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### D9.85 - Rationales and frameworks for stakeholder engagement in radiation protection in the medical field (Part 1), nuclear emergency and recovery preparedness and response (Part 2) and indoor radon exposure (Part 3)

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## Abstract

This report summarises the rationales and frameworks for stakeholder engagement in radiological protection, in relation to the medical use of ionising radiation, emergency preparedness and response, and exposures to indoor radon. It draws on document analysis of legal EU framework, national legislation and derived documents, international guidance and recommendations, as well as interviews with representatives of international organisation or associations in the fields.

The results highlight that legal requirements for stakeholder engagement focus on assuring the provision of information from the responsible actors to the relevant stakeholders. The main motivation for participation is found to be primarily instrumental, applied to secure particular end points, and in few cases normative (e.g. transparency, or the right for information), or substantive (e.g. inherent part of complex decision-making). The level of participation mentioned in these documents generally varies from information to consultation or dialogue. Other documents, which are not part of the legal framework, such as recommendations and guidelines of international organisations or associations, reflect a broader view on stakeholder engagement, not only in terms of interpretation of the concepts of “stakeholder” and “involvement” or “engagement”, but also the motivations or aspirations underlying the calls for participation. Such documents also support enhanced interactions with different groups of stakeholders in activities relating to ionising radiation.

This report will be supplemented by the second deliverable of ENGAGE WP1, which will include a transversal analysis and comparisons between the three fields (medical use of ionising radiation, emergency preparedness and response, and exposures to indoor radon).

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## CONTENT

<b>1. INTRODUCTION AND WP1 OVERVIEW</b>	<b>7</b>
<b>2. ORGANISATION OF WORK AND METHODOLOGY</b>	<b>9</b>
<b>2.1 Analysis of documents</b>	<b>9</b>
<b>2.2 Semi - structured interviews</b>	<b>12</b>
<b>3. DIRECTIVES AND CONVENTIONS</b>	<b>13</b>
<b>3.1. EC EURATOM BSS directive</b>	<b>13</b>
3.1.1. Key Words	13
3.1.2. Definitions and requirements	13
3.1.3. Aspirations	14
3.1.4. Motivations	14
3.1.5. Level of stakeholder engagement	15
3.1.6. Any other observation	15
<b>3.2. EC EURATOM Nuclear Safety directive</b>	<b>15</b>
3.2.1. Key Words	15
3.2.2. Definitions and requirements	15
3.2.3. Aspirations	16
3.2.4. Motivations	16
3.2.5. Level of stakeholder engagement	17
3.2.6. Any other observation	17
<b>3.3. EC EURATOM Drinking Water directive</b>	<b>17</b>
3.3.1. Key Words	17
3.3.2. Definitions and requirements	17
3.3.3. Aspirations	18
3.3.4. Motivations	18
3.3.5. Level of stakeholder engagement	18
3.3.6. Any other observation	18
<b>3.4. EC EURATOM Information in radiological emergency directive</b>	<b>18</b>
3.4.1. Key Words	18
3.4.2. Definitions and requirements	19
3.4.3. Aspirations	19
3.4.4. Motivations	19
3.4.5. Level of stakeholder engagement	19
3.4.6. Any other observation	20
<b>3.5. EC EURATOM Early notification convention</b>	<b>20</b>
3.5.1. Key Words	20
3.5.2. Definitions and requirements	20
3.5.3. Aspirations	21
3.5.4. Motivations	21
3.5.5. Level of stakeholder engagement	21
3.5.6. Any other observation	21

<b>3.6. EC Aarhus convention</b> -----	<b>21</b>
3.6.1. Key Words -----	21
3.6.2. Definitions and requirements -----	22
3.6.3. Aspirations-----	22
3.6.4. Motivations-----	23
3.6.5. Level of stakeholder engagement -----	23
3.6.6. Any other observation-----	23
<b>4. NATIONAL REQUIREMENTS AND FRAMES</b> -----	<b>23</b>
<b>4.1. Medical field</b> -----	<b>23</b>
<b>4.2. Emergency preparedness and recovery</b> -----	<b>29</b>
<b>4.3. Indoor radon</b> -----	<b>34</b>
<b>5. REPORTS AND GUIDELINES FROM INTERNATIONAL ORGANISATIONS</b> -----	<b>40</b>
<b>5.1. Analysing EU science policy paradigm</b> -----	<b>40</b>
<b>5.2. How are the stakeholders defined</b> -----	<b>41</b>
<b>5.3. Stakeholders and ionising radiation in medicine</b> -----	<b>44</b>
<b>5.4. Stakeholders engagement related to the nuclear/radiological emergency field</b> -----	<b>48</b>
<b>5.5. Stakeholders and their engagement in indoor radon</b> -----	<b>55</b>
<b>6. ANALYSES OF INTERNATIONAL INTERVIEWS</b> -----	<b>60</b>
<b>6.1 Medicine</b> -----	<b>60</b>
<b>6.2 Emergency preparedness and response</b> -----	<b>62</b>
<b>6.3 Indoor radon</b> -----	<b>65</b>
<b>7. CONCLUSIONS</b> -----	<b>68</b>
<b>8. REFERENCES</b> -----	<b>71</b>
<b>9. ANNEXES</b> -----	<b>74</b>
<b>9.1. Annex 1: Template for Reporting on Analysis for Tasks 1.1, 1.2 and 1.3</b> -----	<b>74</b>
<b>9.2. Annex 2: Extracts from directives and conventions</b> -----	<b>75</b>
9.2.1. Related extracts from BSS directive -----	75
9.2.2. Related extracts from Nuclear Safety directive-----	81
9.2.3. Related extracts from Drinking Water directive-----	83
9.2.4. Related extracts from Information in radiological emergency directive-----	84
9.2.5. Related extracts from Early notification convention -----	86
9.2.6. Related extracts from Aarhus convention -----	88

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<b>9.3. Annex 3: Overview of national legislation</b> .....	<b>97</b>
9.3.1. Related national analysis in medical field .....	97
9.3.2. Related national analysis in emergency preparedness and response .....	110
9.3.3. Related national analysis in indoor radon exposure .....	127
<b>9.4. Annex 4: Analyses of international documents</b> .....	<b>141</b>
9.4.1. Related international analysis in medical field .....	141
9.4.2. Related international analysis in emergency preparedness and response .....	157
9.4.3. Related international analysis for radon .....	163

## 1. Introduction

The ENGAGE project, funded under the H2020 CONCERT, aims at *ENhancinG stakeholder participation in the GovernancE of radiological risks* [1]. It is a two-year project that started on November 20<sup>th</sup>, 2017, and which seeks to identify and address key challenges and opportunities for stakeholder engagement in relation to medical use of ionising radiation, post-accident exposures and exposure to indoor radon. In all these situations, stakeholder engagement is a key issue for improving the governance of radiological risks and the radiation protection of the exposed individuals.

The ENGAGE project aims are:

- a. to assess why, when and how stakeholders engage in radiation protection;
- b. to develop novel approaches to analysing stakeholder interaction and engagement, and provide guidance to meet the challenges and opportunities identified in response to (a);
- c. to investigate the processes for enhancing radiation protection culture and their role in facilitating stakeholder engagement, and develop guidelines for building radiation protection culture; and
- d. to build a joint knowledge base for stakeholder engagement in radiation protection.

The ENGAGE project is organized in four main work packages (WPs) coordinated by the management WP, which interact to achieve the objectives as presented on the Figure 1.

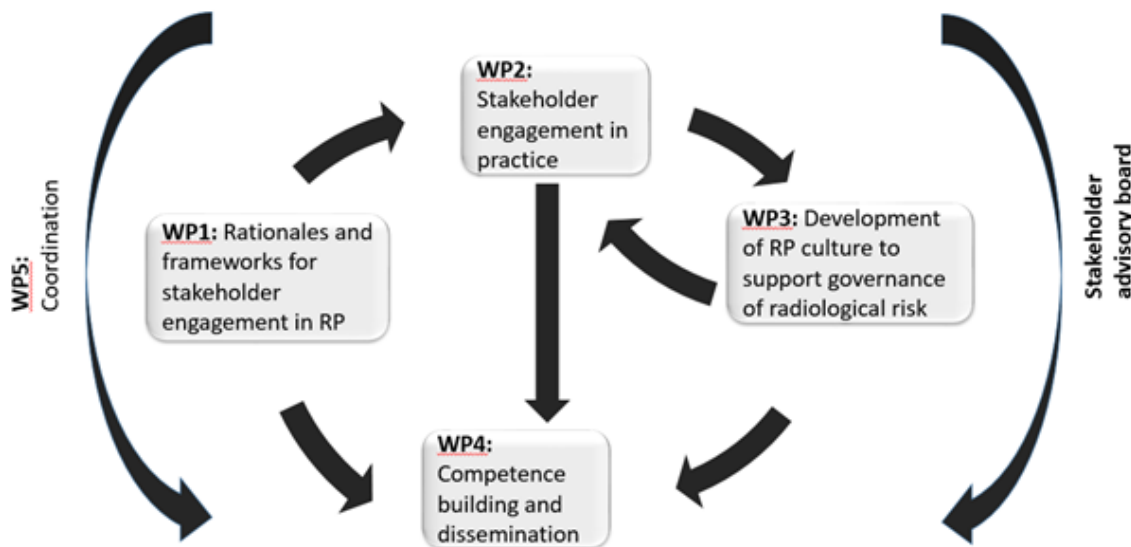


Figure 1: Interaction between ENGAGE work packages

ENGAGE WP 1 on *Rationales and frameworks for stakeholder engagement in radiation protection* clarifies the rationales for stakeholder engagement in radiation protection and the related legal or contextual drivers (why does stakeholder engagement occur, who is involved and for what purpose).

WP 1 aims to investigate the rationales for stakeholder engagement in three different field of radiation protection as:

- i. formulated in EU policy discourse (e.g. Responsible Research and Innovation, past and on-going research),

- ii. formulated in legal requirements and international guidelines related to radiation protection or related to environmental matters (EURATOM BSS and other directives), conventions (Aarhus, ESPOO, ...) and guidelines from ICRP, IAEA, OECD/NEA and others, and
- iii. mobilised by different actors at national and international level in the radiation protection field (for example HERCA, NTW, and other).

The focus of the investigation is the analysis of participation at macro-level, as highlighted in the European and international discourse. It analyses prescriptions and requirements for stakeholder engagement, and how these are transposed at national level in participating countries, as well as the extent and justification for stakeholder engagement.

WP1 is divided in 4 tasks, where three tasks (1.1, 1.2 and 1.3) correspond to three radiation protection contexts addressed in ENGAGE (respectively medicine, emergency preparedness and recovery and indoor radon). A fourth task (1.4) is the methodological and also comparative analysis task. The analysis draws on document analysis of publicly available material related to legal requirements and recommendations for stakeholder engagement in three fields of radiation protection, and interviews with actors at the international level (EU level and international organisations such as NEA and IAEA, but also with representatives of non-institutional and non-governmental organisations). Within Task 1.4 the results from other three tasks are drawn to assess differences and commonalities between stakeholder engagement in different exposure contexts. In addition, transversal European discourse promoting inclusiveness and stakeholder engagement in science policy is analysed.

This report is divided in several chapters. In the second chapter, the organisation of work and the methodological approach is presented. Chapter 3 provides an overview of findings from analyses of directives and conventions which are related to stakeholder engagement in the fields under consideration, while chapter 4 presents the transposition of requirements in the national context in selected countries. The fifth chapter describes the recommendations and guidelines of international documents, followed by chapter 6 with the outcomes from discussions with international interviewees. The report ends with concluding remarks, references used in the deliverable and a set of annexes with details supporting the core text. Further analysis of the collected data will be addressed in the second deliverable in this work package.



## 2. Organisation of work and methodology

The objective of analysis in WP 1 is to clarify what “external” pressures, mandates, demands, and/or expectations have emerged in public venues commending the engagement of stakeholders (including wider publics) in RP. For the purpose of implementation of the WP 1 activities a work plan was developed as follows:

- Collection of documents per field: medical, EP&R and indoor radon, which are related to stakeholder engagement at different levels:
  - EU policy legislation, policy briefs, presentations, also research calls;
  - related EC directives and other EU level adopted conventions (Aarhus, ESPOO, ...);
  - reports and guidelines from international organisations (e.g. IAEA, OECD-NEA, HERCA, ICRP, ENSREG, ...);
  - regulatory and legal documents at national level in the involved countries, statements or documents from RP communities (e.g. research platforms);
  - Civil Society statements or reports.
- First analysis of collected documents to understand what is required or expected, as well who is taking part or which actors (individuals or groups, institutional and non-institutional) are related;
- Coordinated analysis of documents based on a Protocol for analysis in tasks 1.1, 1.2 and 1.3 (Milestone 1.1, WP1) [2] and Reporting template (annex 9.1) to identify legal provisions and provide these as input to WP2 (Milestone 1.2, WP1) [3];
- Further analysis of documents and additional interviews with key actors identified in the through document analysis;
- Finalisation of the report.

The report is organised in several chapters: internationally legally binding documents (like EC directives, conventions and similar), national legal instruments, international recommendations and expectations of different actors.

### 2.1 Analysis of documents

The methodology for the investigation of documents in WP1 is presented in the Protocol for analysis in tasks 1.1, 1.2 and 1.3 [2]. The aim is to better understand why, when and how stakeholders are engaged in radiation protection in the three fields under consideration. This understanding is necessary to facilitate the development of guidelines and a knowledge base for a more robust stakeholder engagement in radiation protection. For this purpose, documents analysis and semi-structured interviews with key actors per field (e.g. policy makers, stakeholder group representatives) is performed.

The following questions and terms have been used as *sensitizing concepts*; that is, as constructs that sensitize us to possible lines of inquiry, and which can be adapted to the case at hand and the developments that ensue during fieldwork (van den Hoonard, 1997; [4]).

- a. What local, regional, national or international sources justify or prescribe stakeholder engagement and public participation in RP? In addition to formal policies and actors, consider other formal and/or informal sources.
- b. Which actors (and which networks) are being summoned/expected to engage or participate in RP, by whom, when, why and how? Are there differences between the three exposure contexts investigated and if so, what is the underlying justification of such differences?

- c. How do the actors mentioned above (policy makers, regulators, CSO's, international organisations, etc.) define "stakeholder" and how do they understand stakeholder engagement? What are their expectations from such processes?
- d. Can you identify aspirations for or trends (over time) towards more or less stakeholder involvement (e.g. engagement of particular social groups)? Can you identify any tensions, ambiguities, contradictions, or divergences present in or indicated by these prescriptions?
- e. What potential implications do these conceptions entail for RP institutes, communities, platforms, and researchers? For scientific practice, conduct, or education? For your specific case? For others who participate in (nuclear) research and development related to ionising radiation?
- f. What else have you found, or should we be asking?

To answer these questions, it can be helpful to highlight:

- **motivations for participation:** one can distinguish between several modes of motivations: *instrumental* (it is applied to secure an end point), *normative* (e.g. "it is the right thing to do", it responds to a certain principle), and *substantive* (it is applied to achieve better decisions)<sup>1</sup>;
- **level of participation:** considering e.g. the influence on decisions, the purpose of participation, the interactions between stakeholders (an example in Figure 2);
- **frames** used to define / recommend engagement: assess how prescriptions explicitly or implicitly convey a *problem definition*, *moral evaluation*, and *treatment recommendation*;
- **stakeholders:** who is involved and/or have interest in interaction in radiation protection, either from legal framework perspective or based on expectations and adopted norms in different fields.

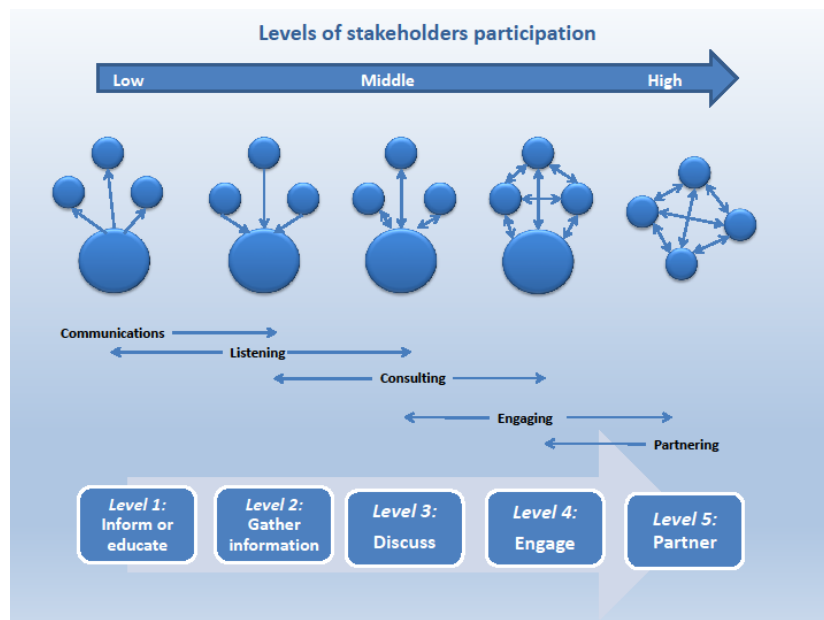


Figure 2: Possible interaction with stakeholders and levels of influence<sup>2</sup>

<sup>1</sup> (see e.g.: <https://assets.publishing.service.gov.uk/media/57a08c6ce5274a31e00011ee/1052734439-stirling.2005-opening.pdf>)

<sup>2</sup> Adapted from Health Canada Policy Toolkit for Public Involvement in Decision Making, 2000, [https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/ahc-asc/alt\\_formats/pacrb-dgapcr/pdf/public-consult/2000decision-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/ahc-asc/alt_formats/pacrb-dgapcr/pdf/public-consult/2000decision-eng.pdf)

For the analysis of publicly available documents, a standard reporting format has been adopted (Annex 1, chapter 9) which proposes a review template and allows for addressing the above questions in the systematic way. It comprises the following information:

- title of the document and the institution/organisation/association which adopted it,
- keywords used to identify how stakeholders and their interactions are described (like ‘stakeholder’, ‘interested parties’, ‘concerned parties’, ‘engagement’, ‘involvement’, ‘participation’ or others),
- definition of ‘stakeholder’ and/or ‘stakeholder engagement’ when provided and related requirements (how the groups are interacting),
- aspirations for stakeholder engagement with description of the trends, contradictions and/or divergences that can be found in the document,
- motivations with description of the instrumental, normative and/or substantive incentive for stakeholder engagement,
- level of stakeholder engagement with description of models of stakeholder engagement mentioned in the documents and/or the level of stakeholder engagement mentioned.

The following documents have been analysed depending of the considered field:

- EU policy legislation, policy briefs, presentations, also research calls,
- Related EC directives and other EU level adopted conventions (Aarhus, ESPOO, ...),
- Reports and guidelines from international organisations/associations (e.g. IAEA, OECD-NEA, HERCA, ICRP, ENSREG, ...),
- Regulatory and legal documents (national level) related to three fields of investigations,
- Statements or documents from other radiation protection actors (e.g. research platforms),
- Civil Society statements, other reports.

In total approximately 150 documents are investigated and can be distributed in the following topics (areas) and countries as presented in Table 1. In this report only the most relevant findings are presented, focusing on results with an added value in the discussed fields. Therefore the repetition of the findings is reduced. Also, the investigations were performed with the most recently published documents.

Table 1: Overview of topics and countries for report on rationales and frameworks for stakeholder engagement in radiation protection

Document – area	Medical	EP&R	Radon
EU policy legislation, policy briefs, presentations, also research calls	X	X	X
Related EC directives and other EU level adopted conventions (Aarhus, ESPOO, ...)	X	X	X
Reports and guidelines from international organisations (e.g. IAEA, OECD-NEA, HERCA, ICRP, ENSREG, ...)	X	X	X
Regulatory and legal documents (national level)	Germany, Italy, Slovenia, Spain	Belgium, Italy, Slovenia, Spain	Belgium, Germany, Slovenia
Statements or documents from RP communities (e.g. research platforms)	X	X	X
Civil Society statements, press releases, reports	X	X	X

## 2.2 Semi - structured interviews

In addition to analysing documents, semi-structured interviews in three investigated fields have been performed. The overall aim of the interviews was to identify macro discourses that justify and/or prescribe stakeholder participation in Radiation Protection. The overarching question to be answered during the interviews is “What are Radiation Protection communities being asked/expected to do?”

Semi-structured interviews are a form of qualitative research most often used in social sciences and humanities. As a methodological tool they are applied in psychological studies and medical studies to analyse people’s experiences, thoughts and feelings on a specific topic or event<sup>3</sup>. This form of interviewing allows the interviewer to go deeply into a topic and ensure in-depth understanding of the answers provided. In the frame of ENGAGE project it was agreed to perform several semi-structured interviews are conducted with international stakeholders (n=3 per radiation protection field i.e. Medical, EP&R and Indoor radon). The national interviews with different stakeholders are reported in WP2. The methodological approach to the investigation and to the analysis of obtained data is provided in [5] and includes the following steps:

- Defining interview questions based on existing literature or previously collected data,
- Determine sample and subgroups,
- Ensure interview consistency,
- Determine interview sequence,
- Design introduction,
- Train interviewers,
- Information of project,
- Data management,
- Analysis of the interviews.

Before an interview took place, the respondents was informed about the ENGAGE project and the research in detail, and given assurance about ethical principles, such as anonymity and/or confidentiality. This gives respondents some idea of what to expect from the interview, increases the likelihood of honesty and is also a fundamental aspect of the informed consent process. The respondent should provide in general answers in the name of organisation which they represent.

All interviews were recorded and transcribed afterwards, as this protects against bias and provides a permanent record of what was and was not said, in order to be analysed. The transcriptions were analysed using pen and paper methodologies or specific ‘coding’ software for qualitative analysis (NVivo). Coding is a method of qualitative data analysis that allows for the management and organisation of data according to emerging frequent, dominant or significant themes.

The interview protocol consisted of a list of topics or focal points on which the interview questions were based. Designing an interview topic list requires a set of rules and guidelines in order to on the one hand design an interview that provides the answers needed and on the other hand reduce (interviewer) bias. Based on the topic list, the interviewer can ask a variety of questions that will influence the type of answers that will be giving. Therefore, it is important that each interviewer is familiar with these varying types of questions and resulting answer in order to obtain the information needed. The following topics were addressed during the interviews in the context of WP1:

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<sup>3</sup> Fylan, Fiona. (2005). Semi-structured interviews: IN Miles, Jeremy and Gilbert, Paul (eds.). A handbook of research methods for clinical and health psychology. New York; Oxford University Press,

- TOPIC 1 (e.g. **Stakeholder engagement** – What are the situations where you encounter the need for stakeholder engagement in the field of medical/EP&R/radon indoor? Who is a stakeholder in each of these situations according to your organisation/institute? How did you come to the definition of stakeholder? Who was consulted?)
- TOPIC 2 (e.g. **Motivations for participation** – Why is stakeholder engagement needed? – to what end? What are the expectations? What is the relationship to decision making? What role do legal requirements for stakeholder engagement play?)
- TOPIC 3 (e.g. **Level of participation** – Model used? Examples? Success stories? Challenges?)
- TOPIC 4 (e.g. **Arrangements or procedures for stakeholder engagement** – How it is organised in your organisation/institute? Who is responsible for implementation? Any particular additional issue: reporting, evaluation, improving)
- Topic 5 (e.g. Triggers and trends - How has stakeholder engagement practiced by your organisation / institution change over time? Have there been triggering events for that change?)

### 3. Directives and conventions

Directives at European Union level and international conventions, also adopted as EU directives, are defining the legally binding instruments for the areas of interest. This chapter focuses on those which provide the requirements for the investigated fields (medicine, emergency preparedness and recovery, indoor radon) in the relation to involvement of stakeholders. The main findings are presented here, the details with analysis are given in Annex 2 using the template for the investigation.

#### 3.1. EC EURATOM BSS directive

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 [6].

##### 3.1.1. Key Words

After the analyses of BSS directive text, the following key words were searched:

- Stakeholders,
- Members of the public, public,
- Involvement,
- Participation.

The extracts from BSS directive as result of the search investigation is provided in the subchapter of annex 2 “Related extracts from BSS directive”. For the rest of the potential keywords as proposed in the Milestone 1.1 (actor(s), participant(s), engagement, interested party/parties, citizens, civil organisations (NGOs)) there was no result.

##### 3.1.2. Definitions and requirements

In the BSS directive there is only definition of "members of the public" which refers to individuals who may be subject to public exposure. As public exposure means exposure of individuals, excluding any occupational or medical exposure, the following exposure situations are: existing, planned and emergency exposure situations. In this relation **members of the public shall be mainly informed in relation to the estimation of doses from authorised practices** (this is part of the planned exposure situations), as well as **they shall be informed for the case of emergency situation**, both in the planning phase and in the case of response to the emergency and that **information shall be communicated to the public**. In addition, in **case of areas with long-lasting residual contamination, the member states shall ensure, in consultation with stakeholders, that arrangements are in place, as necessary, for the**

**ongoing control of exposure with the aim of establishing living conditions that can be considered as normal.** Also, in relation to **indoor exposure to radon the member states shall inform about the related exposure, associated health risks, monitoring and means for reducing radon concentrations.**

Evidently, **members of the public in case they are exposed in medical treatment are excluded from public exposure.** There is a special "**clinical responsibility**" which means responsibility of a **practitioner** (medical doctor, dentist or other health professional) **for individual medical exposures**, in particular, **justification; optimisation**; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; **obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer**, as required; and **giving information on the risk of ionising radiation to patients and other individuals involved**, as appropriate.

The BSS also defines **carers and comforters** as individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and **comfort of individuals undergoing or having undergone medical exposure.** Although the doses for patients due to medical exposures are not limited (but ALARA principle should apply), dose constraints shall be established for the exposure of carers and comforters. In the case of a **patient undergoing treatment or diagnosis with radionuclides**, the **practitioner shall provide the patient or their representative with information on the risks of ionising radiation and appropriate instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable.** For therapeutic procedures these shall be written instructions. These instructions shall be handed out before leaving the hospital or clinic or a similar institution.

Stakeholders are mentioned only four times in BSS directive. In Article 66 (Estimation of doses to the members of the public) where it is required the **competent authority requires records to be kept and be made available on request to all stakeholders relating to measurements of external exposure and contamination, estimates of intakes of radionuclides, and the results of the assessment of the doses received by the representative person.** In Article 73 the member states shall establish **consultation with stakeholders regarding control of exposure in contaminated areas.** In Article 102, member states shall provide as appropriate for the **involvement of stakeholders in decisions regarding the development and implementation of strategies for managing existing exposure situations.** Finally, Annex XI includes **stakeholder involvement into the emergency management systems and emergency response plans** as referred to in Articles 69, 97 and 98. There is no definition of stakeholder in BSS and therefore it could be used as in many other documents – so all actors.

### 3.1.3. Aspirations

Engagement of stakeholders and members of the public is mainly considered as one-way communication with provision of information by the responsible institutions. The consultation is also mentioned but it is related to existing exposure situation. In the context of preparing of the national action plan to address long-term risks from radon exposures also strategy for communication to increase public awareness shall be considered.

### 3.1.4. Motivations

In the BSS directive the communication with the public is basic with some provision of information on the key topics, and in addition to some communication/consultation for the limited areas. The engagement of members of public is very basic, and not specified. The motivation of the participation is mainly instrumental, as it is applied to secure the end point.

### 3.1.5. Level of stakeholder engagement

The level of stakeholders' engagement is mainly limited to provision of different information for topics like estimation of doses from authorised practices (this is part of the planned exposure situations) and partly in the emergency and existing information by responsible authorities. In addition, for some activities the consultation is foreseen. For managing existing exposure situations member states shall provide as appropriate for the involvement of stakeholders in decisions regarding the development and implementation of management strategies.

### 3.1.6. Any other observation

The BSS directive sets minimum standards for the engagement of stakeholders. However, it could be used in many different ways, and it could be implemented in a way that the two-way communication could be established.

## 3.2. EC EURATOM Nuclear Safety directive

COUNCIL DIRECTIVE 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations and amended by Council Directive 2014/87/Euratom of 8 July 2014 [7].

### 3.2.1. Key Words

After the analyses of Nuclear Safety directive text, the following key words were searched:

- Members of the public, public,
- General public,
- Stakeholder.

The extracts from Nuclear Safety directive as result of the search investigation is provided in the subchapter "Related extracts from Nuclear Safety directive" in Annex 2. For the rest of the potential keywords as proposed in the Milestone 1.1 (actor(s), participant(s), participation, involvement, engagement, interested party/parties, citizens, civil organisations (NGOs)) there was no result.

### 3.2.2. Definitions and requirements

In the Nuclear Safety directive there is no definition on the any of the key words used for the investigation of the document. From what is provided in the corresponding article 2, it is clear that the nuclear installations are nuclear power plants, enrichment plants, nuclear fuel fabrication plants, reprocessing plants, research reactor facilities, spent fuel storage facilities and also all radioactive (RW) waste storage facilities on site. From that definition are excluded RW storage facilities off site, and also all types of RW (and spent fuel) disposal facilities. The Nuclear Safety directive also later in the text use the terms like public, general public and also once stakeholders. It provides for the requirements of the transparency in one separate article 8.

Special role is given to the competent regulatory authority (again not defined) for which Member States shall ensure the effective independence from undue influence in its regulatory decision-making. For this purpose, Member States shall ensure that the national framework requires that the **competent regulatory authority provides nuclear safety-related information without clearance from any other body** or organisation, provided that this **does not jeopardise other overriding interests**, such as security, recognised in relevant legislation or international instruments. It is not prescribed how the information shall be provided or to whom they shall be given, but from the context it could be understand that **there shall be information provided to general public (all different groups)** and to use best possible ways (webpage, but also other means).

In special article 8 on Transparency it is required that Member States **shall ensure that necessary information** in relation to the **nuclear safety of nuclear installations and its regulation is made**

available also to the general public. Specific **consideration shall** be given to **local authorities, population and stakeholders in the vicinity of a nuclear installation**. That obligation includes ensuring that the **competent regulatory authority and the licence holders**, within their fields of responsibility, provide in the framework of their **communication policy during normal operation conditions and in case of incidents and accidents**. In the last case the information shall be promptly given to workers and general public, and in addition to the competent regulatory authorities of other Member States in the vicinity of a nuclear installation.

**Information shall be made available to the public in accordance with relevant legislation and international instruments**, provided that this does not jeopardise other overriding interests, such as security, which are recognised in relevant legislation or international instruments. It is not entirely clear which international instruments are foreseen but could be corresponding Directive 2003/4/EC on public access to environmental information which fully adapts European Union (EU) countries' national laws to the 1998 Aarhus Convention on access to information, public participation and access to justice in environmental matters.

Member States shall ensure that the competent regulatory authority engages, as appropriate, in cooperation activities on the nuclear safety of nuclear installations with competent regulatory authorities of other Member States in the vicinity of a nuclear installation, inter alia, via the exchange and/or sharing of information.

Member States shall ensure that **the general public is given the appropriate opportunities to participate effectively in the decision-making process relating to the licensing** of nuclear installations, in accordance with relevant legislation and international instruments. In this respect again, the corresponding Directive 2003/4/EC on public access to environmental information which fully adapts European Union (EU) countries' national laws to the 1998 Aarhus Convention on access to information, public participation and access to justice in environmental matters could be referred.

Member States shall ensure that reports from peer review of relevant nuclear installation regarding the nuclear safety are published with information on the process and its main outcome when results are available.

Also, the reports of European Commission based on Member States reports about the implementation of this Directive shall be submitted to the Council and the European Parliament on progress made with the implementation of this Directive. Additional **stakeholders in this case are therefore the elected representative of the country in European Parliament**.

### 3.2.3. Aspirations

Engagement of stakeholders and general public is considered mainly as one-way communication with provision of information by the responsible institutions (regulatory authority, licence holder, EC). The extent of the information on nuclear safety for nuclear installation is not prescribed. With the amendment of Nuclear Safety directive in 2014 also the effective participation in decision making process relating to licencing of nuclear installation is required. How to implement this is again not very detailed, but in general available relevant legislation and international instruments shall be used. Other interactions with the competent regulatory authority, for example on the information prepared and to be provided, is not requested. Therefore, there is no consultation requested in this directive.

### 3.2.4. Motivations

In the Nuclear Safety directive, the communication with the public are required in several ways: first to provide the information and secondly to assure participation in decision making with regards to licencing of nuclear installations. Still, the engagement of general public is basic, and not specified. The motivation of the participation is mainly instrumental, as it is applied to secure the end point.



### 3.2.5. Level of stakeholder engagement

The level of stakeholders' engagement is mainly limited to provision of different information for nuclear safety of nuclear installations and its regulation. This includes ensuring that the competent regulatory authority and the licence holders, within their fields of responsibility, provide in the framework of their communication policy during normal operation conditions and in case of incidents and accidents. In addition, also effective participation for general public is defined as part of the decision-making for licensing of nuclear installation. There are some other groups exposed in the case of communications: local authorities, population and stakeholders in the vicinity of a nuclear installation, and also competent regulatory authorities of other Member States in the vicinity of a nuclear installation.

### 3.2.6. Any other observation

The Nuclear Safety directive sets possibly advanced standards for the engagement of stakeholders. It could be linked to the Aarhus convention. However, it could be still used in many different ways, and it could be implemented in a way that the two-way communication could be established.

## 3.3. EC EURATOM Drinking Water directive

COUNCIL DIRECTIVE 2013/51/EURATOM of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption [8].

### 3.3.1. Key Words

After the analyses of Drinking Water directive text, the following key words were searched:

- Concerned public,
- General public.

The extracts from Drinking Water directive as result of the search investigation is provided in the subchapter "Related extracts from Drinking Water directive" in Annex 2. For the rest of the potential keywords as proposed in the Milestone 1.1 (stakeholders(s), actor(s), participant(s), engagement, participation, involvement, interested party/parties, citizens, civil organisations (NGOs)) there was no result.

### 3.3.2. Definitions and requirements

In the Drinking Water Directive there is no definition what is meant by general public or public, or as it is also used concerned public. In the related article 2 on definition there is in fact no any related definition. It is however recognised that the general public should be adequately and appropriately informed of the quality of water intended for human consumption. By term **general public and general public concerned it can be understood that it relates to all population which could be affected by consumption of water intended for human consumption** which means:

- **all water**, either in its original state or after treatment, **intended for drinking, cooking, food preparation or other domestic purposes**, regardless of its origin and whether it is supplied from a distribution network, a tanker, or in bottles or containers;
- **all water used in any food-production** undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.

Therefore, it can be interpreted that general public concerned could be called stakeholders.

Member States shall ensure that any failure to comply with a parametric value in the directive is immediately investigated in order to identify the cause and shall assess whether the failure poses a

risk to human health which requires action. In the event that such a risk exists, the Member State shall take remedial action in order to comply with requirements for the protection of human health from a radiation protection point of view. The **Member States shall ensure that the general public concerned is notified of the risk and the remedial action taken and advised on any additional precautionary measures** that may be needed for the protection of human health in respect of radioactive substances.

The Member States shall ensure that the general public concerned is informed also in case of some smaller water supply excluded from directive and of any action that can be taken to protect human health from the adverse effects resulting from any contamination of water intended for human consumption. They need to provide to general public concerned when a potential danger to human health arising from the quality of such water is apparent appropriate advice.

### 3.3.3. Aspirations

Engagement of public, general public or public concerned is mainly considered as one-way communication with provision of information by the responsible institutions. There are no prescribed ways how to do these provisions of information or notifications. The authorities shall ensure that the general public concerned is notified of the risk and the remedial action taken and advised on any additional precautionary measures that may be needed for the protection of human health in respect of radioactive substances.

### 3.3.4. Motivations

In the Drinking Water directive, the communication with the public concerned is basic, with some provision of information on the risk if the water for consumption does not comply with parametric values set in the directive, on the remedial action taken and to give the advice on any additional restriction. There is no other communication activity required. The engagement of public concerned is not specified or requested. The motivation of the participation is mainly instrumental, as it is applied to secure the end point.

### 3.3.5. Level of stakeholder engagement

The level of stakeholders' engagement is mainly limited to provision of different information as presented previously. There is no additional engagement of stakeholders foreseen in the directive.

### 3.3.6. Any other observation

The Drinking Water directive sets no minimum standards for the engagement of stakeholders. It just required the notification and provision of information to the public concerned.

## 3.4. EC EURATOM Information in radiological emergency directive

COUNCIL DIRECTIVE of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (89/618/Euratom) [9].

### 3.4.1. Key Words

After the analyses of Information in radiological emergency directive text, the following key words were searched:

- general public,
- population likely to be affected,
- population actually affected.

The extracts from Information in radiological emergency directive as result of the search investigation is provided in the subchapter "Related extracts from Information in radiological emergency directive" in Annex 2. For the rest of the potential keywords as proposed in the Milestone 1.1 (actor(s),

participant(s), engagement, involvement, participation, interested party/parties, citizens, civil organisations (NGOs)) there was no result.

### 3.4.2. Definitions and requirements

In the Information in radiological emergency directive there are 2 related definitions of groups which can be understood as subgroups to general public. The population likely to be affected in the event of a radiological emergency is defined as any population group for which Member States have drawn up intervention plans in the event of a radiological emergency, and population actually affected in the event of a radiological emergency defined as any population group for which specific protection measures are taken as soon as a radiological emergency occurs. Another special group are persons who might be involved in the organisation of emergency assistance in the event of a radiological emergency and for them also information shall be given. Also, the general public shall be informed about the responsible information in case of emergency.

Member States shall ensure that the **population likely to be affected in the event of a radiological emergency is given information about the health-protection measures applicable to it and about the action it should take in the event of such an emergency**. This information shall **be communicated to the population without any request** being made and shall be regularly updated, circulated and permanently available to the public.

Member States shall ensure that, when a radiological emergency occurs, the **population actually affected is informed without delay of the facts of the emergency, of the steps to be taken and, as appropriate to the case in point, of the health-protection measures applicable to it**.

Member States shall ensure that **any persons who might be involved in the organisation of emergency assistance in the event of a radiological emergency are given adequate and regularly updated information** on the health their intervention might involve and on the precautionary measures to be taken in such an event.

The information shall also mention the authorities responsible for implementing the measures referred.

### 3.4.3. Aspirations

Engagement of stakeholders and public, as defined in the Directive is mainly considered as one-way communication with provision of information by the responsible institutions. There are no consultations foreseen or even the participation of public in the development of information. The information is however prescribed in the Annexes with minimum information to be available. Also, regular update and circulation of the information is requested using regular intervals, or in case of significant new changes.

### 3.4.4. Motivations

In the Information in radiological emergency directive the communication with the public is basic with some provision of information on the key topics, which are prescribed. There are no consultation or participation foreseen or required. The motivation of the participation is mainly instrumental, as it is applied to secure the end point. The directive was adopted in the period just after Chernobyl accident and is aligned with two IAEA convents (on early notification and on assistance in case of nuclear or radiation accident).

### 3.4.5. Level of stakeholder engagement

The level of stakeholders' engagement is mainly limited to provision of different information for listed topics given in the annexes: basic facts about radioactivity and its effects on human beings and on the environment, various types of radiological emergency covered and their consequences for the general

public and the environment, emergency measures envisaged to alert, protect and assist the general public in the event of a radiological emergency, appropriate information on action to be taken by the general public in the event of a radiological emergency. Information in the event of a radiological emergency is connected with particular accident and relevant information for protection.

#### 3.4.6. Any other observation

The Information in radiological emergency directive sets minimum standards for the exchange of vital information to the general public (at least for population likely to be affected). There is no engagement foreseen. The requirements were transposed in BSS directive almost without any changes.

### 3.5. EC EURATOM Early notification convention

2005/844/EURATOM Commission Decision of 25 November 2005 concerning the accession of the European Atomic Energy Community to the Convention on Early Notification of a Nuclear Accident [10].

#### 3.5.1. Key Words

After the analysis of the Early notification convention text, the following keywords were searched:

- States which are or may be physically affected.

The extracts from Early notification convention as result of the search investigation is provided in the subchapter “Related extracts from Early notification convention” in Annex 2. For the rest of the potential keywords as proposed in the Milestone 1.1 (public, actor(s), participant(s), engagement, involvement, participation, interested party/parties, citizens, civil organisations (NGOs)) there was no result.

#### 3.5.2. Definitions and requirements

The Early notification convention is devoted to the exchange of information on nuclear accident between state of origin of the accident and the states which are or may be physically affected by the accident above the dose limits, defined in the BSS directive. In addition, also exchange of information between the state and IAEA is defined. Therefore, this **convention does not include direct information provisions to the general public (all stakeholders) but with the relation to the governments and their competent authorities in case of nuclear accident.**

The convention also includes the content of the information to be provided, like:

- the time, exact location where appropriate, and the nature of the nuclear accident;
- the facility or activity involved;
- the assumed or established cause and the foreseeable development of the nuclear accident relevant to the transboundary release of the radioactive materials;
- the general characteristics of the radioactive release, including, as far as is practicable and appropriate, the nature, probable physical and chemical form and the quantity, composition and effective height of the radioactive release;
- information on current and forecast meteorological and hydrological conditions, necessary for forecasting the transboundary release of the radioactive materials;
- the results of environmental monitoring relevant to the transboundary release of the radioactive materials;
- the off-site protective measures taken or planned;
- the predicted behaviour over time of the radioactive release.

The convention also requires that this information is regularly updated and supplemented at appropriate intervals by further relevant information on the development of the emergency situation, including its foreseeable or actual termination. What are the appropriate intervals is not defined.

Also, the information received may be used without restriction, except when such information is provided in confidence by the notifying state.

### 3.5.3. Aspirations

Engagement of stakeholders and members of the public is in this convention not the main objective and it is transferred to the states that are or may be affected by nuclear accident as defined in EURATOM directive on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency. In the convention beside information provision there is also a possibility to ask for further information or even consultation. All the arrangements are defined on the level of states.

### 3.5.4. Motivations

In the Early notification convention, there is no direct communication with the public, but the exchange of information between states is prescribed and defined. Also, possibility for consultation is available. The motivation of the participation is mainly instrumental, as it is applied to secure the end point. The convention is the result of the Chernobyl accident and the lesson learned due to unorganised information provisions.

### 3.5.5. Level of stakeholder engagement

There is no direct stakeholder involvement, but the informing of the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency is given in corresponding directive (89/618/Euratom).

### 3.5.6. Any other observation

The Early notification convention define the exchange of information in case of nuclear accident between the states, which are than responsible to inform and engage with citizens.

## 3.6. EC Aarhus convention

United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, adopted on 25 June 1998 in Aarhus, entered into force on 30 October 2001 [11].

The Decision on conclusion of the Aarhus Convention by the EC was adopted on 17 February 2005 [Decision 2005/370/EC on the conclusion, on behalf of the European Community, of the Convention on access to information, public participation in decision-making and access to justice in environmental matters]. The EC is a Party to the Convention since May 2005.

Relation to:

- Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC,
- Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC.

Both Directives 2003/4 and 2003/35 contain provisions on access to justice.

### 3.6.1. Key Words

After the analyses of Aarhus convention text, the following key words were searched:

- Members of the public, public, citizens,
- Pubic concerned (also NGOs)
- Public authorities,

- Involvement,
- Participation.

The extracts from Aarhus conventions result of the search investigation is provided in the subchapter “Related extracts from BSS directive” in Annex 2. For the rest of the potential keywords as proposed in the Milestone 1.1 (actor(s), participant(s), engagement, stakeholders, civil organisations) there was no result.

