States could not complete the implementation of the 2013/59/EURATOM directive until yet. However, most of them have confidence to finalize the process until the deadline. The deadline is February 6 of 2018 and the prepared, new legislation framework has to be sent to the EC for precursory validation.

The main challenges were identified on the issues of 'preparedness for emergency situation', 'indoor radon' and 'dose constrains' respectively. Based on the ICRP 115 the relative risk of radon inhalation should be circa two times higher than it was estimated beforehand, but the new conversation factor between radon concentration and effective dose was not published yet. The lack of this factor cause big difficulties during the establishment of new regulation. The application of dose constrains for smaller nuclear facilities gives challenges for some countries, (especially in case of public, medical and non-medical imaging exposure). It was not clear for them the consistency with dose limits.

In the third session, the representatives of member states had to evaluate the subservience of the meetings and summarize the status of the implementation process in their country. Many participants accented the useful impact of the personal conversations during the coffee breaks. They found it a good chance to get examples on the questionable issues. Most of the country raised that they need more instructions and guidance from the EC in given topics and better harmonization would be necessary among the member states.

The Hungarian representatives mentioned that the weak points of the transposition are the issue of indoor radon and radon action plan, regulation of patient dosimetry and preparedness for nuclear emergency situation, respectively. It was questionable that everything should be regulated in the framework of ordinance or law; otherwise it is permitted that some requirement can be put in other type of document? The answer was that the emphasis was not on the format but on the results (efficiency).

## 2.2. Identifying research needs at national level and identifying priorities for European R&D

A Workshop was organised during the ICRP/Radiation Protection Week meeting in Paris, France at October 10, 2017 to conclude Task2.7 related problems, identify national needs. The participants of the workshop were the followings:

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The workshop program included the following presentations:

1.	Introduction: Importance of Task 2.7 for WP2 of CONCERT Geza Sáfrány, Sisko Salomaa
2.	ICRP research priorities (June 2017) Werner Rühm
3.	Article 31 view on research supporting the BSS implementation Patrick Smeesters (TBC)
4.	Cross-country comparisons book "BSS about public information in nuclear emergencies: Countries comparison" Catrinel Turcanu, SCK-CEN (TBC)
5.	RISKAUDIT workshop series on BSS implementation in EU countries Yann Billarand, IRSN
6.	BSS implementation in Poland Boguslaw Michalik, GIG
7.	SCK views on R&D needs for BSS implementation Hildegarde Vandenhove
8.	BSS related work in CONCERT countries: Task 2.7 members
10.	Preparing the Deliverable (submission by 30 November 2017) G. Safrany

Introduction was given by Géza Sáfrány and Sisko Salomaa, drawing the attention of the audience that the transposition of the revised European Basic Safety Standards to national legislation must be done by February 06, 2018. The objective of this meeting was to identify research needs supporting the implementation of BSS in European as well as national level. G. Sáfrány called the attention of the Task2.7 participants that there would be a deliverable D2.11 from Task 2.7 that is due by end of November 2017.

The first speaker was Werner Rühm: "ICRP research priorities (June 2017)" <http://www.icrp.org/docs/ICRP%20Research%20Priorities%202017.pdf>. ICRP priorities highlight the major points where research is needed to support radiation protection. These priorities can be downloaded from the ICRP website. A short overview was given of the main priorities.

1. Effects of protracted exposure and low dose effects

This is of particular importance for ICRP.

2. Mechanism of low dose effects

This is a priority, where much has to be done, especially concerning doses below 100 mGy.

3. Organ-specific and age and sex differences in tissue radiation sensitivity

4. The role of genetic differences in individual radiosensitivity

5. Effects other than cancer and genetic effects and their contribution to detriment

It was highlighted that ICRP releases new recommendations / updates the old ones every 10-15 years, so it is time to start planning the new ICRP recommendations since the last ones were released in 2007. It was also stressed that the mode of calculating the detriment has to be thought of.

More research is needed for the shape of dose response especially below 500 mGy.