### 3.6.2. Definitions and requirements

The Aarhus Convention establishes a number of rights of the **public (individuals and their associations)** with regard to the environment. The Parties to the Convention are required to make the necessary provisions so that public authorities (at national, regional or local level) will contribute to these rights to become effective. The Convention provides for:

- the **right of everyone to receive environmental information** that is held by public authorities ("access to environmental information"). This can include information on the state of the environment, but also on policies or measures taken, or on the state of human health and safety where this can be affected by the state of the environment. Applicants are entitled to obtain this information within one month of the request and without having to say why they require it. In addition, public authorities are obliged, under the Convention, to actively disseminate environmental information in their possession;
- the **right to participate in environmental decision-making**. Arrangements are to be made by public authorities to enable the public affected and environmental non-governmental organisations to comment on, for example, proposals for projects affecting the environment, or plans and programmes relating to the environment, these comments to be taken into due account in decision-making, and information to be provided on the final decisions and the reasons for it ("public participation in environmental decision-making");
- the **right to review procedures to challenge public decisions** that have been made without respecting the two aforementioned rights or environmental law in general ("access to justice").

There are two groups defined: public in the general sense as one or more natural or legal persons and public concerned with the public affected or likely to be affected by, or having an interest in, the environmental decision-making.

### 3.6.3. Aspirations

The Aarhus Convention has been in force since 2001 and was adopted by EU in 2005. It is based on the premise that greater public awareness of and involvement in environmental matters will improve environmental protection. It is designed to help protect the right of every person of present and future generations to live in an environment adequate to his or her health and well-being. To this end, the Convention provides for action in 3 areas:

- ensuring public access to environmental information held by or for the public authorities;
- fostering public participation in decision-making which affects the environment;
- extending the conditions of access to justice in environmental matters.

Engagement of stakeholders and members of the public is considered as a basic right and it is established as two-way communication with provision of information by the public authorities and also participation of public and public concerned in the decision-making process. Environmental information also includes the information about radiation in written, visual, aural, electronic or any other material form.

### 3.6.4. Motivations

In the Aarhus convention defines many rights on the public and public concerned and sets the framework for the communication with provision of information on the all environmental information, also relevant to radiation. It also sets participation procedures for public concerned in case of some nuclear installations and radioactive facilities. The access to information and participation in decision making is also protected by access to justice. The further procedures shall be transposed to the national legislations.

The motivation of the participation is instrumental and defined as much as possible to secure the end point, but also normative (e.g. “it is the right thing to do”, it responds to a certain principle), and substantive (it is applied to achieve better decisions).

### 3.6.5. Level of stakeholder engagement

The level of stakeholders’ engagement is defined comprehensively with provision of different information for environmental issues, participation of public and concerned public in decision making on environmental matter and access to justice. The detail implementation is however left to the states (governments). The Aarhus convention support the real stakeholder engagement in a broad sense.

### 3.6.6. Any other observation

The Aarhus convention sets comprehensive standards for the engagement of stakeholders. However, it could be used in many different ways. It could be implemented also in a way that the two-way communication could be established.

## 4. National requirements and frames

The national requirements in three radiation fields (medical, emergency preparedness and response and indoor radon exposure) are presented in this chapter. Different project partners from participating countries as given in Table 1 collected the national legislation and provided the national overviews of current provisions related to stakeholder engagement. The investigation followed adopted template for analysis of documents as presented in Annex 9.1 and described in chapter 2, the overviews are presented here in tables, but the details for individual countries are given in Annex 3 of the chapter 9.3.

### 4.1. Medical field

The analysis on national requirements has been done on the basis of the main legal and institutional documents recognized in Germany, Italy, Slovenia and Spain, with attention to the medical field. In particular, the national legislation, acts expressing the requirements in radiation protection have been analyzed, accompanied in some cases also with specific national documents relevant to the medical field, as in the case of Germany, for the act to right of patients, and Italy, for the indications of radiation protection in interventional procedures.

A summary of the analysis is presented in the Table 2 and started on the basis of the main driving key words, such as: patients, public, pregnant women, participation, information, consent. In Annex 9.3.1. the complete analysis for each participating country is available, while here after the table is intended to give short views on definitions and requirements, aspirations, motivations and the level of stakeholder engagement. The main focus is placed on the implementation of the new EURATOM BSS Directive, apart from Italy where it has not been yet transposed in legal frameworks. In general, recognition is given to the provision of ‘adequate’ information to patients in general, as well as to specific non-professionals groups, like children, pregnant women, breastfeeding women, caregivers and volunteers. Even more, in most of the examined countries, also the communication with patients in view of the specific diagnostic or therapeutic procedures and in relation to the informed consent is required.

Table 2: Overview of main requirements on stakeholder engagement in the medical field in different countries

Country partner	Germany	Italy	Slovenia	Spain
<b>Title of document and publishing date</b>	<p>1) Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten, by 20th February 2013 (not official translation: “Act to improve rights for patients” [13]).</p> <p>The act deals with changes in relevant laws and codes touching upon the rights of patients.</p> <p>2) Gesetz zur Neuordnung des Rechts zum Schutz vor der schädlichen Wirkung ionisierender Strahlung. National legislation, Germany (“New Radiation Protection Act”, Germany [12]) by 27<sup>th</sup> June 2017. “</p>	<p>1) D. Lgs. 187/2000. Legislative Decree 187/2000. Implementation of Directive 97/43 EURATOM on health protection of persons against the dangers of ionising radiation via medical exposures [14].</p> <p>In Italy the 2013/59 EURATOM Directives has not yet been implemented</p> <p>2) ISISTAN 15/41, 2015</p> <p>Operative indications for the optimization of radioprotection in interventional radiology procedures [15].</p>	<p>Ionising radiation protection and nuclear safety act (ZVISJV-1), Off. Gaz. 76/2017 – Atomic Act [16].</p> <p>Supported with details with Rule on conditions on use of Ionising sources in medicine and for exposure situations in non-medicine treatments, Off. Gaz. 33/2018 [17].</p>	<p>"The royal decree project on justification and optimization of the use of ionising radiations for the radiological protection of people on the occasion of medical expositions" (dated 7/02/2018) [18].</p> <p>Level of implementation: national (Spain). Bases: national (previous Decrees) and international (Euratom directives: the latest 2013/59/Euratom of 5th of December and the previous ones).</p>
<b>Key words</b>	<p>1) Information, information duties.</p> <p>2) Decision, information, consent, participation, stakeholder, interest groups, interested party, concerned.</p> <p>No matches were found related to “stakeholder” or “interest groups” or “interested party” or “concerned party”.</p>	<p>1) Patients, public, participation.</p> <p>In the document there is no attention to the engagement of stakeholders</p> <p>2) Patients, public, participation, engagement, consent</p>	<p>Patients,</p> <p>Other groups: children, pregnant women, breastfeeding women, care workers and volunteers.</p>	<p>Patients; asymptomatic people; medical workers; qualified professionals; sanitary professional; experts; the personnel in practice; pregnant women; breastfeeding women; infants; caregiver/s; volunteers; the prescriber; and in general, medical specialist</p>



<p><b>Definition and requirements</b></p>	<p>1) Relevant paragraphs within article 1 Change of German Civil code: §630c; cooperation of contracting parties; information duties, a) says that the treating physician and patient shall cooperate for application of the treatment; b) is dealing with the duty of the treating physician to explain any circumstances which are essential for the treatment in a comprehensible manner. §630d says that the treating physician has the duty to seek for the patient's consent before implementing the treatment. §630e obligation for elucidation. The treating physician is obligated to inform the patient about all circumstances relevant for the consent, especially type and extent of a treatment, expected consequences and potential risks of the treatment. The information has to be given in a timely manner so that the patient has the possibility to reach his decision to consent well-considered. 2) §36(3), 5. deals with informed agreement related to the application of ionising radiation in</p>	<p><u>Cooperation among specialists and information.</u> A number of commitments and responsibilities are indicated for the medical specialists, like: justification; optimization; clinical evaluation of the result. Specific aspects considered e.g.: the cooperation with other specialists and with staff to be aware of information on previous examinations; the transmission, on request of existing radiological info. It is underlined the attention to benefits for the patients considering that the exposures to patient must show that it is effective enough for the health of the patient, taking into account also damage that the exposure could cause. For the interventional procedure, the part of patient information and informed consent of the patient is particularly delicate and must be adapted to the level of potential risks. <u>Cooperation, involvement of a professional team.</u></p>	<p>The definitions used in Atomic Act correspond to the one used in BSS directive related to the medicine treatments: "medical exposure" "clinical responsibility"  The Atomic Act transposed several requirements from BSS directive in Slovenian legal system which relates to information provisions to different groups for medical treatments, e.g.: -Information on the dose received by the patient, for any radiological procedures -The minister responsible for health determines in detail the conditions for special radiological interventions for children, pregnant women and nursing women. -The minister responsible for health determines in detail the conditions for education and compulsory training and qualification requirements for the relevant medical figures.</p>	<p>There are no explicit definitions of 'stakeholder' and/or 'stakeholder engagement'. However, the following definitions covering different stakeholders' groups are provided (in Annex, pp 22-26) <u>Caregivers (p.23)</u> People who, independently of their occupation, consciously and voluntarily, undergo exposure to ionising radiation, collaborating in the care and well-being of people who are subjected or have been subjected to medical exposures. <u>Prescriber (p.25)</u> Physician, dentist or other health professional authorized to refer persons for medical-radiological procedures, according to the established requirements to a qualified health professional. <u>Healthcare professional enabled (pp. 25-26)</u> Specialist doctor, dentist or podiatrist, within the scope of their competences, authorized to assume the clinical responsibility</p>
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	<p>medical research projects. It says that the ethics committee verifies if the written information on the research project sufficiently clarifies the risks and benefits so that a patient's informed agreement is possible.</p> <p>§84 (3) of the New Radiation Protection Act says that screening for identification of non-communicable diseases will be scientifically evaluated by the Federal Office for Radiation Protection and with the participation of experts. Risks and benefits of screenings have to be weighed against each other.</p>	<p>It is evidenced the importance to promote an appropriate "cultural" awareness, within the National Health Service, to optimize and standardize interventional radiology procedures, in terms of radioprotection of the patient and the operators. This is a main objective to be achieved through an active participation of all the professional and scientific components directly involved.</p> <p>It is recognized as appropriate to know the responsibilities and the roles in the radiation protection of the patient and radiation protection of the operators, in order to guarantee the quality and safety in the use of ionising radiation.</p>	<p>In a separate Rule on conditions on use of Ionising sources in medicine and for exposure situations in non-medicine treatments, adopted in June 2018, more detailed information and instructions on how to implement requirements are set e.g.:</p> <ul style="list-style-type: none"> <li>-For any radiological procedure, the referrer and the practitioner must provide the patient with adequate information.</li> <li>-In the case of pregnant or breastfeeding female special attention shall be given to the justification, particularly the urgency, and the expected exposure of the woman.</li> <li>-The patient with the applied radionuclide must receive written instructions and warnings about radiation hazards and procedures for radiation protection.</li> </ul>	<p>of an individual medical exposure.</p> <p><u>Technician enabled (qualified technician) (p.26)</u></p> <p>Healthcare professional with the qualification of Senior Technician in Diagnosis and Nuclear Medicine or Radiotherapy and Dosimetry enabled as operator, within the scope of their competences, in the practical aspects of medical-radiological procedures.</p> <p><u>Volunteers (p.26)</u></p> <p>People who voluntarily submit to medical exposure on the occasion of their participation in medical or biomedical research projects.</p>
<p><b>Aspiration</b></p>	<p>No attention is given to stakeholder engagement in both documents. Attention is given to appropriate information of the patients as well as informed consent. In the act to</p>	<p>1) – This legislative document is dated 2000 and refers the previous EURATOM Directive. None attention is given to the involvement of stakeholders,</p>	<p>Engagement of patients and other involved in radiological procedures is foreseen in accordance with BSS directive. The general requirements are</p>	<p>Positive trends are observed with proposal of new legislation on Spanish level in terms of radiation protection in medical field. The focus of work is</p>

	<p>improve patients' rights, an interactive moment can be assumed, but the interaction process, in order to ensure the patient's consent and sufficient information, is not specifically described.</p>	<p>while attention is mainly given to information for patients in view of the specific diagnostic or therapeutic procedures. 2) - In the document, it is well expressed the attention to optimization as the key to ensure a high quality of the procedure and a high level of protection for patients and the staff involved. The validity of consent by patient is conditioned by the given information and it requires a correct relationship between the specialist physician and the patient.</p>	<p>transposed in Slovenian legislation, using the main Atomic Act and specific rule with more details. Basically, one-way communication with provision of information by the responsible practitioners and other is required. But during this, also dialogue could be established with all involved in the radiological procedures: patients, carers, pregnant women, breastfeeding women, personnel, visitors, all other people who come in contact with potential exposure.</p>	<p>foreseen mainly related to medical and technical professionals involved in medical exposure; but little with concern of general public. They should sing the informed consent about the information provided by specialists (benefits and risks on medical exposures); however, no formation is provided to these groups of populations at least on very basic or adapted to their comprehension level that they could understand the information provided by medical specialists.</p>
<b>Motivation</b>	<p>In the patients' rights act, the duty of the physician to obtain informed consent is motivated from a normative point of view. In the radiation protection act, an instrumental motivation is base for the requirement to ensure informed agreement related to application of ionising radiation in medical research projects.</p>	<p>1) - The main motivation is expressed in term of quality of the approaches used in medical exposures, and it includes a basic approach towards the cooperation of the relevant medical specialists with members of staff.  2) - The basic motivation is the awareness on the risk and the education: inadequate knowledge and assessment of the risk can lead to an unjustified exposure of the patient. It is recommended to</p>	<p>In the Atomic Act, the communication with the patients is foreseen with delivery of more information than until recently. The motivation is beside instrumental (applied to secure end point) also in a way normative (because it the right thing to do).</p>	<p>The Directive emphasizes the need to justify and optimize medical exposure, including asymptomatic persons, proposing attention on the information to be provided to patients, the registration and notification of doses of medical procedures. The stakeholders' involvement it refers mainly to the normative duties of the medical personal and their responsibilities toward the patient.</p>

		refer to the recent Directive 2013/59, regarding the need of training.		The curricula corresponding to the different professional qualifications will include a course in radiological protection.
<b>Level of engagement</b>	In both cited acts, the level of engagement is mainly information. In the patients' rights act, an interactive approach is implied but not explicitly described. The formulations in both acts focus on information, or rather providing suitable information to the patient.	The stakeholder engagement is mainly seen at level of the related professionals. In interventional procedures the radiologists, medical physicists, technicians for radiology, and other involved health professionals should work closely also in dedicated RP training programmes. The manufacturers are engaged, stressing their important role in the process of optimization.	The level of stakeholders' engagement is based on provision of different information for applied medical treatments and radiological exposures. However, the new details in a separate Rule, published just in June 2018, gives some indications that there could be two ways communications established.	For relevant stakeholders – medical workers, radiologists, technicians, etc. involved either in prescription of IR for medical purposes or administrating it during procedures – the duties to inform patients and justify/optimize of exposure doses, especially concerning children, pregnant and breastfeeding women. Patients, accompanying persons or volunteers who are exposed to IR during medical exposure have more a passive role of engagement – mainly listening and giving an agreement by signing the informed consent.

## 4.2. Emergency preparedness and recovery

The analysis on national requirements has been done on the basis of the main legal and institutional documents recognized in Belgium, Italy, Slovenia and Spain, with attention to the emergency preparedness and recovery. In particular, the national legislation, such as acts expressing the requirements in radiation protection have been analysed, accompanied by specific recognized national documents with attention to the EPR, covering the preparedness phase, emergency phase, transition and recovery phase, if applicable. Also supporting documents were analysed, like EP&R plans (Belgium, Slovenia) or Nuclear Security Council strategic plan (in Spain).

A summary of the analysis is presented in the Table 3 and include the results of search of the key words, such as: emergency workers, population likely to be affected, population actually affected. In the Annex 3 of Chapter 9.3. the complete analysis for each participating country is available, while here after the table 3 is intended to give short views on definitions and requirements, aspirations, motivations and level of stakeholder engagement. Main attention is given to the implementation of the new EURATOM BSS Directive, which was transposed in Belgium and Slovenia, apart from Italy and Spain where it has not been yet transposed in a legal framework. The aspiration, motivation and level of participation for stakeholders is very different for the countries analysed: many times is limited to engagement of official stakeholders (actors in the EP&R), but not to population likely to be affected or to affected population. Some trends to change this and to engage the local population can be observed, however, how to achieve the engagement is still a question. Also, the implementation of requirements for information to be available prior to an accident is achieved mainly with one-way communication with provision of information and procedures to be followed. Only one country distinguishes between different post emergency phases – transition and recovery.

Table 3: Overview of main requirements on stakeholder engagement in EP&amp;R in different countries

Country partner	Belgium	Italy	Slovenia	Spain
<b>Title -date</b>	<b>Royal Decree on the Nuclear and Radiological Emergency for Belgium, 2018 revision [19]</b>	National plan of protective measures against radiological emergencies (March 2010), Presidency of the Council of Ministers, Department of Civil Protection [20].	Ionising radiation protection and nuclear safety act (ZVISJV-1), Off. Gaz. 76/2017 [16].	Nuclear Security Council Strategic Plan 2017-2022 [21] State Civil Protection against Radiological Risk, Royal Decree 1054/2015, [22]
<b>Key words</b>	“stakeholders”, “concerned parties”, “dialogue”, “public”, “participation”, “citizen”, “consultation”, “population”, “concerned”	<b>Public, Stakeholders/involved parties, Involvement, Information, information exchange</b>	Emergency workers, Population likely to be affected, Population actually affected	Stakeholders: public; groups; population; society; people; persons; institutions; NGOs; associations; trade union organisations; professional societies, research centres; neighbours of NPPs; workers; citizens; various actors Involvement; Participation
<b>Definition and requirements</b>	“Stakeholders are defined in a “broad sense”, to include any individual person, group, institute, organisation,..., that may be affected by the consequences (radiological or other) of an emergency situation, and that has to act in order to limit its consequences or participates in the management of the event. The document makes several references to stakeholders, mostly using the word	In plan it is described the organisational model for emergency management with priority for maximum reduction of the effects induced on the population. Bilateral agreements with similar bodies of neighbouring countries are recognized as important for the communication exchange on an event. In the planning and operational strategy importance is given to the exchange of information at national and	For emergency workers training programs must ensure that safety measures are given and regularly updated information on health risks that could be exposed to them during emergency intervention and on the necessary preventive measures for possible accidents. The operators must regularly inform the public of the important facts of the protection and rescue plans, and in particular the protection	<b>CSN is to protect workers, the population and the environment from the harmful effects of ionising radiation, getting nuclear and radioactive facilities to be operated by the owners in a safe manner, and establishing preventive and corrective measures in the face of radiological emergencies, whatever their origin. The CSN relies on the performance of its functions</b>

	<p>"consultation". The impact on actual decisions of such consultation processes, or the form such processes should take, are not clearly described. Broader, increasing stakeholder consultation is foreseen in parallel with moving through the transition and recovery phases, for the establishment of a strategy to return to a normal situation, and in connection to the social and economic impact of countermeasures, as well as in the preparedness phase. No consultation is foreseen in the urgent phase.</p>	<p>international level, and to ensure public information on the evolution of the event and the behaviour to be taken. The operational coordination is by the Civil Protection Department (CPD) which also disseminate information on protection. The population actually affected by the radiological emergency must be immediately informed of the facts relating to the emergency, the behaviour to be adopted and the health protection measures applicable to it in this case.</p>	<p>measures envisaged and the manner in which they are implemented with special request. In case of accident they shall inform authority which immediately inform the population in the affected area of the relevant facts regarding an emergency, and, in particular, of protective measures. The details are adopted in National Emergency Response Plan for Nuclear and Radiological Accidents, Version 3.0, 2010, waiting now for updates. Also new Decree on content and development of EP&amp;R plans present the details of information to be provided.</p>	<p><b>and for the fulfilment of its objectives:</b></p> <ul style="list-style-type: none"> <li>• <b>Independence: make decisions and act with objectivity and impartiality.</b></li> <li>• <b>Rigor and Veracity: dispense certain, relevant, valid and verifiable information.</b></li> <li>• <b>Competence, excellence and responsibility: act with scientific, technical and legal rigor and integrity,</b></li> <li>• <b>Commitment: be aware of the importance of the individual contribution for the fulfilment of the mission and objectives of the CSN.</b></li> </ul>
<p><b>Aspiration</b></p>	<p>The end of emergency is declared also after stakeholder consultation with communication of impact to their daily life. The transition phase has also the objectives of progressively restoring the dialogue with all the concerned parties and consult about preparing the recovery. The management of the recovery phase and the decisions relative to the restoration</p>	<p><b>It is evident how important it is to adjust the level of action and information to the emergency situation, thus distinguishing between the operational phases of early warning and alarm. In both cases it may be necessary to integrate the information, in particular towards the public, with attention to aspects concerning radioactivity and its effects. The measures to protect public health that can be taken in the context of the planning</b></p>	<p>Engagement of stakeholders and members of the public is mainly considered as one-way communication with provision of information by the responsible institutions and operators. The details of information to be prepared in advance to the potentially affected population and to affected population is just recently introduced in secondary level regulation. The further engagement of public in transition and recovery</p>	<p>Engagement of stakeholders and members of the public are mainly considered in terms of protective actions and attitude towards CSN existing requirements on "nuclear security", providing access to information and to some extent the intentions of public participations with implying the following concepts as credibility, transparency, neutrality, independence.</p>

	<p>strategy require a regular consultation.</p> <p>Different actors should be consulted in defining the objectives and strategies, including federal and local authorities, operational disciplines and stakeholders, including populations.</p> <p>Dialogue with the stakeholders (other than emergency actors) is also a part of the preparedness for nuclear emergencies, should be organised to discuss the emergency plan and the emergency measures.</p> <p>The document also describes in detail the information to be provided to the population as part of preparedness and mentions that this should be continuously updated.</p>	<p><b>described in the document, are aimed at reducing the exposure to radioactive contaminants and, therefore, the stochastic effects that may derive from it. For each type of radiological risk, before the planning phase and in collaboration with the involved bodies, it must be considered a technical-scientific assessment phase of the possible reference scenarios, their consequences on the environment and on the health of the population, the necessary means for the detection and the measurement of radioactivity, as well as the territorial areas involved in the accident itself. A real collaboration and effective coordination between the involved bodies is essential in the practice.</b></p>	<p>phase of EP&amp;R are not foreseen. Also, the participation of different not official stakeholders in development of EP&amp;R plan is not a practice.</p>	<p>In case of emergency the authorities:</p> <ul style="list-style-type: none"> <li>• Collect and disseminate information about the emergency, response actions and recommendations to be transmitted to the population affected.</li> <li>• Centralize and coordinate general information about the emergency to the public in general and facilitate it to the social media.</li> <li>• Provide all the information related to family contacts, location of people and data referred to the possible evacuees and transferred to medical assistance centres.</li> </ul>
<p><b>Motivation</b></p>	<p>Stakeholder consultation is substantive, deriving from the complexity of the situation (recovery phase) to define priority actions and the need to return to a normal situation as fast as possible, and instrumental, to ensure the effectiveness and acceptance of countermeasures.</p>	<p><b>It is recognized the importance of the procedures for managing the flow of information and coordination among the involved parties of the main National and Regional components of the Civil Protection. There is not direct involvement of the population in the decision process.</b></p>	<p>In the Atomic Act the communication with the public is basic with some provision of information on the EP&amp;R. There is no engagement of members of public foreseen. The motivation of the participation is mainly instrumental, as it is applied to secure the end point.</p>	<p>The Plan tries to implement the stakeholders' participations in both directions (up to bottom; and bottom to up), especially in the communication with the public with regards to nuclear security in general.</p>



<p><b>Level of engagement</b></p>	<p>The document mentions the establishment of communication strategies for alerting and informing the population in case of a (danger of) nuclear emergency, as well as in the transition and recovery phases. The level of involvement increases gradually from the emergency to the recovery phase.</p> <p>In the <b>emergency phase</b>, the urgency of taking decisions is deemed to not allow for the involvement of other stakeholders than the competent authorities.</p> <p>With reference to establishing the <b>end of emergency</b>, or the <b>recovery phase and related protective actions</b>, the involvement is also described as “consultation”. The interaction with stakeholders is also assumed to take place in the preparedness phase.</p> <p>The impact of the consultation on potential decisions on protective actions cannot be clearly derived from the document, but it can be inferred that stakeholders’ opinion would be a key element.</p>	<p><b>The collaboration between the bodies involved is seen through the coordination system aimed at ensuring, through the univocal identification of responsibilities, the communication flows and the direction of the appropriate interventions to face an emergency.</b></p> <p><b>In the response to national radiological events, the operational coordination is assumed by the CPD in order to guarantee the direction of the interventions with the Civil Protection Operational Committee, the National Risks Commission, and the CEVaD, which act as advisory bodies. The public structures mainly involved in various aspects, both in the pre-alarm phase and in the alarm phase, are: CPD; ISPRA; Ministry of the Interior; Department of Firefighters, Public Assistance and Civil Defense; Regions concerned; Prefectures - Government Territorial Offices involved.</b></p>	<p>The level of stakeholders’ engagement is mainly limited to provision of different information for EP&amp;R from operators and responsible authorities, but there are no instructions how this shall be implemented. Different authorities use mainly websites where information is available, lately (in 2019) also some new information have been added. Local authorities also distributed several leaflets (How to act in case of nuclear accident, Potassium Iodine tablets) to the households.</p>	<p>The level of stakeholders’ engagement is mainly limited to expectations of behavioural accomplishment (prudence and following the norms) in the nuclear security issues. The consultancy to general public is also planned to be established and maintained via electronic resources mainly.</p> <p>In case of emergency it refers mainly to the affected populations and their involvement in the procedures described on a state level (norms, recommendations, information provided and support – physical/logistical as evacuation, psychological and medical, and dose measurements). The only invited stakeholders’ groups mentioned in this document, and only in case of necessity, were from the bodies related or that have the direct relationship with radioactive accident and mitigation of its consequences and in the process of the remediation of the accident.</p>
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Furthermore, data were collected through a questionnaire in the context of a broader study supported by DG energy in 28 EU MS (26 MS responded). Data collection took place from December 2017 to May 2018 and responses reflect positions and views on practices in stakeholder engagement in nuclear emergency management as seen by authorities or other responsible organisations.

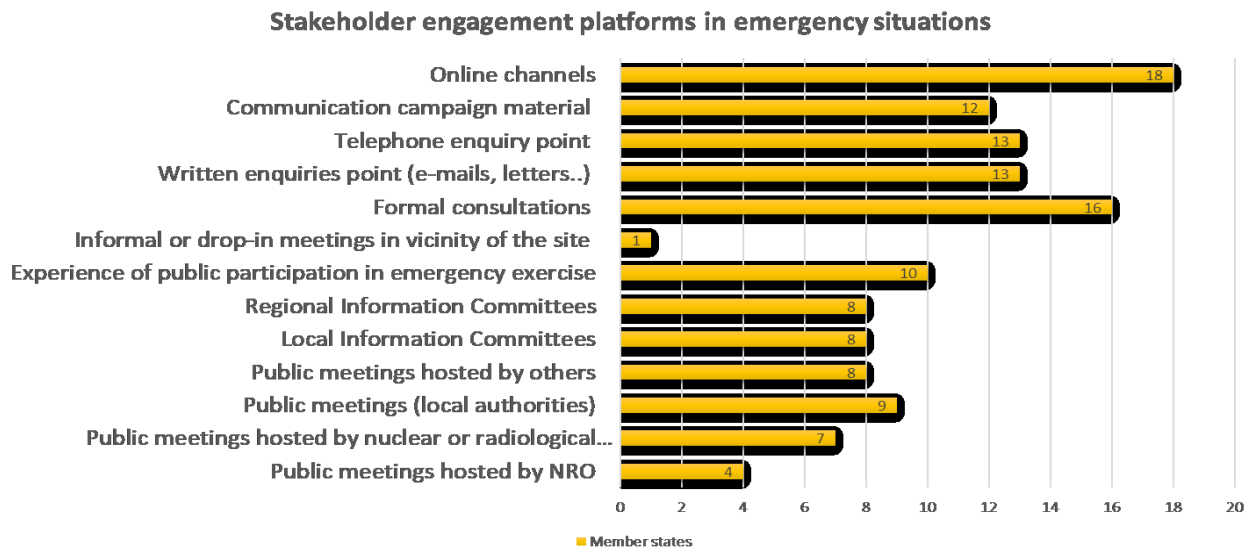


Figure 3 Stakeholder engagement platforms in emergency situations

### 4.3. Indoor radon

The analysis on national requirements has been done on the basis of the main legal and institutional documents recognized in Germany, Slovenia and Belgium, with attention to indoor radon exposure. In particular, the national legislation, such as acts expressing the requirements in radiation protection have been analysed, accompanied by specific recognized national documents with attention to indoor radon.

A summary of the analysis is presented in Table 4 and started on the basis of the key words, such as: stakeholders, interested parties, participation, information, communication, members of the public, public. In the Annex 3, chapter 9.3.3, the complete analysis for each participating country is available, while here after the table is intended to give short views on definitions and requirements, aspirations, motivations and level of stakeholder engagement. Main attention is given to the implementation of the new EURATOM BSS Directive, which was transposed in Germany, Belgium and Slovenia into national laws and other secondary level legislation.

Table 4: Overview of main requirements on stakeholder engagement related to indoor radon in different countries

Country partner	Belgium	Germany	Slovenia
<b>Title of document and publishing date</b>	Belgian national radon action plan, 2017-03-29-BDE-7-4-1-EN; date: 2017-03-29" [23] RADON: Plan de communication; CFA/1 mars 2012" [24]	Radiation Protection Act adopted on 12 May 2017. [12] German radon action plan, publication date March 2019 [25]	Ionising radiation protection and nuclear safety act (ZVISJV-1), Off. Gaz. 76/2017 – Atomic Act. [16] Decree on national radon program regulation, Off. Gaz. 18/2018 [26]
<b>Key words</b>	radon, Belgium	Radiation Protection Act: The relevant paragraphs for radon of the Radiation protection Act were searched through to find declarations on stakeholder involvement or engagement. As there were none, the whole document was searched through with the key words "communication", different German words for "involvement", "public", "society". No matches were found for radon. National radon action plan: participation, information, involvement, stakeholder, concerned parties, public.	Members of the public, public. For the rest of the potential keywords as proposed in the Milestone 1.1 (actor(s), stakeholders, participant(s), engagement, involvement, interested party/parties, citizens, civil organisations (NGOs)) there was no result
<b>Definition and requirements</b>	This document presents the national radon action plan in Belgium, updating the existing action plans with the information required following the EU BSS 2013/59/Euratom (article 103 and annex XVIII). This document covers the period 2018. The document doesn't define stakeholders, although it refers to stakeholders through the all document. <ul style="list-style-type: none"> <li>• "Different <b>stakeholders</b> are regularly invited to take part in specific working</li> </ul>	The Radiation Protection Act provides a definition for the responsible person for a workplace for the purpose of protection against radon at workplaces. The requirements of BSS for information, responsibility and involvement were only transposed into German law with the expression "informing the general public conveniently" (§125). There are no requirements for stakeholder involvement or involvement of the public, except the	The definitions used in Atomic Act correspond to the one used in BSS directive related to the RADON: "members of the public" which means individuals who may be subject to public exposure. The requirements from BSS directive were transposed in relation to raising awareness to the public to Slovene legislation. Further requirements and instructions how these should be achieved is given in Decree on national radon program regulation. In an

	<p>groups aiming at reviewing the existing regulations, as well as the radon action plan itself.” p. 6</p> <ul style="list-style-type: none"> <li>• “A communication plan has been defined by FANC in 2014, aiming at efficiently inform the public, workers, employers and building professionals and to communicate essential messages stimulating the <b>stakeholders</b> to measure, mitigate and protect themselves, their families, their employees.” p. 6</li> </ul> <p>The following stakeholders are mentioned in the document: “the general population, both the public and workers”; “house owners and occupants”; “building professionals and local governmental administrations”; “regional authorities”; “employers”; “local authorities”; “service providers for radon measurements”; “ICRP or Euratom Article 31 Expert Group”; “Association ERA, HERCA, ISIAQ”; “Radon inspections”; “public, workers, employers and building professionals”; “families”; “professional target groups such as lung-cancer specialists, general practitioners, architects, building research and administration”; “professionals such as architects, builders, medics, local authorities, specific students”; “Belgian Building Research Institute (<a href="#">BBRI</a>)”; “building confederation <a href="#">CCW</a>”; “Local administrations (regions, provinces, municipalities, school</p>	<p>formulation in §122 (1) that the Federal Ministry for Environment, Nature Conservation and Nuclear Safety develops a national radon action plan with participation of the Länder (federal states) and revises it at least every ten years, again by involving the Länder.</p> <p>In April 2019, the German radon action plan was published. The word stakeholder (concerned parties) is mentioned one time in the summary of actions but is not further mentioned in the full text. No definition of stakeholder is provided. Paragraph II.1 is dedicated to “Public relations”. Here it is stated that central aspects of a communication strategy on long term health risks due to radon exposure shall be developed on a national level, involving the Länder (federal states in Germany) and potentially Multipliers and specialists.</p> <p>Action 1.1: identification of target groups, Multipliers and target group specific communication paths.</p> <p>Action 1.2: elaboration of the bases for a better public understanding of health risks due to radon. A national communication strategy, developed by involving the Länder, is required to raise public understanding of radon.</p> <p>Action 1.3: Development and implementation of a national strategy for public relations work. The coordination with Länder-specific communication strategies is required as well</p>	<p>area exposed to radon the authority responsible for radiation safety shall provide following:</p> <ol style="list-style-type: none"> <li>1. provides information to the public, employers and local decision-makers through publications about health risks due to radon exposure, particularly relating to smoking;</li> <li>2. prepares guidelines on preventing the entry of radon into buildings, including the identification of construction materials with high radon-release levels, and on implementing the rehabilitation of facilities and new buildings in areas with higher radon;</li> <li>3. organises seminars, expert meetings and workshops on health risks due to radon exposure;</li> <li>4. warns that adequate air quality in indoor areas must be provided where energy saving measures, such as energy rehabilitation and the installation of new windows, are implemented;</li> <li>5. keeps records on radon concentration measures for indoor areas in accordance requirements of Atomic act;</li> <li>6. strives to realise the long-term objective of reducing the risk of lung cancer, by regularly defining risks due to radon in strategic documents on managing cancers, and in programs established for the healthcare of children and young people;</li> </ol>
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	administrations, prevention advisors, labour inspection, labour medicine, ...)”;	as with other strategies of health education. Target group specific information material shall be developed, target groups shall be addresses directly, private persons as well as enterprises, especially small and medium enterprises because of their assumed lack of information on radon. Action 1.4: development of Länder-specific public relations strategies, taking into account the Länder-specific radon situation.	7. within available financial means, supports research to improve understanding of the effects on health of radon exposure; 8. publishes a list of providers of works with knowledge and experience in the field of suitable new constructions and the successful rehabilitation of buildings.
<b>Aspiration</b>	Long term goals to reduce lung cancer risk: Following the European and international recommendations, FANC has set up a national radon action plan that is in application since 2009. The Belgian radon action plan is being published and updated annually. On the FANC website, a specific dossier has been developed on this subject ( <a href="#">link</a> ).	In §125, Radiation Protection Act, informing the public is set in context with gaining knowledge about radon exposure, radon associated health risks, radon measurements and possibilities for reducing radon activity concentration. Thus, information as used in the German Radiation Protection Act related to radon can be interpreted as option to reach those goals. The public relations and communications activities in the German radon action plan aim at public understanding of radon risk. Goal is sensitization and education. Focus is the support of personal initiative as consequence of an appropriate public relations work. When developing the communications strategy, involvement of multipliers and institutions and stimulate exchange.	Engagement of stakeholders and members of the public is mainly considered as one-way communication with provision of information by the responsible institutions through publications and guidelines. In the context of preparing of the national action plan to address long-term risks from radon exposures also a program to raise awareness among employers, the public and health professionals about the health risks posed by radon exposure, and the additional risks associated with smoking shall be determined. As part of this also seminars, expert meetings and workshops on health risks due to radon exposure shall be organised, which could enable two-way communication.
<b>Motivation</b>	The plan considers the activities and strategies (for surveys, communication, building protection, remediation, mapping, and management) to develop and put in practice each year, in order to achieve the	Radiation Protection Act: There are no statements on motivation of information provision. National radon action plan: instrumental motivation, to secure better radon exposure	In the Atomic Act the communication with the public is basic with some provision of information on the awareness related to health risks posed by radon exposure. In the further Decree there are some defined ways

	<p>general goal (reduce the exposure to radon of the population and workers). The current document completes the existing radon action plan with additional content following ANNEX XVIII of 2013/59/Euratom). The action plan consists on the one hand of relatively continuous items, such as strategy, definition of working fields and technical details, completed by variable items such as annual actions, being updated each year.</p>	<p>reduction. Partly also substantive, because information leads to a better risk comprehension and as a consequence to a more motivated protection by the public</p>	<p>how to address public in areas exposed to radon. It could be understood that such activities could be seen as normative (e.g. “it is the right thing to do”, it responds to a certain principle). Interaction with public is foreseen in the areas where there is increased level of exposure to radon for public, employers and local decision-makers.</p>
<p><b>Level of engagement</b></p>	<p>The level of stakeholder engagement is manifold: For radon in existing dwellings, measurement campaigns are organised annually. A dedicated website <a href="http://www.actionradon.be">www.actionradon.be</a> has been developed for this purpose and public awareness campaigns are organised each year were amongst others <a href="#">publications</a> are distributed. To prevent radon in new dwellings: awareness campaigns are organised to inform the public on the radon risk and on the protective measure to take during the construction of the building. Building professionals and local governmental administrations are trained. Regulations on radon protection are included in the building codes in concertation with the regional authorities. For radon in workplaces: For employers, a dedicated website has been developed in order to assist and facilitate the measurements and the declaration</p>	<p>Radiation protection act: The level of stakeholders’ engagement is limited to provision of information related to radon exposure, radon related health risks, radon measurements and radon activity concentration reduction. There are no further explanations what is meant by convenient information. Due to the federal system in Germany, the Länder have a high responsibility also in the radon problematic. Some of the Länder are very active in radon reduction measures, information for the public and building networks with relevant stakeholders. Some of the Länder try to lower radon risk by offensive information and networking activities and pooling relevant experts, associations and organisations as well as other stakeholders. The German national radon action plan shows a more sophisticated approach: the level of communication is mainly focused on information, enriched with the demand for</p>	<p>The level of stakeholders’ engagement is mainly limited to provision of different information for raising awareness on risks posed by radon exposure from responsible authorities. In the more detailed Decree also activities to organise seminars, expert meetings and workshops on health risks due to radon exposure are foreseen. These activities could enable space for interaction between participants, like discussion and involvement. The Atomic Act transposed some basic requirements from BSS directive related to indoor radon and public. The Decree on national radon program cover the transposition also with some suggestions on the communication with stakeholders. These could be used in many different ways, and it could be implemented in a way that the two-way communication could be established.</p>

	<p>(<a href="http://www.radonatwork.be">www.radonatwork.be</a>). Information campaigns, <a href="#">documentation</a>, training of building professionals and local authorities and concertation on regional building codes are carried out.</p> <p>Different stakeholders are involved in reviewing the existing regulations, as well as the radon action plan itself. International organisations (such as <a href="#">ERA</a>, <a href="#">HERCA</a>, <a href="#">ISIAQ</a>) are regularly involved in scientific exchange, reviewing and working-group processes.</p> <p>A communication plan has been defined by FANC in 2014, aiming at efficiently inform the public, workers, employers and building professionals and to communicate essential messages. Communication with specific professional target groups such as lung-cancer specialists, general practitioners, architects, building research and administration takes place.</p> <p>Specific material has been developed in collaboration with the Belgian Building Research Institute (<a href="#">BBRI</a>) and training is provided in collaboration between <a href="#">FANC</a>, <a href="#">BBRI</a> and the building confederation <a href="#">CCW</a>.</p>	<p>target group analysis, target group specific information, communication and involvement and the objective of comprehensible risk presentation.</p>	
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## 5. Reports and guidelines from international organisations

For the purpose of the ENGAGE, reports, documents, recommendations and guidelines of different EU institutions, international organisations and associations have been examined to obtain the frame under which the stakeholder engagement is viewed and proposed to be implemented. The criteria used to examine the documentation were relevance, importance and that they were adopted lately. Therefore, in this overview no complete list of material is investigated, but rather the selection which is important for the stakeholder engagement in the considered fields. The method for analysis followed the template as presented in chapter 2, the results of investigation for main reports are given in annex 4 of the chapter 9.4.

### 5.1. Analysing EU science policy paradigm

For this macro discourse of Responsible Research and Innovation (RRI) extracts from documents were taken:

- [1] *“Building on the success of Science in Society projects in engaging the general public and civil society in debates around science, RRI aims to go one step further and engage all societal actors – from researchers through policy makers, to citizens, businesses, etc. – to work together throughout the research and innovation process in order to ensure that the results meet the needs of the world we live in.”* (European Foundation Centre, 2012)
- [2] *“RRI refers to the comprehensive approach of proceeding in research and innovation in ways that allow all stakeholders that are involved in the processes of research and innovation at an early stage (A) to obtain relevant knowledge on the consequences of the outcomes of their actions and on the range of options open to them and (B) to effectively evaluate both outcomes and options in terms of societal needs and moral values and (C) to use these considerations (under A and B) as functional requirements for design and development of new research, products and services. The RRI approach has to be a key part of the research and innovation process and should be established as a collective, inclusive and system-wide approach.”* (EU’s Directorate General for Research and Innovation, 2013)

Stakeholder are all societal actors, from researchers through policy makers, to citizens, businesses, etc. They should be engaged at an early stage and work together throughout the research and innovation process. There are several frames and framing components:

- **Problem definition:** The introduction of science and technology into society fails when this process and the values it stands for conflict with societal values.
- **Moral evaluation:** Societal needs and values need/deserve to be heard and aligned with scientific research and innovation agendas.
- **Treatment recommendation:** The scientific, policy, and industry communities must solicit society’s views by listening to what society has to say about science and technology innovations.

There are also different rationales why to engage stakeholders:

- **Substantive:** to improve decisions, policies, and assessments by including as many viewpoints as possible in research and innovation,
- **Instrumental:** to support preconceived, often short-term policy commitments (e.g. educating citizens about science),
- **Normative/democratic:** because it’s the morally right thing to do.



RRI refers to the level of Member States and is prominent in NI, DK, UK, D, to a lesser extent in FI. For example, the Netherlands Organisation for Scientific Research (NWO), under the responsibility of the Ministry of Education, Culture and Science, has developed the responsible innovation research programme (NWO-MVI). NWO-MVI research identifies the ethical and societal aspects of technological innovations at an early stage so that these can be taken into account in the design process. Typically, countries and regions where RRI concept is implemented are with a strong science, technology and innovation (STI) knowledge base that heavily invest in new and emerging technologies and innovation and with established traditions of science-society mediation (e.g. technology assessment). EC's "RRI tools" contains many case examples: <https://www.rri-tools.eu/>.

RRI is distinct policy, not found in EURATOM. However, RP actors (technical researchers, science policy makers, oversight bodies) stress the importance of stakeholder involvement and ongoing dialogue between scientific experts, civil society organisations, and publics in the face of nuclear risk governance challenges (e.g. EURATOM directives).

In addition, RP actors increasingly summon Social Sciences and Humanities (SSH) researchers to help them identify and manage "the needs in radiation protection for the public" (e.g. "European radiation protection research: Outcome of Euratom integration policy and future perspectives," May 2017).

## 5.2. How are the stakeholders defined

Several documents of international organisations were reviewed from the perspective of definition of stakeholders. There are many similarities among used definitions, but also some differences. It can be seen that some definitions are in a way old, not harmonized with the current points of view, where stakeholders can be everyone and should be involved in the decision-making process and beyond.