6. Relating exposure, doses and effects in predicting viability of non-human biota

7. Reliability of dose estimates

e.g. It is questionable to average the absorbed dose to the whole organ for alpha emitters

8. Dosimetry and protection methods in medicine

It is necessary to keep the space in dosimetry with the rapidly evolving medical procedures.

9. Ethical and social dimensions in radiation protection

It is necessary to develop ethics for common values.

10. Mechanisms for interactions with stakeholders

ICRP maintains a public website called ICRPiwia, which informs the large public on main issues on radiation protection. It is planned that one page will be dedicated for every ICRP report on this webpage to explain it for the general public.

The development of special liaisons is planned with other related organisations acting in the radiation protection domain, such as UNSCEAR, EURADOS, and MELODI.

Next speaker: Patrick Smeesters – “Article 31 view on research supporting the BSS implementation”

Based on Article 31 a group of independent scientific experts was set up with the specific role of assisting the European Commission to implement the BSS. The main task of this group is to look for scientific evidence, which could be employed in radiation protection. The RIHSS subgroup (Research Implications on the Health and Safety Standards) was created specifically focusing on the following objectives:

- summarizing state of the art
- acting as peer reviewer
- suggesting potential regulations for implementation

During the workshop organized by RIHSS on 16/09/2016 the potential topics for research, development and assessment in radiation protection were reviewed and new research topics were identified such as:

- non-cancer radiation effects (mainly circulatory effects and effects on the central nervous system especially after exposure in children)
- effects of interaction of radiation exposure with other toxicants

Some of the above two topics were partly addressed by the former EU-funded project CEREBRAD. The work performed in this project paved the way for further research, which is definitely needed.

- chronic internal exposure

This is a central topic for further nuclear accidents and it is a topic relatively unexplored.

- development of quantities other than effective dose which could quantify the risk
- low dose irradiation in utero

There are still many uncertainties, epigenetic effects should be considered. Long-term effects should be considered, which is a major issue in this subtopic, since few/no data exist so far.

- transgenerational mutagenesis

This topic has been assessed in animal studies only up to now. There is a difference between internal and external exposure.

It is important to highlight that a substantial overlap exists between the RIHSS priorities and MELODI priorities.

RIHSS formulated other non-low dose exposure related priorities also important in radiation protection such as:

- field doses in radiotherapy leading to secondary cancers, cardiovascular effects especially important for irradiation in children
- management of emergency situations (e.g. lessons learnt from Fukushima)
- communication with stakeholders and public
  - ethical aspects
  - communication of uncertainties
  - how to use "new" media

The next speaker was Catrinel Turcanu, SCK-CEN: "Cross-country comparisons book "BSS about public information in nuclear emergencies: Countries comparison"

The talk was given on behalf of T. Perco.

A thorough comparison was made between the old and new BSS regarding public communication issues.

The new BSS includes legal obligation to include emergency communication to exposed population. There is a legal obligation to inform public in the pre-alarm phase. There is legal obligation to provide information for the public for routine and emergency related cases.

The speaker presented the work package activity including its methodology, where an emphasis was put on the role of national contact points.

The overview of legal aspects in all EU countries has already been done. A future workshop will be organized in Brussels, June 2018.

As future perspective the work package plans to write a book on national practices in implementing the BSS.

The next speaker was Yann Billarand, IRSN: "RISKAUDIT workshop series on BSS implementation in EU countries"

As member of the RISKAUDIT group, the speaker presents latest work performed in this group. The main objectives of the RISKAUDIT group are:

- to monitor the evolution of Member States' strategy and plans for the transposition and implementation of the BSS. It is stressed the difference between transposition and implementation.
- to facilitate exchange of experience between member states
- to identify good practices
- to identify issues related to further implementation

The speaker summarized the current status of the transposition process, presented strategies and plans for facilitating the transposition process, where a major issue is identifying the legislation that need to be adopted.