In **IAEA INSAG** [27] document on "Stakeholder involvement in Nuclear Issues", 2006, stakeholders are defined as those who have a specific interest in a given issue or related decision-making processes. The group can include also the general public. Some used terms:

- Internal stakeholders are those involved in the decision-making process,
- External stakeholders are most often affected by the potential outcome of the project, either directly or emotionally:
  - elected representatives,
  - authorities,
  - organisations and individuals.

In the IAEA terminology used in nuclear safety and radiation protection (**IAEA Safety Glossary**, 2007, [28]) it is stated that *"The term stakeholder has disputed usages and is misleading and too all-encompassing for clear use. In view of the potential for misunderstanding, use of the term is discouraged in favour of 'interested parties' or 'concerned parties', for example"*. Instead of stakeholder the term interested party or concerned party should be used. The term stakeholder should be used as:

- A person, company, etc., with a concern or (especially financial) interest in ensuring the success of an organisation, business, system, etc.
- Stakeholder means an interested party — whether a person or a company, etc. — with an interest or concern in ensuring the success of an organisation, business, system, etc. To 'have a stake in' something, figuratively, means to have something to gain or lose by, or to have an interest in, the turn of events. The term stakeholder is used in a broad sense to mean a person or group having an interest in the performance of an organisation. Those who can influence events may effectively become interested parties — whether their 'interest' is regarded as

'genuine' or not — in the sense that their views need to be considered. Interested parties have typically included the following: customers, owners, operators, employees, suppliers, partners, trade unions; the regulated industry or professionals; scientific bodies; governmental agencies or regulators (local, regional and national) whose responsibilities may cover nuclear energy; the media; the public (individuals, community groups and interest groups); and other States, especially neighbouring States that have entered into agreements providing for an exchange of information concerning possible transboundary impacts, or States involved in the export or import of certain technologies or materials.

In the **ICRP 2016** [29] publication on “Radiological Protection against Radon Exposure” stakeholders include individuals who have a personal, financial, health, or legal interest in policy or recommendations that directly affect their well-being or that of their environment:

- In most cases, the role of stakeholders is to aid and inform the decision-making process.
- There may be situations where stakeholders have the authority and responsibility for making or recommending decisions (such as a nationally appointed board or committee).
- Generally, however, the operator and regulator are the decision makers, and the stakeholders help in the process by providing information and guidance related to decisions being made.

International Radiation Protection Association in their **Guiding Principles for establishing a radiation protection culture** [30] from 2014 stress that radiation protection practitioners must be aware that some interaction with wider stakeholders can assist in the development and application of workplace culture. Obtaining the confidence and support of stakeholders can help to develop a pride in the workplace, and hence assist in embedding an effective radiation protection culture. The RP professional should identify the main stakeholders who need to be involved in the improvement program. Key stakeholders which should be considered (depending on context and workplace) include:

- The workforce (at all levels) medical and health professionals, especially but not exclusively those who are using ionising radiation,
- Senior managers and Directors,
- Contractors, Equipment manufacturers, vendors and suppliers,
- Regulators and other authorities,
- Functional leaders and risk managers,
- Patients.

In this case, the wider interested parties are normally all those that are involved in nuclear and radiation affairs, including:

- authorities of different levels, regulatory bodies, competent authorities for special fields of application of ionising radiation,
- local or national politicians,
- news media,
- academics/researchers,
- citizens,
- special and public interest groups, consumer groups, other non-governmental groups,
- informal opinion makers.

In the paper **The state of radiological protection: views of the radiation protection profession** [31] from 2012, it is emphasized that the motto of RP profession should be “Living with radiation, engaging with society”. Stakeholders’ in radiological protection situations should be engaged: “In making radiological protection decisions, be they for worker, patient, public or environmental protection,

decision makers must address the science of radiological protection and its uncertainty, and the social values and economic situations of affected stakeholders and their diversity.”

In summary report of NEA-OECD from **Workshop on Stakeholder Involvement in Nuclear Decision Making** [32], 2017: “Stakeholders are not only the ones who support your organisation and its objectives or who express confidence in what you do, but also those who are deeply skeptical, who offer critiques, constructive and otherwise, and even those who are largely indifferent, except when [organisations] receive media attention.” Stakeholder as one who is involved in or affected by a course of action could be:

- those who live near or work in nuclear facilities,
- own or run the facilities,
- govern at the national, regional or local level,
- manufacture the components or the fuel,
- regulate the output or use of the facility,
- benefit from the use of radiological material and nuclear installations,
- and those who might be adversely affected in any way by materials or facilities.

Stakeholders also include the media who convey information to others, and the non-governmental organisations that represent the views of many individuals.

The conceptualisation of the term stakeholder was also addressed in three round tables performed during the NERIS workshop in Dublin on 25<sup>th</sup> of April 2018:

1. Who is (should be) a stakeholder in radiation protection in your experience?
2. Why should stakeholders be involved in emergency preparedness and response?

The participants in the round tables were mainly professionals in radiation protection attending the workshop.

When answering the question “who is (should be) a stakeholder in your experience”, it is noteworthy that the members of the round table provided descriptive answers stating the underlying motivation for stakeholder engagement rather than providing specific stakeholder groups. Stakeholders are described as people, persons, anybody who is affected by a decision or an action, who can affect a decision, who has a stake, who is engaged, who is involved and even someone who is not involved.

Stakeholders can be a person, an authority, a representative of a certain group. Stakeholders do not necessarily have to be actively engaged, or even be directly involved or affected. A stakeholder can also be someone who *thinks* they will be affected by the decision, who has a good idea, or even the future generation.

The round table participants however also gave contradicting messages. For example, on the one hand a stakeholder is someone who is formally appointed or informally involved with the condition that they actively participate. However, stakeholder can also be future generation, unable to actively participate, or children. The consensus here being that the representative of the inactive stakeholders, plays an active role. Finding these representatives or stakeholder groups is considered challenging.

The Aarhus convention was referenced stating the stakeholder is clearly defined as “the public concerned”; the public affected or likely to be affected by, or having an interest in, the environmental decision-making. This implies that NGO’s are also stakeholders with an interest and who can improve solutions, including anti-nuclear NGO’s.

Specific suggestions were made on how to define and limit the stakeholder involved. For example, a suggestion is made that at a local level those who are affected can be defined according to the distance

from the incident or accident, those who were within the vicinity at the time, people who live in contaminated areas. Additionally, this includes people who visit the area on occasion, consumers of products from this area, taxpayers in general, etc. The determination of who stakeholders are, should however be targeted and dependent on the occasion and issue/topic of discussion.

An additional group of stakeholders that was suggested are students; those who are educated within the subject, try to transmit what is the problem, provide information on how to behave and address citizens' vigilance. For example, in the case of radon students should be informed and educated.

When asking the question "why should stakeholders be involved in EP&R?" the answers are diverse. Initially it is stated that there is no other choice than to involve stakeholders. When dealing with an emergency, stakeholders are there; it is necessary to understand how they will react as great emergency plans are useless if they are not implemented.

The question is raised whether stakeholders should be involved in the emergency phase or rather in the preparedness. It is indicated that a shift has emerged towards this preparedness phase and later in the recovery phase. It is fairly agreed upon that stakeholders should not be involved in the emergency phase. The reasoning presented is that in case stakeholders are involved from the beginning, they will better understand and manage the accident as they are unwilling to just accept the situation. Additionally, it was noted that in some countries such as France it is legally obliged to involve stakeholder, in Ireland this is merely a suggestion. The reasons for being a stakeholder can also change, for example: if food is contaminated, consumers become stakeholders and even decision-makers. It is however important to note that stakeholders and decision-makers are not considered the same.

### 5.3. Stakeholders and ionising radiation in medicine

With respect to other field of exposure, the use of ionising radiation in medicine for patients has unique aspects, as the consideration that exposure for patients is related to the expectation of direct individual health benefits to the exposed patient, the fact that the dose to the patient cannot be reduced indefinitely without compromise the intended result, and the use of different degrees of informed consent involving the patients in the decision on ionising radiation exposure. In the medical field the RP focuses on justification and optimization differently from other type of exposures, the medical exposure is not applying dose limits. When decisions are taken on justifying a medical procedure, the optimization is requiring the greater specific attention. Thus, we can say that stakeholder views and concerns have a highly meaningful role in the medical field.

The 2007 Recommendations of the International Commission on Radiological Protection, **ICRP Publication 103** [33], explicitly introduced 'the need to account for the views and concerns of stakeholders when optimizing protection':

- "The exposure of patients is deliberate",
- "The patient, or legal guardian, agrees or consents to a medical procedure using radiation. This decision is made with varying degrees of informed consent",
- "The amount of information provided in order to obtain informed consent varies based on the exposure level (e.g., whether diagnostic, interventional, or therapeutic)",
- "The final responsibility for the medical exposure of patients lies with the physician, who therefore should be aware of the risks and benefits of the procedures involved",
- "This decision-making process may often include the participation of relevant stakeholders rather than radiological protection specialists alone".

*“Societal values usually influence the final decision on the level of radiological protection. Therefore, while this report should be seen as providing decision-aiding recommendations mainly based on scientific considerations on radiological protection, the Commission’s advice will be expected to serve as an input to a final (usually wider) decision-making process, which may include other societal concerns and ethical aspects, as well as considerations of transparency (ICRP, 2006a). This decision-making process may often include the participation of relevant stakeholders rather than radiological protection specialists alone.”* But, in ICRP 2006a, corresponding to **ICRP Publication 101** [34] and with attention to the part 2, it is reported that *“(5) This report addresses all exposure situations where radiological exposures are amenable to control, except patient exposures which are dealt with separately.”*

In ICRP 101 part 2, 2006 it is remembered that in the ICRP 82, 1999, it was considered that decision making process ‘*may take into account attributes other than those directly related to radiological protection*’ and ‘*will include the participation of relevant stakeholders rather than radiological protection specialists only*’. In ICRP 101 part2, 2006, ‘*the Commission now considers that the involvement of stakeholders is an important input of the optimization process, because it introduces the necessary flexibility in the management of the radiological risk that is necessary to achieve more effective and sustainable decisions.*’

At the same time, it has to be noted that the above-mentioned document “The Optimization of Radiological Protection: Broadening the Process” ICRP 101 part 2, does not include in the considered radiation exposure the medical exposures. This document explicitly indicates that it addresses all exposure situations where radiological exposures are amenable to control, except patient exposures.

**ICRP Publication 105** [35], 2007, well remembers, even in the Editorial, the specificity of justification of medical exposure compared to justification in other radiation exposure, with a direct benefit and risk from radiation for the same person. Moreover, for particular procedures occupational exposure could be related to patient exposure, and other individual as parents, family members and friends could also be exposed.

Note that in the judgement of benefits for patients the consideration of the family is also taken in the view of the health benefits for the patients and at the same time of the indirect benefits to family members involvement as care and comforters either in hospital as at home in support of patients. The decision on patient exposure is voluntary in nature, combined with attention to direct benefit to the patient and based on varying degrees of informed consent of patients, in relation to potential risks and on the basis of the procedure.

The involvement of stakeholders in the optimization process introducing the needed adaptability in the management of radiological risk to achieve more effective and sustainable decisions, could be of great interest in the medical exposure. Indeed, the optimization of protection in medical exposures does not necessarily mean the reduction of doses to the patient and, for example in diagnostic and interventional procedures, the management of the patient dose commensurate with the medical task is an appropriate mechanism (ICRP 105).

**ICRP Publication 129**, [36], 2015, dedicated to Radiological Protection in Cone Beam Computed Tomography (CBCT), has the purpose to identify radiological protection issues for patients and workers and report recommendations for all stakeholders. Recommendations are set out for all stakeholders as day-to-day clinical users, auxiliary support workers, buyers, manufacturers, and policy directing committees. It is evident in the document how new challenges in dose management to ensure patient safety and guidelines are needed for various stakeholders, as imaging professionals, medical physicists, and manufacturers.

A specific primary audience is indicated as: health professionals working with CBCT, other workers tasked with radiological protection and image quality optimization in CBCT, manufacturers of imaging equipment, regulators, and policy makers in charge of radiological protection. The attention is directly given to the responsibilities of the different stakeholders for appropriate use of CT scanning with attention to the avoidable level of radiation dose that derived from unjustified or inappropriate examinations, and recommendations are discussed.

Note that this document applies to a technology that is in high evolution. It is an example, in the medical field, of a practical guidance for the already involved stakeholders, that enters directly on what and how the stakeholders can do their best in their role. The view of uncritical application of CBCT, by taking the assumption that it is a modality related to minimal dose consequences could result in significant doses in some circumstances, and this view is well recognised in the document as not appropriate for protection of the patient.

From the **Action plan of IAEA**, [39] in consultation with PAHO, WHO and UNSCEAR, resulting from the 2001 conference, a broad description of stakeholders can be found in the indication that *‘the involvement of international organisations and professional bodies is crucial to performing the actions and achieving the goals [of the action plan]’*.

As an overall objective, the action plan aims to make progress in patient safety as a whole, starting from the statement that *“patients have a right to expect the radiation to be used in a safe and effective manner”*.

Even if no precise descriptions or definitions of these stakeholders are provided, and there are limited references to specific stakeholders throughout the document, the action plan itself mostly focuses on training, education, guidance and information exchange, with a particular focus on health professionals (medical practitioners, technologists, nurses, medical physicists, radio pharmacists, equipment designers, equipment maintenance engineers, biomedical and clinical engineers, administrators, regulators, etc. and organisational actors.

Health professionals are perceived as the “critical link”, and it is thus recognized how the involvement of professional bodies and international organisations is a requirement for the success of the actions presented in the document.

‘Involvement’ seems to take a rather unidirectional approach when it comes to health professionals, as emphasis is mostly put on training, guidance, and information exchange. However, at some points, the direct input of health professionals is also sought after; e.g. providing info on (near) accidents and incidents, providing input on guidance documents, or consultation of manufacturers in regard to standardization of computerized systems.

Although the document itself makes little reference to specific stakeholders, it has been developed with the help of a large range of organisational actors, thus reflecting a broad involvement of stakeholders at the level of setting the actions presented in the document. The organisations, involved at different level, are: IAEA, PAHO, WHO, UNSCEAR, the European Commission, ICRU, ICRP, IEC, IOMP, ISO, ISRO, ISRRT, ISR, WFNMB.

The **Bonn Call for Action**, [37], Joint Position Statement by IAEA and WHO, seeks to foster coordinated work to address issues arising in radiation protection in medicine. The 2012 conference aimed to:

- strengthen the radiation protection of patients and health workers overall;
- attain the highest benefit with the least possible risk to all patients by the safe and appropriate use of ionising radiation in medicine;

- aid the full integration of radiation protection into health care systems;
- help improve the benefit/risk-dialogue with patients and the public;
- enhance the safety and quality of radiological procedures in medicine.

An important outcome of the conference was the identification of responsibilities and a proposal for priorities for stakeholders regarding radiation protection in medicine for the next decade.

The Conference introduced ten Actions to Improve Radiation Protection in Medicine. Significant actions by all stakeholders are encouraged and among the numerous sub-actions described the following are included: to develop harmonized evidence-based criteria to strengthen the appropriateness of clinical imaging; to support and improvement in risk communication skills of health care providers and radiation protection experts; to strengthen collaboration in education and training among education providers in health care, the international organisations and professional societies.

*With the aim to foster an improved radiation benefit risk dialogue, technical and communication experts are envisioned in collaboration with patient associations to improve the risk communication in develop clear and adequate messages for the best communication towards specific interest groups.*

Supporting the implementation of Bonn Call for Action International Conference on Radiation Protection in Medicine: Achieving Change in Practice, IAEA, co-sponsored WHO, PAHO was organized in 2017. The Conference reviewed the overall approach to the implementation of these actions and look at how international organisations and other stakeholders could harmonize their actions for better impact. The stakeholders discussed the new developments affecting radiation protection in medicine. Participants proposed the creation of a ‘Bonn Call for Action Implementation Toolkit’

**HERCA Report CT Manufacturers Stakeholder Involvement** from 2017, [38], promoted collaboration between stakeholders on the issue of education and training. The stakeholders included: COCIR, professional organisations (ESR, EANM, ISRRT, ESTRO...), international organisations (IAEA, EC, WHO, IRPA, ...). In this document HERCA evidence that *“all stakeholders involved in the radiological process should be part of this important initiative to reduce patient dose”* and this in view of need for action against the increasing trend to higher medical exposures.

The 2017 meeting was the last meeting of a process initiated in 2010, between HERCA and the stakeholder COCIR, in particular, HERCA considered the CT manufactures to be one of the most important stakeholder in the field of medical radiation protection and consequently the HERCA working group medical applications created a subgroup “Work Package Stakeholder Involvement of CT Manufacturers”.

Note that CT is a very high developed technology accompanied by high increase in its use. It is a benefit to patients and society as a whole; however, it has led to a large increase in medical exposure (CT contributes for about 57% of the collective dose from all x-ray radiological procedures). As result of the process, the COCIR CT manufacturers were willing to underline their responsibility on patient dose reduction and commit themselves to actions towards this goal, including:

- the development and implementation of a standardized benchmark for CT system,
- the implementation of dose reduction in CT,
- the implementation of dose management and reporting tools, and
- the provision of specific training curricula.

Within these commitments there is the aim from manufactures to provide transparency and easily understood values to characterize system performance through standardized test and conditions to ensure appropriate, safe and effective use of imaging equipment. To describe the role of CT

manufacturers and other stakeholders in education and training a HERCA Position Paper: “The process of CT dose optimization through education and training and role of CT Manufacturers” was published in October 2014

Annual face to face HERCA-COCIR meetings allowed reporting the level of the actions and multi-stakeholder meetings were an opportunity to exchange views with a number of key stakeholders, with the focus to ensure an optimized balance between image quality and dose. Note that this is an example of a very productive initiative of involvement of different stakeholders motivated by self-commitment and cooperation. The large diffusion of the participation and the good results with significant benefits for the patients and also for the involved parts, suggests a more detailed study on the conditions and management methods that can be highlighted by this example of lesson learned.

#### 5.4. Stakeholders engagement related to the nuclear/radiological emergency field

While the term “stakeholder” is neither mentioned in IAEA Method for Developing a Communication Strategy and Plan for a Nuclear or Radiological Emergency (2015) nor in IAEA GSR Part 7 Preparedness and Response for a Nuclear or Radiological emergency (2015), IAEA guidance on Communication with the Public in a Nuclear or Radiological Emergency (2012) highlights their importance without clearly defining the term. Only in its publication on **Stakeholder involvement throughout the life cycle of nuclear facilities** (2011), [41], the IAEA provides an overview of possible stakeholder definitions: “A broad definition of a stakeholder is anyone who feels impacted by an activity, whether physically or emotionally.” The document acknowledges that this definition makes it difficult to identify all relevant stakeholders in particular circumstances, as some stakeholders may be self-selecting and situational. IAEA documents also use term “interested parties” defined in IAEA GSR, Part 7 (as from IAEA Safety Glossary), as “a person, company, etc. with a concern or interest in the activities and performance of an organisation, business, system, etc.”

The IAEA **Handbook on Nuclear Law** (2003), [40], states that: “Owing to the differing views on who has a genuine interest in a particular nuclear related activity, no authoritative definition of stakeholder has yet been offered, and no definition is likely to be accepted by all parties. However, stakeholders have typically included the following: the regulated industry or professionals; scientific bodies; governmental agencies (local, regional and national) whose responsibilities arguably cover, or ‘overlap’ nuclear energy; the media; the public (individuals, community groups and interest groups); and other States (especially neighbouring States that have entered into agreements providing for an exchange of information concerning possible trans-boundary impacts, or States involved in the export or import of certain technologies or material)”.

A useful distinction sometimes used, which touches on the IAEA Handbook on Nuclear Law quotation above, is between ‘statutory’ and ‘non-statutory’ stakeholders. This distinguishes between those organisations and bodies that are by law required to be involved in any planning, development or operational activity and those that will be impacted, directly or indirectly, by it. From a facility or programme proponent or operator’s perspective, such ‘statutory’ stakeholders therefore include: the regulator, local or national planning authorities, various service related bodies (power, water and emergency planning) that will service or be impacted by a development and national and local government entities involved in policy making and implementation. ‘Non-statutory’ stakeholders include those organisations and individuals who feel in whatever way impacted or affected by an activity (thus some stakeholders in this category may be self-selected). Local communities and non-governmental organisations (NGOs) fall into this group, and recognition of their importance cannot be overestimated. Their adequate inclusion or exclusion, for whatever reason, can contribute significantly to the success or failure of a nuclear facility project.



The IAEA Handbook on Nuclear Law states in Chapter 2.3.6 on public information *“Although it is not referred to in the Convention on Nuclear Safety or the Joint Convention, most regulatory bodies have programmes for the provision of information to other stakeholders (the public, the media, the legislature, local government and industry) about issues and activities relevant to nuclear and radiation safety. Indeed, public confidence that nuclear material and techniques are being used safely is closely linked to the regulatory body’s track record of providing prompt, accurate and complete information on such issues and activities. Independence is also relevant in this context. National legislation should make it clear that the regulatory body is authorized to communicate its requirements, decisions and opinions, and the basis for them, to the public independently. Furthermore, it should enable the regulatory body to communicate directly with high level governmental authorities when communication with them is considered necessary for the effective exercise of the regulatory body’s functions. Finally, legal authority is needed in order to ensure that the regulatory body can make available, to other governmental bodies, international organisations and the public, information on incidents and abnormal occurrences, and other information, as appropriate.”*

IAEA GSR Part 7 on **Preparedness and Response for a Nuclear or Radiological Emergency** [42] obliges the government in the Requirement 10 to *“provide instructions, warnings and relevant information to the public (who are affected or are potentially affected by a nuclear or radiological emergency) for emergency preparedness and response”*. That include permanent population, transient population groups and special population groups or those responsible for them and special facilities within the emergency planning zones and emergency planning distances.

In the Requirement 13 the government have to *“ensure that arrangements are in place for communication with the public throughout a nuclear or radiological emergency.”* Arrangements shall be made for providing useful, timely, true, clear and appropriate information to the public in a nuclear or radiological emergency, with account taken of the possibility that the usual means of communication might be damaged in the emergency or by its initiating event (e.g. by an earthquake or by flooding) or overburdened by demand for its use. Arrangements shall be made so that in a nuclear or radiological emergency information is provided to the public in plain and understandable language. The government shall ensure that a system for putting radiological health hazards in perspective in a nuclear or radiological emergency is developed and implemented with the following aim: to support informed decision making concerning protective actions and other response actions to be taken; to help in ensuring that actions taken do more good than harm; to address public concerns regarding potential health effects.

According to GSR Part 7 the goals of emergency response are *“to keep the public informed and to maintain public trust”* in a nuclear or radiological emergency without a differentiation. According to Article 4.10. *“The government shall [...] (i) [to] coordinate effective communication with “the public” in preparedness for a nuclear or radiological emergency”* without distinction between members of the public, workers, emergency workers and patients. In addition, it explicitly establishes requirements for arrangements to be made to provide promptly a warning and instruction to permanent, transient and special population groups or those responsible for them and to special facilities in the Precautionary Action Zone (hereinafter referred to as PAZ) and the Urgent Protection Action Planning Zone (hereinafter referred to as UPZ) upon declaration of an emergency class. Thus, authorities responsible for emergency communication shall include instructions in the languages mainly spoken in these zones on the immediate actions to be taken. According to this review, most countries inform the public within the emergency preparedness zone (EPZ), some decide who to inform depending on the distance from facility or depending on local or regional government boundaries.

Regarding information requirements, GSR Part 7 indicates that the term “the public” summarizes all groups of individuals:

- “Special population groups” are those members of the public for whom special arrangements are necessary in order for effective protective actions to be taken. Examples include disabled persons, hospital patients and prisoners.
- “vulnerable members of the public”: e.g. children, pregnant women, etc;
- Members of the public directly affected by an effluent discharged to the environment;
- Members of the public in the vicinity of a nuclear installation.

In the transition phase, from emergency to post emergency, the GSR Part 7 also requires that the protective actions and other response actions shall be made by a formal process that includes consultation of interested parties. This include also the decision on the termination of a nuclear or radiological emergency.

The IAEA GSR Part 7 also stress the need for appropriate infrastructure, such as requirement for coordination of emergency preparedness and response between the operating organisation and authorities at the local, regional and national levels which include the arrangements for communication with the public. The sufficient logistical support and facilities shall be in place to enable emergency response functions to be performed effectively in a nuclear or radiological emergency. This includes arrangements for continued communication with the public, and for monitoring of public opinion and the reaction in the news media.

The IAEA **Method for Developing a Communication Strategy and Plan for a Nuclear or Radiological Emergency** (2015), [43], is devoted to the development of a national radiation emergency communication plan. In this document the term ‘public communication’ is defined as any activity that communicates information to the public and the media during a nuclear or radiological emergency. It focusses on communicating during an emergency, but also emphasis that communication prior to an emergency (routine communication) plays an important role in the effectiveness of communication during an emergency (emergency communication). The publication stresses the importance for target audiences mapping including their information needs, priorities and means (information channels), and provides also the proposals for most effective communication activities, information products and tools, as well as the channels through which messages would be communicated.

The IAEA **Communication with the Public in a Nuclear or Radiological Emergency** (2012), [44], provides practical guidance for public information officers on the preparation for and response to a nuclear or radiological emergency before, during and after a radiation emergency. The publication describes how to prepare and train for emergency communications before a radiation emergency occurs, explains the need for effective public communications in radiation emergencies and provides communication principles and tools to assist responsible in achieving effective communication. Both documents are very useful for good public communication, but public, even if understood in very broad way, is here not seen as engaged partner. However, all principles of communication and practical suggestions can assure proper dissemination of information. Also, media is seen here as additional to the public, as they receive and also transmit the information.

In IAEA General Safety Guide no. 11, **Arrangements for the termination of a nuclear or radiological emergency** (2018), [45], detail guidelines are recommended to the government to ensure that arrangements are made for “the termination of a nuclear or radiological emergency, with account taken of the need for the resumption of social and economic activity.” Compared to the urgent response phase and, to some extent, the early response phase, the transition phase is not driven by urgency and allows for adapting, justifying and optimizing protection strategies as the

emergency evolves and for interested parties to be consulted. Consultation with interested parties is required before the termination of the emergency with intention to help increase the public trust in and the public acceptance of the decision to terminate the emergency. Before the termination of the emergency, the guide propose the topics to be discussed with and communicated to the public and other interested parties: basis and rationale for the termination of the emergency and an overview of the actions taken and the restrictions imposed, need to adjust imposed restrictions, to continue protective actions or to introduce new protective actions with time estimations, any necessary modifications to people's personal behaviours and habits, options for the implementation of self-help actions, need for continued environmental monitoring after the termination of the emergency, need for continued efforts to restore services and workplaces and radiological health hazards associated with the new exposure situation. Even more, the involvement of, and consultation with, relevant interested parties should start as early as possible in the preparedness stage and should develop with an aim to continue, as appropriate, throughout the transition phase and after the termination of the emergency. Consultation with relevant interested parties should be based on effective communication mechanisms that are founded on transparency, inclusiveness, shared accountability and measures of effectiveness and should allow for feedback to be accommodated in a timely fashion.

In HERCA Working Group Emergency document **Practical proposals for further harmonisation of the reactions in European countries to any distant nuclear or radiological emergency** (2013), [46], some topics were identified which form a basis for communication with the public:

- *“The technical capabilities must be good enough to be able to quickly and understandably share information on the progression of the accident.*
- *The use of the INES scale in a developing accident situation must be pre-agreed and understood.*
- *The radiation protection concepts (e.g. ALARA and the reference level approach) do not necessarily make communication easier. Therefore, pre-emergency discussion between HERCA members of the practicalities of these concepts in response would be of assistance.*
- *Experts in the field must be prepared to deal with questions from media and the press.*
- *The sharing of dispersion predictions and monitoring data with the public must be pre-agreed and understood (e.g. common templates for situation displays should be a goal).*
- *There should be a common basis for comparison with other accidents such as Chernobyl.”*

In the document it is stressed that successful communication with stakeholders is the ultimate test of successful crisis management. However, there are several issues which have not been dealt with further by the HERCA WGE and would need to be addressed more, like, use of single spokesperson in a crisis situation, common talking points, joint press conferences between the operator, the local and the national officials, communication from non-governmental professional organisations might contribute to better understanding, public awareness and involvement in emergency preparedness and response should be strengthened through exercises, seminars etc on a regular basis.

In addition, WGE also gives some guidance on the information that should be addressed in the communication material based on past experiences that show the general public does not understand or know the effects arising from a radiological emergency situation. The material should contain:

- *“the possible pathways by which people could be exposed to radiation,*
- *orders of magnitude of radiation doses to people from different sources (such as natural background radiation or medical practices) to allow people to make a comparison with doses from other sources of radiation and understand the associated risk,*

- *a description of how people can reduce radiation doses and minimise the possible health effects,*
- *the possible health implications of the doses received, and symptoms to be aware of,*
- *the contact point for future questions and information (institution, address, telephone, web-sites and email)."*

The OECD/NEA Forum on Stakeholder Confidence identifies a stakeholder as: "any actor-institution, group or individual with an interest in or a role to play in the societal decision-making process". Also, the OECD/NEA Forum on **Stakeholder Confidence Annotated Glossary** (2013), [47], provides a large list of possible stakeholders (in no particular order) regarding radioactive waste management processes: the general public, demographic groups (like young people), residents, representatives or elected officials of local communities, national/regional government ministries/departments, regulators, national/local NGOs, local pressure groups, trade unions, the media, the scientific research community, implementing organisation, the nuclear industry, contractors, waste producers, international organisations.

In OECD/NEA **Stakeholder Involvement in Decision Making: A Short Guide to Issues, Approaches and Resources** (2015), [48], early involvement of stakeholders also corresponds to preparedness, and may make a vital contribution to achieving the objectives of safety and security which interest governments, institutions and all of society. For instance, the NEA Committee on Radiation Protection and Public Health (CRPPH) pointed out that "the active participation of stakeholders is necessary not only in the implementation of post emergency strategies, but also before any radiological emergency, during the preparation and planning phase". Early involvement here improves plans, enables concerned stakeholders to prepare themselves to a post-emergency situation, and reinforces the potential for co-operation, communication and co-ordination in actual crisis or during recovery. Future development of stakeholder engagement will probably reflect and address the need to accompany institutions in achieving participation as a long-term and continuous requirement, foster a solid democratic culture in the population and support to civil society representatives in ongoing knowledge, competence and capacity building and deliberative activities.

In ICRP publication on **Recommendations for the Protection of People in Emergency Exposure Situation** (2009), [49], it is indicated that the change from an emergency exposure situation to an existing exposure situation will be based on a decision by the authority responsible for the overall response and that the transfer should be undertaken in a co-ordinated and fully transparent manner, and should be understood by all parties involved. The stakeholders referred in the document include many different types of people and organisations, e.g. the public affected by the emergency, the authority responsible for the emergency response, the licensee of the facility or activity causing the emergency exposure situation, the regulatory authority licensing the facility or activity causing the emergency exposure situation, local public officials within and perhaps near the areas affected by the emergency exposure situation, emergency workers including first responders, and others. The procedures for the implementation of protective actions to be justified and optimised during an emergency, should be agreed in advance in order to facilitate their acceptance by the public during the emergency. The engagement with stakeholders is an important component of justification and optimisation of protection strategy in emergency exposure situations, especially as the emergency exposure situation progresses. The incorporation of stakeholder input into decisional processes should be tuned by structures, processes, and procedures, and perhaps legislation and regulation to encourage such participation.

Considering that there may be international consequences in large-scale emergency, stakeholders are not limited to those groups affected in the country, since there would be the perceived need for

protective measures in other countries, the need to harmonise the response across country borders; and the need for authorities to ensure the safety of their nationals and to deal appropriately with people from an affected country crossing their borders.

In ICRP publication on **Recommendations for the Protection of People Living in Long-term Contaminated Areas after a Nuclear Accident or a Radiation Emergency** (2009), [50], ‘the complexity of post-accident situations, which cannot be managed without addressing all the affected domains of daily life, i.e. environmental, health, economic, social, psychological, cultural, ethical, political, etc.’ is recognised. Therefore, the need for involvement of “affected population and local professionals in the management of the situation” is emphasised with creation of conditions and means favouring the involvement and empowerment of the population. From past experience of long-term contamination, it is demonstrated the effectiveness of the direct involvement of inhabitants and local professionals in management of the situation. It is the responsibility of the authorities to favour the involvement and empowerment of the population, by taking into account local social and economic living conditions with the aim to help individuals to regain control of their lives. In long-term contaminated areas the inhabitants are recognised to take their own actions called ‘self-help protective actions’, such as by monitoring their own exposure and the exposure of the people for whom they have responsibility, e.g. children and elderly, and by adapting their way of life accordingly to reduce the exposure.

Forums are foreseen to allow sharing info and favour common assessment of the effectiveness of strategies. The local forums should be facilitated by authorities and representatives of the affected population together with relevant experts are involved. Since protective actions are implemented by the inhabitants themselves, they must be informed and trained in order to take informed decisions with net benefit, by taking into consideration from one side the desire to improve the situation, and on the other side the possible burden induced by the implementation of protective actions.

WHO works closely with IAEA to prepare for and respond to nuclear accidents and radiological emergencies, principally to provide, coordinate and consult medical assistance to victims of such events where severe radiation exposure has occurred. In WHO **Emergency response framework** (2017), [51], the general frame is presented on how WHO responds to different emergencies, including nuclear and radiological accident. In its role WHO also provides up-to-date information on the health situation and health sector performance. It is responsible for the coordination of WHO’s response to media and public queries for information and develops and disseminates both internal and external communication products. Working with other response agencies and technical experts, the communications takes a pro-active approach so that risk and crisis communications are coherent and consistent. WHO collaborates with the Ministry of Health and partners such as UNICEF, to frame the event and risk, and provide authoritative information using all relevant communication platforms. Special function assesses the social and cultural context of populations at risk, engages stakeholders at national and local levels, develops tailored and targeted messages for dissemination, ensuring that they are technically sound and socio-culturally appropriate, and conducts rapid surveys and other assessments to determine the barriers to adopting health advice. It delivers health messages using the most effective means preferred by the target population in local languages and monitors their effectiveness. As part of WHO activities there are also materials developed for different health preparedness (e.g. **Iodine thyroid blocking: Guidelines for use in planning and responding to radiological and nuclear emergencies**, 2017, [52]).

Within **NERIS** platform (European Platform on Preparedness for Nuclear and Radiological Emergency Response and Recovery) the **Strategic Research Agenda**, [53], was adopted in 2017 where Research area 3, entitled *Challenges in setting-up a trans-disciplinary and inclusive framework for preparedness for emergency response and recovery*, focuses on the overall emergency response and recovery

framework, including reference levels, stakeholder engagement, the involvement of the public, communication research and non-radiological perspectives such as health, ethical and societal aspects. Within this area also multidisciplinary research to cope with incomplete information, typical for emergency situations, and improve decisions under high uncertainty is integrated. Several key topics were identified in this research area:

- *Emergency response and recovery framework, including reference levels* with objective to develop radiological decision criteria and implementation frameworks to improve and ensure the sustainability of emergency response and recovery management, addressing societal and ethical issues.
- *Stakeholder engagement, involvement of the public and communication* with objective to improve the efficiency and social robustness of emergency response and to ensure that stakeholders are involved in decisions that impact on their lives.
- *Integrated emergency management – non-radiological aspects* (health surveillance, ethical aspects, economic issues,...) with objective to better addressing non-radiological aspects for developing guidance and framework to improve emergency response and recovery management.
- *Uncertainty and incomplete information handling* with objective to improve the capabilities to perform sensible and robust decisions under high uncertainty. This includes communication and visualisation of uncertainties in models results but also the consideration of how uncertainties are used when making decisions.

French based non-governmental organisation with EU level membership Nuclear Transparency Watch (NTW) also published the **Report of Working Group on Emergency Preparedness and Response** (2015), [54], in which finding from civil society point of view in relation to EP&R are presented. The objective of the activity was to check the reality of nuclear off-site emergency preparedness and response, to inform the public on the findings and to provide guidance for further activities of the interested public. Several different stakeholders were involved in investigation, including the responsible authorities, professional institutions, interested public and local citizens, environmental non-governmental organisations and media. Based on the investigation of civil society organisation (CSO) in relation to the stakeholder involvement in EP&R in Europe the NTW concluded that citizens are insufficiently informed and involved. Current EP&R is in practice at best a bureaucratic list of good intentions since plans are not realistic and not tested with those for which they are prepared. The non-institutional stakeholders are not involved in development of plans, as the plans are developed as usual top-down approach. This approach should be changed and the local populations and interested civil society organisations should be involved in this development. Several proposals were given in relation to stakeholder involvement:

- The gaps in national EP&R need to be overcome: NTW recommends that gaps in local emergency preparedness and response are identified systematically in partnership with national authorities and national civil society organisations in a way that reflects the real situation, is based on the interest of (local) citizens and takes trans-boundary arrangements into account where necessary.
- Operators and/or national authorities have to allocate appropriate resources to local municipalities, civil rescue teams, medical support, CSOs and civil initiatives to participate in exercises and evaluations.
- Creating a legally based role for CSOs in EP&R: NTW believes that there is a need for developing a legal framework related to EP&R requiring the involvement of CSOs at each level of EP&R preparation and for related decisions, in the spirit of and in compliance with the requirements of the Aarhus Convention. Efficient EP&R can be expected only where there is cooperative action by all concerned stakeholders in order to co-manage the situation.

- Management of information during the emergency phase: NTW takes note of the proposal of HERCA-WENRA regarding the management of early information and co-ordination in the emergency phase (which is characterised by strong uncertainty) while suggesting further investigation into the consistency and trustworthiness of the proposed options. It should be noted that different groups of the affected populations will have different criteria regarding credibility of information sources and the risk of communication chaos exists. There should not only be attention for good practice, but especially challenges in information management should be addressed. Such an assessment should involve civil society in order to test and update public information provisions. The obligation to organise such reviews has to be included in the regulatory framework of nuclear installation operation.
- Independent experts, local NGOs, CSO representatives, and stakeholders involved in emergency response should have direct access to technical information related to the accident as required by Article 5.1.(c) of the Aarhus Convention.
- Harmonisation of the EP&R measures: NTW is very keen to examine how it is possible to harmonise national provisions for EP&R measures in a trans-boundary context, like emergency zoning for evacuation, sheltering, and distribution of iodine prophylaxis.
- Long term management of radiological contamination: NTW sees an urgent need for proper post-accident strategies and operational programs that should in principle prepare society for the challenges after a nuclear disaster. As a first step, the European Parliament and the European Commission should strengthen the legal framework to address this issue on EU level.
- Food standards harmonisation: A repetition of the chaos in food standards after the Fukushima catastrophe has to be prevented at all cost. The situation of confusion caused mistrust in the legal framework and the responsible institutions. The European Commission and other authorities should create a transparent, scientifically sound and publicly accepted set of standards and create harmonisation across Europe.

Only lately, some changes on the approaches to EP&R have been noticed, like the discussion on EP&R plans in France with CLIs (Commission Locale d'Information), involvement of environmental NGOs in development of new Royal Decree on the Nuclear and Radiological Emergency for Belgium in 2018 revision and similar. In recently developed EP&R plans there are much more attention to the requirements set in the EU legislation. Nevertheless, the general trends in most of the EU countries are still not supportive to the engagement of local population, environmental NGOs or any other interested parties.

### 5.5. Stakeholders and their engagement in the management of indoor radon

In **Radon in Homes, Factsheet for Decision Makers**, IAEA, [55], information is given for stakeholders on what actions are required. National authorities need to provide relevant information to target groups - the public, local stakeholders, decisionmakers and building professionals.

In **Protection of the Public against Exposure Indoors due to Radon and Other Natural Sources of Radiation**, IAEA Specific safety guide form 2015, [56], the following is advised:

- Stakeholder: no matches. Also, no matches for other key words, except information and consultation. Description of "target group": building owners, local authority, staff, surveyors, builders, housing professionals, estate agents, solicitors, health, and safety professionals and the medical profession.
- "The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public

- exposure due to radon indoors.” The requirement to provide public information applies irrespective of whether or not radon measurements are being carried out or are planned.
- If a national policy to control public exposure due to radon needs to be developed, the national authority should prepare information and make it available to all interested parties. This includes decision makers, medical practitioners, building professionals (including architects, engineers, quantity surveyors and builders) and the public. Information should be provided clear and consistent.
  - When setting a reference level, the national authority should consult interested parties. Reference levels should be selected such that the resulting activities are seen to be practicable and manageable. For example, it would be impractical to set a reference level such that corrective actions would be necessary for the majority of existing dwellings. The percentages of dwellings that would require corrective actions under different reference levels should be considered in the choice of an appropriate reference level.
  - Monitoring the effectiveness of the action plan on radon: „The level of awareness may be evaluated on the basis of the number of requests for information or the number of requests for radon measurements to be made, or by means of market research surveys“.
  - Cooperation: The national authority should ensure cooperation with the authorities responsible for the regulation of the planning and construction of buildings when incorporating preventive measures for 222Rn into national building codes. This includes those authorities responsible for addressing other aspects of indoor air quality and energy efficiency. Site inspection forms an important part of building regulation. Such building regulation should include communication with and training of both building inspectors and professionals in the construction industry
  - Public awareness of the risks of exposure due to 222Rn is low in many States. However, a radon reduction programme requires the cooperation of the public in order to be successful in reducing high activity concentrations of radon in dwellings. As part of any action plan on radon, the national authority should develop strategies to inform the public about the risks due to radon and about preventive measures and corrective actions. These strategies should also target bodies and professional groups concerned with housing and with public health, such as builders, architects and regional and local government authorities and the medical profession. Details are provided in Annex V.
  - PUBLIC INFORMATION PROGRAMMES ON RISKS DUE TO RADON: Perhaps the most important group to be targeted by activities for awareness of radon are building owners, but other important groups include local authority staff, surveyors, builders, housing professionals, estate agents, solicitors, health and safety professionals and the medical profession. The broad message to be conveyed is the same in all cases but the specified focus and the degree of detail and packaging needs to be tailored to their specific needs.

The Annals of the ICRP, **ICRP Publication 126**, Radiological Protection against Radon Exposure. ICRP 2014, [57], provides:

- Stakeholder, involve: Domestic radon exposure management should address a number of issues (e.g. environmental, health, economic, architectural, and educational) involving a wide range of stakeholders. The strategy should be straightforward, appropriately scaled with other health hazards, supported and implemented on a long-term basis, and involve all stakeholders.
- The national radon protection strategy should be implemented through a national radon action plan established by national authorities with the involvement of relevant stakeholders. The action plan should establish a framework with a clear infrastructure, determine priorities and responsibilities, and describe the successive steps to deal with radon in the country. Depending on the exposure conditions, it should identify stakeholders, such as those who are exposed and



those who should provide support or implement action; address ethical issues, particularly those associated with responsibilities; and provide information, guidance, support, and conditions for sustainability.