Certain open issues still exist, which have to be identified and further discussed in the frame of a general workshop, where recommendations for the transposition and implementation process are formulated.

The RISKAUDIT group took part in the organisation of an Emergency preparedness and response workshop as well as a NORM, BM and radon workshop. In the frame of this latter workshop it was formulated the need for further guidance and regulations in the field. A graded approach is needed with respect to the need for trained personnel and safety assessment.

The RISKAUDIT group had a meeting in June 2017, where several conclusions were drawn:

- there is an expectation from the member states for further workshops, where further exchange takes place to facilitate implementation
- the need for the introduction of the new concepts of radiation protection expert (RPE) and radiation protection officer (RPO)
- the need for the implementation of a radon plan action
- the need for the endorsement of the ENETRAP documents
- regarding building material there is a need to harmonize methods on measuring of radionuclides
- emergency preparedness and response issues

Géza Sáfrány asked for feedback from EU representatives present at the meeting. Stefan Mundigl reacted and highlighted that BSS transposition in the different member states can be divided in two phases: 1. transposing BSS legislation schemes and 2. implementing it in reality.

Yann Billarand answered that different approaches can be adopted in the different member states, for example radon can be assessed differently. Stefan Mundigl expressed the need to launch further working groups in the topic. Géza Sáfrány reacted that a common statement is expected from EU for radon conversion factor. ICRP representative answered that the issue will be discussed in a forthcoming meeting.

The next speaker was Boguslaw Michalik, GIG: "BSS implementation in Poland".

Six groups of experts were set up in Poland by the responsible ministry in August 2014. The details of implementation of NORM were summarized as follows:

- graded approach
- notification of the NORM industry
- broadened list of NORM industry
- diversification of responsibilities

Criteria for exemption were set:

- clearance limit 1 kBq/kg
- effective dose: 1 mSv/year

There is a need to set the competence and responsibility for the assessment.

- there are no limits expressed as activity concentration for the liquid effluents. For this reason, a complex analysis is required.

If these criteria are exceeded, NORM are treated as regular radionuclides.

As a problem it was raised what to be considered radioactive waste? Specific limits were set for <sup>226</sup>Ra and <sup>228</sup>Ra but not for other radionuclides.

The speaker presents some details for the implementation:

- for radon reference level was set to 300 Bq/m<sup>3</sup>.
- obligatory monitoring of Rn and progeny in workplaces.
- the assessment of indoor Rn activity concentration is a parameter applicable in the real estate market but it is not obligatory

Problems to be solved:

- how to classify NORM above clearance level
- how to classify NORM above limit for radioactive waste
- how to treat NORM in liquid phase
- deficiency in NORM and Rn issues in training programs

Not yet solved: EU BSS Art 30 and 65.

Current status: the amendment of the Atomic Law and the preparation of 28 requirements.

The next speaker was Hildegard Vandenhove (SCK-CEN): "SCK views on R&D needs for BSS implementation"

The speaker grouped her talk on a number of research domains identified in the BSS where the SCK considers further R&D work is necessary.

Research domain 1: Emergency preparedness – related to Articles 7, 53, 69, 70 and to orphan sources.

Research domain 2: Building materials and NORM – related to Article 75.

Research domain 3 and 4: Non-medical and occupational exposures – related to Articles 22 and 31.

Research domain 5: Medical exposure doses, radiation protection education and training – related to Articles 5, 6, 58, 60 and 61.

Research domain 6: Irradiation in utero

Research domain 7: Radiation induced risk, protection of health – related to Articles 1 and 2.1.

It should be considered:

- non-cancer effects
- combined effects
- chronic internal exposure
- transgenerational mutagenesis

Research domain 8: Impact assessment and compliance – related to Articles 30, 61, 66, 72 and 73.