- The national action plan should also deal with radon measurement techniques and protocols; radon surveys to identify radon-prone areas; methods for mitigating radon exposure and their applicability in different situations; supporting policies, including information, training, and involvement of stakeholders; and assessment of effectiveness.
- Public health considerations: Considering the ubiquity of radon exposure, and the multiplicity and diversity of situations and decision makers, a straightforward, realistic, and integrated radon protection strategy, addressing most situations with the same approach, is appropriate. It must be supported and implemented on a long-term, potentially permanent basis, and involve all the relevant stakeholders.
- Responsibilities of stakeholders: describes justification for a graded approach for the responsibility of different stakeholders for taking action against radon.
- Optimisation of protection the involvement of the relevant stakeholders is described as important part of the optimisation process
- Graded approach: Where a building has high radon concentrations, the response should include the involvement of, and communication with, relevant stakeholders, such as the building users.
- National action plan: A national radon action plan should be established by national authorities with the involvement of relevant stakeholders. The objective is to reduce the collective risk of the population and the individual risk to indoor radon exposures by implementing the optimisation principle. The national radon action plan should, as far as possible, be integrated in a manner consistent with other strategies concerning buildings, such as indoor air quality or energy saving, in order to develop synergies and avoid contradictions.
- Information: ... so that general information should be, where possible, made available to enable individuals to reduce their doses.
- Graded approach in control of radon exposure: The Commission now recommends that a graded approach should be applied for the control of radon exposures. In such an approach, the radon protection strategy should start with a programme aimed at encouraging relevant decision makers to promote self-help protective actions, such as measurement and, if needed, remediation. This process can be implemented through information, advice, incentives, practical assistance and, where necessary, more formal requirements. The level of enforcement of these various actions should be dependent upon the degree of legal responsibility for the situation, and the level of ambition of the national radon protection strategy.
- The radon protection strategy should include a programme of actions including provision of general information on radon behaviour and risk, campaigns aiming to increase awareness among the targeted public, campaigns of concentration measurements, and organisation of technical or financial support for measurements and remediation actions (see Section 4).
- The action plan may contain both incentive-based and mandatory provisions. Given that responsibility for taking action against radon will often fall on individuals who cannot be expected to perform a detailed optimisation exercise, the action plan should provide appropriate information and support to those individuals to be able to address the radon issue themselves through self-help protective actions, such as self-measurement or access to appropriate measurement services, proper use of buildings, and simple remediation techniques.
- The first step in securing support of a national radon strategy is the development of awareness, which appears to be very weak in many countries. Easily available information about radon, how it can be trapped inside enclosed spaces, related risks, and how to identify and mitigate high concentrations should be disseminated to the general population, notably through elected

representatives, civil servants in administrative divisions, homeowners, landlords, employers, children at school, etc.

- Appropriate information and training should also be provided to other concerned professionals (e.g. health, real estate).

Definition: There are no definitions given for the keywords mentioned above. This is interesting, especially in view of the important role “stakeholder” plays in this publication. The term stakeholder is described and illustrated with examples as follows:

- stakeholders, such as those who are exposed and those who should provide support or implement action,
- individual householder; builder or the seller of a property towards the buyer, landlord towards the tenant, of the employer towards the employee, and, generally speaking, of the responsible person for any building towards its users; the individual, general population,
- owner of a house, employers, manager of a school, the local authority, building users.

In **RADPAR Project**, RADPAR FINAL SCIENTIFIC REPORT Radon Prevention and Remediation, [60], it is emphasized:

- Stakeholder: “For categories 1 and 2: A comprehensive strategy (developed with all stakeholders) has to be implemented by means of National Action Plans, involving also local authorities and expertise, and coordination with other related programs/activities (cigarette smoking, IAQ, energy saving) should be promoted.
- The dissemination of information on radon and its risks to the general population and other relevant stakeholders has been found to be the first step in the development of awareness of radon and on how to deal with it. Raising awareness should not, however, be seen as an end in itself.
- Inform: The biggest problem the radiation protection community faces in dealing with public exposure to radon in existing dwellings appears to be apathy. It is very difficult to persuade members of the public to measure for radon in their homes. Even when informed that the radon concentration in their home is above a national reference level only a disappointingly low percentage of householders will decide to remediate. Knowledge on building protection is not shared enough with building professionals and it is needed to spread this information on building protection.
- Involve: Social marketing techniques have been used to persuade people not to smoke in public areas, to use seat belts, to follow speed limits etc. Social marketing is, unfortunately a skill not normally present in the skill set of radiation protection practitioners, epidemiologists, physicists or other scientific experts. Therefore, just as non-radiation professionals such as architects, engineers, constructors, etc. play an important role in dealing with radon social marketing specialists should be involved in radon risk communication.
- It is remarkable, that RADPAR is mostly about “informing”, “persuading”, but not about „involving“, Stakeholder engagement, or rather “information” or “persuasion” is used in an instrumental sense.
- The level of stakeholder engagement is information, raising awareness. Involvement is used in the sense, to involve other stakeholders in the radon risk communication.

**WHO Handbook on indoor radon**, A public health perspective, WHO, 2009, [58], reports:

- Stakeholder, collaboration: The handbook is intended for countries that plan to develop national programmes or extend their activities regarding radon, as well as for stakeholders involved in

radon control such as the construction industry and building professionals. Key elements for a successful national programme include collaboration with other health promotion programmes (e.g. indoor air quality, tobacco control) and training of building professionals and other stakeholders involved in the implementation of radon prevention and mitigation.

- Measurement protocols: It is important to seek input on these protocols from stakeholders including researchers, radon measurement providers, builders, and officials who are responsible for implementing regional and national health guidance.
- National radon programmes: The development of a radon programme involves the setting-up of a clear organisational structure and a range of components in order to monitor radon levels, facilitate prevention and mitigation, and provide radon risk communication services to the public and other stakeholders.
- Organisation of a national radon programme: The implementation of an effective radon programme aimed at protecting the public against indoor radon exposures requires input from many national agencies and other stakeholders. These include the national, regional and local organisations responsible for public health and radiation protection. Expertise from other agencies, entities or experts such as geological survey institutes, public and/or private radon measurement laboratories, building engineers and scientists, the construction industry and agencies that implement and enforce building regulations or building codes is another key element in any radon strategy. Governments should promote a national radon programme of coordinated actions and designate one organisation or agency to take the lead in driving and coordinating it. National data should be gathered by this organisation in order to evaluate the effectiveness of the programme.
- Engagement: The communication channels and the approaches to be used should be a combination of passive (information is provided without the ability to have a dialogue with the provider) and active (information is provided, and the recipient can interact and have a dialogue) engagement techniques (WHO 2002).
- Concern: Public awareness campaigns should encourage householders in these areas to test their homes for radon. These strategies could target organisations and professionals concerned with public health and with housing, such as builders, architects, regional and local government authorities and the medical community.
- The stakeholder involvement described might be a form of instrumental and substantive engagement, no clear description is given.
- Level of stakeholder engagement: Involvement, information, elaborating national action plans together.

**“Common understanding and recommendations related of the BSS requirements on radon in workplaces”, HERCA 2016, [59], states:**

- To identify engagement aspects related to radon, the document was searched by the key words: Radon, Information, Communication, Involvement, Participation, Public, Interaction, Exchange, Stakeholder, interested parties, concerned parties, engagement, involvement.
- The term “stakeholder” is mentioned twice in the HERCA paper on radon workplaces:
  - The national action plan should include preventive and educative actions developed for all employees, involving stakeholders such as Labour Unions and Employers Associations.
  - Radon risk communication is a key aspect of any radon action plan. As a part of the action plan, customized information should be prepared for employers, employees and their representatives, and other stakeholders. Appropriate communication channels should be used, with particular attention given to small and medium-sized enterprises.
- “Information” is additionally mentioned in two further recommendations.

- „Participation” is mentioned in:
  - Mechanisms for worker participation in managing radon risk should be encouraged. That could be interpreted as stakeholder engagement.
  - Is dedicated to risk communication: “HERCA draws national authorities’ attention to the radon risk management in workplaces with public access, particularly on the issue of risk communication. In a situation where the radon concentration remains above the reference level, even after optimization, risk communication should cover both the public and workers’ exposures. The communication should allow for the difference between the regulatory frameworks (existing exposure situation without dose limitation on the one hand and an existing exposure situation deliberately managed as a planned exposure situation under certain circumstances, with dose calculation, on the other hand). The elements for risk communication toward the workers and the public should be generally prepared in advance, particularly in schools and kindergartens”.
- There is no description of motivation. It can be interpreted as a mixture between instrumental, normative and substantive motivation for stakeholder engagement.
- The level of “engagement” ranges from information to communication to participation.
- This reference is for occupational exposure, not for general public.

## 6. Analyses of international interviews

The international interviews with representatives of international organisations were conducted in all three different field of interest. The procedure for the interviews is described in the chapter 2 (subchapter 2.2 semi structured interviews) with basic questions/topics to be followed. The number of interviewees is given in each of the following subchapters, also the names of organisations are provided, although the names of participants are anonymous. Before the interview it was emphasized that the collected opinions are valid for institutions.

An inductive approach to qualitative data analysis was used, building on the principles of ‘open’ and ‘axial’ coding as introduced in Glaser and Strauss’s (1967) Grounded Theory. ‘Open coding’ refers to the subdivision of data in meaningful concepts (codes), remaining close to the original data source. ‘Axial coding’ then comprises a further level of abstraction, as it searches for meaningful links between codes, thus looking for links between excerpts of data (Mortelmans 2007). The analysis was further guided through the use of sensitizing concepts derived from the project’s framework, such as ‘definitions’, ‘motivations’ and ‘arrangements’ of/for stakeholder engagement.

### 6.1 Medicine

Four interviews were conducted with representatives of relevant organisations working on radiation protection in the medical field; WHO, IAEA, ICRP and HERCA. The interviews were conducted in English, with the use of Skype and/or telephone, and lasted between 40 minutes and 1 hour. After being transcribed, they were analyzed with the help of NVivo12 software.

Overall, we can say that respondents perceive a growing importance of stakeholder engagement in their field, and/or in society in general. Cited triggers for this are: societal changes in general (where people have evolved from rather passive roles to more active roles), disasters with a strong impact such as the Chernobyl nuclear accident, and/or more formal calls for action (e.g. BSS Directive, Bonn Call for Action, the 2001 Malaga conference on radiation protection of patients, etc.). All respondents have professional experiences regarding stakeholder participation, but in different degrees; some mention their experience as being rather limited, whereas others tend to perceive stakeholder engagement as a central aspect of their (organisation’s) tasks.

Reasons to set up initiatives for stakeholder engagement differ. On a more practical level it is stated how certain actions are taken in order to live up to internally or externally set requirements (e.g. demands regarding the development of standards and guidelines developing guidelines, the BSS Directive demanding that collaboration exists between regulatory body, health authority and professional organisations), and one respondent also refers to stakeholder engagement as a way to 'convince' stakeholders that expert knowledge offers the 'right way' to go. More 'ethical' than 'practical' reasons are: 'giving a voice to those affected by certain decisions', 'offering ways to express needs and wishes', or 'creating trust'. And as overarching objectives, reference is made to the wish to install a more inclusive approach to radiation protection (making it an integral part of medical practice, instead of treating it as a separate aspect), and to provide the best possible care and safety for both patients and professionals. A respondent also argued that "there is always an interest for stakeholders to get involved". Stakeholders' motivations might be different to those listed above; politicians might for example be driven primarily through political motivations related to their image, or doctors through their will to take up a leadership role.

When it comes to defining stakeholders, respondents refer to the importance of identifying those actors relevant to a certain discussion/decision (i.e. because they will be affected by it), and acknowledge the different roles of these actors in the process of stakeholder engagement (e.g. regulatory bodies as facilitators, professional organisations as providers of information based on their expertise, patients as providing input based on experience). One respondent mentioned how the identification process of stakeholders sometimes takes a rather 'ad hoc' form, learned through trial and error, while another interviewee refers to a more formal 'stakeholder mapping exercise' being used. Interestingly, the interviewees speak mostly about 'professional' stakeholders, as distinguished from the more 'general' public (i.e. patients).

Thus, reference is frequently made to professional organisations (e.g. of medical specialists, physicists, technicians) as key stakeholders, and also regulatory bodies and international organisations are repeatedly mentioned. Patients and patient organisations, however, are perceived as key stakeholders, but only in one interview are they also explicitly referred to as one of the parties who are –if relevant- consequently brought to the table in discussions on radiation protection. One of our respondents indicated regrets the difficulties in engaging patient organisations as stakeholders, and another respondent expressed appreciation for those cases in which patients' voices are heard at meetings. Yet another respondent distinguishes between 'internal' (professionals/experts) stakeholders, as opposed to 'external' (community) stakeholders and discusses mostly the engagement of the former. Given the objective of providing the best possible care and safety for both professionals and patients, it is rather remarkable that patients are –according to most of the interviewees- not given a direct position at the discussion table.

The level of stakeholder engagement and participation in part depends on the actors involved. One respondent stated that "*in a closed room of expert stakeholders you come rather quickly to a conclusion*", and thus seems to imply that this is not the case if non-expert stakeholders are also engaged. Another respondent remarks that the involvement of stakeholders might take an entirely different form if only a small number of stakeholders are involved, versus when a large number are involved (as the latter is more challenging). The topic affecting the stakeholders plays an important role here: some topics require other stakeholders' involvement than others.

In terms of legal requirements, the BSS Directive is repeatedly mentioned as setting a framework also for stakeholder engagement. One respondent recognizes these standards as a trigger to engage with stakeholders, and another mentions how at the national level, the BSS Directive demands "that the regulatory body works closely with the health authority and the professional organisations".

Requirements of the BSS Directive regarding stakeholder engagement at the level of patients are not mentioned. However, this should not necessarily mean that respondents are unaware of these, as one interviewee notices how “the patient has the right to know, in fact, everything, all the exams, all procedures performed”. Based upon the interviews, it is hard to establish how specific requirements are also directly impacting upon the work of the studied organisations. One interviewee refers – besides the BSS- also to the proceedings of the 2001 Malaga conference and the Bonn Call for Action as guiding documents, but does not go into the specifics of this guidance. Others mention internal organisational requirements for stakeholder engagement, such as requirements on the production of guidelines, or requirements for public communication.

Regarding the challenges for setting up stakeholder engagement, an important challenge is the search for a common language, or a common ground of understanding, which is needed to tackle an issue at hand. As one of our respondents puts it: “everybody has their own ideas and the common ground of understanding is not there in the beginning, it has to grow”. Also, the position of different stakeholders in the process can be an issue of concern, as there might be a lack of equal recognition among stakeholders, or one stakeholder might take a controlling, ‘top-down’ attitude, thus blocking the engagement of other stakeholders. Furthermore, the definition of stakeholders itself might offer a challenge, as the composition of organisations tends to change, stakeholders might face time-constraints, some organisations might lack skilled spokespersons, or some potential stakeholders might be forgotten or overlooked by those setting up a process. Engagement might also remain ‘superficial’ (e.g. inviting parties to the table, but not doing much with their input), or there might be a lack of willingness to participate altogether.

Identified factors for success then comprise the possibility to find a common ground of understanding (e.g. through exchange of experiences, trainings, or skilled moderators), and the possibility to engage stakeholders at an early stage of the process. Also, the provision of a win-win is identified as an important factor, thus acknowledging the idea that not all stakeholders might have the same motivation to take part in a process, but nonetheless can be moved to take part. Flexibility, freedom and focus are as well identified as factors leading to success, thus also stressing the importance of the way in which the participation process itself is organized/moderated.

In conclusion, some remarks can be made. First, it should be noted that at some points it was difficult to differ between what respondents said as a representative of the organisation, and what was said based upon experiences outside the organisation (e.g. based upon former employments, personal life).

And as a final remark, it should be noted that most interviewees seemed to take a positive stand regarding stakeholder engagement and participation. However, one respondent (although also seeing the value of stakeholder engagement in certain cases) at different points during the interview alluded to stakeholder engagement as a sort of obstacle. This respondent found it at times cumbersome that non-experts could express standpoints which seemed in opposition to scientific agreement, and thus needed to be ‘convinced’ of scientific expertise, and repeatedly stressed that in some cases (e.g. fast decisions) stakeholder participation was to be avoided.

## 6.2 Emergency preparedness and response

Three interviews were done with experts working in three different but meaningful contexts regarding EP&R. The three interviewees respectively represent an environmental activism group (Greenpeace), an umbrella association of RP regulators (HERCA) and an association of research institutes concerned with radiological protection related to EP&R (NERIS platform). All three organisations are international in nature. All three interviewees have longstanding and deep experience in their respective fields of

work. All interviews took one hour each and were done via Skype. The audio was transcribed, and the qualitative analysis of the interview texts was done without the use of analytic software.

Bearing in mind that the proposed overarching question to be answered during the interviews was “What are Radiation Protection communities being asked/expected to do?”, we have to take into account that two of the three interviewees are actually positioned to think from the perspective of a radiation protection community while obviously the person representing an environmental activism group is not. That interviewee made critical comments towards authorities but not directly towards (formal) radiation protection communities.

The ‘macro discourses that justify and/or prescribe stakeholder participation in Radiation Protection’ – being the main focus of ENGAGE WP1 – that are detectable in the interviews cover the traditional discourses, being empowerment of local citizens and the right to become involved in matters that (might) negatively affect them, but also better communication and knowledge generation on complex cases and trust building in the short and long term.

Regarding reasons to set up initiatives for stakeholder engagement, one understands, that in the context of EP&R, obviously distinction has to be made between stakeholder engagement in ‘normal’ situations anticipating potential incidents and accidents on the one hand and stakeholder engagement in post incident or accident situations on the other hand. In the latter case, the reason to set up stakeholder engagement is of course the incident or accident itself, and the cases most mentioned are the nuclear accidents of Chernobyl and Fukushima. From the responses it became clear that while in the Fukushima case also authorities and international organisations now see the need for stakeholder engagement (and especially the need to involve the affected local population), that was certainly not the case with the Chernobyl accident. In that case, as elaborated by the representative of the environmental activism group, it was primarily activist groups who assisted the local population in defending their integrity and rights towards the authorities and the international community. The fact that things have evolved in a positive way in the time between the two accidents is confirmed by the two interviewees representing formal RP communities: stakeholder engagement in post-accident conditions is now not only seen as a right of the potentially affected but also as a mean to better deal with the consequences of the accident in the short and longer term.

In terms of perception of the need for stakeholder engagement, we can say all three interviewees were convinced of that need. All three primarily recognize it as the right of stakeholders to become involved in matters that (might) negatively affect them. When it comes to capacity building, a difference can be noted between the rationales of the representatives of the two formal RP communities on the one hand and the representative of the environmental activism group on the other hand. While for the first, stakeholder engagement is more seen as an essential element of trustful, transparent and robust long-term EP&R policy making (including research policy), for the second the need for stakeholder engagement is more understood as capacity building ‘against’ authoritative power and possible manipulations of information.

For instance, the two RP community representatives emphasized the need ‘to develop arrangements’ for effective ‘response’ in both accident and incident situations and to develop ‘guidance’ by involving stakeholders such as decision makers, local citizens and NGOs, but also international trade organisations and private companies. It was said that stakeholder engagement is needed to find out whether specific EP&R approaches are ‘acceptable and implementable’. It was stressed that, from the perspective of safety requirements, ‘stakeholder involvement is really essential’. All need to be included, being it decision makers, regulators, NGOs, the private sector and the media. In other words: ‘all who have a role in emergency response or are affected by emergency response’. It was said that it

is crucial to make sure that EP&R systems meet the needs of the public and the society and that one cannot respond successfully if there is no dialogue with society during preparation. Specifically, for research, it was stressed that there is a need for a network that would ‘allow not only official organisations and authorities but also organisations at the local level to participate in topics of research’. Those organisations should include also farmers and agricultural organisations and ‘consumer and producers’ stakeholders’. It was said that, since the early phases of research on transition and recovery after a nuclear or radiological emergency, it was clear that this research cannot be done without direct participation of stakeholders.

On the other hand, from the perspective of the environmental activism organisation, stakeholder engagement in actual incident and accident situations is primarily understood as providing the affected local population with credible (reliable) information on what happened, including information on food measures and other constraints. For this, interaction is needed not only with the directly affected people around NPPs and other installations, but also with plant operators, regulators, (emergency) authorities and the media. It was said that, in order to ensure adequate emergency response and to limit the exposure of the population, one needs ‘constant and flexible communication between all parties’. The organisation sees its role also as a ‘watchdog’ and assistant of the affected population, as it engages in critical scrutiny of ‘official information’ on the incident or accident and in delivering (alternative) insights and expertise to the affected population in order for them to be able to better respond to the emergency situation. The statement was made that EP&R ‘could be a lot worse’ if there would be no stakeholder engagement. The reason given was that ‘in spite of all possible preparation, the reality of a nuclear emergency is so complex that the expectations of what authorities can do are simply too high’.

With respect to the level of engagement and forms of engagement, also here a distinction needs to be made between the RP community perspective on the one hand and the environmental activism perspective on the other hand. For the first, in the interest of capacity building in policy and better knowledge generation, it is important to invite stakeholders from the private sector, civil society, authorities and the media to participate in long term formal processes of dialogue and knowledge generation (working groups, partnerships, ...). Specifically, in the context of research, one saw the emergence of ‘inclusive platforms’, ‘participatory frameworks’ and ‘strategic research agendas’ co-produced with stakeholders as essential forms of engagement. From the second perspective, emphasis was made that forms of engagement should be two-way (not only informing but also consulting the local population). The critique was made that EP&R policy processes are too often confined in a political context (a ‘bubble’) with insufficient involvement of the (potentially) directly affected, and this while precisely those potentially affected can provide essential insights for just and effective EP&R policies.

When it comes to legal requirements for stakeholder engagement, it was recognized that stakeholder involvement is not directly addressed in the BSS Directive. In other international safety requirements, such as the IAEA General Safety Requirements on EP&R, stakeholder involvement is really a topic with a special focus on the general public. The representative of the environmental activism group suggested that the legal basis for stakeholder engagement in existing EU and national legislation is still not strong enough, especially taking into account the requirements related to access to information, the right to participation and access to justice as formulated in the Aarhus convention. It was stressed that NGOs play a crucial role in enforcing authorities to translate these recommendations into concrete EU and national law. Also, in the Fukushima post-accident recovery phase, the local population could benefit from a stronger legal basis that would protect their rights and needs, more precisely with regard to evacuation and compensation measures.



Regarding the challenges for setting up stakeholder engagement, from the responses, the traditional challenges can be identified: dealing with limited resources, robustness and sustainability of the engagement process, trust building, effectiveness (leading to concrete results satisfactory for all parties), communication challenges (trustfulness of the source of information, language, level of complexity, level of detail, ...). In research context, also the need for objective evaluation criteria (for instance for the evaluation of the processes in different countries) was emphasized.

In conclusion, as a side remark, the analysis shows that the interviews contain much more information that falls outside of the focus of the prepared questions. Given their richness in detail while being concise in form and length, and also given the fact that the information and insights provided by the interviewees does not contain confidential information, it should be considered whether the interviews cannot be published as additional sources of information in the ENGAGE project as such.

### 6.3 Indoor radon

Four interviews were conducted with representatives of relevant organisations working on radiation protection in the field of indoor radon; ERA, ICRP, IAEA and BAG Switzerland. Three of the studied organisations have a primary locus at the international level, while BAG Switzerland is a national organisation. 3 interviews were conducted in English, and one in German. Except for one interview, which was delivered through email, all interviews were conducted in person or with the help of Skype/telephone. The interviews lasted between 35 and 70 minutes. After being transcribed, they were analyzed with the help of NVivo12 software.

An important specificity of radon, is that the risk of exposure is linked to the fact that radon can be trapped indoor, thus offering many sites in which exposure can take place, as radon is a natural substance to be found in abundant locations. This implicates that a lot of stakeholders can be identified when protection from radon exposure is at issue. In terms of stakeholder definition, our respondents identified the following stakeholders; governments, authorities (e.g. on building and construction, workplace safety, health, education), building professionals, companies, health and education professionals, measurement and calibration institutions, international organisations (e.g. WHO, IAEA, UNSCEAR), experts, researchers and universities, building and source managers (e.g. home-owners, owners of offices, mines or other workplaces), and the general public in the form of residents or employees. As one of the respondents put it; "the stakeholders [...] could be any type of people who have some relationship with the situation". In this light, another respondent referred to the relevance of responsibility, stating that those people and parties, which have a responsibility, should be brought to the table.

Although a broad plethora of stakeholders was identified, the studied organisations do not engage with all of them in a direct way, given the (inter)national level at which they operate. This was made explicit by some respondents, as for example one interviewee stated how "[the organisation's] primary interlocutors are government representatives", while the general public is not. Regarding the stakeholder definitions used by the studied organisations, three respondents stated that they followed established stakeholder definitions in their demarcation of the field; one referred to ICRP's interpretation of stakeholders (publication 101, part 2), another mentioned the list of 'interested parties' as provided through GSR part 3 and the SSG-32 guidelines, while the third respondent specified to adhere to WHO's stakeholder definition as provided in the 2009 Radon Handbook. The fourth respondent did not refer to a definition but a requirement: parties working in an area with interfaces to radon (measurement, education and training, building, energy saving, policy), who can contribute to improving radon protection and who can contribute to better mitigation, have to be regarded as stakeholders.

Three respondents from international organisations connected stakeholder engagement to the objective of raising awareness. Overall, stakeholder engagement is perceived as a way to reach the general objective of reducing the exposure to radon (through prevention and/or mitigation). As some of the aforementioned stakeholders (certainly the general public in the form of house-owners, residents and employees, but also for example building professionals) are perceived as generally unaware about radon, they have to be informed in order to reduce exposure. Engaging stakeholders in the form of awareness raising (e.g. through training, websites, events) is a way to achieve this overall objective. Another –related- objective of stakeholder engagement mentioned by our respondents is the creation of involvement of different stakeholders who have to take up a role in the reduction of radon exposure. In this sense, stakeholder engagement helps to build mutual trust, and to set up a dialogue and knowledge exchange among stakeholders. A respondent also mentioned how stakeholder engagement is motivated by the process of designing new regulations; in order to ensure the best possible regulations, which are implementable into practice, and which are accepted by the relevant parties.

Respondents also referred to legal and regulatory frameworks that impact upon stakeholder engagement in the field of radon protection. The BSS directives are mentioned by all respondents in this context. Also ICRP documents and safety guide SSG-32 are mentioned by some as setting a regulatory framework for stakeholder engagement. Two respondents stated that legislation on radon protection offers a foundation for stakeholder engagement at the level of nation states, and also remark that some stakeholders –i.e. the building industry- will only engage themselves in the issue of radon protection if there are legal requirements which bind them to provide this protection. Another refer interviewee noted how the BSS directive “establishes the responsibility of the national governments and authorities to engage with interested parties for decision making on several aspects of radiation protection and safety”. However, side notes are made as well, as this same respondent continued; “but a good engagement process is dependent to a large extent on the understanding of the usefulness of the process by the relevant decision makers”. A third interviewee argued that a legal framework on stakeholder engagement offers no guarantee that actual involvement will take place.

When turning to the organisation of stakeholder engagement, two respondents mentioned the use of tools such as the sharing of success stories and good practices, or challenges and solutions, while the other respondents stated not to use a particular established model of stakeholder engagement. However, all mentioned several challenges and/or factors for success when organizing stakeholder engagement. A first challenge, already alluded to above, is a lack of awareness on radon among different stakeholders, which needs to be tackled in order to empower these stakeholders, and to get them involved. This also relates to a second challenge, namely the complexity of radon. While measures of radon concentrations might be rather straightforward, measuring radon doses is not –e.g. the (recently adapted) conversion factors. Moreover, some situations of radon exposure are complex to tackle. This complexity might arise when controversy exists, when those responsible to tackle the issue are difficult to identify, or when multiple sources might be at play. The use of facilitators in the stakeholder engagement process might offer a solution in such complex situations according to one respondent. Another respondent also reported the success of such facilitators (namely competence centres or “radon delegates”), which themselves have specific tasks in education and training on diverse levels. Finally, also perceived financial or time investments related to radon protection might pose challenges to get stakeholders involved. Related to this point, the involvement of some actors (e.g. in the building sector) requires legal or monetary incentives. Monetary incentives are particularly challenging, as they raise questions on the amount of financial benefits to be attributed, and to whom they should be attributed – and to whom not.

A first factor which contributes to the success of stakeholder engagement in reducing radon exposure, is the involvement of a range of different stakeholders. As one respondent put it: “whatever the strategies or regulations, if you don’t have a way, a process to involve different types of people, you cannot be successful.” For this reason, stakeholders should understand the usefulness of their involvement (related again to the issue of stakeholder awareness). Another respondent in this light stressed the importance of putting stakeholders on the same level in the engagement process, by acknowledging that every stakeholder brings relevant expertise and knowledge to the table. Related to the specific issue of radon, this same respondent made a plea for comprehensibility towards all stakeholders; stakeholders need simple and understandable ways to manage radon, in order to be engaged. A way to achieve comprehensibility, and to involve stakeholders who are otherwise potentially unaware or unwilling to participate, is -according to this interviewee- the framing of indoor radon in the broader issue of indoor air quality, “because the improvement of indoor quality of your air is today a global concern, and many bodies are engaged in this way”. Another respondent mentioned the importance of a database showing detailed measurement data on the level of smaller governmental units. This respondent also expressed that the interests and goals of each stakeholder should be taken into account: Every stakeholder has its role and responsibility, and can only contribute when those are considered on the respective level. Moreover, continuity in engaging and in exchanging to share scientific knowledge, recommendations and their own experiences is an important success factor for stakeholder engagement. In this light of continuity, this interviewee advocates that Radon Information days should be offered at least yearly.

In terms of evolutions and future prospects, one respondent noted how at the organisational level, an evolution has taken place, in a sense that the number of identified stakeholders has broadened over the years, as for example also building authorities are embarked in the process of reducing radon exposure. In another case, however, stakeholders who were involved in radon measurements in earlier years, were no longer directly engaged with in terms of radon protection strategy; while in this particular country during the 1990’s citizens were invited to provide radon measures in order to establish a detailed database, this specific motive for involvement vanished when the database was complete. Another respondent stressed how stakeholder engagement has over the past decades grown in importance in the field of radon protection. Whereas in previous times, emphasis was put on gaining insight into the issue of radon, learning which factors impact upon indoor radon, and how it can be controlled, emphasis is now put on stakeholder engagement, as the realization has grown that “we need to inform stakeholders about the problem”. The interviewee perceives the 1996 BSS Directive as a triggering event for this evolution. This perception of a growing presence of stakeholder engagement over the past decades is shared by a third respondent. This interviewee also stated that stakeholder engagement would be easier taken into account today than 20 years ago. A fourth interviewee did not speak about past evolutions, but rather about future hopes. Nowadays, this respondent perceived an emphasis on regulation in the field of indoor radon protection, while prominence should be given to engaging stakeholders. Interestingly, this interviewee also referred to the BSS Directive in this context, however not as a trigger for stakeholder engagement, but rather as an example of an overtly regulative approach. In terms of future prospects, one interviewee also stressed that there is still a lot to do, as radon is often perceived as a program that has to compete with other (e.g. health or energy) programs, instead of being complementary to them. Finally, this respondent highlights how a step forward can be taken through evaluating the national radon strategy, and thus also the interactions with and engagement of stakeholders. This evaluation process in itself would thus require the engagement of different stakeholders.

## 7. Conclusions

This report presents the findings of the analysis within the Work Package 1 “Rationales and frameworks for stakeholder engagement in radiation protection”. It deals with three fields of investigation: medical applications, EP&R and indoor radon. It follows the adopted methodology and includes analysis of stakeholder engagement in relation to mentioned exposure situations in three field. The material for analysis comprises by:

- the relevant legally binding instruments for areas of interest, like directives of European Union and related international conventions, also adopted as EU directives, which provides the requirements for investigated fields (medicine, emergency preparedness and recovery, indoor radon) in the relation of stakeholder engagements;
- the adopted national requirements for stakeholder engagement in three radiation fields (medical, emergency preparedness and response and indoor radon exposure) as referred in national legislation of ENGAGE partners or other adopted documents linked with legal framework (e.g. EP&R plans, action plans, ...);
- the reports, documents, recommendations and guidelines of different EU institutions, international organisations and associations to obtain the frame under which the stakeholder engagement is viewed and proposed to be implemented; and
- results of interviews with representatives of international organisations in all three different field of interest following the discussion topics as in adopted methodology.

In general, the results of analysis show that the legal requirements for stakeholder engagement are mainly basic and instrumental to secure an end point with some evidences to be also normative (e.g. “it is the right thing to do”, it responds to a certain principle). The directives and also conventions which were adopted as directives, set basic requirements for stakeholder engagement. They refer mainly to provision of information to stakeholders, although some specific cases they stipulate participation in decision making or foresee further consultation and communication with stakeholders. National legislations reflect mostly the requirements from European directives and thus, again provide the basic frame for stakeholder engagement. There are some examples of broadening stakeholder engagement, especially in those national legal frameworks adopted recently. Proactive engagement and involvement of stakeholders are more and more suggested by different international institutions, organisations and associations. It can be seen that expected level of stakeholder engagement increases from legally binding documents, to recommendations from international organisations and further to positions of Civil Society Organisations (CSOs) as given in Figure 4.

Stakeholders are defined and addressed differently in different documents; most of these also include the members of the public who are concerned or affected.

Other documents, which are not part of the legal framework, such as recommendations and guidelines of international organisations or associations, reflect a broader view on stakeholder engagement, not only in terms of interpretation of the concepts of “stakeholder” and “involvement” or “engagement”, but also the motivations or aspirations underlying the calls for participation. Such documents also support enhanced interactions with different groups of stakeholders in activities relating to ionising radiation.

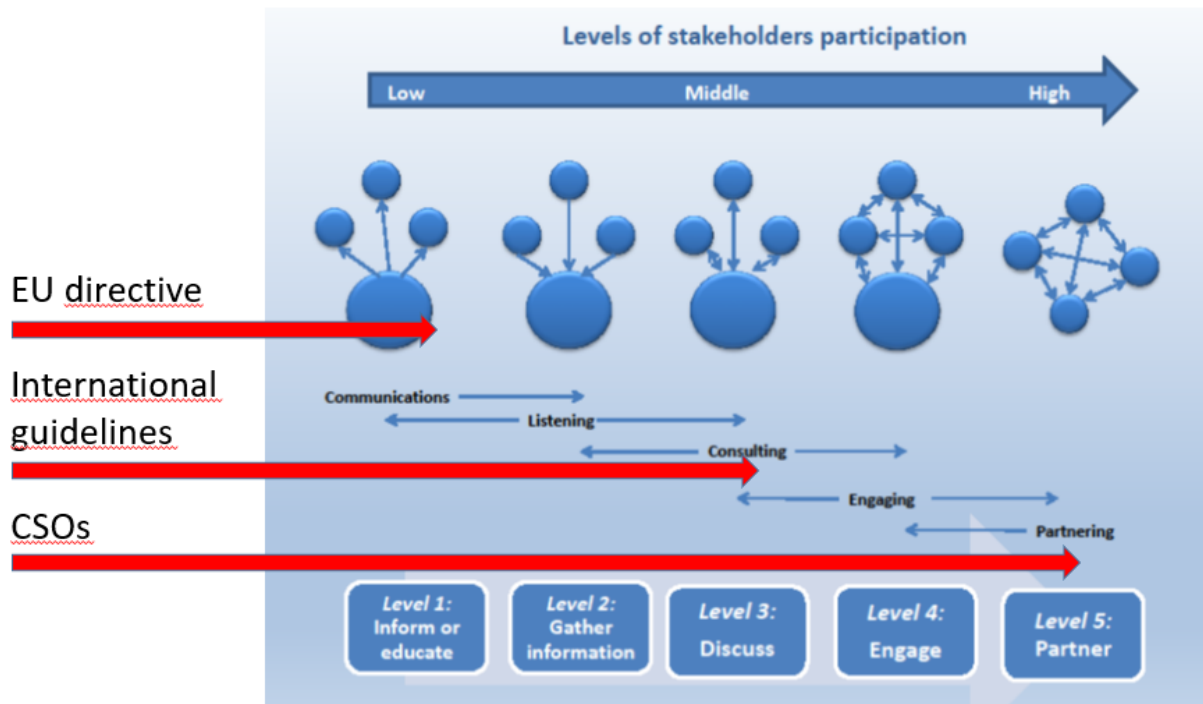


Figure 4: Levels of stakeholders' participation in different material

In the medical field, an increasing attention to stakeholder engagement can be noticed; this is substantiated in the recent call for actions, in developing guidelines and a view towards a more inclusive approach in radiation protection, to contribute to provide the best possible care and safety for patients and professionals. Examples of very productive initiatives emerged, in practice, in the IAEA-WHO, and in the HERCA actions with involvement of different stakeholders motivated by self-commitment and cooperation. Reference is made frequently to professional organisations as key stakeholders and to international organisations, even if patients and patient organisations are also perceived as key stakeholders. The involvement of stakeholders in the optimization process introducing the needed adaptability in the management of radiological risk to achieve more effective and sustainable decisions, could be of great interest in the medical exposure, as indicated by ICRP. This is relevant for instance for procedures where occupational exposure could be related to patient exposure, and other individuals such as parents, family members and friends could also be exposed.

For the EP&R, the requirements for stakeholder engagement are mainly basic, i.e. provision of information from responsible authorities to the public likely to be affected or affected public in case of radiological emergency. Lately, with the revised BSS directive and its obligatory transposition, the required information is also prescribed. The national legal systems define the requirements for communication and participation in similar way, and only some countries propose higher levels of citizen involvement. Involvement is generally seen to be mainly limited to the responsible authorities and the emergency response actors. An exception is the case of long-lasting residual contamination, where wider consultation is foreseen (e.g. with the public) for re-establishing living conditions that can be considered as normal. The international guidelines, recommendations and the views of representatives from these organisations broaden this framework and perceive the need for wider engagement, including citizens, as vital. Many different positive aspects of a more active involvement and participation of citizens, especially potentially affected public, are revealed and could become a new normality.

For radon, stakeholder engagement plays a role at the level of international organisations such as WHO and ICRP already since a couple of years. This understanding of a rather active role of stakeholder engagement found its way to the national level only partially. Here, the level of stakeholder engagement is mostly limited to provision of information. Only hesitantly the aspiration of real engagement and exchange spreads further. For example, the activities in Belgium are a promising approach in that direction. Though, it can also be observed that with the national radon action plans, a further step is taken towards a more reflected approach to information, exchange and participation.

In the second deliverable within WP1 the focus will be on transversal issues in the field and cross the fields, and specifics of different exposure situations in relation to stakeholder engagement. In that report also additional analyses of the collected data will be given.

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## 9. Annexes

### 9.1. Annex 1: Template for Reporting on Analysis for Tasks 1.1, 1.2 and 1.3

It is expected that each review will discuss the questions outlined in the methodology document Milestone 1.1 in the format proposed below.

Document analysis of all publicly available material related to legal requirements and international recommendations for stakeholder engagement in radiation protection.

#### **The title of the document**

Provide the title of the document for the analyses and which level of references it does provide: EC, national (legislation, guides), international associations and standards, other.

#### **Key Words**

Indicate which keywords were used to identify the relevant sections of the documents. These keywords include 'stakeholder', 'interested parties', 'concerned parties', 'engagement', 'involvement', 'participation' or others. Please justify the choice for the keywords.

#### **Definitions and requirements**

Extract from the document a definition of 'stakeholder' and/or 'stakeholder engagement' when provided. Please indicate the page numbers from which the definition is extracted.

Please provide the type of stakeholder that is mentioned in each document and the page number on which this description can be found.

#### **Aspirations**

Please provide a description of the trends, contradictions and/or divergences that can be found in the document (when possible).

#### **Motivations**

Please provide a description of the instrumental, normative and/or substantive (or others) motivation for stakeholder engagement (when possible).

#### **Level of stakeholder engagement**

Please provide a description of models of stakeholder engagement mentioned in the documents and/or the level of stakeholder engagement mentioned. The latter includes any description of methodologies described for stakeholder engagement (e.g. Arnstein's ladder, etc).

#### **Any other observation that may be relevant to the study**

#### **Extract from document**

## 9.2. Annex 2: Extracts from directives and conventions

### 9.2.1. Related extracts from BSS directive

#### **Preamble**

(7) *The provisions of this Directive should follow the situation-based approach introduced by ICRP Publication 103 and distinguish between **existing, planned and emergency exposure situations**. Taking into account this new framework, this Directive should cover all exposure situations and all categories of exposure, namely **occupational, public and medical exposures**.*

#### **Article 1 Subject matter**

*This Directive establishes uniform basic safety standards for the protection of the health of individuals subject to occupational, medical and **public exposures against the dangers arising from ionising radiation**.*

#### **Article 2 Scope**

*1. 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.*

#### **Article 4 Definitions**

- *"**clinical responsibility**" means responsibility of a practitioner for individual medical exposures, in particular, justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;*
- *"**carers and comforters**" means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure;*
- *"**members of the public**" means individuals who may be subject to public exposure;*
- *"**public exposure**" means exposure of individuals, **excluding any occupational or medical exposure**;*
- *"**medical exposure**" means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research;*
- *"**representative person**" means an individual receiving a dose that is representative of the more highly exposed individuals in the population, excluding those individuals having extreme or rare habits;*
- *"**emergency exposure situation**" means a situation of exposure due to an emergency;*
- *"**existing exposure situation**" means an exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken;*
- *"**planned exposure situation**" means an exposure situation that arises from the planned operation of a radiation source or from a human activity which alters exposure pathways, so as to cause the exposure or potential exposure of people or the environment. Planned exposure situations may include both normal exposures and potential exposures;*

- **"practitioner"** means a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements;

#### **Article 55 Justification**

1. Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

#### **Article 56 Optimisation**

1. Member States shall ensure that all doses due to medical exposure for radio diagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors.

For all medical exposure of patients for radiotherapeutic purposes, exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radio diagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and where appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

3. Member States shall ensure that for each medical or biomedical research project involving medical exposure:

(a) the individuals concerned participate voluntarily;

(b) these individuals are informed about the risks of exposure;

(c) a dose constraint is established for individuals for whom no direct medical benefit is expected from exposure;

(d) in the case of patients who voluntarily accept to undergo an experimental medical practice and who are expected to receive a diagnostic or therapeutic benefit from this practice, the dose levels concerned shall be considered on an individual basis by the practitioner and/or referrer prior to the exposure taking place.

4. Member States shall ensure that the optimisation includes the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical radiological procedures, quality assurance, and the assessment and evaluation of patient doses or the verification of administered activities, taking into account economic and societal factors.

5. Member States shall ensure that:

(a) dose constraints are established for the exposure of carers and comforters, where appropriate;

(b) appropriate guidance is established for the exposure of carers and comforters.

6. Member States shall ensure that in the case of a patient undergoing treatment or diagnosis with radionuclides, the practitioner or the undertaking, as specified by Member States, provides the patient or their representative with information on the risks of ionising radiation and appropriate instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable. For therapeutic procedures these shall be written instructions.

These instructions shall be handed out before leaving the hospital or clinic or a similar institution.

#### **Article 66 Estimation of doses to the members of the public**

1. Member States shall ensure that arrangements are made for the **estimation of doses to members of the public from authorised practices**. The extent of such arrangements shall be proportionate to the exposure risk involved.

2. Member States shall ensure the identification of practices for which an **assessment of doses to members of the public** shall be carried out. Member States shall specify those practices for which this assessment needs to be carried out in a realistic way and those for which a screening assessment is sufficient.

3. For the realistic assessment of doses to the members of the public, the competent authority shall:

d) require records to be kept and be made **available on request to all stakeholders** relating to measurements of external exposure and contamination, estimates of intakes of radionuclides, and the results of the assessment of the doses received by the representative person.

#### **Article 70 Information to the members of the public likely to be affected in the event of an emergency**

1. Member States shall ensure **that the members of the public** likely to be affected in the event of an emergency **are given information** about the health protection measures applicable to them and about the action they should take in the event of such an emergency.

2. The information supplied shall include at least the elements set out in Section A of Annex XII.

3. **The information shall be communicated to the members of the public referred to in paragraph 1 without any request being made.**

4. Member States shall ensure that **the information is updated and distributed** at regular intervals and whenever significant changes take place. This information shall be **permanently available to the public**.

#### **Article 71 Information to the members of the public actually affected in the event of an emergency**

1. Member States shall ensure that, when an emergency occurs, **the members of the public actually affected are informed without delay about the facts of the emergency, the steps to be taken and, as appropriate, the health protection measures** applicable to these members of the public.