Research domain 9: Environmental protection

Research domain 10: communication

*Because of the extreme importance of this task SCK-CEN views on the research needs of the BSS transposition are attached as ANNEX 1 at the end of this deliverable.*

The next speaker Antonella Rossi (ISS) reported the Italian approach of BSS transposition

In Italy a workgroup was established in 2014 to facilitate the implementation of the BSS. The speaker gave a short overview on the workgroup methodology. It is expected to reach the ultimate goal by 06 February, 2018. At present the transposition level is 80%.

At the end of the workshop Géza Sáfrány thanked the speakers and the audience for their contribution and for coming. It was agreed that a draft of the deliverable will be prepared in due time and will be circulated among task members for comments. Sisko Salomaa suggested the deliverable to be prepared in an outline similar to the presentation given by Hildegard Vandenhove which gave linked research needs to specific Articles of BSS. Dr Vandenhove informed that she actually has the presentation in Word format. **The views of SCK-CEN are considered extremely important in the context of the research needs for the transposition and implementation of the BSS not only in Belgium, but also in other EU countries. Therefore it is provided as Annex I to this deliverable.**

### 3. Providing input to Joint Programming of integrative research actions (WP3)

During the work performed in Task 2.7 of CONCERT our general observation was that national authorities are currently heavily occupied by the legal aspects of BSS rather than in research needs helping the implementation process.

One point that constantly shined up during the consultations was that radiation protection in medical radiations (repository for patient dosimetry, imaging meta-data and bio-banking, integrated with health databases), is a very important unresolved issue. The new BSS emphasizes not only the justification of medical exposure but also requirements that concern provision of information to the patient, recording and reporting doses resulting from medical procedures, using diagnostic reference levels and the provision of equipment that provide data on doses. Such repository would be very useful for research purposes too. Digitalisation of information opens new opportunities.

Other very important points were raised by the Article 31 group. During the preparative work of the second CONCERT call we strongly emphasized that the following points from the Article 31 group suggestions should be taken to serious consideration in the call topics:

- New data on radiation-induced health effects (MELODI)
  - Non cancer radiation-induced effects including Nervous Central System and circulatory diseases (MELODI, EURAMED)
  - Combined effects: interaction of ionising radiation with other toxicants (ALLIANCE)
  - Chronic internal exposures (EURADOS, MELODI)
  - Transgenerational mutagenesis (ALLIANCE)
  - development of quantities other than effective dose which could quantify the specific individual risk (EURADOS, EURAMED)
- Low dose irradiation in utero (MELODI, EURADOS)
- Organ doses (EURADOS, EURAMED, MELODI)
- Dosimetry, particularly (EURADOS)
  - in occupational exposure (EURADOS)
  - with respect to radon exposure (EURADOS, ALLIANCE? - NORM)
- Emergency situations (NERIS)
  - practical implementation of the new reference level approach
  - assessments based on well-defined scenarios



- optimal equipment and harmonized protocols for first responders
- strategy for deciding upon a monitoring programme after an emergency
- post-accident strategies
- Societal issues, including communication, and stakeholder involvement (SSH)
- Methodologies to find back orphan sources
- Communication about the effects of ionising radiation (SSH)

ICRP is another important stakeholder for the radiation protection research community. The new European BSS are based on the recommendations of the ICRP from 2007. ICRP has recently given their view on research priorities, which to a great extent identify research that is needed to remove uncertainties in our understanding of radiation risks, thus forming foundation for the future ICRP recommendations and future BSS based on it. The ICRP research priorities include the following topics:

- Effects of protracted exposure and low dose effects
- Mechanism of low dose effects
- Organ-specific and age and sex differences in tissue radiation sensitivity
- The role of genetic differences in individual radiosensitivity
- Effects other than cancer and genetic effects and their contribution to detriment
- Relating exposure, doses and effects in predicting viability of non-human biota
- Reliability of dose estimates
- Dosimetry and protection methods in medicine
- Ethical and social dimensions in radiation protection
- Mechanisms for interactions with stakeholders

## 4. Annex I.

Research domains which would support the implementation of the new BSS

*SCK-CEN's view in support of Art 31 and in support of CONCERT*

Hildegarde Vandenhove, Johan Camps, Filip Vanhavere, Lara Struelens, Roel Quintens