2. The information provided shall cover those points listed in Section B of Annex XII which are relevant to the type of emergency.

#### **Article 73 Contaminated areas**

1. Member States shall ensure that optimised protection strategies for managing contaminated areas shall include, where applicable, the following:

(a) objectives, including long-term goals pursued by the strategy and corresponding reference levels, in accordance with Article 7;

- (b) delineation of the affected areas and identification of the affected members of the public;*
- (c) consideration of the need for and extent of protective measures to be applied to the affected areas and members of the public;*
- (d) consideration of the need to prevent or control access to the affected areas, or to impose restrictions on living conditions in these areas;*
- (e) assessment of the exposure of different groups in the population and assessment of the means available to individuals for controlling their own exposure.*

*For areas with long-lasting residual contamination in which the Member State has decided to allow habitation and the resumption of social and economic activities, Member States shall ensure, **in consultation with stakeholders**, that arrangements are in place, as necessary, for the ongoing control of exposure with the aim of establishing living conditions that can be considered as normal, including:*

- (a) establishment of appropriate reference levels;*
- (b) establishment of an infrastructure to support continuing self-help protective measures in the affected areas, such as information provision, advice and monitoring;*
- (c) if appropriate, remediation measures;*
- (d) if appropriate, delineated areas.*

#### **Article 74 Indoor exposure to radon**

- 1. Member States shall establish national reference levels for indoor radon concentrations. The reference levels for the annual average activity concentration in air shall not be higher than 300 Bq/m<sup>3</sup>.*
- 2. Under the national action plan referred to in Article 103, Member States shall promote action to identify dwellings, with radon concentrations (as an annual average) exceeding the reference level and encourage, where appropriate by technical or other means, radon concentration-reducing measures in these dwellings.*
- 3. Member States **shall ensure that local and national information is made available on indoor radon exposure and the associated health risks**, on the importance of performing radon measurements and on the technical means available for reducing existing radon concentrations.*

#### **Article 77 Transparency**

*Member States shall ensure **that information in relation to the justification of classes or types of practices, the regulation of radiation sources and of radiation protection is made available** to undertakings, workers, **members of the public, as well as patients and other individuals subject to medical exposure**. This obligation includes ensuring that the competent authority provides information within its fields of competence. Information shall be made available in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.*

#### **Article 98 Emergency preparedness**

- 1. Member States shall ensure that emergency response plans are established in advance for the various types of emergencies identified by an assessment of potential emergency exposure situations.*
- 2. The emergency response plans shall include the elements defined in Section B of Annex XI.*

3. The emergency response plans shall also include provision for the transition from an emergency exposure situation to an existing exposure situation.

4. Member States shall ensure that emergency response plans are tested, reviewed and, as appropriate, revised at regular intervals, taking into account lessons learned from past emergency exposure situations and taking into account the **results of the participation in emergency exercises at national and international level.**

#### **Article 99 International cooperation**

1. Member States shall cooperate with other Member States and with third countries in addressing possible emergencies on its territory which may affect other Member States or third countries, in order to facilitate the organisation of radiological protection in those Member States or third countries.

2. Each Member State **shall, in the event of an emergency** occurring on its territory or likely to have radiological consequences on its territory, **promptly establish contact** with all other Member States and with third countries which may be involved or are likely to be affected **with a view** to sharing the assessment of the exposure situation and **coordinating protective measures and public information by using**, as appropriate, bilateral or international information exchange and coordination systems. These coordination activities shall not prevent or delay any necessary actions to be taken on a national level.

#### **Article 102 Implementation of strategies**

1. Member States shall assign responsibilities for the implementation of strategies for the management of existing exposure situations and ensure appropriate coordination between relevant parties involved in the implementation of remedial and protective measures. Member States shall **provide as appropriate for the involvement of stakeholders in decisions regarding the development and implementation of strategies for managing exposure situations.**

#### **Article 104 Inspections**

(4) Member States shall ensure that **outlines of the inspection programmes and the main findings** from their implementation **are available to the public.**

**ANNEX XI Emergency management systems and emergency response plans** as referred to in Articles 69, 97 and 98

- A. Elements to be included in an emergency management system
  - 8. Public information arrangements;
  - 9. Involvement of stakeholders;

**ANNEX XII Information to members of the public about health protection measures to be applied and steps to be taken in the event of an emergency** as referred to in Articles 70 and 71

#### **A. Prior information to the members of the public likely to be affected by an emergency**

- 1. Basic facts about radioactivity and its effects on human beings and on the environment;
- 2. The various types of emergency covered and their consequences for the public and the environment;
- 3. Emergency measures envisaged to alert, protect and assist the public in the event of an emergency;

4. *Appropriate information on action to be taken by the public in the event of an emergency.*

**B. Information to be provided to the affected members of the public in the event of an emergency**

1. *On the basis of the emergency response plan previously drawn up in the Member States, the members of the public actually affected in the event of an emergency shall rapidly and regularly receive:*

(a) *information on the type of emergency which has occurred and, where possible, its characteristics (e.g. its origin, extent and probable development);*

(b) *advice on protection, which, depending on the type of emergency, may:*

(i) *cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements;*

(ii) *be accompanied, where necessary, by special warnings for certain groups of the members of the public;*

(c) *announcements recommending cooperation with instructions or requests by the competent authority.*

2. *If the emergency is preceded by a pre-alarm phase, the members of the public likely to be affected shall already receive information and advice during that phase, such as:*

(a) *an invitation to the members of the public concerned to tune in to relevant communication channels;*

(b) *preparatory advice to establishments with particular collective responsibilities;*

(c) *recommendations to occupational groups particularly affected.*

3. *This information and advice shall be supplemented, if time permits, by a reminder of the basic facts about radioactivity and its effects on human beings and on the environment.*

**ANNEX XVIII List of items to be considered in preparing the national action plan to address long-term risks from radon exposures as referred to in Articles 54, 74 and 103**

(1) *Strategy for conducting surveys of indoor radon concentrations or soil gas concentrations for the purpose of estimating the distribution of indoor radon concentrations, for the management of measurement data and for the establishment of other relevant parameters (such as soil and rock types, permeability and radium-226 content of rock or soil).*

(2) *Approach, data and criteria used for the delineation of areas or for the definition of other parameters that can be used as specific indicators of situations with potentially high exposure to radon.*

(3) *Identification of types of workplaces and buildings with public access, such as schools, underground workplaces, and those in certain areas, where measurements are required, on the basis of a risk assessment, considering for instance occupancy hours.*

(4) *The basis for the establishment of reference levels for dwellings and workplaces. If applicable, the basis for the establishment of different reference levels for different uses of buildings (dwellings, buildings with public access, workplaces) as well as for existing and for new buildings.*



- (5) *Assignment of responsibilities (governmental and non-governmental), coordination mechanisms and available resources for implementation of the action plan.*
- (6) *Strategy for reducing radon exposure in dwellings and for giving priority to addressing the situations identified under point 2.*
- (7) *Strategies for facilitating post construction remedial action.*
- (8) *Strategy, including methods and tools, for preventing radon ingress in new buildings, including identification of building materials with significant radon exhalation.*
- (9) *Schedules for reviews of the action plan.*
- (10) Strategy for communication to increase public awareness and inform local decision makers, employers and employees of the risks of radon, including in relation to smoking.**
- (11) *Guidance on methods and tools for measurements and remedial measures. Criteria for the accreditation of measurement and remediation services shall also be considered.*
- (12) *Where appropriate, provision of financial support for radon surveys and for remedial measures, in particular for private dwellings with very high radon concentrations.*
- (13) *Long-term goals in terms of reducing lung cancer risk attributable to radon exposure (for smokers and non- smokers).*
- (14) *Where appropriate, consideration of other related issues and corresponding programmes such as programmes on energy saving and indoor air quality.*

### 9.2.2. Related extracts from Nuclear Safety directive

#### **Article 1 Objectives**

*The objectives of this Directive are:*

- (a) *to establish a Community framework in order to maintain and promote the continuous improvement of nuclear safety and its regulation;*
- (b) *to ensure that **Member States shall provide for appropriate national arrangements for a high level of nuclear safety to protect workers and the general public against the dangers arising from ionising radiations from nuclear installations.***

#### **Article 3 Definitions**

*For the purposes of this Directive the following definitions shall apply:*

1. **'nuclear installation'** means:

- (a) *a nuclear power plant, enrichment plant, nuclear fuel fabrication plant, reprocessing plant, research reactor facility, spent fuel storage facility; and*
- (b) *storage facilities for radioactive waste that are on the same site and are directly related to nuclear installations listed under point (a);*

2. **'nuclear safety'** means the **achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers and the general public from dangers arising from ionising radiations from nuclear installations;**

### **Article 5 Competent regulatory authority**

2. Member States shall ensure the effective independence from undue influence of the competent regulatory authority in its regulatory decision-making. For this purpose, Member States shall ensure that the national framework requires that the **competent regulatory authority**:

*(f) provides nuclear safety-related information without clearance from any other body or organisation, provided that this does not jeopardise other overriding interests, such as security, recognised in relevant legislation or international instruments.*

### **Article 8 Transparency**

1. Member States shall ensure that necessary information in relation to the nuclear safety of nuclear installations and its regulation is made available to workers and the general public, with specific consideration to local authorities, population and stakeholders in the vicinity of a nuclear installation. That obligation includes ensuring that the **competent regulatory authority and the licence holders**, within their fields of responsibility, **provide in the framework of their communication policy**:

*(a) information on normal operating conditions of nuclear installations to workers and the general public; and*

*(b) prompt information in case of incidents and accidents to workers and the general public and to the competent regulatory authorities of other Member States in the vicinity of a nuclear installation.*

2. **Information shall be made available to the public in accordance with relevant legislation and international instruments**, provided that this does not jeopardise other overriding interests, such as security, which are recognised in relevant legislation or international instruments.

3. Member States shall, without prejudice to Article 5(2), **ensure that the competent regulatory authority engages, as appropriate, in cooperation activities on the nuclear safety of nuclear installations with competent regulatory authorities of other Member States in the vicinity of a nuclear installation, inter alia, via the exchange and/or sharing of information.**

4. Member States shall ensure that **the general public is given the appropriate opportunities to participate effectively in the decision-making process relating to the licensing of nuclear installations**, in accordance with relevant legislation and international instruments.

### **Article 8e Peer reviews**

1. Member States shall, at least once every 10 years, arrange for periodic self-assessments of their national framework and competent regulatory authorities and invite an international peer review of relevant segments of their national framework and competent regulatory authorities with the aim of continuously improving nuclear safety. Outcomes of such peer reviews shall be reported to the Member States and the Commission, when available.

2. Member States shall ensure that, on a coordinated basis:

*(a) a national assessment is performed, based on a specific topic related to nuclear safety of the relevant nuclear installations on their territory;*

*(b) all other Member States, and the Commission as observer, are invited to peer review the national assessment referred to in point (a);*

(c) appropriate follow-up measures are taken of relevant findings resulting from the peer review process;

(d) relevant **reports are published on the above mentioned process and its main outcome when results are available.**

4. In case of an accident leading to situations that would require off- site emergency measures or protective measures for the general public, the Member State concerned shall ensure that an international peer review is invited without undue delay.

### **Article 9 Reporting**

1. Member States shall submit a report to the Commission on the implementation of this Directive for the first time by 22 July 2014, and then by 22 July 2020.

2. On the basis of the Member States' reports, the **Commission shall submit a report to the Council and the European Parliament on progress made with the implementation of this Directive.**

### 9.2.3. Related extracts from Drinking Water directive

#### **Preamble**

*The **general public should be adequately and appropriately informed** of the quality of water intended for human consumption.*

#### **Article 1 Subject matter**

*This Directive lays down **requirements** for the protection of the health of the **general public with regard to radioactive substances in water intended for human consumption**. It lays down parametric values and frequencies and methods for monitoring radioactive substances.*

#### **Article 2 Definitions**

(1) 'water intended for human consumption' means:

(a) all water, either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, a tanker, or in bottles or containers;

(b) all water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form;

#### **Article 3 Scope and exemptions**

**3. Member States may exempt from this Directive:**

(b) water intended for human consumption from an individual supply providing on average less than 10 m<sup>3</sup> a day, or serving fewer than 50 persons, unless the water is supplied as part of a commercial or public activity.

4. Member States that have recourse to the exemptions provided for in paragraph 3(b) **shall ensure that:**

(a) the **general public concerned is informed thereof and of any action that can be taken to protect human health** from the adverse effects resulting from any contamination of water intended for human consumption;

(b) **when a potential danger to human health arising from the quality of such water is apparent, the general public concerned promptly be given appropriate advice.**

#### **Article 7 Remedial action and notification of the general public**

1. Member States shall ensure that any failure to comply with a parametric value laid down pursuant to Article 5(1) is immediately investigated in order to identify the cause.

2. Where a failure to comply with a parametric value occurs, the Member State shall assess whether the failure poses a risk to human health which requires action.

3. In the **event that such a risk** referred to under paragraph 2 exists, the Member State shall:

(a) take remedial action in order to comply with requirements for the protection of human health from a radiation protection point of view; and

(b) **ensure that the general public concerned is:**

(i) **notified of the risk and the remedial action taken; and**

(ii) **advised on any additional precautionary measures that may be needed for the protection of human health in respect of radioactive substances.**

### 9.2.4. Related extracts from Information in radiological emergency directive

#### **Article 1 Objective**

This Directive is intended to define, at Community level, common objectives with regard **to measures and procedures for informing the general public for the purpose of improving the operational health protection provided in the event of a radiological emergency.**

#### **Article 4 Definition**

For the purposes of this Directive the following terms shall have the meanings hereby assigned:

(a) **population likely to be affected** in the event of a radiological emergency: any population group for which Member States have drawn up intervention plans in the event of a radiological emergency;

(b) **population actually affected in the event** of a radiological emergency: any population group for which specific protection measures are taken as soon as a radiological emergency occurs.

#### **Article 5 Prior information**

1. Member States shall ensure that **the population likely to be affected** in the event of a radiological emergency **is given information about the health-protection measures applicable to it and about the action it should take in the event of such an emergency.**

2. The information supplied shall at least include the elements set out in Annex I.

3. This information **shall be communicated to the population** referred to in paragraph 1 without any request being made.

4. Member **States shall update the information** and circulate it at regular intervals and whenever significant changes in the arrangements that it describes take place. This information shall be permanently available to the public.

#### **Article 6 Information in the event of a radiological emergency**

1. Member States shall ensure that, when a radiological emergency occurs, the **population actually affected is informed without delay of the facts of the emergency, of the steps to be taken and, as appropriate to the case in point, of the health-protection measures applicable** to it.

2. The **information provided shall cover the points contained in Annex II** which are relevant to the type of radiological emergency.

#### **Article 7 Information of persons who might be involved in the organisation of emergency assistance in the event of a radiological emergency**

1. Member States **shall ensure that any persons** who are not on the staff of the facilities and/or not engaged in the activities defined in Article 2(2) but **who might be involved in the organisation of emergency assistance** in the event of a radiological emergency **are given adequate and regularly updated information on the health their intervention might involve and on the precautionary measures to be taken in such an event**; this information shall take into account the range of potential radiological emergencies.

2. As soon as a radiological emergency occurs, this information shall be supplemented appropriately, having regard to the specific circumstances.

#### **Article 8 Implementation procedures**

The information referred to in Articles 5, 6 and 7 shall also **mention the authorities responsible** for implementing the measures referred to in those Articles.

#### **ANNEX I Prior information referred to in Article 5**

1. Basic facts about radioactivity and its effects on human beings and on the environment.
2. The various types of radiological emergency covered and their consequences for the general public and the environment.
3. Emergency measures envisaged to alert, protect and assist the general public in the event of a radiological emergency.
4. Appropriate information on action to be taken by the general public in the event of a radiological emergency.

#### **ANNEX II Information in the event of a radiological emergency referred to in Article 6**

1. On the basis of the intervention plans previously drawn up in the Member States, the population actually affected in the event of a radiological emergency will rapidly and regularly receive:

(a) information on the type of emergency which has occurred and, where possible, its characteristics (e.g. its origin, extent and probable development);

(b) advice on protection which, depending on the type of emergency, might:

- cover the following: restrictions on the consumption of certain foodstuffs likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements,
  - be accompanied, where necessary, by special warnings for certain population groups;
- (c) announcements recommending cooperation with instructions or requests by the competent authorities.
2. If the emergency is preceded by a pre-alarm phase, the population likely to be affected in the event of a radiological emergency should already receive information and advice during that phase, such as:
- an invitation to the population concerned to tune in to radio or television,
  - **preparatory advice to establishments with particular collective responsibilities,**
  - recommendations to occupational groups particularly affected.
3. This information and advice will be supplemented if time permits by a reminder of the basic facts about radioactivity and its effects on human beings and on the environment.

### 9.2.5. Related extracts from Early notification convention

#### **Article 1 Scope of application**

1. This Convention shall apply in the event of any accident involving facilities or activities of a State Party or of persons or legal entities under its jurisdiction or control, referred to in paragraph 2 below, from which a release of radioactive material occurs or is likely to occur and which has resulted or may result in an international transboundary release that could be of radiological safety significance for another State.
2. The facilities and activities referred to in paragraph 1 are the following:
  - (a) any nuclear reactor wherever located;
  - (b) any nuclear fuel cycle facility;
  - (c) any radioactive waste management facility;
  - (d) the transport and storage of nuclear fuels or radioactive wastes;
  - (e) the manufacture, use, storage, disposal and transport of radioisotopes for agricultural, industrial, medical and related scientific and research purposes; and
  - (f) the use of radioisotopes for power generation in space objects.

#### **Article 2 Notification and information**

In the event of an accident specified in article 1 (hereinafter referred to as a "nuclear accident"), the **State Party referred to in that article shall:**

- (a) **forthwith notify**, directly or through the International Atomic Energy Agency (hereinafter referred to as the "Agency"), those **States which are or may be physically affected** as specified

*in article 1 and **the Agency of the nuclear accident, its nature, the time of its occurrence and its exact location where appropriate; and***

*(b) promptly **provide the States** referred to in sub-paragraph (a), directly or through the Agency, **and the Agency with such available information relevant to minimizing the radiological consequences** in those States, as specified in article 5.*

### **Article 3 Other Nuclear Accidents**

*With a view to minimizing the radiological consequences, States Parties may notify in the event of nuclear accidents other than those specified in article 1.*

### **Article 4 Functions of the Agency**

*The Agency shall:*

*(a) forthwith inform States Parties, Member States, other States which are or may be physically affected as specified in article 1 and relevant international intergovernmental organisations (hereinafter referred to as "international organisations") of a notification received pursuant to sub-paragraph (a) of article 2; and*

*(b) promptly provide any State Party, Member State or relevant international organisation, upon request, with (the information received pursuant to sub-paragraph (b) of article 2.*

### **Articles Information to be provided**

**1. The information to be provided pursuant to sub-paragraph (b) of article 2 shall comprise the following data as then available to the notifying State Party:**

*(a) the time, exact location where appropriate, and the nature of the nuclear accident;*

*(b) the facility or activity involved;*

*(c) the assumed or established cause and the foreseeable development of the nuclear accident relevant to the transboundary release of the radioactive materials;*

*(d) the general characteristics of the radioactive release, including, as far as is practicable and appropriate, the nature, probable physical and chemical form and the quantity, composition and effective height of the radioactive release;*

*(e) information on current and forecast meteorological and hydrological conditions, necessary for forecasting the transboundary release of the radioactive materials;*

*(f) the results of environmental monitoring relevant to the transboundary release of the radioactive materials;*

*(g) the off-site protective measures taken or planned;*

*(h) the predicted behaviour over time of the radioactive release.*

**2. Such information shall be supplemented at appropriate intervals by further relevant information on the development of the emergency situation, including its foreseeable or actual termination.**

**3. Information received pursuant to sub-paragraph (b) of article 2 may be used without restriction, except when such information is provided in confidence by the notifying State Party.**

### **Article 6 Consultations**

A State Party providing information pursuant to sub-paragraph (b) of article 2 shall, as far as is reasonably practicable, **respond promptly to a request for further information or consultations sought by an affected State Party** with a view to minimizing the radiological consequences in that State.

### 9.2.6. Related extracts from Aarhus convention

#### **Preamble**

*Recognizing that, in the field of the environment, improved access to information and public participation in decision-making enhance the quality and the implementation of decisions, contribute to public awareness of environmental issues, give the public the opportunity to express its concerns and enable public authorities to take due account of such concerns,*

#### **Article 1 OBJECTIVE**

*In order to contribute to **the protection of the right of every person of present and future generations to live in an environment adequate to his or her health and well-being**, each Party shall guarantee the **rights of access to information, public participation in decision-making, and access to justice in environmental matters** in accordance with the provisions of this Convention.*

#### **Article 2 DEFINITIONS**

*For the purposes of this Convention,*

1. *“Party” means, unless the text otherwise indicates, a Contracting Party to this Convention;*
2. *“Public authority” means:*
  - (a) *Government at national, regional and other level;*
  - (b) *Natural or legal persons performing public administrative functions under national law, including specific duties, activities or services in relation to the environment;*
  - (c) *Any other natural or legal persons having public responsibilities or functions, or providing public services, in relation to the environment, under the control of a body or person falling within subparagraphs (a) or (b) above;*
  - (d) *The institutions of any regional economic integration organisation referred to in article 17 which is a Party to this Convention. This definition does not include bodies or institutions acting in a judicial or legislative capacity;*
3. *“Environmental information” means any information in written, visual, aural, electronic or any other material form on:*
  - (a) *The state of elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites, biological diversity and its components, including genetically modified organisms, and the interaction among these elements;*
  - (b) *Factors, such as substances, energy, noise and **radiation**, and activities or measures, including administrative measures, environmental agreements, policies, legislation, plans and programmes, affecting or likely to affect the elements of the environment within the scope of subparagraph (a) above, and cost-benefit and other economic analyses and assumptions used in environmental decision-making;*



(c) *The state of human health and safety, conditions of human life, cultural sites and built structures, inasmuch as they are or may be affected by the state of the elements of the environment or, through these elements, by the factors, activities or measures referred to in subparagraph (b) above;*

**4. “The public” means one or more natural or legal persons, and, in accordance with national legislation or practice, their associations, organisations or groups;**

**5. “The public concerned” means the public affected or likely to be affected by, or having an interest in, the environmental decision-making; for the purposes of this definition, non-governmental organisations promoting environmental protection and meeting any requirements under national law shall be deemed to have an interest.**

### **Article 3 GENERAL PROVISIONS**

1. *Each Party shall take the necessary legislative, regulatory and other measures, including measures to achieve compatibility between the provisions implementing the information, public participation and access-to-justice provisions in this Convention, as well as proper enforcement measures, to establish and maintain a clear, transparent and consistent framework to implement the provisions of this Convention.*

2. *Each Party shall endeavor to ensure that **officials and authorities assist and provide guidance to the public in seeking access to information, in facilitating participation in decision-making and in seeking access to justice in environmental matters.***

3. *Each Party shall promote environmental education and environmental awareness among the public, especially on how to obtain access to information, to participate in decision-making and to obtain access to justice in environmental matters.*

4. *Each Party shall provide for appropriate recognition of and support to associations, organisations or groups promoting environmental protection and ensure that its national legal system is consistent with this obligation.*

5. *The provisions of this Convention shall not affect the right of a Party to maintain or **introduce measures providing for broader access to information, more extensive public participation in decision-making and wider access to justice** in environmental matters than required by this Convention.*

6. *This Convention shall not require any derogation from existing rights of access to information, public participation in decision-making and access to justice in environmental matters.*

7. *Each Party shall promote the application of the principles of this Convention in international environmental decision-making processes and within the framework of international organisations in matters relating to the environment.*

8. *Each Party shall ensure that persons exercising their rights in conformity with the provisions of this Convention shall not be penalized, persecuted or harassed in any way for their involvement. This provision shall not affect the powers of national courts to award reasonable costs in judicial proceedings.*

9. *Within the scope of the relevant provisions of this Convention, the public shall have access to information, have the possibility to participate in decision-making and have access to justice in environmental matters without discrimination as to citizenship, nationality or domicile and, in the case*

of a legal person, without discrimination as to where it has its registered seat or an effective centre of its activities.

#### **Article 4 ACCESS TO ENVIRONMENTAL INFORMATION**

1. Each Party shall ensure that, subject to the following paragraphs of this article, public authorities, in response to a request for environmental information, make such **information available to the public**, within the framework of national legislation, including, where requested and subject to subparagraph (b) below, copies of the actual documentation containing or comprising such information:

(a) Without an interest having to be stated;

(b) In the form requested unless:

(i) It is reasonable for the public authority to make it available in another form, in which case reasons shall be given for making it available in that form; or

(ii) The information is already publicly available in another form.

2. The environmental information referred to in paragraph 1 above shall **be made available as soon as possible and at the latest within one month after** the request has been submitted, unless the volume and the complexity of the information justify an extension of this period **up to two months** after the request. The applicant shall be informed of any extension and of the reasons justifying it.

3. A **request for environmental information may be refused** if:

(a) The public authority to which the request is addressed does not hold the environmental information requested;

(b) The request is manifestly unreasonable or formulated in too general a manner; or

(c) The request concerns material in the course of completion or concerns internal communications of public authorities where such an exemption is provided for in national law or customary practice, taking into account the public interest served by disclosure.

4. A request for environmental information **may be refused if the disclosure** would adversely affect:

(a) The confidentiality of the proceedings of public authorities, where such confidentiality is provided for under national law;

(b) International relations, national defense or public security;

(c) The course of justice, the ability of a person to receive a fair trial or the ability of a public authority to conduct an enquiry of a criminal or disciplinary nature;

(d) The confidentiality of commercial and industrial information, where such confidentiality is protected by law in order to protect a legitimate economic interest. Within this framework, information on emissions which is relevant for the protection of the environment shall be disclosed;

(e) Intellectual property rights;

(f) The confidentiality of personal data and/or files relating to a natural person where that person has not consented to the disclosure of the information to the public, where such confidentiality is provided for in national law;

(g) *The interests of a third party which has supplied the information requested without that party being under or capable of being put under a legal obligation to do so, and where that party does not consent to the release of the material; or*

(h) *The environment to which the information relates, such as the breeding sites of rare species.*

*The aforementioned grounds for refusal shall be interpreted in a **restrictive way, taking into account the public interest** served by disclosure and taking into account whether the information requested relates to emissions into the environment.*

5. *Where a public authority does not hold the environmental information requested, this public authority shall, as promptly as possible, inform the applicant of the public authority to which it believes it is possible to apply for the information requested or transfer the request to that authority and inform the applicant accordingly.*

6. *Each Party shall ensure that, if information exempted from disclosure under paragraphs 3 (c) and 4 above can be separated out without prejudice to the confidentiality of the information exempted, public authorities make available the remainder of the environmental information that has been requested.*

7. *A **refusal of a request shall be in writing** if the request was in writing or the applicant so requests. A refusal shall state the reasons for the refusal and give information on access to the review procedure provided for in accordance with article 9. The refusal shall be made as soon as possible and at the latest within one month, unless the complexity of the information justifies an extension of this period up to two months after the request. The applicant shall be informed of any extension and of the reasons justifying it.*

8. *Each Party may allow its public authorities to make a charge for supplying information, but such charge shall not exceed a reasonable amount. Public authorities intending to make such a charge for supplying information shall make available to applicants a schedule of charges which may be levied, indicating the circumstances in which they may be levied or waived and when the supply of information is conditional on the advance payment of such a charge.*

#### **Article 5 COLLECTION AND DISSEMINATION OF ENVIRONMENTAL INFORMATION**

1. *Each Party shall ensure that:*

(a) ***Public authorities possess and update environmental information** which is relevant to their functions;*

(b) *Mandatory systems are established so that there is an **adequate flow of information to public authorities about proposed and existing activities** which may significantly affect the environment;*

(c) *In the event of any imminent threat to human health or the environment, whether caused by human activities or due to natural causes, all information which could enable the public to take measures to prevent or mitigate harm arising from the threat and is held by a public authority is disseminated immediately and without delay to members of the public who may be affected.*

2. *Each Party shall ensure that, within the framework of national legislation, **the way in which public authorities make environmental information available to the public is transparent and that environmental information is effectively accessible**, inter alia, by:*

(a) Providing sufficient information to the public about the type and scope of environmental information held by the relevant public authorities, the basic terms and conditions under which such information is made available and accessible, and the process by which it can be obtained;

(b) Establishing and maintaining practical arrangements, such as:

(i) Publicly accessible lists, registers or files;

(ii) Requiring officials to support the public in seeking access to information under this Convention; and

(iii) The identification of points of contact; and

(c) Providing access to the environmental information contained in lists, registers or files as referred to in subparagraph (b) (i) above free of charge.

3. Each Party shall ensure that environmental information progressively **becomes available in electronic databases** which are easily accessible to the public through public telecommunications networks. Information accessible in this form should include:

(a) Reports on the state of the environment, as referred to in paragraph 4 below;

(b) Texts of legislation on or relating to the environment;

(c) As appropriate, policies, plans and programmes on or relating to the environment, and environmental agreements; and

(d) Other information, to the extent that the availability of such information in this form would facilitate the application of national law implementing this Convention, provided that such information is already available in electronic form.

4. Each Party shall, at regular intervals not exceeding three or four years, publish and disseminate a national report on the state of the environment, including information on the quality of the environment and information on pressures on the environment.

5. Each Party shall take measures within the framework of its legislation for the purpose of disseminating, *inter alia*:

(a) Legislation and policy documents such as documents on strategies, policies, programmes and action plans relating to the environment, and progress reports on their implementation, prepared at various levels of government;

(b) International treaties, conventions and agreements on environmental issues; and

(c) Other significant international documents on environmental issues, as appropriate.

6. Each Party shall **encourage operators whose activities have a significant impact on the environment to inform the public regularly** of the environmental impact of their activities and products, where appropriate within the framework of voluntary eco-labelling or eco-auditing schemes or by other means.

7. Each Party shall:

(a) Publish the facts and analyses of facts which it considers relevant and important in framing major environmental policy proposals;

*(b) Publish, or otherwise make accessible, available explanatory material on its dealings with the public in matters falling within the scope of this Convention; and*

*(c) Provide in an appropriate form information on the performance of public functions or the provision of public services relating to the environment by government at all levels.*

8. Each Party shall develop mechanisms with a view to ensuring that sufficient product information is made available to the public in a manner which enables consumers to make informed environmental choices.

9. Each Party shall take steps to establish progressively, taking into account international processes where appropriate, a coherent, nationwide system of pollution inventories or registers on a structured, computerized and publicly accessible database compiled through standardized reporting. Such a system may include inputs, releases and transfers of a specified range of substances and products, including water, energy and resource use, from a specified range of activities to environmental media and to on-site and offsite treatment and disposal sites.

10. Nothing in this article may prejudice the right of Parties to refuse to disclose certain environmental information in accordance with article 4, paragraphs 3 and 4.

#### **Article 6 PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES**

1. Each Party:

*(a) Shall apply the provisions of this article with respect to **decisions on whether to permit proposed activities listed in annex I;***

*Nuclear power stations and other nuclear reactors including the dismantling or decommissioning of such power stations or reactors 1/ (except research installations for the production and conversion of fissionable and fertile materials whose maximum power does not exceed 1 kW continuous thermal load);*

*Installations for the reprocessing of irradiated nuclear fuel;*

*Installations designed: For the production or enrichment of nuclear fuel; For the processing of irradiated nuclear fuel or high-level radioactive waste;*

*For the final disposal of irradiated nuclear fuel;*

*Solely for the final disposal of radioactive waste;*

*Solely for the storage (planned for more than 10 years) of irradiated nuclear fuels or radioactive waste in a different site than the production site.*

*(b) Shall, in accordance with its national law, also apply the provisions of this article to decisions on proposed activities not listed in annex I which may have a significant effect on the environment. To this end, Parties shall determine whether such a proposed activity is subject to these provisions; and*

*(c) May decide, on a case-by-case basis if so provided under national law, not to apply the provisions of this article to proposed activities serving national defense purposes, if that Party deems that such application would have an adverse effect on these purposes.*

2. The **public concerned shall be informed, either by public notice or individually as appropriate, early in an environmental decision-making procedure, and in an adequate, timely and effective manner, inter alia, of:**

- (a) *The proposed activity and the application on which a decision will be taken;*
- (b) *The nature of possible decisions or the draft decision;*
- (c) *The public authority responsible for making the decision;*
- (d) *The envisaged procedure, including, as and when this information can be provided:*
  - (i) *The commencement of the procedure;*
  - (ii) *The opportunities for the public to participate;*
  - (iii) *The time and venue of any envisaged public hearing;*
  - (iv) *An indication of the public authority from which relevant information can be obtained and where the relevant information has been deposited for examination by the public;*
  - (v) *An indication of the relevant public authority or any other official body to which comments or questions can be submitted and of the time schedule for transmittal of comments or questions; and*
  - (vi) *An indication of what environmental information relevant to the proposed activity is available; and*
- (e) *The fact that the activity is subject to a national or transboundary environmental impact assessment procedure.*

3. The **public participation procedures shall include reasonable time-frames for the different phases, allowing sufficient time for informing** the public in accordance with paragraph 2 above and for the public to prepare and participate effectively during the environmental decision-making.

4. Each Party shall provide for early public participation, **when all options are open and effective public participation can take place.**

5. Each Party should, where appropriate, encourage prospective applicants to identify the public concerned, to enter into discussions, and to provide information regarding the objectives of their application before applying for a permit.

6. Each Party shall require the **competent public authorities to give the public concerned access for examination**, upon request where so required under national law, free of charge and as soon as it becomes available, to all information relevant to the decision-making referred to in this article that is available at the time of the public participation procedure, without prejudice to the right of Parties to refuse to disclose certain information in accordance with article 4, paragraphs 3 and 4. The relevant information shall include at least, and without prejudice to the provisions of article 4:

- (a) *A description of the site and the physical and technical characteristics of the proposed activity, including an estimate of the expected residues and emissions;*
- (b) *A description of the significant effects of the proposed activity on the environment;*

- (c) A description of the measures envisaged to prevent and/or reduce the effects, including emissions;
- (d) A non-technical summary of the above;
- (e) An outline of the main alternatives studied by the applicant; and
- (f) In accordance with national legislation, the main reports and advice issued to the public authority at the time when the public concerned shall be informed in accordance with paragraph 2 above.

7. Procedures for **public participation shall allow the public to submit, in writing or, as appropriate, at a public hearing or inquiry with the applicant, any comments, information, analyses or opinions that it considers relevant to the proposed activity.**

8. Each Party shall ensure that in the **decision due account is taken of the outcome of the public participation.**

9. Each Party shall ensure that, when the decision has been taken by the public authority, the public is promptly informed of the decision in accordance with the appropriate procedures. Each Party shall make accessible to the public the text of the decision along with the reasons and considerations on which the decision is based.

10. Each Party shall ensure that, when a public authority reconsiders or updates the operating conditions for an activity referred to in paragraph 1, the provisions of paragraphs 2 to 9 of this article are applied *mutatis mutandis*, and where appropriate.

11. Each Party shall, within the framework of its national law, apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment.

#### **Article 7 PUBLIC PARTICIPATION CONCERNING PLANS, PROGRAMMES AND POLICIES RELATING TO THE ENVIRONMENT**

Each Party shall make appropriate practical and/or other provisions for the **public to participate during the preparation of plans and programmes relating to the environment, within a transparent and fair framework, having provided the necessary information to the public.** Within this framework, article 6, paragraphs 3, 4 and 8, shall be applied. The public which may participate shall be identified by the relevant public authority, taking into account the objectives of this Convention. To the extent appropriate, each Party shall endeavour to provide opportunities for public participation in the preparation of policies relating to the environment.

#### **Article 8 PUBLIC PARTICIPATION DURING THE PREPARATION OF EXECUTIVE REGULATIONS AND/OR GENERALLY APPLICABLE LEGALLY BINDING NORMATIVE INSTRUMENTS**

Each Party shall strive to promote **effective public participation at an appropriate stage, and while options are still open, during the preparation by public authorities of executive regulations and other generally applicable legally binding rules that may have a significant effect on the environment.**

To this end, the following steps should be taken:

- (a) Time-frames sufficient for effective participation should be fixed;
- (b) Draft rules should be published or otherwise made publicly available; and

(c) *The public should be given the opportunity to comment, directly or through representative consultative bodies.*

*The result of the public participation shall be taken into account as far as possible.*

#### **Article 9 ACCESS TO JUSTICE**

1. *Each Party shall, within the framework of its national legislation, **ensure that any person who considers that his or her request for information under article 4 has been ignored, wrongfully refused, whether in part or in full, inadequately answered, or otherwise not dealt with in accordance with the provisions of that article, has access to a review procedure before a court of law or another independent and impartial body established by law. In the circumstances where a Party provides for such a review by a court of law, it shall ensure that such a person also has access to an expeditious procedure established by law that is free of charge or inexpensive for reconsideration by a public authority or review by an independent and impartial body other than a court of law. Final decisions under this paragraph 1 shall be binding on the public authority holding the information. Reasons shall be stated in writing, at least where access to information is refused under this paragraph.***

2. *Each Party shall, within the framework of its national legislation, ensure that **members of the public concerned***

*(a) Having a sufficient interest or, alternatively,*

*(b) Maintaining impairment of a right, where the administrative procedural law of a Party requires this as a precondition,*

*have **access to a review procedure before a court of law and/or another independent and impartial body established by law, to challenge the substantive and procedural legality of any decision, act or omission subject to the provisions of article 6 and, where so provided for under national law and without prejudice to paragraph 3 below, of other relevant provisions of this Convention.***

*What constitutes a sufficient interest and impairment of a right shall be determined in accordance with the requirements of national law and consistently with the objective of giving the public concerned wide access to justice within the scope of this Convention. To this end, the interest of any non-governmental organisation meeting the requirements referred to in article 2, paragraph 5, shall be deemed sufficient for the purpose of subparagraph (a) above. Such organisations shall also be deemed to have rights capable of being impaired for the purpose of subparagraph (b) above.*

*The provisions of this paragraph 2 shall not exclude the possibility of a preliminary review procedure before an administrative authority and shall not affect the requirement of exhaustion of administrative review procedures prior to recourse to judicial review procedures, where such a requirement exists under national law.*

3. *In addition and without prejudice to the review procedures referred to in paragraphs 1 and 2 above, each Party shall ensure that, where they meet the criteria, if any, laid down in its national law, members of the public have access to administrative or judicial procedures to challenge acts and omissions by private persons and public authorities which contravene provisions of its national law relating to the environment.*

4. *In addition and without prejudice to paragraph 1 above, the procedures referred to in paragraphs 1, 2 and 3 above shall provide adequate and effective remedies, including injunctive relief as appropriate, and be fair, equitable, timely and not prohibitively expensive. Decisions under this article shall be given*



or recorded in writing. Decisions of courts, and whenever possible of other bodies, shall be publicly accessible.

5. In order to further the effectiveness of the provisions of this article, each Party shall ensure that information is provided to the public on access to administrative and judicial review procedures and shall consider the establishment of appropriate assistance mechanisms to remove or reduce financial and other barriers to access to justice.

### 9.3. Annex 3: Overview of national legislation

#### 9.3.1. Related national analysis in medical field

##### Germany

***Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten***, by 20th February 2013 (not official translation: “Act to improve rights for patients”). Source: „Bundesgesetzblatt Jahrgang 2013 Teil I Nr. 9, ausgegeben zu Bonn am 25. Februar 2013“

The act deals with changes in relevant laws and codes touching the rights of patients, amongst others the “German Civil Code” and the “Code of Social Law”. Relevant passages can be found in Article 1, Change of German Civil Code.

##### **Key Words**

Information, information duties: Relevant paragraphs within article 1 Change of German Civil code:

- §630c; cooperation of contracting parties; information duties. (1) says that the treating physician and patient shall cooperate for application of the treatment. (2) is dealing with the duty of the treating physician to explain any circumstances which are essential for the treatment in a comprehensible manner.
- §630d says that the treating physician has the duty to seek for the patient’s consent before implementing the treatment.
- §630e obligation for elucidation. The treating physician is obligated to inform the patient about all circumstances relevant for the consent, especially type and extent of a treatment, expected consequences and potential risks of the treatment. The information has to be given in a timely manner so that the patient has the possibility to reach his decision to consent well-considered.

No matches were found regarding the key words participation, stakeholder, informed consent. Instead of “informed consent”, the Code uses the term “consent”.

##### **Level of stakeholder engagement**

Information, consent, information duties. Involvement of participating parties. Cooperation of contracting parties.

***Gesetz zur Neuordnung des Rechts zum Schutz vor der schädlichen Wirkung ionisierender Strahlung***. National legislation, Germany (“New Radiation Protection Act”, Germany) by 27<sup>th</sup> June 2017. Source: „Bundesgesetzblatt Jahrgang 2017 Teil I Nr. 42 ausgegeben zu Bonn am 3. Juli 2017“

##### **Key Words**

The following key words were searched in the “New Radiation Protection Act”: decision, information, consent, participation, stakeholder, interest groups, interested party, concerned.

No matches were found related to “stakeholder” or “interest groups” or “interested party” or “concerned party”. Only a few matches were found with relevance for ENGAGE focus on stakeholder engagement related to medical exposure and informed consent. The following paragraphs deal with the topic Information, decision making, involvement / participation in a broader sense:

- §36, ethics committee. §36 (3), 5. deals with informed agreement related to the application of ionising radiation in medical research projects. It says that the ethics committee verifies if the written information on the research project (which is required in another paragraph) sufficiently clarifies the risks and benefits so that a patient’s informed agreement is possible. This is the only place in the New Radiation Protection Act where “informed consent” is mentioned.
- §84 (3) of the New Radiation Protection Act says „Früherkennungsuntersuchungen zur Ermittlung nicht übertragbarer Krankheiten werden durch das Bundesamt für Strahlenschutz unter Beteiligung von Fachkreisen wissenschaftlich bewertet, wobei Risiko und Nutzen der Früherkennungsuntersuchung gegeneinander abzuwägen sind”. Free translated (no official English translation available!), it says that screening for identification of non-communicable diseases will be scientifically evaluated by the Federal Office for Radiation Protection and with the participation of experts. Risks and benefits of screenings have to be weighed against each other. However, up to now, no general administrative regulation exists. It is not clear if the term “participation” in that paragraph will be regulated in a more specific manner.

### **Definitions**

There are no definitions on stakeholder, interested parties or other comparable terms available.

### **Aspirations and Motivations**

Not further motivations are described.

### **Level of stakeholder engagement**

The only place where “stakeholder engagement” is mentioned is the paragraph stating that experts have to be involved in the scientific evaluation of application of screening for identification of communicable diseases. However, this is not yet further specified or described.

### **Italy**

***D. Lgs. 187/2000. Attuazione della direttiva 97/43 EURATOM in materia di protezione sanitaria delle persone contro i pericoli delle radiazioni ionizzanti ad esposizioni mediche.*** (Legislative Decree 187/2000. Implementation of Directive 97/43 EURATOM on health protection of persons against the dangers of ionising radiation at medical exposures.) In Italy the 2013/59 EURATOM Directives has not been yet transposed.

### **Key Words**

The following key words were searched:

- pazienti -patients

- persone - public
- coinvolgimento – engagement - (in the document there is no attention on this point)
- partecipazione - participation

### ***Definitions***

Cooperation among specialists and information: In art. 2-c, a number of commitments and responsibilities are indicated for the medical specialists, like: justification; optimization; clinical evaluation of the result. Moreover, the following aspects are also considered: the cooperation with other specialists and with staff delegated for practical aspects; to be aware of information on previous examinations; the transmission, on request of existing radiological information or documents to other specialist or prescribing doctors; the information of patients and other interested persons, where appropriate, about the risks of ionising radiation.