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### **Research domain 1: Emergency situations**

#### **Page 5 (41) Management of emergency exposure: Adapt the current approach based on intervention levels and replace by more comprehensive approach reference**

- Will require a different view of the emergency management. As the text says, it comprises an assessment of potential emergency exposure situations, an overall emergency management system, emergency response plans, and pre-planned strategies for the management of each postulated event. It will require the development of guidelines, approaches and the required assessment models.
- More research is needed how to come to practical implementation and to further develop methods (models and monitoring) for assessing the situation and for better predicting a 1 year dose.
- Societal issues and stakeholder involvement exercises in various MS, with the idea to optimize the policy in various (post-) accident situations already from the preparedness stage.
- More stringent exemption limits may require adapted monitoring techniques.

#### **Article 7. Reference levels (1-3) + Annex 1 (20-100 mSv/ acute or per year)**

- Further development of radiological assessment methods (models and monitoring) and strategies to estimate & determine especially the 1-year dose.
- Further development of methods for robust decision making and optimisation of protection
- Stakeholder involvement to determine societal criteria

#### **Article 42. Dose assessment in the case of accidental exposure**

- Retrospective dosimetry and anthropogammametry methods ranging from detailed assessments to assessment methods for large groups of people.

#### **Article 53. Emergency occupational exposure**

- Further development of state-of-the-art equipment for first responders (detection and protection) covering all exposure pathways.
- Development of reliable active neutron dosimeters

### **Article 69. Emergency response**

- Further development of fast radiological assessment tools (models and monitoring): e.g. airborne monitoring with helicopters, drones ...
- Research on the relation between operational dose and contamination levels and the very generic reference level of 20-100 mSv acute or /year
- Including model and monitoring uncertainty in (the visualization) of assessments
- Evaluating and re-thinking early warning networks with involvement of measurements by the public
- More in-depth study of protective actions

### **Article 70: Communication**

- Support of better communication during and in aftermath of crisis

### **Article 72-73**

- Further development of monitoring techniques for characterizing contaminated areas (environmental monitoring programs) including new techniques such as drones, measurements by the public (apps, small detectors, ...)
- Further development of models for all exposure pathways
- Develop local and regional based models for dose assessment
- Determine regional and national model parameter values that are necessary for environmental modelling
- Develop guidance for exposure control
- Develop models/guidance to establish appropriate reference levels post-emergency

### **Article 92 Orphan sources**

- Further development of detection techniques to find orphan sources and reach back capabilities to enhance the identification of these sources
- Scenario development.

### **Article 98 Emergency preparedness**

- Development of strategies for:
  - monitoring
  - countermeasures
  - taking into account uncertainty in dose assessment
  - evaluation of risk reduction methodologies

### **Research domain 2: building materials and NORM (art. 75 as key article)**

- Study and harmonization of the approach in various countries to apply the BSS (and check for other legislation that might be applicable, e.g. related to construction requirements, waste issues, general ventilation issues and air quality regimes etc.) for use and reuse of building and/or NORM materials for construction: exemption, control, concentration levels, dose estimate approach, standards and their application,....
- Interface with other regulations
  - construction product directive CPR 305/11 and role of radiological experts in support of their development
  - leaching in relation with drinking water directive

### **Research domain 3: non-medical exposures**

#### **Article 22 – deliberate exposure of humans for non-medical imaging purposes**

- Doses evaluation in case of exposure of humans to non-medical imaging

### **Research domain 4: occupational exposure**

#### **Article 31. Protection of exposed workers**

- Development of a practical eye lens dosimetry, either by developing an improved eye lens dosimeter or by improved correlations between the other dose indicators and the eye lens dose.
- Development of reliable (active) neutron dosimeters

### **Research domain 5: medical exposures**

- General – justification and ethics

#### **Articles 5 and 6: optimization and dose constraints**

- Evaluation and optimisation of organ doses, particularly for heart and arteries

#### **Article 56 – Medical exposure - Optimization**

- Development of dose-optimization tool
- Development of better simulation tools to assess the relationship between organ dose of patient and dose indicators in medical applications, required for optimisation and justification.

#### **Article 58 – Procedures**

- QA for dosimetry in radio-diagnostics and radiotherapy

## **Article 61 – special practices**

- For exposure of children and treatments involving high doses to the patients (interventional radiology, nuclear medicine, CT, radiotherapy → quality assurance and dose assessment
- QA of mentioned practices
- Development of dose assessment models or dose monitoring systems for mentioned practices
- Improve, validate and implement new biokinetic models and the associated dose evaluation following internal exposure.

## **Research domain 6: irradiation in utero**

- There are still many uncertainties regarding the effects of irradiation in utero: risk of radiation-induced childhood leukaemia, congenital malformations, radiation-induced effects on gene expression, subtle effects or long-term effects after Nervous Central System irradiation, non-cancer effects of internal (OBT ..,) and chronic exposures...
- Low dose effects from in utero exposure are currently somewhat out of concern, but could cause bad surprises in the future. The potential implications are important, particularly in emergency situations and in medical exposures.
- More research is needed in this field.

## **Research domain 7: radiation-induced risks; protection of health (art 1 and 2.1)**

- Interaction of ionising radiation with other risks (combined effects)
- Non cancer radiation-induced effects: important potential impact on organ dose limitations: research should further be supported
- Chronic internal exposures: limited data on effects of chronic internal exposure of populations
  - Is there is always equivalence of risk for external and internal exposures?
  - Is currently used concept of equivalent/effective dose right risk indicator for all types of effects (including all types of non-cancer effects)
  - Role of radiation-induced modifications in gene expression and genomic instabilities in chronic internal exposures should be further explored.
- Transgenerational mutagenesis:
  - up to now observed only in animals but such effects occurring, would have wide implications
  - possible differences in genetic changes between external and internal exposures are another important issue

## **Research domain 8: Impact assessment and compliance**

### **Article 30: Release from regulatory control**

- Development of models/guidance to assess if an activity can be exempted from regulatory control if amount or activity concentration of radioactive substances exceeds limits in Table A or B (30.2.e)
- More stringent guidelines may require adaptation of monitoring techniques

### **Article 61: Special practices**

- Development of dose assessment models or dose monitoring systems for mentioned practices

### **Article 66: Dose estimations to members of the public**

- Develop tiered approach for dose assessment to the public

### **Article 72-73: Further development of monitoring techniques for characterizing contaminated areas; further development of models for all exposure pathways**

- Develop local and regional based models for dose assessment
- Determine regional & national model parameter values for transfer modeling
- Develop guidance for exposure control

## **Research domain 9: Environmental protection**

Environmental protection is not really considered within BSS, except as support for protection of man, as illustrated below. Yet, there are situations where the environment is/may be impacted when man is not. There may also be public concern for environmental impact. Also other (conventional) contaminant regulation) regulations include the protection of the environment. Therefore, also in radiation protection of the environment should be considered.

- **Article 2 : Scope** “This Directive applies to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation which cannot be disregarded from a radiation protection point of view or with regard to the environment in view of long-term human health protection.”
- [27] “The contamination of the environment may pose a threat to human health. The Community's secondary legislation so far has regarded such contamination only as a pathway of exposure to members of the public directly affected by radioactive effluent discharged to the environment. While the state of the environment can impact long-term human health, this calls for a policy protecting the environment against the harmful effects of ionising radiation.”

**Research domain 10: Communication (various articles)**

- communication of risk at low doses,
- communication of risk evaluation uncertainties,
- support of better communication during and in aftermath of crisis
- numerical risk approach in relation to risk perception,
- ethical aspects of communication ,
- communication regarding (dose) justification and optimisation,
- the best way to engage stakeholders
- the use of new media in risk communication.