Patients and persons assisting and comforting patients: In art. 3. It is underlined the attention to benefits for the patients considering that the exposures to patient must show that they are effective enough for the health of the patient, taking into account the direct benefits, the medical exposures, as well as the damage that the exposure could cause; the related justifications and constraints of dose have to be considered.

In art 4. In the case of a patient undergoing treatment or a diagnosis with radionuclides, the nuclear physician or radiotherapist shall provide the patient himself with written instructions. This is an approach to give information on how to reduce, as far as it is reasonably achievable, the doses for people in direct contact with the patient.

The exposures of people who consciously and voluntarily, outside of their working activity, assist and comfort patients undergoing medical exposures are not allowed in the case of pregnant women and under 18 years.

### ***Aspirations***

As mentioned before this legislative document is dated 2000 and refers the previous EURATOM Directive. None attention is given to the involvement of stakeholders. Attention is mainly given to information towards patients and members of the public in relation of possible risks, in view of the specific diagnostic or therapeutic procedures considered for the specific situation, as well as to all the medical and technical aspects, with attention to justification, optimization for patient exposure, and constrain where relevant.

### ***Motivations***

In the document, the main motivation is expressed in term of quality of the approaches used in medical exposures in terms of scientific and technical aspects and it includes a basic approach towards the cooperation of the relevant medical specialists with other specialists and with the members of staff delegated for practical aspects.

### ***Level of stakeholder engagement***

Information, consent, information duties. Involvement of participating parties. Cooperation of contracting parties.

### ***Any other observation that may be relevant to the study***

*Here after is reported part of the D.Lgs. 187/2000 text, in relation to Definition and requirements*

*Art. 2, c) la responsabilità riguardo a esposizioni mediche individuali attribuita ad uno specialista. In particolare: giustificazione; ottimizzazione; valutazione clinica del risultato; cooperazione con altri specialisti e con il personale eventualmente delegato per aspetti pratici; reperimento di informazioni, se del caso, su esami precedenti; trasmissione, su richiesta, di informazioni radiologiche esistenti o di documenti ad altri medici specialisti o prescriventi; informazione dei pazienti e delle altre persone interessate, se del caso, circa i rischi delle radiazioni ionizzanti.*

*Art. 3 comma 8: 8. Le esposizioni di cui all'articolo 1, comma 3, devono mostrare di essere sufficientemente efficaci per la salute del paziente, tenendo conto dei vantaggi diretti, dei vantaggi per le persone di cui all'articolo 1, comma 3, nonché del danno che l'esposizione potrebbe causare; le relative giustificazioni e i relativi vincoli di dose sono quelli indicati nell'allegato I, parte I.*

*Art. 1 comma 3: 3. Il presente decreto legislativo si applica inoltre alle esposizioni di persone che coscientemente e volontariamente, al di fuori della loro occupazione, assistono e confortano persone sottoposte a esposizioni mediche.*

*Art. 3 comma 9: 9. Le esposizioni di cui all'articolo 1, comma 3, sono vietate nei confronti dei minori di 18 anni e delle donne con gravidanza in atto.*

*Art. 4 comma 8: 8. Nel caso di un paziente sottoposto ad un trattamento o ad una diagnosi con radionuclidi se del caso, il medico nucleare o il radioterapista fornisce al paziente stesso o al suo tutore legale istruzioni scritte volte a ridurre, per quanto ragionevolmente conseguibile, le dosi per le persone in diretto contatto con il paziente, nonché le informazioni sui rischi delle radiazioni ionizzanti. Tali istruzioni sono impartite prima di lasciare la struttura sanitaria.*

**Indicazioni operative per l'ottimizzazione della radioprotezione nelle procedure di radiologia interventista – Rapporti ISISTAN 15/41, 2015.** (Operative indications for the optimization of radioprotection in interventional radiology procedures – Report ISISTAN 15/41, 2015)

Document of the Italian Health National Institute and of the National Institute for Insurance against Accidents at Work.

### **Key Words**

The following key words were searched:

- pazienti -patients
- persone - public
- coinvolgimento - engagement
- partecipazione - participation
- consenso- consent

### **Definitions**

Cooperation and involvement of a professional team:

It is clearly evident, already from the introduction of the document, the importance to promote an appropriate "cultural" awareness, within the National Health Service, to optimize and standardize interventional radiology procedures, in terms of radioprotection of the patient and the operators. This is a main objective to be achieved through the active participation of all the professional and scientific components directly involved.

In interventional activities, it is foreseen the simultaneous participation of numerous professionals' figures, acting according to their training and competence and as necessary, for the medical act. It is recognized as well appropriate to know the responsibilities and the roles in the radiation protection of the patient and radiation protection of the operators, in order to guarantee the quality and safety in the use of ionising radiation.

Considering the complexity of the radiological systems used in interventional practice and other specific clinical procedures, a multidisciplinary approach is indicated, through a core team (medical specialist, medical physician, medical radiology technician and nurse) in order to reduce the exposure to the patient through the optimization of the radiological technique, the clinical procedure and the performance of the equipment in use.

The central role of the document is given, through chs. 2 and 3, to the radiological protection of patients and to the radiological protection of the operators with emphasis on the cooperation among the involved professionals. Moreover, it is recognised the importance of an open collaboration with the technicians of the equipment supply company.

Patient consent:

For the interventional procedure, the part of patient information and informed consent of the patient is particularly delicate and must be adapted to the level of potential risks that may include both the stochastic and the deterministic risks. There is no indication for a specific modality in which the patient's consent is expressed, but, at the same time, it is recalled the need to indicate, in the optimization, the lower dose consistent with the achievement of the diagnostic purpose, in compliance with the ethical principles and legislation in radiation protection

### ***Aspirations***

In the document, it is well expressed the attention to the suitable principle of optimization as the key to ensure a high quality of the procedure and a high level of protection for the patient and the staff involved. Furthermore, the attention is very focused on informed consent. An interventional radiology procedure cannot be performed without the valid consent of the person concerned; the patient must receive appropriate information and sufficient elements regarding the examination to which she/he will be submitted, also in relation to the risks that may arise. The validity of consent is conditioned by the given information and it requires a correct relationship between the specialist physician and the patient. The only possible exception to the consent principle is given by the state of necessity: in case of urgency / emergency, when the patient is not able to express his or her opinion.

### ***Motivations***

A basic motivation, in this document, is the awareness on the risk and the education.

It is remembered that inadequate knowledge and assessment of the risk associated with the use of ionising radiation can lead to an unjustified exposure of the patient or may discourage the execution of procedures necessary for the diagnosis and treatment of the patient's pathologies. As for training, it is recommended to refer to what was expressed in the recent EURATOM Directive 2013/59, regarding the need to ensure that specialist doctors and subjects involved in the practical aspects of medical-radiological procedures have adequate education, information and both theoretical and practical training for medical-radiological practices and an adequate competence in radioprotection.

### ***Level of stakeholder engagement***

The stakeholder engagement is mainly seen at level of the related professionals. It is indicated that radiologists, medical physicists, technicians for radiology and other health professionals involved in the activities of interventional radiology should work closely for the creation and conduction of radiation protection actions and training programmes, as needed and properly dedicated. Optimization is the key to ensuring a high quality of the procedure and a light of the involvement of non-specialist doctors among the complementary figures. The equipment manufacturers are engaged, considering their important role in the process of optimizing radiation protection.

### **Any other observation that may be relevant to the study**

*Here after is reported the part of the document, in relation to Definition and requirements.*

Introduction of the document. Per quanto sopra esposto, è certamente obiettivo importante promuovere una opportuna sensibilizzazione “culturale” all’interno delle strutture del Servizio Sanitario Nazionale per ottimizzare e standardizzare le procedure di radiologia interventistica in termini di radioprotezione del paziente e degli operatori. Le presenti indicazioni operative sono state elaborate proprio secondo questa logica, ed hanno visto la partecipazione attiva di tutte le componenti professionali e scientifiche direttamente coinvolte.

In ch. 1. Appare opportuno illustrare il ruolo e la responsabilità delle diverse figure professionali coinvolte in tali attività, per una migliore conoscenza delle problematiche legate alla garanzia di qualità e sicurezza nell’impiego delle radiazioni ionizzanti.

Le figure professionali che operano in radiologia interventistica, per le quali esistono precisi riferimenti normativi sono:

- *per la protezione del paziente:* medico specialista dell’area radiologica (anche come responsabile dell’impianto radiologico), medico specialista di altra area, fisico medico, TSRM, infermiere;
- *per la protezione del lavoratore:* esperto qualificato e medico incaricato della sorveglianza medica.

In ch. 2. Ad es Il gantry, il lettino porta paziente e la catena televisiva per la produzione delle immagini radiologiche dovrebbero essere posizionati al centro della sala: è fondamentale la collaborazione tra gli utenti finali e i tecnici della ditta fornitrice durante la pianificazione dell’installazione per far sì che tutte le necessità operative vengano propriamente analizzate e le soluzioni implementate.

In ch.2. L’attenzione posta per ridurre al minimo l’esposizione del paziente, la complessità dei sistemi radiologici impiegati e delle procedure cliniche richiedono un approccio multidisciplinare che vede il medico specialista, il fisico medico, il TSRM e l’infermiere (*core team*) impegnati ad ottimizzare la tecnica radiologica, la procedura clinica e le performance dell’apparecchiatura radiologica. Ciò in osservanza di principi etici ma anche della normativa di radioprotezione che richiede che, fatte salve le competenze e le responsabilità delle diverse figure professionali, l’esposizione del paziente sia ottimizzata ovvero che sia la minore possibile, compatibilmente con il raggiungimento del fine diagnostico (1, 2).

In ch. 2. Questo capitolo fornisce indicazioni sul consenso informato e informazione al paziente con riferimento alle esposizioni ai raggi X e, per procedure ripetute e complesse, ai potenziali rischi di danno cutaneo.

Pertanto, nelle procedure di radiologia interventistica esso dovrà essere modulato in funzione

del livello di dose, e quindi del rischio stocastico e deterministico, che la procedura, o l'insieme delle procedure eseguite, può potenzialmente impartire.

Non esiste una disposizione normativa per cui il consenso debba essere espresso in forma scritta, tranne che per trasfusioni di sangue o emoderivati.

La Corte di Cassazione ha stabilito infatti che la semplice apposizione della firma su un modulo prestampato non rappresenta un consenso dato validamente, poiché non dimostra una corretta fase informativa e un'adeguata comprensione da parte del paziente.

*In ch. 3.* Nell'ambito della radiologia interventistica la radioprotezione degli operatori è strettamente connessa a quella del paziente che rappresenta la sorgente principale di esposizione per chi opera nelle sue vicinanze: pertanto diminuire la dose al paziente, seguendo gli accorgimenti riportati nel precedente capitolo, dovrebbe consentire come diretta conseguenza, nella maggior parte dei casi, di diminuire la dose anche agli operatori. L'ottimizzazione della radioprotezione delle figure professionali che lavorano in radiologia interventistica sarà l'obiettivo di questo capitolo.

### **Slovenia**

Ionising radiation protection and nuclear safety act (ZVISJV-1), Off. Gaz. 76/2017 – Atomic Act, supported with details also by Rule on conditions on use of ionising sources in medicine and for exposure situations in non-medicine treatments, Off. Gaz. 33/2018.

### ***Key Words***

After the analyses of Atomic act text, the following key words were searched:

- Patients,
- Other groups: children, pregnant women, breastfeeding women, care workers and volunteers.

The extracts from ZVISJV-1 (Atomic Act) as result of the search investigation is provided in the subchapter "Related extracts from Atomic Act". For the rest of the potential keywords as proposed in the Milestone 1.1 (actor(s), stakeholders, participant(s), engagement, involvement, interested party/parties, citizens, civil organisations (NGOs)) there was no result.

### ***Definitions and requirements***

The definitions used in Atomic Act correspond to the one used in BSS directive related to the medicine treatments:

- "medical exposure" means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research;
- "clinical responsibility" means responsibility of a practitioner for individual medical exposures, in particular, justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and **giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate.**

The Atomic Act transposed several requirements from BSS directive in Slovenian legal system which relates to information provisions to different groups for medical treatments:

- For any radiological procedures the information must also include information on the dose received by the patient.
- In the case of radiological intervention, it must be ensured that information on the patient's exposure due to radiological intervention is an integral part of the survey report.
- The minister responsible for health determines in detail the conditions for special radiological interventions for children, pregnant women and nursing women, and voluntary care and care services for patients. In the separate rule also written instructions for patients are prescribed after they leave the hospital.
- The minister responsible for health determines in detail the conditions for education and compulsory training and qualification requirements for doctors responsible for radiological intervention and radiological intervention providers.
- The holder of an authorization to carry out a radiation practice must inform the medical doctor, the doctor responsible for the radiological intervention, and the patient or his legal representative of clinically relevant unintentional exposures and findings of the analysis of these events.
- Every patient or his legal representative shall have the right in the manner prescribed by the law governing the patient's rights for acquaintance with the medical documentation, to obtain data from the doctor responsible for the radiological procedure on the doses received during the conduct of radiological procedures.

In a separate Rule on conditions on use of Ionising sources in medicine and for exposure situations in non-medicine treatments, adopted in June 2018, more detailed information and instructions on how to implement requirements are set. The following is defined:

- For any radiological procedure, the referrer and the practitioner must provide the patient, its legal guardian or carer with adequate information relating to the benefits and risks associated with the medical exposure before the procedure.
- The written instructions following dismissal from the health-care institution after the therapeutic use, when radionuclides are input into the body of the patient or for procedures in nuclear medicine shall be given to inform the patient or his legal guardian on the risks of radiation and appropriate instructions to minimise, as far as reasonably achievable, the irradiation of people, who come in contact with the patient.
- In the case of pregnant or breastfeeding female special attention shall be given to the justification, particularly the urgency, and the expected exposure of the woman. The licence holder must have established written procedures for the procedures. Where appropriate and possible (e.g. in waiting rooms outside the facilities in which radiological procedures are taking place), the licence holder must alert women to inform the practitioner of the possibility of being pregnant, or they are breastfeeding.
- The practitioner, responsible for radiological procedure, must established and implement the dose constrains for carers and must inform the carers about the risk associated with the radiological procedure and, if necessary, issue appropriate written instructions.



- When entering the facilities where brachytherapy irradiation takes place, personnel and visitors must comply with written procedures approved by an authorised medical physics expert.
- The patient with the applied radionuclide must receive written instructions and warnings about radiation hazards and procedures for radiation protection before dismissal from the hospital, which the patient must consider reducing the risk of unnecessary external irradiation or contamination of other persons.
- Autopsy and cremation of deceased persons who have received radionuclides for therapeutic purposes should be carried out in accordance with the instructions for radiation protection that the operator must have in written form.

### **Aspirations**

Engagement of patients and other involved in radiological procedures is foreseen in accordance with BSS directive. The general requirements are transposed in Slovenian legislation, using the main Atomic Act and specific rule with more details. Basically, one-way communication with provision of information by the responsible practitioners and other is required. But during this, also dialogue could be established with all involved in the radiological procedures: patients, carers, pregnant women, breastfeeding women, personnel, visitors, all other people who come in contact with potential exposure.

### **Motivations**

In the Atomic Act, the communication with the patients is foreseen with delivery of more information than until recently. The motivation is beside instrumental (applied to secure end point) also in a way normative (because it the right thing to do).

### **Level of stakeholder engagement**

The level of stakeholders' engagement is based on provision of different information for applied medical treatments and radiological exposures. However, the new details in a separate Rule, published just in June 2018, gives some indications that there could be two ways communications established.

### **Any other observation**

The Atomic Act transposed basic requirements from BSS directive for medical exposures, but for this particular area also further details are provided in Rule.

### **Related extracts from ZVISJV -1**

#### **Article 76: conditions for carrying out a radiological intervention**

*(1) A single radiological procedure may be carried out only if it is prescribed by a medical doctor and approved by the doctor responsible for the radiological procedure and bears clinical responsibility for it. The holder of an authorization for the use of a radiation source shall provide the referral physicians with criteria for referrals with radiological procedures, which must also include **information on the dose received by the patient.***

*(4) In the case of radiological intervention, it must be ensured that:*

- **information on the patient's exposure due to radiological intervention is an integral part of the survey report;**

(8) The minister responsible for health determines in **detail the conditions for the implementation** of screening, biomedical and medical research, **special radiological interventions for children, pregnant women and nursing women, and voluntary care and care services for patients**; education and compulsory training and qualification requirements for doctors responsible for radiological intervention and radiological intervention providers; criteria for the acceptability of radiological equipment; special procedures for radiotherapy, diagnostic and interventional radiology and nuclear medicine; special conditions regarding the involvement of accredited experts in medical physics; quality assurance programs and form of professional supervision.

#### **Article 81: unintentional exposure**

(3) The holder of an authorization to carry out a radiation practice **must inform** the medical doctor, the doctor responsible for the radiological intervention, and **the patient** or his legal representative of **clinically relevant unintentional exposures** and findings of the analysis of these events.

#### **Article 83: database of doses due to radiological procedures**

(4) The **central register of performed radiological procedures** shall contain the following information: name of the radiological intervention provider, **year of birth and gender of the patient**, year of intervention, type of intervention, data on the implementation of the procedure, which are the basis for the calculation of the dose received.

(6) **Every patient or his legal representative shall have the right in the manner prescribed by the law governing the patient's rights for acquaintance with the medical documentation, to obtain data from the doctor responsible for the radiological procedure on the doses received during the conduct of radiological procedures.**

(7) The body responsible for radiation protection shall exchange aggregated data on performed radiological interventions with international institutions, professional associations and competent authorities of other countries in the field of patient care in radiological procedures.

#### **Spain**

Project of a **Royal Decree on Justification and Optimization of the use of ionising radiations for the Radiological Protection of persons on the occasion of Medical Expositions** (dated 07/01/2018)

National level: Spain, also incorporation of the European legislation, Directive 2013/59/Euratom

The aim of the project is:

“In order to comply with the provisions of Directive 2013/59 / Euratom, it is necessary to make the necessary modifications to the basic regulations governing the matter, represented essentially by Royal Decree 815/2001, of July 13, **on justification of the use of ionising radiation for the radiological protection of people on the occasion of medical expositions**, in order to promote its homogenous application throughout the national territory and to enable the opportune developments by the autonomous sanitary administrations in the exercise of their competence faculty”(p.3).

“The object of this Royal Decree is to establish the basic principles of justification and optimization in the use of ionising radiation for the radiological protection of people, against the following exposures medical:

1. Exposure of patients for diagnosis or medical treatment.
2. The exposure of workers during health monitoring.
3. The exposure of people in health screening programs.

4. The exposure of asymptomatic persons or patients who participate voluntarily in medical or biomedical research programs, diagnosis or therapy.” (pp. 5-6).
5. The exposure of caregivers.

### **Key Words**

Different stakeholders groups or representatives should be included within radiation protection: professionals (medical workers, technicians, etc.), patients (who is exposed during the diagnosis or treatment, etc.) and general public (who can be met in the hospitals where nuclear medicine is set or those who meet or stay near with a person after radiation exposure). State, authorities and other institutions or bodies who are responsible for the legislation development are also considered to be RP stakeholders.

In the proposals, the following key words relevant to stakeholders were found: “the qualified professionals”, “prescriber”, “sanitary professional”, “technician enabled as operator”, “medical worker”, “physician”, “dentist”, “podiatrist”, “cardiologist”, “health surveillance workers”, “patients”, “asymptotic people”, “experts in medical physics”, “persons in practice”, “children”, “pregnant women”, “breastfeeding women”, “caregivers” and “volunteers” (who help patients or are involved in the medical or biomedical investigation).

### **Definitions**

No any definition of ‘stakeholder’ and/or ‘stakeholder engagement’ is provided in the document. The relevant categories of stakeholders that are met in the document are listed in Key Words part.

The only more explicated definition of “volunteers” is provided (p.4) as the following one and referring to a subject of particular attention of radiation protection: “people who voluntarily assist patients undergoing medical exposures, who are in contact with patients undergoing treatment or diagnosis with radionuclides or who participate in medical or biomedical research projects”. (also defined in Annex).

It was mentioned also the Human Resources Commission of the National Health System (p.2) as responsible for coordination of the sanitary system in area of radiation protection area of professionals who are carrying out the interventional radiology.

In Annex, the following definitions of stakeholders are given:

**“Caregivers** - People who, independently of their occupation, consciously and voluntarily, undergo exposure to ionising radiation, collaborating in the care and well-being of people who are subjected or have been subjected to medical exposures.”

**“Prescriber** - Physician, dentist or other health professional authorized to refer persons for medical-radiological procedures, according to the requirements established to an authorized health professional.”

**“Enabled Healthcare professional** - Specialist doctor, dentist or podiatrist, within the scope of their competences, authorized to assume the clinical responsibility of an individual medical exposure.”

**“Enabled Technician** - Healthcare professional with the qualification of Senior Technician in Diagnosis and Nuclear Medicine or Radiotherapy and Dosimetry enabled as operator, within the scope of their competences, in the practical aspects of medical-radiological procedures.”

### **Aspirations**

The Directive emphasizes, in the first place, the need to justify and optimize medical exposure, including that of asymptomatic persons, proposing more stringent requirements as regards the information to be provided to patients, the registration and notification of doses of medical-radiological procedures, the use of reference levels for diagnosis and the availability of dose-indicating devices.

In the current Directive it is considered to be fundamental of existence of high level of competence and clear definition of responsibilities and functions *between all professionals involved in medical exposure*: “This applies to physicians, dentists and other health professionals authorized to take on the clinical responsibility of an individual medical exposure, other specialist physicians and professionals involved in the practical aspects of medical-radiological procedures” (Art.3).

“The section on the specific training in radiological protection of professionals involved in medical-radiological procedures acquires special relevance, and refers both to the undergraduate curricula corresponding to the different degrees in the field of health sciences, as well as specialized health training programs in Radiation Oncology, Radiodiagnosis, Nuclear Medicine and other medical specialties, as well as in the degrees in Odontology and Podiatry and those of Superior Technicians qualified as operators in said procedures, as well as in the needs of continuous formation.” Here is also was a special mention with reference to “the second level of training in radiological protection required for medical specialists in Radiodiagnosis, Cardiology and other specialties who perform interventional radiology procedures, in the terms established in Order SCO / 3276/2007 , of October 23, by which the Agreement of the Human Resources Commission of the National Health System is published, through which the second level of training in radiological protection of professionals who carry out interventional radiology procedures is articulated” (p.4).

With regards to patients, the Directive emphasizes the conditions and requirements of the information that professionals must provide to patients on the benefits and risks associated with the dose of radiation due to exposure, as well as on the aspects related to the application of the informed consent protocol.

### **Motivations**

Though the Decree itself does not pay much attention to questions and forms of work with patients and other stakeholders; during the process of preparing this Royal Decree, different stakeholders were involved: among others, the autonomous communities and cities with autonomy status and the corresponding public information process has been carried out. Likewise, favourable reports have been received from the Nuclear Safety Council and the Interterritorial Council of the National Health System, as well as from the Ministry of the Presidency and for the Territorial Administrations.

### **Level of stakeholder engagement**

The Decree mentions the **professional training on RP** of professionals involved in or dealing with medical radiation exposure (two levels of trainings, mentioned above).

For patients, their caregivers and volunteers, the medical workers should provide information about risks and benefits of this medical application (diagnostic or treatment) before signing the informed consent: “**Any person subjected to medical exposure** or, where appropriate, **their legal representative**, whenever feasible and before the exposure occurs, **should receive adequate information about the benefits and risks associated with the radiation dose due to exposure.**”

“In addition, in **radio diagnostic examinations and interventional procedures that involve high doses of radiation, in radiotherapy treatments and in therapeutic procedures with radiopharmaceuticals**, the **specialist doctor will obtain the corresponding informed consent, which will have to be signed by the patient himself or by his legal representative**, in case of disability, and by the doctor who informs, in accordance with established procedures.” (Art.3).

For **professionals in practice** (part of training): “New types of practices involving medical exposures will be justified before their widespread adoption in clinical practice.

The types of existing practices that involve medical exposures should be reviewed each time new evidence of their effectiveness and / or derived risks is obtained.

The justification for these types of practices will be included in the corresponding quality assurance program of the care unit and will be available to the competent health authority.” (Art.3)

From the other hand, following the process of “optimization” and “justification” of radiation exposure, **patients** should inform doctor/s about other exposures he/she was involved (if they were taken by other doctors or centres): “For the justification of an exposure to ionising radiation, both the prescribing physician and the specialist doctor and the dentist, and the podiatrist, within the scope of their competences, must previously obtain previous diagnostic information or relevant medical reports and other pertinent medical information, always possible, and will take these data into account to avoid unnecessary exposures. To this end, the availability of this information for the professional will be ensured according to the established procedures, in each case, by the competent health authority. Likewise, **the patient will inform the specialist doctor and the prescribing doctor of the diagnostic procedures with ionising radiation to which he has been previously submitted**. (Art.3).

For the **volunteers involved in scientific (medical) research**, the corresponded ethical committee decides or approve the study: “Medical exposures for medical or biomedical research must be examined by an ethical committee, formed in accordance with the applicable legal provisions and procedures of application.” (Art.3).

Also they will have the restriction in doses and should be informed about the risks of exposure before to agree to participate in it (Art.10).

**Children** are considered as a “special case and care”: “**In medical exposures of children**, those that are part of a health screening program or that involve high doses to the patient, which may occur in some interventional procedures, nuclear medicine, computed tomography and radiotherapy, medical radiological equipment will be used, the appropriate techniques and auxiliary equipment, **with special attention being paid in the corresponding quality assurance programs to the evaluation of the dose and verification of the activity administered in the cases mentioned**. The qualified health professional and the authorized technicians to carry out the practical aspects in the previous medical-radiological procedures, they must have the appropriate specific training in these cases, in accordance with current regulations.” (Art.5).

Art. 6 is dedicated to special protection of **women during pregnancy and lactation**. Also special attention given to information of patients: “**The head of the health center where the corresponding care unit is located** will adopt the **necessary measures**, such as the placement of **posters** in the appropriate places or others, to inform women who have to undergo diagnostic or therapeutic procedures that use ionising radiation, about the need, before undergoing the procedure, to communicate to the doctor responsible for the same if she is pregnant or thinks she is pregnant, or in the period of lactation.” (Art.6).

Art. 7&8 refer to **caregivers and volunteers**: “In medical exposures **only dose restrictions** will apply **with respect to the protection of caregivers and volunteers who participate in medical or biomedical research**. These restrictions will be established in terms of effective dose or individual equivalent over a period of time.” (Art. 7).

“...[D]ue to the characteristics of the diagnostic or therapeutic procedure with ionising radiation **it is necessary to immobilize the patient**, this will be done by means of the **use of appropriate mechanical restraints**. **If this is not possible, caregivers will be used, among whom in no case will be under eighteen years of age or pregnant women. These caregivers, who will always be the least possible number, will receive the precise instructions to minimize their exposure to radiation**, will try at all times not to be exposed to the direct beam and must be provided with the appropriate protection material, which should be available in enough to allow simultaneous use. **If caregivers are not available, the immobilization will be carried out by professionally exposed personnel, in rotating shifts.**” (Art.8)

Protection of **the persons who are staying in the contact with patients under treatment and diagnostics with radionuclides**: “In the case of patients who are undergoing treatment or diagnosis with radionuclides, **the specialist physician or person to whom they delegate will provide the patient or their representative with written information about the risks of ionising radiation for people who may be in contact with the patient**, .., and the appropriate instructions, also in written form, in order to restrict the doses of these people, as far as reasonably possible. This information and instructions, prepared by the health professional authorized in collaboration with the specialist, a hospital radiophysician, and must be delivered before leaving the hospital, clinic or other health centers.” (Art.9).

Art.11 stays for the medical clinical responsibility about medical exposure and cooperation with other specialists to obtain the overall patient’s history of medical exposure:

“**the qualified health professional** with respect to individual medical exposures will be responsible for: the justification; the optimization; the clinical evaluation of the results; **the cooperation with other specialists** and, where appropriate, with the technical personnel authorized as operator, in relation to the practical aspects of the medical-radiological procedures; the obtaining of information, if necessary, on previous explorations; **the provision of existing radiological medical information and medical records to other licensed health professionals** or to the prescriber, as appropriate; and the provision of information about the risk of ionising radiation to patients and other people involved, when appropriate.” (Art. 11).

**Training in radiological protection is required and should be included in medical education** in specialization where nuclear medicine and radiation exposure can be used (Art.14).

#### **Any other observation that may be relevant to the study**

By means of the present Royal Decree, Chapter VII, Article 83 and Articles 1, 2, 4, 5, 6, 14, 18, 19 and 96 in relation to medical exposures of EURATOM Directive 2013/59 are incorporated into Spanish law: 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.

### 9.3.2. Related national analysis in emergency preparedness and response

## **Belgium**

**Royal Decree on the Nuclear and Radiological Emergency for Belgium, 2018 revision.** The document is a revision of the former emergency plan (of 2003) that takes into account, among others, the national advice (Superior Health Council, advice of the scientific committee of the nuclear safety authority FANC/AFCN), international advice and guidelines (HERCA-WENRA, BSS directive, IAEA GSR7), and lessons learned from real events such as the radiological incident in Fleurus and the accident in Fukushima. Several stakeholders were consulted for this revision, including NGO's, mayors of nuclear communities, associations of cities and communes (pp. 18747).

The document is a framework that establishes guiding principles that have to be translated to operational procedures. It discusses in detail the different phases of an emergency but focuses on the early phase.

### **Key Words**

The keywords used were the translations in French of the words "stakeholders", "concerned parties", "dialogue", "public", "participation", "citizen", "consultation", "population", "concerned":

"Parties prenantes" (translation of "stakeholders"), "parties concernées", "dialogue", "public", "participation", "citoyen", "consultation", "population", "concern".

### **Definitions**

"Stakeholders" (in Dutch "stakeholders", in French "parties prenantes") are defined in a "broad sense", to include any individual person, group, institute, organisation,..., that may be affected by the consequences (radiological or other) of an emergency situation, and that i) has to act in order to limit its consequences or ii) participates in the management of the event (footnote in pp. 18854)<sup>4</sup>.

### **Aspirations**

**The end of emergency** is declared when a number of actions /processes have been carried out, among which a stakeholder consultation (pp. 18855). However, "this consultation should not delay ending the emergency phase" ("*cette consultation ne saurait toutefois retarder la sortie de la phase d'urgence*"). Another action is to "communicate to the population explaining the reasons for the end of the emergency, justify the adjustment of the restrictions and the protective actions, explain the remaining risk for the public health, the necessity to change habits and behaviours, and describe the surveillance programmes for the environment and the follow up of the exposed populations".

**The transition phase** has, among other, the objectives of progressively restoring the dialogue with all the concerned parties (pp. 18854) and preparing the recovery. Within this phase, another "consultation with the stakeholders directly affected will be organised for the establishment of the strategy to return to a normalised situation, and their involvement will progressively increase" <sup>5</sup>(pp 18889).

The management of the **recovery phase** (pp. 18855) and the decisions relative to the restoration strategy require a regular "consultation with the stakeholders representing the populations and sectors". This consultation has to be started and coordinated by the federal and regional departments concerned. The document mentions (pp. 18896, see also point below) that different actors should be consulted in defining the objectives and strategies, including federal and local authorities, operational

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<sup>4</sup> « Les parties prenantes sont les parties concernées dans un sens très large (chaque personne individuelle, la collectivité, l'institut, l'organisation...) qui peuvent être touchées par les conséquences (radiologiques et autres) d'une situation d'urgence, qui doivent agir pour en limiter les conséquences ou qui participent à la gestion de l'évènement. » (p. 18854)

<sup>5</sup> « durant cette phase, la consultation des parties prenantes directement concernées dans la mise en place de la stratégie du retour vers une situation normalisée est à nouveau organisée et leur implication augmente progressivement » (pp. 18889)

disciplines and stakeholders, notably, “social and economic actors and populations” that are directly concerned.

With respect to recovery, the document mentions that “it is therefore necessary that the different actors are involved from the **preparedness phase** in a reflection on the strategies to manage the consequences of an accident”<sup>6</sup> (pp. 18896). A specific subsection in chapter 5 (dedicated to emergency preparedness) is entitled “information, dialogue and training” (section 5.1.3). This mentions that dialogue with the stakeholders (other than emergency actors) is also a part of the preparedness for nuclear emergencies<sup>7</sup> (pp. 18896). This “structured dialogue” between the competent governmental authorities and the stakeholders, notably the population, should be organised to discuss the emergency plan and the emergency measures. Stakeholders include representatives of civil and economic society, elected, interest groups, consumers’ organisations, professional associations, representatives of economic sectors, local committees. This dialogue is interrupted during the emergency phase and continued as soon as possible during the transition phase<sup>8</sup> (pp. 18901). In addition, the emergency plan can be consulted on the websites of the safety authority (FANC/AFCN) and of the Federal Crisis Centre.

The document also describes in detail the information to be provided to the population as part of preparedness and mentions that this should be continuously updated (subsection 5.1.3.1).

### **Motivations**

With reference to the **end of emergency** (see above), the stakeholder consultation has to be carried out in order “to define the priority actions and the operational intervention levels”.

For the **transition phase** the general objective (thus, implicitly, also of the stakeholder consultation) is to allow the return as fast as possible to normal living conditions for the population<sup>9</sup> (pp. 18889).

For the **recovery phase**, broader stakeholder involvement is justified by the different aspects involved in the management of consequences of an accident situation, including economic and social aspects<sup>10</sup> (pp. 18896). This paragraph suggests a motivation primarily substantive, as the involvement of different actors supports the management of the situation.

However, it further states (next paragraph) that “stakeholders’ acceptance of decisions and their consequences is essential for ensuring the effectiveness of the actions initiated and for preparing the return to a normalized social and economic life” and that “transparency of information is one of the

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<sup>6</sup> « Il est donc également indispensable que les différents acteurs soient impliqués dès le stade de la préparation dans les réflexions sur les stratégies de gestion des conséquences d’un accident » (pp. 18896)

<sup>7</sup> « L’étape suivante dans le processus de préparation aux situations d’urgence nucléaires est la diffusion préalable d’informations et la formation. Il s’agit d’une part de la diffusion préalable d’informations à la population et le dialogue avec les parties prenantes, et d’autre part de la diffusion préalable d’informations et de formation aux acteurs impliqués dans le plan d’urgence nucléaire et radiologique aux différents niveaux concernés » pp. 18896)

<sup>8</sup> « En outre, un dialogue structuré est organisé sur le plan d’urgence nucléaire et les mesures d’urgence entre les autorités gouvernementales compétentes et les parties prenantes, en particulier la population. Ce dialogue se déroule à travers des groupes représentatifs de la société civile et économique : élus, groupes d’intérêt, organisations de consommateurs, groupes professionnels, représentants des secteurs économiques, comités de quartier... Ce dialogue a lieu préalablement aux situations d’urgence; il est interrompu pendant la phase d’urgence mais repris dès que possible dans la phase de transition. » (pp. 18901)

<sup>9</sup> « L’objectif est de permettre le plus rapidement possible le retour à un mode de vie normal de la population” » (pp. 18889)

<sup>10</sup> « La gestion des conséquences d’une situation post-accidentelle intègre des enjeux variés, incluant la radioprotection et les aspects économiques et sociaux. Elle implique donc de nombreux acteurs, aux niveaux national et local, couvrant des domaines de compétences ou de préoccupations variés. La définition des objectifs et des stratégies doit laisser une part importante à la concertation entre les représentants des autorités fédérales, fédérées et locales, les disciplines et les parties prenantes, notamment les acteurs économiques et sociaux et les populations directement concernées. » (pp. 18896).



essential conditions for this consultation”. This points more towards an instrumental rationale and contradicts to a certain extent the previous paragraph (in terms on influence on decisions), as it mentions the effectiveness and acceptance of actions already initiated<sup>11</sup> (pp. 18896). This also serves as justification for broader stakeholder engagement in reflection on potential strategies for recovery in the preparedness phase.

Concerning **protective actions** (chapter 6), the document mentions that some actions require information or dialogue with stakeholders given their characteristics and impact<sup>12</sup> (pp. 18806).

### **Level of stakeholder engagement**

The document mentions the establishment of communication strategies for alerting and informing the population in case of a (danger of) nuclear emergency (responsible for communication is the Federal Crisis Centre- CGCCR). Later on, in the transition phase, a communication strategy will be put in place to “ensure objective and transparent information describing the evolution of the situation, the residual risks and the protective actions.

In the **emergency phase**, (pp. 18856), the urgency of taking decisions is deemed to not allow for the involvement of other stakeholders than the competent authorities<sup>13</sup> (pp. 18854). However, several stakeholders from local, regional, national authorities and operational disciplines are included in the Federal Coordination Committee (see last point).

With reference to establishing the **end of emergency**, the level of stakeholder engagement prescribed is consultation. Since “this consultation should not delay ending the emergency phase”, it implies, indirectly, low or no impact on decisions about ending the emergency phase.

With reference to the **recovery phase**, the involvement is also described as “consultation”. It mentions larger stakeholder involvement in defining objectives and strategies, while it also highlights the importance of stakeholder acceptance as regards actions initiated that (see previous point). The decision process and the impact on potential decisions cannot be clearly derived from the document. A specific section (4.2.5) is entitled “Stakeholder involvement”. This contains however only the mention that “the interaction with stakeholders, reintroduced in the transition phase must be continued and enlarged”<sup>14</sup> (pp. 18898).

Affected population will also be regularly informed about the evolution of the situation and the perspectives (“Elles doivent continuer à être régulièrement informées de l’évolution de la situation et des perspectives”).

**Protective actions:** The return to evacuated areas and the relocation « will be authorized only after consultation with the affected population and the application of the ALARA an precautionary principle »<sup>15</sup> (pp. 18826 return and pp. 18832 for relocation). The level of influence on decision-making is not explicit. The document mentions that if the return is found as not acceptable (to affected

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<sup>11</sup> « L’adhésion des parties prenantes aux décisions et leur implication dans la gestion post-accidentelle sont essentielles pour assurer l’efficacité des actions engagées et pour préparer le retour à une vie économique et sociale normalisée. La transparence de l’information est une des conditions essentielle de cette concertation) » (pp. 18896)

<sup>12</sup> « Certaines des actions requièrent le cas échéant une information ou une consultation avec les parties prenantes directement concernées (intervenant concerné ou population concernée), vu leur caractère et impact. » (pp. 18806)

<sup>13</sup> « La gestion de la phase d’urgence relève uniquement des autorités compétentes car l’urgence des décisions durant cette phase ne permet pas la concertation les autres parties prenantes » (pp. 18854)

<sup>14</sup> « L’interaction avec les parties prenantes, réinstaurée dans la phase de transition, doit être poursuivie et étendue » (pp. 18898)

<sup>15</sup> « Le retour à domicile ne sera autorisé qu’après consultation de la population concernée et en tenant compte des circonstances, de l’application de l’ALARA et du principe de précaution ») (pp. 18826)

people?), the evacuation is changed to relocation. Consultation is also deemed necessary for decisions on relocation.

For a number of protective actions such as decontamination of inhabited areas as well as the lifting or revision of restrictions or limitations of presence in specific areas; restrictions on production of foodstuffs; measures for agricultural decontamination; and lifting or adaptation of such restrictions or measures, “decisions would be based mainly on radiological criteria, but would take into account also economic aspects and the opinion of stakeholders” <sup>16</sup>(pp. 18937). Such measures should always be accompanied by information of concerned sectors and populations.

#### ***Any other observation that may be relevant to the study***

The document makes reference to the context requiring an updated emergency plan reflecting the evolutions in the field and the international recommendations and directives, taking into account notably the “anxiety and perception of a part of the population, and in the neighbouring countries, concerning the radiological risk” (pp. 18747 ).

Several stakeholders are involved in crisis management. Within the Federal Coordination Committee of the Government member include representatives of federal services of departments responsible for discipline operational on the field: public health, civil protection, defence, police; nuclear safety authorities; food safety authorities; the Crisis Centre (D5), representative of the Ministry of Interior. The president of the Federal Crisis Coordination Committee may decide to extent this committee, depending on the situation, with representatives of other departments and federal services responsible for specific socio-economic sectors: foreign affairs, mobility, economic activities, energy, telecommunication, prisons,...; persons acting as liaisons with affected provinces; persons acting as liaisons with regional authorities / regional crisis centres; representatives of countries affected or threatened; persons acting as liaisons for international assistance mechanisms; other representatives of departments or federal services for multi-risk events.

At local level, coordination is ensured by the province governor supported by the provincial crisis centre, together with mayors of communes located in the emergency planning zones.

#### ***Conclusion***

The document makes several references to stakeholders, mostly using the word "consultation". The impact on actual decisions of such consultation processes, or the form such processes should take, are not clearly described.

Broader, increasing stakeholder consultation is foreseen in parallel with moving through the transition and recovery phases, for the *establishment of a strategy to return to a normal situation*, and in connection to the social and economic impact of countermeasures, as well as in the preparedness phase. The document points to a continuity of dialogue with stakeholders initiated in the preparedness phase and continued after the urgent phase. The document argues that given the urgency of the situation, no consultation is possible in the urgent phase.

The justification for stakeholder consultation is substantive, deriving from the complexity of the situation (recovery phase) to define priority actions and the need to return to a normal situation as fast as possible, and instrumental, to ensure the effectiveness and acceptance of countermeasures.

#### **Italy**

[-PIANO NAZIONALE DELLE MISURE PROTETTIVE CONTRO LE EMERGENZE RADIOLOGICHE (Marzo 2010) Presidenza del Consiglio dei Ministri, Dipartimento della Protezione Civile.] NATIONAL PLAN OF PROTECTIVE MEASURES AGAINST RADIOLOGICAL EMERGENCIES (March 2010), Presidency of the Council of Ministers, Department of Civil Protection.

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<sup>16</sup> « *La décision, principalement basée sur des critères radiologiques, prend donc également en considération les aspects économiques et les avis des parties prenantes* » (pp. 18937)

### **Short introduction**

In Italy there was an abandon of nuclear power in 1987. This document deals with the situation related to existing Nuclear Installations and to the associated decommissioning programmes. The attention to the need of keeping up to date competences and capabilities on nuclear safety, was recognised in the past years, at maintaining effective infrastructures to ensure a safe conduct of the decommission activities and safe management of radioactive waste. A consideration is given to maintain adequate emergency preparedness capabilities in relation to nuclear accidents potentially affecting reactors located in neighbouring countries.

The National Plan (Plan) identifies and regulates the measures necessary to deal with the consequences of accidents in nuclear plants that are located outside the national territory, which require coordinated actions at national level.

The Plan is drawn up in compliance with the provisions of: Legislative Decree 230/95 (including the implementation of Directives 89/618/Euratom, 90/641/Euratom, 92/3/Euratom, 96/29/Euratom); Legislative Decree 112/98 for the preparation, in agreement with the regions and local authorities involved, of emergency plans; Legislative Decree 343/2001 for the predisposition of risk prevention and forecasting programs, as well as national rescue programs and plans for the implementation of the consequences of emergency measures.

The Plan is written considering the national legislation and also the International Conventions, the Regulations and the Community Directives, as: 87/600/EURATOM; 89/618/EURATOM; IAEA Convention on Early Notification of a Nuclear Accident, Sept 1986, and revision, Oct 1989; IAEA Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, Sept 1986, and revision April 1990.

Italian legislation (Legislative Decree 230/95) establishes that the technical requirements for cross-border incidental accident scenarios are proposed by ISPRA (Inspectorate for Nuclear Safety and Radiation Protection – the Italian National Regulatory Body), after consulting the Technical Commission for Nuclear Safety and Health Protection. For the dosimetric values of reference for the planning of interventions in emergency conditions, the Plan refers Legislative Decree 230/95

### **Key Words**

The following key words were searched:

- Public
- Stakeholders/involved parties
- Involvement
- Information, information exchange

### **Definitions**

In the Plan it is recognized the importance of the operational procedures for managing the flow of information between the various parties involved, the activation and the coordination of the main components of the National Civil Protection Service. Furthermore, it is described the organisational model for emergency management with the indication of priority interventions at national level for maximum reduction of the effects induced on the Italian population and on the environment from the radiological emergency.

Bilateral agreements with similar bodies of neighboring countries are recognized as important for the communication exchange on an event. Close official and continuous reports are held with the entities of the neighboring countries that perform the functions of the supervisory body (Switzerland, France and Slovenia) with technical scientific support functions to the national civil protection authorities in

the management of nuclear and radiological emergencies. These reports are aimed at the rapid exchange of information in the event of incidental events involving nuclear installations.

In the planning and operational strategy, the main objectives to be achieved for an effective emergency management include: - to ensure the functionality of the alert system with the exchange of information at national and international level; - ensure public information on the evolution of the event and the behavior to be taken.

For example, regarding the emergency response at the operational level, after receiving the notification of a nuclear accident two operational level are defined by the Plan: a Warning Level and an Alert Level. The first level refers the case of an accident at a nuclear plant within 200 km from the Italian border, the second level refers to the involvement of the national territory and possible activation of protection measures. At both the levels the related activities include the public information and, among the objectives of the Alert Level, the activation of structures of the national service of the Civil Protection is one of the of the objectives. The definition and implementation of the protective measures, as sheltering and iodine prophylaxis, are taken in Alert Level.

In the emergency response, operational coordination by the Civil Protection Department (CPD) is foreseen and involvement as consultative technical bodies of the National Risks Commission and CEVaD (Data Processing and Evaluation Center - established at ISPRA)

The collection, verification and dissemination of information on protection is activated through the coordination center, 'SISTEMA' of the CPD, which is active full-time.

Operational coordination at regional and provincial level of CPD, Regions, Government Territorial Office, and Statutory Auditors is foreseen through the exchange of information to: provide the population with complete information on the type of event and the evolution of the event, the measures undertaken and any behavior to be taken to reduce exposure to ionising radiation. The population actually affected by the radiological emergency must be immediately informed of the facts relating to the emergency, the behavior to be adopted and the health protection measures applicable to it in this case.

The Regions, according to their organisational models, contribute to the planning of public information and ensure its timely and widespread dissemination to the population by the Mayors. In particular, regarding the organisation of the dissemination of information, the primary objective is to promptly inform the population that is likely to be involved or is affected by a radiological or nuclear event, already starting from the early warning phase, so as to avoid or contain at the most the phenomena of unrest and unpredictable reactions. The information dissemination tools must be the most direct: national televisions and radios, national newspapers, free press, teletext and SMS.

### ***Aspirations***

It is evident how important it is to adjust the level of action and information to the emergency situation, thus distinguishing between the operational phases of early warning and alarm. In both cases it may be necessary to integrate the information, in particular towards the public, with attention to aspects concerning radioactivity and its effects. The measures to protect public health that can be taken in the context of the planning described in the document, are aimed at reducing the exposure to radioactive contaminants and, therefore, the stochastic effects that may derive from it.

For each type of radiological risk, before the planning phase and in collaboration with the involved bodies, it must be considered a technical-scientific assessment phase of the possible reference scenarios, their consequences on the environment and on the health of the population, the necessary means for the detection and the measurement of radioactivity, as well as the territorial areas involved in the accident itself. A real collaboration and effective coordination between the involved bodies is essential in the practice.

### ***Motivation***

It is recognized the importance of the operational procedures for managing the flow of information between the various parties involved, the activation and the coordination of the main components of

the National Civil Protection Service. Operational coordination at regional and provincial level is foreseen with the primary objective to promptly inform the population that is likely to be involved or is affected by a radiological or nuclear event. There is not direct involvement of the population in the decision process.

### ***Level of stakeholder engagement***

The collaboration between the bodies involved is seen through the coordination system aimed at ensuring, through the univocal identification of responsibilities, the communication flows and the direction of the appropriate interventions to face an emergency.

In the response to national radiological events, the operational coordination is assumed by the CPD in order to guarantee the direction of the interventions with the Civil Protection Operational Committee, the National Risks Commission, and the CEVaD, which act as advisory bodies.

The public structures mainly involved in various aspects, both in the pre-alarm phase and in the alarm phase, are: CPD; ISPRA; Ministry of the Interior; Department of Firefighters, Public Assistance and Civil Defense; Regions concerned; Prefectures - Government Territorial Offices involved.

### **Slovenia**

Ionising radiation protection and nuclear safety act (ZVISJV-1), Off. Gaz. 76/2017.

### ***Key Words***

After the analyses of ZVISJV-1 text, the following key words were searched:

- Emergency workers,
- Population likely to be affected,
- Population actually affected

The extracts from ZVISJV-1 (Atomic Act) as result of the search investigation is provided in the subchapter "Related extracts from Atomic Act". For the rest of the potential keywords as proposed in the Milestone 1.1 (actor(s), stakeholders, participant(s), engagement, involvement, interested party/parties, citizens, civil organisations (NGOs)) there was no result.

### ***Definitions and requirements***

The definitions used in Atomic Act in relation to different stakeholders correspond to the one used in BSS directive related to the EP&R. It includes two groups: population likely to be affected and actually affected population. In the article devoted to definitions they are not described, and they are introduced just in articles. The only related definition is "members of the public" which means individuals who may be subject to public exposure.

The Atomic Act transposed several requirements from BSS directive in Slovenian legal system which relates to information provisions to different groups:

- The training programs for emergency workers must ensure that safety measures are given and regularly updated information on health risks that could be exposed to them during emergency intervention and on the necessary preventive measures in such cases. This information must take into account a set of possible accidents and means of transmission. In case of accident information shall be supplemented with current information.
- The operator of a radiation or nuclear facility and other planning entities must regularly inform the public of the important facts of the protection and rescue plans, and in particular the protection measures envisaged and the manner in which they are implemented.

- The notification referred to in the preceding paragraph must be carried out without explicitly inquiring of the public, and the information must be updated at regular intervals or in the event of major changes. They must be accessible on a permanent basis.
- In the event of an accident, the operator of the facility or the practitioner of the radiation activity shall ensure that the authority issuing the permit for carrying out the practice of radiation is informed of the event as soon as possible and other competent authorities, in accordance with the regulations on protection against natural and other accidents, which immediately inform the population in the affected area of the relevant facts regarding an emergency, and, in particular, of protective measures.
- In the case of transport of nuclear materials, radioactive materials, spent fuel and radioactive waste, the obligation to notify under the preceding paragraph shall be with transporter and the organizer of the transport.

There is also entire and detailed transposition of requirements from BSS Directive, Annex XII, section A, Prior information to the members of the public likely to be affected in the event of an emergency (in connection to Article 70 of BSS) and section B, Information to be provided to the affected members of the public in the event of an emergency (in connection to Article 71 of BSS directive) in April 2019 adopted Decree on content and development of emergency preparedness and response plans.

There is also adopted The National Emergency Response Plan for Nuclear and Radiological Accidents, Version 3.0, 2010, based on threat assessment and complies with the Protection against natural and other disaster act, Ionising radiation protection and nuclear safety act and other legislation. It is the operationalisation of the requirements from acts. It includes among others:

- General Information on Nuclear and Radiological Accidents and some basic facts about ionising radiation, external and internal radiation and the consequences of deterministic and stochastic effects.
- Sources of danger with description on nuclear facilities where accidents can happen in Slovenia, radiation facilities with some examples, examples of where radiological incidents can occur and how accidents abroad could impact Slovenian population.
- Emergency measures envisaged to alert, protect and assist the public in the event of an emergency, like initial notification, and then separately for case of accident in NPP, for other facilities and accident abroad,
- Information on actions and measures to be taken by the public in the event of an emergency, again for accident in NPP and in general for all accidents.

### ***Aspirations***

Engagement of stakeholders and members of the public is mainly considered as one-way communication with provision of information by the responsible institutions and operators. With decree from 2019 the details of information to be prepared before the accident and in case of accident are defined.

### ***Motivations***

In the Atomic Act the communication with the public is basic with some provision of information on the EP&R. There is no engagement of members of public foreseen. The motivation of the participation is mainly instrumental, as it is applied to secure the end point.

### **Level of stakeholder engagement**

The level of stakeholders' engagement is mainly limited to provision of different information for EP&R from operators and responsible authorities, but there are no instructions how this shall be implemented. Different authorities use mainly websites where information is available, lately (in 2019) also some new information have been added. Local authorities also distributed several leaflets (How to act in case of nuclear accident, Potassium Iodine tablets) to the households.

### **Any other observation**

The Atomic Act transposed some basic requirements from BSS directive, the transposition of annex XII was done just recently (April 2019). The requirements could be used in many different ways, and it could be implemented in a way that the two-way communication could be established.

### **Related extracts from ZVISJV -1**

#### **Article 133: prior notification of protective measures providers**

- (1) Providers of protective measures must be properly trained and have all the information necessary for the performance of their tasks.**
- (2) The training programs for providers must ensure that safety measures are given and regularly updated information on health risks that could be exposed to them during emergency intervention and on the necessary preventive measures in such cases. This information must take into account a set of possible extraordinary events and means of transmission.**
- (3) Upon the occurrence of an emergency, the information referred to in the previous paragraph shall be supplemented with current information.**
- (4) The persons responsible for the protection must ensure that the training and information referred to in the preceding two paragraphs are carried out, including practical exercises where necessary. The training should also include relevant content in the field of radiation protection.**

#### **Article 134: informing the public that could have been affected during an emergency**

- (1) The operator of a radiation or nuclear facility and other planning entities must regularly inform the public of the important facts of the protection and rescue plans, and in particular the protection measures envisaged and the manner in which they are implemented.**
- (2) The notification referred to in the preceding paragraph must be carried out without explicitly inquiring of the public, and the information must be updated at regular intervals or in the event of major changes. They must be accessible on a permanent basis.**

#### **Article 135: information to the public and competent authorities in case of emergencies**

- (1) In the event of an accident in accordance with this Act, the operator of the facility or the practitioner of the radiation activity shall ensure that the authority issuing the permit for carrying out the practice of radiation is informed of the event as soon as possible and other competent authorities, in accordance with the regulations on protection against natural and other accidents which immediately inform the population in the affected area of the relevant facts regarding an emergency, and, in particular, of protective measures.**
- (2) In the case of transport of nuclear materials, radioactive materials, spent fuel and radioactive waste, the obligation to notify under the preceding paragraph shall be with transporter and the organizer of the transport.**

- (3) *Regulations in the field of protection against natural and other uses shall apply to the method and extent of informing the general public, the population in the affected area, the competent ministries and bodies under this Article and for the process of regular review and confirmation of public notifications on important facts from the protection and rescue plans legislation.*

**Article 136: international information and cooperation**

- (1) *The competent authorities involved in the response to an emergency should cooperate with the competent authorities in the EU Member States and third countries in the preparation of protective measures that would be necessary in the territories of these countries due to accidents in the territory of the Republic of Slovenia.*
- (2) *In the event of an accident in the Republic of Slovenia or in an emergency that may have radiological consequences in the territory of the Republic of Slovenia, the competent authorities referred to in the preceding paragraph **must contact all the countries that may be affected, provide for the exchange of information on the estimated exposure with these countries, and coordinate with them protective and public information**, exchanging information through bilateral or international information exchange and coordination systems.*
- (3) *The activities referred to in the preceding paragraph shall not prevent or hinder the execution of the necessary measures in the territory of the Republic of Slovenia.*
- (4) *The Government shall decide on the acceptance of assistance by foreign countries and the International Atomic Energy Agency and the provision of assistance to foreign countries in the event of an emergency.*
- (5) *If necessary, it shall cooperate with other countries when planning the transition from an emergency exposure to an existing exposure.*

**Spain**

**Spanish CSN (Nuclear Security Council) Strategic Plan 2017-2022 (1<sup>st</sup> document)**

The Strategic Plan of the Spanish Nuclear Security Council (CSN) document is issued as the revision of the previous document – The Strategic Plan of 2011-2016 (approved in 31<sup>st</sup> of May 2011 and considered the challenge of dealing with the unforeseen and not planned situation as the reply to the Fukushima Daiichi Nuclear Power Plant (NPP) in March 2011 in Japan in general terms.

The current Plan (2017-2022) represents the commitment of the CSN to confront with certainty the regulatory challenges in the coming years in relation to its primary objective "nuclear, radiological and physical safety", the objective around which the activity of the CSN is circumscribed and developed during the period of validity of the Plan.

The activities carried out by the CSN fall within the concept of public service, so that all the Institution's actions must be impregnated with the concept of service to citizens.

The actions of the CSN affect multiple groups, including public institutions of state administration, regional and local, population and society in general, companies with an interest in the subject (owners of facilities and activities, manufacturers and suppliers), workers exposed to regulated facilities and activities, CSN staff and interested stakeholders (people living in the vicinity of facilities, trade union organisations, non-governmental organisations, the media, professional associations, scientific and professional societies, research centres, universities, international organisations and political parties).

**Key Words**



After the analyses of the Spanish Strategic Plan 2017-2022, the following key words were searched:

- Stakeholders
- Members of the public; public; groups; population; society; people; persons; institutions; NGOs; associations; trade union organisations; professional societies, research centres; neighbours of NPPs; workers; citizens; various actors
- Involvement; Participation.

### ***Mission, vision, values and commitment of the CSN (Spanish Nuclear Security Council)***

*The Mission of the CSN* is to protect **workers**, the **population** and the environment from the harmful effects of ionising radiation, getting nuclear and radioactive facilities to be operated by the owners in a safe manner, and establishing preventive and corrective measures in the face of radiological emergencies, whatever their origin.

*The Vision on the CSN* is that it is a regulatory authority, independent of the General State Administration and the owners of the facilities, which reports to the Congress and the Senate. Qualified technically so that its proposals and decisions are rigorous and to develop its activity effectively, efficiently, transparently and neutrally, so that it deserves the trust of **Spanish society** and constitutes a benchmark in the international arena.

*The Values:* The CSN relies on the performance of its functions and for the fulfillment of its objective in the definition and adhesion of its human team to a set of personal values, which are closely linked to the mission and vision and that are developed within the framework of the code of ethics of the organisation and the safety culture that should guide the institution permanently:

- *Independence:* make decisions and act with objectivity and impartiality.

- *Rigor and Veracity:* dispense certain, relevant, valid and verifiable information.

- *Competence, excellence and responsibility:* act with scientific, technical and legal rigor and integrity, based on the available knowledge and experience, sharing knowledge and best practices, and assuming responsibility for their actions and decisions.

- *Commitment:* be aware of the importance of the individual contribution for the fulfillment of the mission and objectives of the CSN

### ***Aspirations***

Engagement of stakeholders and members of the public are mainly considered in terms of protective actions and attitude towards CSN existing requirements on “nuclear security”, providing access to information and to some extent the intentions of public participations with implying the following concepts:

- **Credibility**, which “is understood in two ways: as the confidence of **society** in the capacity of the CSN to protect it against the harmful effects of ionising radiation, and as the confidence of **society** in the Council for the coherence of its actions, due to the objectivity of them.
- “**Transparency** is about providing **citizens with access to information** and facilitating the understanding of the regulatory process by society, and achieving the reduction of asymmetry of information among the **various actors** involved in security.

To achieve this objective, the CSN must:

- Increase transparency towards **society**, reducing the degree of asymmetry in information, facilitating access to available information and **involving society in the regulatory process** in the manner established in article 12 of Law 15/1980.

- **Promote transparency in the flow of information, from society to the Agency**, for which it may rely, among other measures, on the activities developed by the Advisory Committee on Information and **Public Participation**, as a key tool to improve transparency, or in the possibility of receiving complaints about known facts that could affect the safe operation of the facilities and activities.

- **Neutrality** is understood as the non-adoption of a particular position, in favor or against, with respect to the use of nuclear technology and ionising radiation in any of its applications, and implies keeping away from any considerations of a political nature and its consequences in the rest of the economic sectors.

To guarantee neutrality, the CSN must:

- Consolidate as a source of information and impartial regulation, with the necessary technical knowledge and experience.

- Limit their performance to the regulatory function, leaving it to the Congress and the Senate or the Government, as appropriate, to mark the political objectives they consider necessary.

- **Independence** is the ability to make decisions with autonomy vis-à-vis third parties and constitutes the basis of any regulatory body.

Independence is achieved, first, with an adequate institutional design referring to the status of the president and the councilors, to the relationship with the Government, the Congress and the Senate, to financial and organisational autonomy, and to the assigned regulatory powers.

Second, independence is achieved through the way in which the Board carries out the exercise of its regulatory powers, avoiding those facts and circumstances that may compromise security through the imposition of other interests of others or in conflict.

To preserve the independence of the Government, of the owners of the facilities and activities and, in general, of all the stakeholders with interests in the matter, the CSN must:

- Maintain the degree of autonomy and freedom in the exercise of the activities that are conferred by law and **avoid both the imposition and the request of guidelines on the regulatory activity that is within its competence**.

- Avoid the influence of the regulated subject in the regulator and implement the internal control mechanisms necessary to eliminate conflicts of interest.

- **Avoid any influence of other actors (media and other interest groups) in their way of regulating and supervising**.

### **Motivations**

The current document (Strategic Plan) has shown an intention to implement the stakeholders' participations in both directions (up to bottom; and bottom to up), especially in the communication with the public with regards to nuclear security in general. Since CSN is of more expertise than the major part of the general public, the professionals form the CSN expect more trust and following their norms and recommendations; as well they are open for receiving and answering to complains. However, it is not clear how all this work in a real practice. And some moments (a little bit

contradictory) – as “avoid any influence of other actors” can be interpreted that this competent organisation prefers do not be influenced much by other stakeholders or groups of interests (though such influence, of course, could be both, of negative, positive or of mixed results).

Nevertheless, as it is shown in the section III.1.9, related to radioactive waste and irradiated fuel managements, “CSN promote the active participation of the groups and projects related to amelioration” of these and other (as transportation of fuel) processes.

In the section III.2.6 of this Plan, specifically dedicate to “Information and Public participation”, the CSN has an intention to improve the communication and public participation to be more transparent and in favour of open access to their information from society; as well by establishing the mail box for communication for the external consultancies to reply with prioritization to those which require the major urgency or severity of issue and need quicker resolution from the CSN. However, as mentioned in sections III.3.4 (“Technologies and security of information”) and III.3.5 (“Ethical Code”), the confidentiality, integrity and disposition of information is provided; as well of regulation of the possible conflicts of interests.

The section IV.5 (“Policy of external relations”) describes more with a potential and beneficial stakeholders’ engagement. Thus, CSN’s intention is to develop and maintain schemes of collaboration with interested groups that could add a value to the activities of the CSN and potentiate the specific initiatives from the Spanish institutions and international regulatory organisms; to participate actively in national and international forums.

#### ***Level of stakeholder engagement***

The level of stakeholder engagement is mainly limited to expectatives of behavioural accomplishment (prudence and following the norms) in the nuclear security issues; participation in the I+D projects and diffusion of the results; participation in formative activities and reading the information provided openly on a web or other resources of information (reunions, periodical bolletins, etc.). Also stakeholders can give their opinion about the CSN activities and the relevant stakeholders groups (which can positively contribute to CSN activities) will be encouraged to do it. The consultancy to general public is also planned to be established and maintained via electronic resources mainly.

#### ***Spanish State Civil Protection against Radiological Risk (2<sup>nd</sup> document)***

(associated document: Royal Decree 1054/2015, of November 20, by which the Plan is approved, retrieved from <https://www.csn.es/planes-de-emergencia/radiologico-exterior-pei>)

#### ***Key Words***

After the analyses of the Spanish Strategic Plan 2017-2022, the following key words were searched:

- Stakeholders
- Members of the public; public; groups; population (affected population); society; people; persons; institutions; NGOs; associations; professional societies, research centres; neighbours of NPPs; workers; citizens; various actors
- Involvement; Participation.

#### ***Aspirations & Motivations***

The responsible bodies that are implied in the State Plan for Radiological Risk in Spain:

- 1) Board of Directors of the State Plan.
- 2) Operational Direction of the State Plan.
- 3) State Committee of Coordination (CECO).
- 4) Integrated Operative Coordination Centers of Community Plans (CECOPI)
- 5) Autonomous communities directly affected.
- 6) Integrated Operative Command (post on the autonomous community level).

1) *The Board of Directors of the State Plan* is the highest support body for the Minister of the Interior in emergency management that have been declared of national interest.

The Steering Council of the State Plan has the character of a collegiate body, in accordance with the provisions of section three of article 40.1 of Law 6/1997 of 14 April, Organisation and Operation of the General State Administration.

Composition:

President: Minister of the Interior.

Vice President: Assistant Secretary of the Ministry of the Interior.

Vowels:

- General Director of Civil Protection and Emergencies.
- General Head of the Military Emergency Unit (GEJUME).
- Director of Radiological Protection of the Nuclear Safety Council.
- Representatives of the governing bodies of the affected autonomous communities.

In terms of stakeholders' relationship in case of emergency, *The Board of Directors* refers only to information provided to the affected population, social media and professionals involved: "Propose information policies aimed at the population affected by the emergency, to the social media and the intervening personnel", "to keep informed the CSN (Nuclear Security Council)" and to coordination between central government and affected local communities: "Facilitate coordination between the General State Administration and the communities autonomous affected".

2) *Operational Direction of the State Plan* is the organ of participation of the General State Administration in the functions of preparation, implementation, updating and application of the State Plan for Risk Radiological, created by Royal Decree 1564/2010, of November 19 through which approves the Basic Guideline for Civil Protection Planning for Radiological Risk.

Composition:

President: Assistant Secretary of the Minister of the Interior.

Vice President: General Director of Civil Protection and Emergencies.

Secretary: Deputy Director General of Prevention and Planning.

Members: One representative, with a minimum rank of Assistant General Manager or equivalent, of each of the following bodies:

- Nuclear Safety Council.
- General directorate of police.
- General Directorate of the Civil Guard.
- General Directorate of Defense Policy.
- General Directorate of Public Health, Quality and Innovation.
- Department of National Security.
- Meteorology Statal Agency.
- General direction of traffic.

**When circumstances require it**, depending on the type and magnitude of the emergency, and at the request of the CECO president, **may join the Committee with advisory functions**, representatives, with minimum rank of deputy general manager or equivalent, of the following organisms and entities:

- General Directorate of Quality and Environmental Evaluation.
- Center of Studies and Experimentation of Public Works (CEDEX).
- Carlos III Health Institute.
- National Institute for Occupational Safety and Hygiene.
- Center for Energy, Environmental and Technological Research (CIEMAT).
- National Company of Radioactive Waste (ENRESA).
- General Directorate of the Merchant Navy.
- Public Business Entity of Maritime Rescue (SASEMAR).

Here only advisors and expert participation, mentioned of the bodies (at the directive level) that could be implied or related to nuclear security and possible nuclear accidents.

3) *State Committee of Coordination (CECO)* is planned:

- To coordinate the measures to be adopted for the mobilization of all means and resources civilians located outside the territorial scope of the affected autonomous community, requirement of the management body of the Plan of the autonomous community affected or of the Operational Direction, in case of emergency of national interest.
- Coordinate the assistance of international character that is needed.
- Participate in the preparation of the State Plan and its successive revisions and updates, as well as in the realization of exercises and simulations.

Concerning the general public, they refer only to affected populations and mainly for informative purposes and their support in emergency. CECO should:

- **Collect and disseminate information** about the emergency, response actions and **recommendations** to be transmitted to the **population affected**.
- **Centralize and coordinate general information about the emergency to the public** in general and **facilitate it to the social media**.

- **Provide all the information related to family contacts, location of people and data referred to the possible evacuees** and transferred to medical assistance centers.
- 4) *The Integrated Operational Coordination Center (CECOPI)* is a body that will be constituted at the request of the governing body of the Plan of the autonomous community affected, in cases of ordinary emergency that require it, or at the request of the Delegate of the Government, when an emergency has been declared of national interest. In this last case, as many CECOPIs will be set up as autonomous communities directly affected.

Also in case of emergency of national interest, CECOPI may be constituted, request of the General Directorate of Civil Protection and Emergencies, in those autonomous communities not affected, where it is necessary to mobilize means and resources for emergency care.

Their relationship to general public refers as the corresponded informative communication at the State level.

- 5) Autonomous communities (affected and those which are involved in the reception of evacuees) mainly are responsible for the complementation of the central State directives and also **provide information** to the **affected public** as per State directives; and operative support by mobilising the community resources.
- 6) Integrated Operative Command (on autonomous community level) are responsible for logistics of goods provided by external help and to keep updated the information about the emergency situation: damage occurred, created needs, means and resources mobilized and actions taken among other duties.

This body provides information about the accident and its dynamics and also support in receiving and collocating evacuees, family reagrupation, measurements on individual contamination doses, etc.

The operational system is provided to the affected public by creating specific **Centers of Attention and Information to the Citizens (CAIC)**.

“The Centers of Attention and Information to the Citizens (CAIC) are **destined to welcome the evacuated population in an emergency**, and they will develop the following functions:

a) Welcome the evacuated population, which, in turn, implies:

- Carry out the filiation of the evacuated persons.
- Provide emergency accommodation in the places provided for it, including the provisioning during the time of permanence.
- Provide basic material support, such as personal hygiene kits, or facilitate its acquisition by the people who require them, medications for use continued, items for baby care etc.
- Help family reunification.

**b) Ensure the information, individual and collective, to the population, in all aspects related to the emergency: on the evolution of the accident, on the state of the environment in the affected territory, on the tasks of cleaning and decontamination that could have started, etc.**

**c) Provide recommendations about the behaviors to be followed to avoid or reduce contamination, mainly by way of ingestion, and on good practices for farmers, ranchers and other professions closely linked to the environment.**

d) **Provide a first psychological, medical and legal assistance (compensation) or guide towards the specific services that can provide it.**

e) **Allow the realization of radiometries to people who have not passed through a Classification and Decontamination Station and exposure conditions deducted from the affiliation questionnaire will advise, in order to direct the people who need the corresponding Classification and Decontamination Station.**

f) **Centralize the demands of the public and guide people towards services adequate to meet them (psychological help, specialized health care, concern for relatives and friends etc.), as well as detect the false rumors that they would have to be clarified by adequate information.”**

In general the document describes the specific functions and actions by different state bodies to be implied in the three phases: pre-emergency, emergency and actions on recovery (long-term) including return people to their homes (for those who were evacuated and are allowed to return. The measures are of preventive character in the pre-emergency phase and more operative ones during the other two ones.

#### ***Level of stakeholder engagement (resume)***

Different stakeholders groups are involved in nuclear or radiological risk actions and this document describes mainly the state competent bodies that are most responsible for it.

As for the general public, it refers mainly to the affected populations and their involvement in the proceedings described on a state level (norms, recommendations, information provided and support – physical/logistical as evacuation, psychological and medical, and dose measurements). The only invited stakeholders groups mentioned in this document, and only in case of necessity, were from the bodies related or that have the direct relationship with radioactive accident and mitigation of its consequences who are expert on the relevant issues to be considered in the process of the remediation of the accident.

### **9.3.3. Related national analysis in indoor radon exposure**

#### **Germany**

##### ***Title of documents***

Radiation Protection Act, adopted on 12 May 2017 and German national radon action plan, published March 2019.

##### ***Key Words***

For radon, the relevant paragraphs of the Radiation protection Act were searched through to find declarations on stakeholder involvement or engagement. As there were none, the whole document was searched through with the key words “communication”, different German words for “involvement”, “public”, “society”. No matches were found for radon.

National radon action plan: participation, information, involvement, stakeholder, concerned parties, public.

##### ***Definitions and requirements***

The Radiation Protection Act provides a definition for the responsible person for a workplace for the purpose of protection against radon at workplaces.

The requirements of BSS for information, responsibility and involvement were only transposed into German law with the expression “informing the general public conveniently” (§125; no official translation). There are no requirements for stakeholder involvement or involvement of the public, except the formulation in §122 (1) that the Federal Ministry for Environment, Nature Conservation and Nuclear Safety develops a national radon action plan with participation of the Länder (federal states) and revises it at least every ten years, again by involving the Länder.

National radon action plan: The word stakeholder (concerned parties) is mentioned one time in the summary of actions, but is not further mentioned in the full text. No definition of stakeholder is provided, however, in the course of the text several parties are mentioned which should be informed or which shall inform others about diverse radon relevant aspects. Paragraph II.1 is dedicated to “Public relations”. Here it is stated that central aspects of a communication strategy on long term health risks due to radon exposure shall be developed on a national level, involving the Länder (federal states in Germany) and potentially Multipliers and specialists. The four actions within this topic are:

- Action 1.1: identification of target groups, Multipliers and target group specific communication paths.
- Action 1.2: elaboration of the bases for a better public understanding of health risks due to radon. A national communication strategy, developed by involving the Länder, is required to raise public understanding of radon.
- Action 1.3: Development and implementation of a national strategy for public relations work. The coordination with Länder-specific communication strategies is required as well as with other strategies of health education. Target group specific information material shall be developed, target groups shall be addresses directly, private persons as well as enterprises, especially small and medium enterprises because of their assumed lack of information on radon.

Action 1.4: development of Länder-specific public relations strategies, taking into account the Länder-specific radon situation.

### *Aspirations*

In §125, Radiation Protection Act, informing the public is set in context with gaining knowledge about radon exposure, radon associated health risks, radon measurements and possibilities for reducing radon activity concentration. Thus, information as used in the German Radiation Protection Act related to radon can be interpreted as option to reach those goals.

German national radon action plan: informing about consequences from radon exposure is seen as means to raise willingness to undertake measurements and protective actions. As one step before, by informing the public and concerned parties, a deeper understanding of the topic radon in the general public is expected. Aim of the public relations work described in the national radon action plan is sensitization and education of the public.

### *Motivations*

Radiation Protection Act: There are no statements on motivation of information provision.

The public relations work described in the national radon action plan is instrumentally motivated, as deeper knowledge on radon, deeper understanding of radon risk and a better education is expected to lead to more self-motivated measurements and protective actions.



### *Level of stakeholder engagement*

Radiation protection Act: The level of stakeholders' engagement is limited to provision of information related to radon exposure, radon related health risks, radon measurements and radon activity concentration reduction. There are no further explanations what is meant by convenient information.

The German national radon action plan displays a more sophisticated approach: the level of communication is mainly focused on information, enriched with the demand for target group analysis, target group specific information, communication and involvement and the objective of comprehensible risk presentation. Related to several aspects of radon information, coordination between the national and the Länder-level is required, as well as with local municipalities.

### *Any other observation*

The German Radiation Protection Act is very reserved relating to information and engagement. Information is only formulated to a very limited extent. The National radon action fills these minimal requirements by law with a lot more life.

Due to the federal system in Germany, the Länder have a high responsibility also in the radon problematic. Some of the Länder are very active in radon reduction measures, information for the public and building networks with relevant stakeholders. For example, the Bavarian State Office for Environment established the "Bavarian Radon Network" in the year 2012 as a platform for communication and cooperation. The radon network serves as point of contact for all questions regarding radon in buildings. It organises a yearly radon network meeting and provides information about radon specialists in Bavaria and news on radon protection. Similar activities can be observed in Saxony (e.g. the yearly Saxon Radon Day with a lot of presentations and discussion) and Baden-Württemberg – Länder which try to lower radon risk by offensive information and networking activities and pooling relevant experts, associations and organisations as well as other stakeholders.

### *Related extracts from Radiation Protection Act*

*§125 Informing the public; reduction of radon concentration, "(1) The Federal Ministry for Environment, Nature Conservation and Nuclear Safety as well as the responsible Länder authorities inform the general public conveniently about the exposure through radon in living rooms and the associated health risks, about the importance of radon measurements and about the technical possibilities for reducing radon-222 activity concentration" (not official translation).*

### **Slovenia**

#### ***Title of document***

Ionising radiation protection and nuclear safety act (ZVISJV-1), Off. Gaz. 76/2017 – Atomic Act and Decree on national radon program regulation, Off. Gaz. 18/2018

#### ***Key Words***

After the analyses of Atomic Act text, the following key words were searched:

- Members of the public, public.

The extracts from ZVISJV-1 (Atomic Act) as result of the search investigation is provided in the subchapter "Related extracts from Atomic Act". For the rest of the potential keywords as proposed in the Milestone 1.1 (actor(s), stakeholders, participant(s), engagement, involvement, interested party/parties, citizens, civil organisations (NGOs)) there was no result.

### ***Definitions and requirements***

The definitions used in Atomic Act correspond to the one used in BSS directive related to the RADON: "members of the public" which means individuals who may be subject to public exposure.

The government shall adopted a national radon program in which also a separate program to raise awareness among employers, the public and health professionals about the health risks posed by radon exposure, and the additional risks associated with smoking is part. This shall also include the importance of carrying out measurements of radon and measures to reduce exposure. The program shall be developed for period of 10 years and every new revision shall include also the assessment how well the previous one was implemented.

The requirements from BSS directive were transposed in relation to raising awarness to the public to Slovene legislation.

Further requirements and instructions how these should be achieved is given in Decree on national radon program regulation. In an area exposed to radon the authority responsible for radiation safety shall provide following:

1. provides information to the public, employers and local decision-makers through publications about health risks due to radon exposure, particularly relating to smoking;
2. prepares guidelines on preventing the entry of radon into buildings, including the identification of construction materials with high radon-release levels, and on implementing the rehabilitation of facilities and new buildings in areas with higher radon;
3. organises seminars, expert meetings and workshops on health risks due to radon exposure;
4. warns that adequate air quality in indoor areas must be provided where energy saving measures, such as energy rehabilitation and the installation of new windows, are implemented;
5. keeps records on radon concentration measures for indoor areas in accordance requirements of Atomic act;
6. strives to realise the long-term objective of reducing the risk of lung cancer, by regularly defining risks due to radon in strategic documents on managing cancers, and in programs established for the healthcare of children and young people;
7. within available financial means, supports research to improve understanding of the effects on health of radon exposure;
8. publishes a list of providers of works with knowledge and experience in the field of suitable new constructions and the successful rehabilitation of buildings.

### ***Aspirations***

Engagement of stakeholders and members of the public is mainly considered as one-way communication with provision of information by the responsible institutions through publications and guidelines. In the context of preparing of the national action plan to address long-term risks from radon exposures also a program to raise awareness among employers, the public and health professionals about the health risks posed by radon exposure, and the additional risks associated with smoking shall be determined. As part of this also seminars, expert meetings and workshops on health risks due to radon exposure shall be organised, which could enable two-way communication.

### ***Motivations***

In the Atomic Act the communication with the public is basic with some provision of information on the awareness related to health risks posed by radon exposure. In the further Decree there are some defined ways how to address public in areas exposed to radon. It could be understood that such

activities could be seen as normative (e.g. “it is the right thing to do”, it responds to a certain principle). Interaction with public is foreseen in the areas where there is increased level of exposure to radon for public, employers and local decision-makers.

#### *Level of stakeholder engagement*

The level of stakeholders’ engagement is mainly limited to provision of different information for raising awareness on risks posed by radon exposure from responsible authorities. In the more detailed Decree also activities to organise seminars, expert meetings and workshops on health risks due to radon exposure are foreseen. These activities could enable space for interaction between participants, like discussion and involvement.

#### *Any other observation*

The Atomic Act transposed some basic requirements from BSS directive related to indoor radon and public. The Decree on national radon program cover the transposition also with some suggestions on the communication with stakeholders. These could be used in many different ways, and it could be implemented in a way that the two-way communication could be established.

#### **Related extracts from Atomic Act**

##### *Article 73: National radon program*

- (1) *In order to manage long-term health risks due to radon exposure, the government shall adopt a national radon program to determine:*
1. *a management strategy for increased exposure due to radon, which includes targets and performance indicators to reduce health risks and takes into account the principle of optimization of protective measures;*
  2. *the reference level of concentrations of radon in the working and living environment;*
  3. *criteria for the designation of multiple radon areas and specific radiation protection measures in those areas;*
  4. *method and methodology for determining the annual mean concentration of radon;*
  5. *the program of the systematic review referred to in Article 66 of this Act;*
  6. *type and scope of measurements:*
    - *as part of the systematic review referred to in Article 66,*
    - *carry out measurements at the posts referred to in Article 67 and*
    - *carry out re-measurements for checking the implemented measures referred to in paragraph 7 of Article 68;*
  7. *methodology for assessing doses due to exposure to radon and*
  8. *a program to raise awareness among employers, the public and health professionals about the health risks posed by radon exposure, and the additional risks associated with smoking, and the importance of carrying out measurements of radon and measures to reduce exposure.*
- (2) *The body responsible for radiation protection shall regularly review the implementation of the national radon program, evaluate the performed radon measurements and the received dose due to exposure to radon, and report this in the Annual Report on the Protection against Ionising Radiation and Nuclear Safety referred to in Article 168 of this Act.*
- (3) *The national radon program shall be adopted by a government for period of ten years which, even before the end of the implementation of the previous national radon program, evaluates the implementation of the program and prepares proposals for further optimization of radiation protection measures and reduction of exposure due to radon.*

## **Belgium**

### ***Title of analysed documents:***

“Belgian national radon action plan, 2017-03-29-BDE-7-4-1-EN; date: 2017-03-29”

“RADON: Plan de communication; CFA/1 mars 2012” and presentation “Approach and evaluation of the radon communication plan in Belgium”

**Publicly available materials from FANC-AFCN (Federal Agency for Nuclear Control from Belgium): presentations at conferences, scientific articles, dedicated radon internet pages.**

### ***Keywords:***

radon, Belgium

**Title of the document: Belgian national radon action plan, 2017-03-29-BDE-7-4-1-EN; date: 2017-03-29**

### ***Level of the document:***

This document presents the national radon action plan in Belgium, updating the existing action plans with the information required following the EU BSS 2013/59/Euratom (article 103 and annex XVIII). This document covers the period 2018.

### ***Context of the document:***

The existing regulatory framework is essentially published in the FANC [Law](#) from 1994, The [Royal Decree](#) of 20 July 2001, The [FANC Decree](#) of 30 November 2015 and the procedures and registration published on the FANC Website ([link](#)). In order to implement the scientific findings published after the 1990's ([WHO, 2009](#)), the international Basic Safety Standards ([IAEA BSS](#)), and the European Directive [2013/59/Euratom](#), the existing regulations are in the process of being updated. The current action plan uses the definitions, reference levels and dose values fixed in the EU BSS, while some of the above mentioned national documents are in the process of revision.

### ***Definitions:***

The document doesn't define stakeholders, although it refers to stakeholders through the all document.

- “Different **stakeholders** are regularly invited to take part in specific working groups aiming at reviewing the existing regulations, as well as the radon action plan itself.” p. 6
- “A communication plan has been defined by FANC in 2014, aiming at efficiently inform the public, workers, employers and building professionals and to communicate essential messages stimulating the **stakeholders** to measure, mitigate and protect themselves, their families, their employees.” p. 6

The following stakeholders are mentioned in the document: “the general population, both the public and workers”, p.3; “house owners and occupants”, p.3; “building professionals and local governmental administrations”; p.3, 4; “regional authorities”, p.4; “employers”, p.4, 6; “local authorities”, p.4; “service providers for radon measurements”, p. 5; “ICRP or Euratom Article 31 Expert Group”, p. 5; “Association ERA, HERCA, ISIAQ”, p. 6; “Radon inspections”, p.6; “public, workers, employers and building professionals”, p. 6; “families”, p.6; “professional target groups such as lung-cancer specialists, general practitioners, architects, building research and administration”, p.6.; “professionals such as architects, builders, medics, local authorities, specific students”, p.6; “Belgian

Building Research Institute ([BBRI](#))”, p.6; “building confederation [CCW](#)”, p.6; “Local administrations (regions, provinces, municipalities, school administrations, prevention advisors, labour inspection, labour medicine, ...)”, p. 7;

**Aspirations:** -

**Motivations:**

Long term goals to reduce lung cancer risk: Following the European and international recommendations, FANC has set up a national radon action plan that is in application since 2009. The Belgian radon action plan is being published and updated annually. On the FANC website, a specific dossier has been developed on this subject ([link](#)). The plan considers the activities and strategies (for surveys, communication, building protection, remediation, mapping, and management) to develop and put in practice each year, in order to achieve the general goal (reduce the exposure to radon of the population and workers). The current document completes the existing radon action plan with additional content following ANNEX XVIII of 2013/59/Euratom). The action plan consists on the one hand of relatively continuous items, such as strategy, definition of working fields and technical details, completed by variable items such as annual actions, being updated each year.

**Level of stakeholder engagement**

For radon in existing dwellings: measurement campaigns are organised annually, allowing house owners and occupants to measure in a simple and cheap way the radon concentration in their homes. A dedicated website [www.actionradon.be](http://www.actionradon.be) has been developed for this purpose. In order to stimulate the population to measure radon, public awareness campaigns are organised each year between October and January, and [publications](#) are distributed.

For radon in new dwellings: In order to prevent radon ingress in new dwellings, awareness campaigns are organised to inform the public on the radon risk and on the protective measure to take during the construction of the building. Besides informing the public by [publications](#), and [interactive mapping](#) applications, training of building professionals and local governmental administrations is essential. Including regulations on radon protection in the building codes, a regional competence, is essential in order to implement radon protection in a structural and sustainable way. Concertation with the regional authorities on the implementation of these protective measures in the building codes is essential in attaining the goals.

For radon in workplaces: As described in the Royal Decree dealing with radiation protection ([RD of 20 July 2001](#)), radon measurements and mitigations are mandatory in specific workplaces in the areas defined by FANC ([FANC Decree of 30 November 2015](#)), following the procedures published on the FANC website ([link](#)). Employers, being responsible for the measurements in their premises and declaration of the results to the authority (FANC). A dedicated website has been developed in order to assist and facilitate the measurements and the declaration ([www.radonatwork.be](http://www.radonatwork.be)).

As for new dwellings, protections of new buildings is stimulated by information campaigns, [documentation](#), training of building professionals and local authorities and concertation on regional building codes.

In collaboration with local authorities, FANC provides diagnostic services on request.

Different stakeholders are regularly invited to take part in specific working groups aiming at reviewing the existing regulations, as well as the radon action plan itself. International organisations such as the European Radon Association [ERA](#), [HERCA](#), [ISIAQ](#) and others are regularly involved in scientific exchange, reviewing and working-group processes.

A communication plan has been defined by FANC in 2014, aiming at efficiently inform the public, workers, employers and building professionals and to communicate essential messages stimulating the stakeholders to measure, mitigate and protect themselves, their families, their employees. Communication with specific professional target groups such as lung-cancer specialists, general practitioners, architects, building research and administration, etc. aims at progressively inform and stimulate protective/preventive activities.

Increasing awareness of the risks and solutions related to radon exposure to the public, the workers, the employers and the specific professionals is a basic task and specific actions on this field are defined annually in the section actions and activities.

Specific material has been developed in collaboration with the Belgian Building Research Institute ([BBRI](#)) and training is provided in collaboration between [FANC](#), [BBRI](#) and the building confederation [CCW](#). The building professionals who followed specific training on radon and who are active in the radon field are listed on the FANC website ([link](#)).

Local administrations (regions, provinces, municipalities, school administrations, prevention advisors, labour inspection, labour medicine ...) are being trained and informed during specific workshops, meetings or conferences.

In order to assure the state-of-the-art of radon management activities, the participation and organisation of national and international collaborations and projects form subject of the radon action plan.

#### **Stakeholder engagement activities in 2017-2018**

- Reactivation of the collaboration with the Walloon Government concerning the Walloon regional action plan and focusing on the demands of BSS Art. 103 regarding new building protection
- Training courses of building professionals in collaboration with CCW et le BBRI ;
- Organisation of the national Radon Action in October ([www.actionradon.be](http://www.actionradon.be) ), stimulating the public to measure and mitigate, with press releases and road shows
- Measurement campaign in workplaces ([www.radonatwork.be](http://www.radonatwork.be) )
- Round table session for labor medicals and prevention advisors
- Detailing and updating the radon mapping in high risk areas based on new measurements in sub-soil information (geology, karst, ...)
- Further development of the European map of natural radiation, in collaboration with JRC (Ispra)
- Evaluation of radon in water and building materials, measurement campaigns
- Continuous evaluation of changes in building techniques (low energy building, ventilation...) on the indoor radon concentrations
- Finalization of the regulatory documents: Royal Decree, FANC Decree, FANC procedures, recommendations and Specifications.
- Continuous international collaboration with the neighboring countries (FR, LU, GE, NL) for mapping and public awareness.

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**Title of the document: “RADON : Plan de communication; CFA/1 mars 2012” and presentation “Approach and evaluation of the radon communication plan in Belgium”**

**Level of the document:** RADON : Plan de communication; CFA/1 mars 2012 is an internal document of the Belgian authorities FANC-AFNC and “Approach and evaluation of the radon communication plan in Belgium” is a presentation given by Boris Dehandschutter, Michel Sonck, Patrick van der Donckt Health and Environment, Federal Agency for Nuclear Control and Pol Gosselin, CPES, Région Wallonne

### *Definitions*

The following stakeholders and stakeholder groups are listed in the document: Population: general population, population in radon prone areas; Building professionals: architects, building contractors, radon mitigators (and measurement firms); medical professionals; authorities: local administration (solicitors, dept. of land use, housing ...), regional and provincial authorities, IAQ dept./agencies; academics/health departments, p. 1

The document provides the following list of partners for the communication campaign. Health prevention workers: Federal Employment department (workplaces), Federal health department, Regional health/employment departments, Provincial departments (health), Municipal departments (housing/health), Building research institute (CSTC-WTCB), Building Confederation (CCW-VCB) p.1.

### *Aspirations*

The communication campaign has been evaluated by general practitioners (GP). The applied methodology (reach the public through GP's) has been negatively evaluated. The most common remarks to the campaign were:

Radon risk is not conceived as an important health risk by many GP. The focus is on tobacco.

Many GP consider radon only of importance in the highly exposed radon-prone areas.

Many GP's feel drowned in the information/brochures/posters they receive.

Several GP's suggested other ways for radon awareness activities, such as conferences for GP's, GP federations, medical journals.

### *Motivations*

The objectives of the communication plan are to increase the public awareness and to convince the stake-holders of the benefit of taking action: Inform the stake-holders; Increase the knowledge; Guide the stake-holders to the right information; Changes in the behaviour of the stakeholders.

### *Level of stakeholder engagement*

The communication campaign is mainly founded on one-way information using the following tools:

- Radon Web site,
- Brochures: General (triplet); Detailed (12 p.); Remediation (20p.); Prevention (10 p.); brochure for general practitioners,
- Articles and press releases: Local, regional and national press; Magazines (architects, medical, consumers ...).

*The communication campaign has some higher level of involvement activities, with opportunity for a dialogue: Road shows and Building fairs (Low energy building).*

Efficiency of the communication was evaluated through surveys: Assessment of brochures ( 57 people sampled from ordinary population who received the brochures have been contacted by telephone for a short survey - 10 questions; and Satisfaction of the medical doctors (A sample of 50 GPs (out of 6000) have been solicited by telephone for a short survey - 8 questions.

**Title of the documents: Publicly available materials from FANC-AFCN (Federal Agency for Nuclear Control from Belgium): presentations at conferences, scientific articles, dedicated radon internet pages**

Active and enforced legal document related to radon in Belgium: 30/11/15 Determination of the risk zones referred to in Art. 4 and art. 70 of the Royal Decree of 20/07/01; Decree of the Federal Agency for Nuclear Control of 30 November 2015 determining the risk zones and the zones referred to respectively in Article 4 and Article 70 of the Royal Decree of 20 July 2001 concerning general regulations for the protection of the population, of the employees and the environment against the danger of ionising radiation (KB, 2015).

Legal documents related to radon in Belgium: ARBIS (KB 20/07/2001)

- Art. 4 en Art. 9: control workplaces exposed to NORM and radon
- Art. 20 (workplaces): dose level of 3 mSv/y or 800 kBq/h/m<sup>3</sup>
- Art. 70: define radon-prone areas and control radon in dwellings and workplaces



- Art. 72bis: intervention at existing exposure situation: mitigation or monitoring/control system Existing legal requirements or specific recommendations related to radon issues in Belgium don't address stakeholder engagement directly. It is worth to mention, that new Basic Safety Standards directive (BSS) (2013/59/EURATOM) is legal requirement for Belgian authorities which still has to be transposed in the national legislation.

Stakeholder engagement is in Belgium addressed in documents reporting on practical level of radon measurement and mitigation, for instance presentations, proceedings and the radon internet pages. In this publicly available material, authorities explain who stakeholders in radon issues are and how they engage with them. Consequently, this ENGAGE analysis brings together the following publicly available material in order to identify definitions, aspirations, motivations and level of stakeholder engagement:

- Dehandschutter, B. (2016). Radon in the indoor air environment. FANC, Belgian Federal Agency for Nuclear Control Department Health & Environment Surveillance of the Territory & Natural Radiation (accessed on 31.10.2018)(<https://www.afcn.fgov.be/fr/system/files/health-risks-radon-management-workplaces.pdf>).
- Dehandschutter, B., Pepin, S., Vanderlink, A., & Sonck, M. (2017). European Basic Safety Standards: Harmonisation of the requirements concerning radon. Paper presented at the BVS-ABR, Brussels, Belgium.
- FANC-AFCN. (2018). RADONACTIE.
- 30/11/15 Vaststelling van de risicozones bedoeld in art. 4 en art. 70 van het KB van 20/07/01 Besluit van het Federaal Agentschap voor Nucleaire Controle van 30 november 2015 houdende de vaststelling van de risicozones en de zones bedoeld in respectievelijk artikel 4 en artikel 70 van het koninklijk besluit van 20 juli 2001 houdende algemeen reglement op de bescherming van de bevolking, van de werknemers en het leefmilieu tegen het gevaar van de ioniserende stralingen (2015).
- Tondeur, F., Cinelli, G., & Dehandschutter, B. (2015). High radon areas in the Walloon region of Belgium. *Radiat Prot Dosimetry*, 164(4), 563-568. doi:10.1093/rpd/ncv312

### ***Definitions: residents and workers***

Definition of 'stakeholder' and/or 'stakeholder engagement' is not provided in any document related to Radon in Belgium. However, FANC-AFCN engages with two groups of stakeholders: stakeholders from the affected communities, indicated (defined) on detailed radon map published on-line ([www.actonradon.be](http://www.actonradon.be)) and employers and employees ([www.radonatwork.be](http://www.radonatwork.be)).

Affected communities are indicated in the legal document by name of the community (Art .2, Art. 5) and based on the cadastral parcel Art. 5 (KB, 2015). In the latter case, the stakeholders are owners and residents of the specific cadastral parcel.

In addition, FANC - AFCN identified among the affected population the following stakeholders in radon prone areas: schools, kindergartens, daycare centers, buildings with public access, administrations, libraries and medical centers, building sector, architects, local politicians. The radon measurement campaign is done in cooperation with local partners, e.g. local communities and municipalities (Dehandschutter, 2016).

## Aspirations

Contradictions or divergences that can be found in the document analysed relate to contradictions between legal requirements and practice, media reporting about radon issues, lack of the evidence based approach to radon actions and lack of stakeholder engagement.

Contradictions between legal requirements and practice

- The new BSS directive with requirements for a concrete communication plan (Annex XVIII) and involvement of stakeholders in decisions related to radon exposure situations (Art. 102) is not transposed in national legislations although would need to be transposed to Belgian national legislation until 6<sup>th</sup> of February 2018. (status of national documents on 31<sup>st</sup> of October 2018) The transposition of the BSS is technically finished and practically ongoing: all documents are ready and, in the line, waiting for approval and publication of other Royal Decrees of which they depend.

The new BSS directive requests from Belgium that it “provides as appropriate for the involvement of stakeholders in decisions regarding the development and implementation of strategies for managing exposure situations” (Art. 102), the existing national practices focus mainly on increasing public awareness of radon and communication campaigns. See: <https://fanc.fgov.be/nl/nieuws/radonactie-2018-bewust-maken-voor-het-radonrisico> (accessed on 31.10.2018)

## Low media interest

Radon issues mainly appear in a public discourse through mass media whenever an increased level had been found in a public building, e.g. school or kindergarten. This rather ‘non-stakeholder engagement’ in radon exposure situations, resulted in low radon awareness and sensational media reporting instead of empowering stakeholders for informed decision-making.

## Lack of the evidence based approach

While there are regular communication “Radon Action” campaigns conducted on a yearly basis in Belgium, there is lack of empirical evidence and systematic measures of behavior change after radon communication campaigns, as well as no research that would identify change agents for radon actions and no scientific evidence on the approach to effective radon communication.

## Lack of stakeholder engagement

Contradictions related to passive houses and radon mitigation actions

Although FANC-AFNC recognizes building industry and architects as an important stakeholders and conducts special training courses for builders, there are contradictions that confuse stakeholders. For instance, in media articles with title “FANC warns of radioactive gas” is stated: “*Particularly in low-energy houses and in passive houses there is a chance that if the ventilation system does not function properly, there will be increased concentrations of Radon.*” [https://www.vrt.be/vrtnws/nl/2014/10/16/fanc\\_waarschuwt\\_voorradon-1-2120558/](https://www.vrt.be/vrtnws/nl/2014/10/16/fanc_waarschuwt_voorradon-1-2120558/) Experts from building industry don’t agree with this statement. “*I find it peculiar that passive houses are targeted: there should be a pretty good airtight shell present and there is also mandatory ventilation. Or does anyone know of a study that many passive houses have a malfunctioning ventilation system? It seems to me that the problem with classic houses is much bigger on windless days (little to no natural ventilation), than with passive houses ...*” <https://www.ecobouwers.be/forum/post/radon-passiefhuizen-en-lew> (accessed on 31.10.2018). This contradiction points a need for engagement on a higher level and mutual learning between authorities and industry.

## Motivations: Public health and legal requirements

Motivations for stakeholder engagement mainly relate to public health and legal requirements.

Radon is estimated to cause approximately 480 cases of lung cancer per year in Belgium (FANC-AFCN, 2018). Recent dose coefficients published by ICRP (ICRP, 2017) show that the average residential indoor radon concentration in Belgium ( $48 \text{ Bq/m}^3$ ) leads to an effective dose of  $2 \text{ mSv/y}$ . About 48 % of the Walloon region is expected to be affected by radon, which means that more than 1 % of houses are above the reference level of  $300 \text{ Bq/m}^3$  (Tondeur, Cinelli, & Dehandschutter, 2015).

The European Commission in the new Basic Safety Standards directive (BSS) (2013/59/EURATOM) requires from Member States (including Belgium) to develop National Action Plans, due to the increased risk of lung cancer from long-term exposure to indoor radon levels over the order of  $100 \text{ Bq/m}^3$ .<sup>17</sup> Among others, these plans aim at increasing public awareness of the risk of radon, methods and tools for measurements, and remedial measures. For instance, it is requested (in Annex XVIII) to develop a „*strategy for communication to increase public awareness and inform local decision makers, employers and employees of the risks of radon, including in relation to smoking*“ (EU, 2014). Furthermore, concerning stakeholder involvement the new BSS Directive (Art. 102) requires that „*Member States shall provide as appropriate for the involvement of stakeholders in decisions regarding the development and implementation of strategies for managing exposure situations*“ (EU, 2014).

Due to implementation of new Basic Safety Standards (2013/59/Euratom) the Belgium needs to transpose the following: Reduce the Reference level from  $400 \text{ Bq/m}^3$  to  $300 \text{ Bq/m}^3$ , and address within new legislation planned exposure situation, justification of the protection, make Radon action plan, and address building materials (Dehandschutter, 2016).

The Motivations of the FANC-AFCN Radon Action plan are the following: Long term: general prevention for new buildings (targeted level of  $100 \text{ Bq/m}^3$ ) and substantial reduction of lung cancer incidence and Short term: remediation of high levels trace buildings with high exposure and remediate buildings above the Action Level ( $AL=400 \text{ Bq/m}^3$  corresponding to  $10 \text{ mSv/y}$ ) (Dehandschutter, Pepin, Vanderlink, & Sonck, 2017).

## Level of stakeholder engagement: public awareness, partnership with local communities and authorities

Analysis of the public available material revealed that there are many different levels and approaches to radon issues applied in Belgium. They range from one way information, increasing public awareness to partnership approach with local communities and engagement at international policy-making level.

To make the Belgian population aware of the problem of radon, the Federal Agency for Nuclear Control (FANC) annually organizes the Radon Action. In addition, it receives the support of the five Walloon provinces and the Brussels Region, represented by the SAMIs (Services of the Analysis of Environment in Liège, Namur and Walloon Brabant), the LPI (Lab of the Pollutions Intérieures in Hainaut) and the RCIB (Regional Unit for Intervention in Indoor Air Pollution in Brussels). With this initiative, the FANC encourages the citizens to measure the radon concentration in their homes and to carry out any remedial action. The campaign in 2018 started on 1 October and will end on 31 December (or when the stock is exhausted). During the Radon Action the cost price of a radon detector (including

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<sup>17</sup> The reference level  $300 \text{ Bq/m}^3$  accumulates  $10 \text{ mSv}$  per year for residential exp. maximum as defined in new BSS Directive, Art. 74.

assistance with possible remedial actions) is € 20. If a stakeholder participates in this action, it also authorizes the FANC to use the measurement data and results obtained for refining the statistics and for completing the Belgian radio cartography (FANC-AFCN, 2018).

**The following activities have been organized:** Road-shows conducted, brochures and flyers distributed, special web-site published and radon day organised.

FANC-AFCN organizes information sessions, training courses for building professionals, offers free control test (after remediation) and free test extractors (Dehandschutter, 2016; Dehandschutter et al., 2017).

Nuclear safety control FANC-AFCN “*negotiate with local governments*” to include radon preventive measures in the building code, provides detailed scale radon maps for new builders, trains local governments to provide radon info for new builders, distributes brochures for new builders and train architects and building professionals (Dehandschutter, 2016).

In addition, FANC-AFCN actively participated at several workshops in order to exchange experiences, formulate recommendations and develop common understandings: ASN-NRPA (2014), European radon association workshop in Krakow (2015) and HERCA workshop Radon in Workplaces (2016) (Dehandschutter et al., 2017).

FANC-AFCN is also a founder and Executive Committee member of the European Radon Association (ERA) - community in Europe of professionals such as scientists, technologists, public health officials and decision makers working in the radon field. ERA interacts with decision and policy makers. Position papers are produced, representing the opinion of the Radon professionals in Europe. A key activity of ERA should be the yearly organisation of a Radon conference, dealing with scientific and practical topics of interest, combined with a technical exposition on radon measurements, mitigation and prevention methods. ERA contacts scientific journals in order to publish the most relevant works presented in the conference. ERA helps the development of high quality training and education courses and stimulates the elaboration of a harmonized European certification scheme for radon mitigations and measurement providers. As an association, ERA contributes its particular point of view to the new international standards (ISO) concerning radon gas whilst in draft format. <http://radoneurope.org/> (accessed on 31.10.2018)

#### References:

1. Dehandschutter, B. (2016). Radon in the indoor air environment. FANC,, *Belgian Federal Agency for Nuclear Control Department Health & Environment Surveillance of the Territory & Natural Radiation* (accessed on 31.10.2018)(<https://www.afcn.fgov.be/fr/system/files/health-risks-radon-management-workplaces.pdf>).
2. Dehandschutter, B., Pepin, S., Vanderlink, A., & Sonck, M. (2017). *European Basic Safety Standards: Harmonisation of the requirements concerning radon*. Paper presented at the BVS-ABR, Brussels, Belgium.
3. COUNCIL DIRECTIVE 2013/59/EURATOM”. Accessed from: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0059&from=en>. Retrieved 20 June 2017, (2014).
4. FANC-AFCN. (2018). RADONACTIE.
5. ICRP. (2017). Occupational Intakes of Radionuclides: Part 3. ICRP Publication 137. *Ann. ICRP*, 46(3/4).
6. 30/11/15 Vaststelling van de risicozones bedoeld in art. 4 en art. 70 van het KB van 20/07/01 Besluit van het Federaal Agentschap voor Nucleaire Controle van 30 november 2015 houdende de vaststelling van de risicozones en de zones bedoeld in respectievelijk artikel 4 en artikel 70 van het koninklijk besluit van 20 juli 2001 houdende algemeen reglement op de bescherming

van de bevolking, van de werknemers en het leefmilieu tegen het gevaar van de ioniserende stralingen (2015).

7. Tondeur, F., Cinelli, G., & Dehandschutter, B. (2015). High radon areas in the Walloon region of Belgium. *Radiat Prot Dosimetry*, 164(4), 563-568. doi:10.1093/rpd/ncv312

## 9.4. Annex 4: Analyses of international documents

### 9.4.1. Medical field

#### **International Action Plan for the Radiological Protection of Patients.**

Action plan of IAEA, in consultation with PAHO, WHO and UNSCEAR, resulting from the 2001 conference on Radiological protection of patients in Malaga<sup>18</sup>.

#### **Key Words**

The document makes no use of key words such as ‘stakeholder’, ‘engagement’, or ‘participation’. Reference is made to ‘involvement’ of parties in order to make progress in patient safety as a whole.

#### **Definitions**

No definition of stakeholder engagement is provided. A broad description of the types of stakeholders can be found in the following statement: “The involvement of international organisations and professional bodies is crucial to performing the actions and achieving the goals [of the action plan]” (p2 of the action plan).

The action plan itself mostly focuses on training, education, guidance and information exchange, with a particular focus on health professionals (medical practitioners, technologists, nurses, medical physicists, radio pharmacists, equipment designers, equipment maintenance engineers, biomedical and clinical engineers, administrators, regulators, etc. (p3)) and organisational actors. No precise descriptions or definitions of these stakeholders are provided, and there are limited references to specific stakeholders throughout the document.

#### **Aspirations**

As an overall objective, the action plan aims to make progress in patient safety as a whole, starting from the statement that “patients have a right to expect the radiation to be used in a safe and effective manner” (p2). Health professionals are perceived as the “critical link” (p2), and it is thus recognized how the involvement of professional bodies and international organisations is a requirement for the success of the actions presented in the document.

Although reference is made to patients’ rights regarding a safe and effective treatment, patients themselves do not feature as stakeholders to be directly involved in the proposed actions.

‘Involvement’ seems to take a rather unidirectional approach when it comes to health professionals, as emphasis is mostly put on training, guidance, and information exchange. However, at some points, the direct input of health professionals is also sought after; e.g. providing info on (near) accidents and incidents, providing input on guidance documents, or consultation of manufacturers in regard to standardization of computerized systems.

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<sup>18</sup> Note: the document only consists of 13 pages, and mentions how the safety standards that this Action Plan adheres to are the standards as found in the BSS Directive.

Interesting is that particular attention is directed towards the recognition of medical physicists and technologists as stakeholders in radiation protection; formal recognition of the former, and recognition of the impact of the latter are lacking, and the Action Plan strives to change this situation.

### ***Motivations***

Remains general, as stated above. A more precise rationale or motivation for stakeholder engagement is lacking.

### ***Level of stakeholder engagement***

No particular mention of models of stakeholder involvement. The level of stakeholder engagement is mainly limited to providing and exchanging information (e.g. in the form of training, guidance or further research), or is not discussed in the document (in the case of patients).

### ***Any other observation that may be relevant to the study***

Although the document itself makes little reference to specific stakeholders, it has been developed with the help of a large range of organisational actors, thus reflecting a broad involvement of stakeholders at the level of setting the actions presented in the document. These organisations are: IAEA (main actor), PAHO, WHO and UNSCEAR (consulting role in the development of the action plan), the European Commission, the International Commission on Radiation Units and Measurements, the International Commission on Radiological Protection, the International Electrotechnical Commission, the International Organisation for Medical Physics, the International Organisation for Standardization, the International Radiation Protection Association, the International Society of Radiation Oncology, the International Society of Radiographers and Radiological Technologists, the International Society of Radiology, and the World Federation of Nuclear Medicine and Biology (involvement in the preparation of the draft Action Plan).

### **Radiation Protection and Safety Radiation Sources: International Basic Safety Standards. General Safety Requirements Part 3, 2014, IAEA**

#### ***Key Words***

After the analyses of IAEA BSS<sup>19</sup> text the following key words were searched:

- stakeholder(s)
- patients
- member of the public
- engagement (consent)
- participation
- involvement

#### ***Definitions and requirements***

IAEA BSS are based on the system of protection and safety with the aim to assess, manage and control exposure to radiation. The system of protection and safety is related to radiation risks under normal circumstances, consequence of incidents and to safety measures in preventing incidents.

The session 2 of General Requirements for Protection and Safety applies to all exposure situations and all categories of exposure (medical exposure included). In 'Management Requirements', Req.5 on

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<sup>19</sup> Analysis of the IAEA BSS has the only aim to consider the aspects of MEDICAL EXPOSURES and this is not a complete analysis of the document.

Management for protection and safety, it is indicated that the 'principal parties' shall promote and maintain safety culture by taking into account different points, including: -to encourage the participation of workers and their representatives and other relevant persons in the development and implementation of policies, rules and procedures dealing with protection and safety; -to encourage open communication with regard to protection and safety within the organisation and with relevant parties, as appropriate; -to encourage a questioning and learning attitude.

The part of the document dedicated to medical exposure (session 3. Planned Exposure Situations – Medical exposure) is consistent within this system.

In this document the 'medical exposure' considers patients, carers and comforters, and diagnostic investigation of volunteers participating in a programme of biomedical research.

The introduction of the IAEA BSS indicated that the prime responsibility for safety must rest with the person or organisation responsible for facilities and activities that given rise to radiation risk.

In case of medical exposure, the prime responsible for protection and safety for patient lies with the 'health professional' responsible for administration of the radiation dose, who is referred in the text as 'radiological medical practitioner' (1.8)

The term 'stakeholder' is not present in the document and therefore not even in the part dedicated to medical exposure.

(patient) No patient, symptomatic or asymptomatic, is subject to exposure unless: there is the request of referring medical practitioner with indication of the clinical context or of approved health screening programme; the medical exposure is justified by means of a consultation between radiological medical practitioner and the referring medical practitioner. Information has to be given to the patient (or to the legal authorized representative) on the expected diagnostic or therapeutic benefits and risk, as appropriate. (3.151, Req.36).

In the release of patients after radionuclide therapy, appropriate attention for the radiation protection of the family members of the patient and of members of the public is needed, and the patient (or the legal guardian) has to receive information on the radiation risk and written instructions to keep ALARA the dose to persons who are in contact or in the vicinity of the patient and also for avoiding the spread of contamination (3.178, Req. 40).

The female patient, when considering radiological procedure, is requested to notify to the radiological medical practitioner the case she is or might be pregnant, or she is breast-feeding (in consideration of administration of radiopharmaceuticals). With this purpose, indications, 'signs in appropriate language', shall be placed in public places like the patient waiting rooms, and other means of communication shall be used, as appropriate, including to explicitly ask the female patients. (3.175, Req. 39). For radiological procedure that could result in significant dose to the embryo-fetus, procedures for ascertaining the pregnancy or arrangements for define if the female patient is currently breastfeeding have to be available in place. This information is considered in the justification of the radiological procedure and in the optimization process. (3.176, Req.39). Note that the female patient, as a patient, is expected to receive information on diagnostic or therapeutic benefits and risk, as appropriate, as indicated in 3.151, Req.36, even if in this part of the document dedicated to 'Pregnant or breast-feeding female patients' it is not explicitly indicated.

Regarding any unintended medical exposures, apart from the estimate of the received dose and distribution, the patient (or the patient's legal authorized representative) and referring medical practitioner have to be informed of the unintended or accidental exposure. (3.181 in Req. 40 ).

(volunteers) The medical exposure of volunteers in biomedical research programme needs justification and it is subjected to approval by an ethical committee. In the document it is not explicitly indicated the need of information to volunteers, but the article dedicated to medical exposure to volunteers (3.161) remembers the need to be in accordance with three main documents considering the subject ( World Medical Association; Council for International Organisations of Medical Sciences, World Health Organisation; International Commission on Radiological Protection) and one of this document is ICRP 62, indicated in the ICRP 103 Recommendations.

(carers, comforters) Any individual, prior to provide care and comfort to an individual subjected to a medical exposure, shall receive relevant information on radiation protection and radiation risk and has to indicated an understanding. (3.153, Req. 36).

(asymptomatic individual) Any radiological procedure intended for early detection of disease on asymptomatic, that is not part of an approved health screening programme require justification, specifically for that individual, given by the radiological medical practitioner and the referring medical practitioner in accordance with guidelines of the relevant professional bodies and health authority. As part of this process the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure. (3.160, Req. 37).

(consent). The word consent is not used in the document, a part in the session dedicated to 'Definitions' when defining the term 'approval' as 'the granting of consent by a regulatory body'.

Thus, no indication about consent is related to medical exposure, even in the case of possible pregnant patient.

(consultation, cooperation and involvement of relevant professionals) In the Scope of Medical Exposure, it is indicated that the consultation between the health authority, relevant professional bodies and the regulatory body is used in the definition of : -diagnostic reference levels for medical exposure in medical imaging (3.148, Req.34); and dose constraints for exposures of carers and comforters, and to be used in biomedical research programmes (3.149, Req.34).

The radiological medical practitioner assumed responsibility for ensuring the protection and safety for patient, in planning, delivery and in justification and optimization, in cooperation with the medical physicists and the medical radiation technologist. For diagnostic radiological procedures and imaging interventional procedures the degree of involvement of a medical physicist is based on the complexity of the procedures and associated radiation risks. (3.154).

For therapeutic radiological procedures, the radiological medical practitioner is asked to ensure for each patient the proper dose for the planning target, with dose maintained ALARA for the other volumes, in cooperation with the medical physicist and the medical radiation technologist. (3.164). When radiopharmaceuticals are used in therapeutic radiological procedures the radiological medical practitioner is asked to ensure for each patients the administration of the proper radiopharmaceutical and activity, in cooperation with the medical physicist and the medical radiation technologist, and if appropriate with the radiopharmacist or radiochemist (3.165).

An active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate, is indicated with the aim to establish a comprehensive programme of quality assurance for medical exposure. (3.170).



### ***Aspirations***

The term 'stakeholder' is not present in the document and therefore not even in the part dedicated to medical exposure. In the IAEA BSS the term 'interested party' is used as 'a person, company, etc .., with a concern or interest in the activities and performance of an organisation, business, system, etc.' and it is well present in the session 2. General Requirements for Protection and Safety. This term is present in the three successive sessions (3.Planned Exposure Situations, 4.Emergency Exposure Situations, 5. Existing Exposure Situations) but in the planned exposure situations it is present only in one point dedicated to constraints of dose (3.120 'The government or the regulatory body shall establish or approve constraints on dose and constraints on risk to be used in the optimization of protection and safety for members of the public. When establishing or approving constraints in respect of a source within a practice, the government or the regulatory body shall take into account, as appropriate: (...) (d) The views of interested parties.'). This point relates to the public exposure, while in the part of medical exposure neither the attention to 'interested parties' is given.

### ***Motivations***

In the IAEA BSS the attention to all possible aspects of communication appears poor within the medical exposure, and it is mainly limited to information, for example to the patient.

Attention is dedicated to carers, comforters (3.153), since they have to receive information on radiation protection and on radiation risk and their indication of understanding is needed before providing assistance and comfort to an individual subjected to radiological procedure.

The 'consent' by the patient to the medical exposure is not cited.

More attention is given to the communication among the professionals and with health authority and regulatory body, by including different levels as: consultation, cooperation, involvement, and active participation.

### **The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).**

### ***Key Words***

After the analyses of ICRP Publ 103<sup>20</sup> (the ICRP Recommendations) text, the following key words were searched:

- stakeholder(s)
- patients
- member of the public
- engagement (consent)
- participation
- involvement

Note that, with respect to other field of exposure, the use of ionising radiation in medicine for patients has unique aspects, as the consideration that exposure for patients is related to the expectation of direct individual health benefits to the exposed patient, the fact that the dose to the patient cannot be reduced indefinitely without compromise the intended result, and the use of different degrees of informed consent involving the patients in the decision on ionising radiation exposure.

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<sup>20</sup> Analysis of the ICRP 2007 has the only aim to consider the aspects of MEDICAL EXPOSURES and this is not a complete analysis of the document.

Note that in the medical field the RP focuses on justification and optimisation, differently from other type of exposures, the medical exposure is not applying dose limits. When decisions are taken on justifying a medical procedure, the optimisation is requiring the greater specific attention. Thus we can say that stakeholder views and concerns have a highly meaningful role in the medical field.

### **Definitions and requirements**

ICRP 103, Definition 'Medical exposure' - Exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly, while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.

1-In the Editorial, by the ICRP Chair, it is remembered that the “ the Commission has initiated a much more open process than that used for the development of the previous recommendations. It should also be noted that the Commission mentions, for the first time, the need to account for the views and concerns of stakeholders when optimising protection.”

2-In the same Editorial, it is written: “The Commission has therefore solicited input from a broad spectrum of radiological protection stakeholders, ranging from government institutions and international organisations to scientists and non-governmental organisations. The draft recommendations have been discussed at a large number of international and national conferences and by the many international and national organisations with an interest in radiological protection.”

Note the concept expressed here above is very important. We can say that ICRP changes the modality to produce/approve documents of RP, (which are of interest and implementation in the different concerned field from authority of the different countries in the world). This (ICRP 103) was the first document prepared within ICRP and then opened to consultation (given free access for anybody, organisations, institutions and also single person) before publication. In this sense any stakeholder, member of the public, or worker or patient (...) can see the first version of the ICRP text and upload her/his comments (it is sufficient to go on ICRP web that is complexly open access). Then the comments are taken into consideration by ICRP (since everybody can have good ideas !!).

3- Always in the Editorial: “Recommendations have been prepared after two phases of international public consultation. By following this policy of transparency and involvement of stakeholders, ICRP is expecting a clearer understanding and wide acceptance of its Recommendations.” – This concept is also in the EXECUTIVE SUMMARY.

Note this sentence clarify the concept in the above point 3, and introduce the 'involvement of stakeholders' (in the text of the recommendations). In the reality, I was like this. The first recommendations text was changed in some important aspect through the open consultation

4- (223) All aspects of optimisation cannot be codified; rather, there should be a commitment by all parties to the optimisation process. Where optimisation becomes a matter for the regulatory authority, the focus should not be on specific outcomes for a particular situation, but rather on processes, procedures, and judgements. An open dialogue should be established between the authority and the operating management, and the success of the optimisation process will depend strongly on the quality of this dialogue.

(224) Societal values usually influence the final decision on the level of radiological protection. Therefore, while this report should be seen as providing decision-aiding recommendations mainly based on scientific considerations on radiological protection, the Commission's advice will be expected to serve as an input to a final (usually wider) decision-making process, which may include other societal

concerns and ethical aspects, as well as considerations of transparency (ICRP, 2006a). This decision-making process may often include the participation of relevant stakeholders rather than radiological protection specialists alone.

Note these two points of the paragraph “5.8. Optimisation of protection” of the ICRP recommendation Publ 103 are clearly of interest for this analysis, but it is a general part, not specifically dedicated to the medical part and this aspect is clear when dealing with an open dialogue between authority and operating management, and when including the participation of relevant stakeholders. (This process is in ICRP 103 but not addressed specifically for medical exposures)

5- “(209) Medical exposure of patients calls for a different and more detailed approach to the process of justification. The medical use of radiation should be justified, as is any other planned exposure situation, although that justification lies more often with the profession than with government or the competent regulatory authority. (.....) The responsibility for the justification of the use of a particular procedure falls on the relevant medical practitioners, who need to have special training in radiological protection.”

Note here the importance of the first RP principle ‘Justification’. In the medical exposure the justification has a great role; consider we have here 3 level of justification (only for the medical exposure).

6- “(224) Societal values usually influence the final decision on the level of radiological protection. Therefore, while this report should be seen as providing decision-aiding recommendations mainly based on scientific considerations on radiological protection, the Commission’s advice will be expected to serve as an input to a final (usually wider) decision-making process, which may include other societal concerns and ethical aspects, as well as considerations of transparency (ICRP, 2006a). This decision-making process may often include the participation of relevant stakeholders rather than radiological protection specialists alone.”

Note that this is the only case, in the document, of the use of the word ‘stakeholders’ a part the attention given regarding the procedure on how to define the final text of this document. At the same time we have to consider that this part of the document do not specifically refers to the medical exposure and moreover the cited document (ICRP, 2006a) indicated that “This report a addresses all exposure situations where radiological exposures are amenable to control, except patient exposures which are dealt with separately.”

7- “(327) The exposure of patients is deliberate. Except in radiation therapy, it is not the aim to deliver a radiation dose, but rather to use the radiation to provide diagnostic information or to conduct an interventional procedure. Nevertheless, the dose is given deliberately and cannot be reduced indefinitely without prejudicing the intended outcome. Medical uses of radiation are also voluntary in nature, combined with the expectation of direct individual health benefit to the patient. The patient, or legal guardian, agrees or consents to a medical procedure using radiation. This decision is made with varying degrees of informed consent that includes not only the expected benefit but also the potential risks (including radiation). The amount of information provided in order to obtain informed consent varies based on the exposure level (e.g., whether diagnostic, interventional, or therapeutic) and on the possible emergent medical complications that may be attributable to radiation exposure.”

Note the concept that ‘exposure of patients is deliberate’, the patients have direct advantage and that they have to give the consent, we know it. For some aspects the medical field appears as a backward approach (a sort of an old approach for exposed persons, with very poor stakeholder engagement) but

probably (we can discuss on it) information, consent and the direct advantage (provided that the diagnostic exams are really well justified) are points that lead to a balance on this view.

8- “(358) The ethical and procedural aspects of the participation of volunteers in biomedical research and its justification have been addressed by the Commission in Publication 62 (ICRP, 1991c). . . .” .  
(359) In many countries, radiation exposure of pregnant females as subjects in biomedical research is not specifically prohibited. However, their involvement in such research is very rare and should be discouraged . . . .’.

Note it seems useful to refer to ICRP 62:

ICRP 62 (Radiological Protection in Biomedical Research) – 2.Ethical aspects – ‘(10) Whether the benefit is specific or general, no-one should be subjected to medical or scientific investigations without giving free and informed consent. This means that the risks and likely benefits of the proposed research should be explained in advance. The subject has the right to accept the risk voluntarily, and has an equal right to refuse to accept. By free and informed consent is meant genuine consent, freely given, with a proper understanding of the nature and consequence of what is proposed, obtained from adults who are of sound mind. This intentionally makes it difficult to carry out such investigations on children or those who are mentally ill or defective, as they cannot give free and informed consent in this sense.’

“(13) Even though a subject may have given consent to the investigation at the start, this consent can be withdrawn at any time by the subject”

Note the concept of consent as ‘free and informed consent’ is not only present in the document, when saying that no-one should be subjected to medical or scientific investigations without giving it, but it is also explain as ‘genuine consent, freely given, with a proper understanding of the nature and consequence of what is proposed’.

9- “(346) Termination of pregnancy owing to radiation exposure is an individual decision affected by many factors. Absorbed doses below 100 mGy to the embryo/fetus should not be considered a reason for terminating a pregnancy. At embryonic/ fetal doses above this level, the pregnant patient should receive sufficient information to be able to make informed decisions based upon individual circumstances, including the magnitude of the estimated embryonic/fetal dose and the consequent risks of serious harm to the developing embryo/fetus and risks of cancer in later life.”

Note This is a very sensitive case, accompanied by a number of aspects based on ethical issues, cultural aspects, individual behaviours, views ... all these together with the aspects of uncertainties in science.

### ***Motivations***

Note that in the medical field the RP focuses on justification and optimisation, differently from other type of exposures, the medical exposure is not applying dose limits. For the medical exposure the responsibility for the justification of the use of a particular procedure falls on the relevant medical practitioners. In this document no attention is given on the involvement of stakeholder in the medical field, but the same organisation (ICRP) in its other documents enters in the attention to stakeholders even in the medical area. Other documents by ICRP will be analysed within WP1.

### ***Level of stakeholder engagement***

A very good level of citation for stakeholder and transparency and involvements of stakeholder is present in the Editorial of this ICRP Recommendations (see the above point 1-3). In the remaining Recommendations text (more than 250 pages) only one point refers the participation of relevant stakeholders. It seems that the attention to stakeholders in this publication is related to the procedure

in preparation of the final document with open consultation, more than a real involvement of stakeholders in the radiological protection in the practice. But, at the same time we have to consider that with respect to other field of exposure, the use of ionising radiation in medicine for patients has unique aspects. There is the consideration that exposure for patients is related to the expectation of direct individual health benefits to the exposed patient, the fact that the dose to the patient cannot be reduced indefinitely without compromise the intended result, and the use of different degrees of informed consent involving the patients in the decision on ionising radiation exposure.

### **ICRP, 2007 - Radiological Protection in Medicine. ICRP Publication 105. Ann. ICRP 37 (6)**

#### ***Key words***

The following key words were searched:

- stakeholder(s)
- patients
- member of the public
- engagement/involvement (consent)

#### ***Definitions and requirements***

-In the Editorial it is remembered that the “Justification in radiological protection of patients is different from justification of other radiation applications, in that generally the very same person enjoys the benefits and suffers the risks associated with a procedure.”, and moreover that “There may be other considerations: attendant occupational exposures could be correlated with patient doses or sometimes there can be a trade-off; screening programmes may benefit the population rather than every screened person. “

Note how this point, in consideration to benefits-risks in the medical procedures, clearly evidence that in some cases there is a link between patients and professionals who could be also exposed is correlation.

- “(9) .. staff, and other individuals are also exposed to radiation. The other individuals include parents holding children during diagnostic procedures, and family or close friends who may come close to patients following the administration of radiopharmaceuticals or during brachytherapy. Exposure to members of the general public resulting from the use of radiation in medicine also occurs, but it is almost always at very low levels. “

Note that the voluntary involvement of parents, family and close friends is well recognised in the role of comforters of the patients, in particular therapeutic procedures and with attention either in hospital as at home in support of patients.

#### ***Motivation***

“ (62)... *The total benefits from a medical procedure include not only the direct health benefits to the patient, but also the benefits to the patient’s family and to society.*”

“(123) Friends and relations helping in the support and comfort of patients are also volunteers, but there is a direct benefit both to the patient and those who care for them.”

Note that in the judgement of benefits for patients the consideration of the family is also taken in the view of the health benefits for the patients and at the same time of the indirect benefits to family members involvement as care and comforters either in hospital as at home in support of patients.

### ***Level of stakeholder engagement***

The decisions to adopt any human activity involve a review of the benefits and disadvantages on the options. In the justification of a medical radiological practice the basis of experience and professional judgement are considered together with common sense and quantitative decision-aiding techniques. The decision on patient exposure is voluntary in nature, combined with attention to direct benefit to the patient and it is based on varying degrees of informed consent of patients including also attention to potential risks, on the basis of the procedure.

The involvement of stakeholders in the optimization process introducing the needed adaptability in the management of radiological risk to achieve more effective and sustainable decisions, could be of great interest in the medical exposure. Indeed, the optimization of protection in medical exposures does not necessarily mean the reduction of doses to the patient and, for example in diagnostic and interventional procedures, the management of the patient dose commensurate with the medical task is an appropriate mechanism to avoid unnecessary or unproductive radiation exposure (ICRP 105).

### **ICRP, 2015 - Radiological Protection in Cone Beam Computed Tomography (CBCT). ICRP Publication 129. Ann. ICRP 44 (1)**

#### ***Key words***

The following key words were searched:

- stakeholder(s)
- patients
- member of the public
- engagement/involvement

#### ***Definitions and requirements***

In the Editorial it is indicated that “This publication provides a helpful direction for policy makers, imaging professionals, medical physicists, and manufacturers to optimise protection of both patients and workers”.

ICRP 129, 2015, dedicated to Radiological Protection in Cone Beam Computed Tomography (CBCT), has the purpose to identify radiological protection issues for patients and workers, and report recommendations for all stakeholders.

“(28) Over the years, manufacturers have played a vital role in technological developments to reduce patient doses from particular CT examinations. The Commission, while acknowledging this role, hopes that manufacturers will remain at the forefront of developing new technologies for radiological protection of patients and workers.”

The publication provides recommendations on radiation dose management directed at different stakeholders, and covers principles of radiological protection, training, and quality assurance aspects. It provides a helpful direction for policy makers, imaging professionals, medical physicists, and manufacturers to optimise protection of both patients and workers.

#### ***Motivation***

“(18) The purpose of this publication is to identify radiological protection issues for patients and workers and, in line with other ICRP publications, recommendations are set out for all stakeholders

ranging from day-to-day clinical users, auxiliary support workers, buyers, manufacturers, and policy directing committees.”

“(29) . . . uncritical application of CBCT under the assumption that it is a modality with minimal dose consequences could result in significant doses in some circumstances, and is not appropriate for protection of the patient.”

For high-dose procedure “(84) . . . *It is therefore essential to involve a medical physicist or another suitably qualified expert (. . .) early on in optimisation, as well as the audit of patient and occupational dose levels*”

It is evident in the document how new challenges in dose management to ensure patient safety and guidelines are needed for various stakeholders, as imaging professionals, medical physicists, and manufacturers.

### **Level of stakeholder engagement**

“(27). . . As a referring practitioner best understands the clinical need for the examination, he/she must interact with an imaging professional to decide upon the radiological examination or procedure that is in the best interests of the patient.”

For the best interest of the patient a direct cooperation is recognised in CBCT among those who have prior education in medical radiation physics and radiological protection. A specific primary audience is indicated as: health professionals working with CBCT, other workers tasked with radiological protection and image quality optimization in CBCT, manufacturers of imaging equipment, regulators, and policy makers in charge of radiological protection. The attention is directly given to the responsibilities of the different stakeholders for appropriate use of CT scanning and to the avoidable level of radiation dose that derived from unjustified or inappropriate examinations, and recommendations are discussed. Note that this document applies to a technology that is in high evolution. It is an example, in the medical field, of a practical guidance for the already involved stakeholders, that enters directly on what and how the stakeholders can do their best in their role.

### **Bonn Call for Action - Joint Position Statement by IAEA and WHO - 2012, International Conference on Radiation Protection in Medicine , held in Bonn.**

#### **Key words**

The following key words were searched:

- stakeholder(s)
- patients
- member of the public
- engagement/involvement

#### **Definitions and requirements**

The Conference introduced ten Actions to Improve Radiation Protection in Medicine. The outcome of the conference was the identification of responsibilities and a proposal for priorities for stakeholders regarding radiation protection in medicine for the next decade.

The 2012 conference aimed to:

- strengthen the radiation protection of patients and health workers overall;

- attain the highest benefit with the least possible risk to all patients by the safe and appropriate use of ionising radiation in medicine;
- aid the full integration of radiation protection into health care systems;
- help improve the benefit/risk-dialogue with patients and the public; and
- enhance the safety and quality of radiological procedures in medicine.

### **Motivation**

Within the ten main actions it is emphasized the strengthening of radiation protection

in medicine. Significant actions by all stakeholders are encouraged and among the numerous sub-actions described the following are included:

-“Develop harmonized evidence-based criteria to strengthen the appropriateness of clinical imaging, including diagnostic nuclear medicine and non-ionising radiation procedures, and involve all stakeholders in this development”.

-“Strengthen cooperation and communication between manufacturers and other stakeholders, such as health professionals and professional societies”.

-“Support improvement of risk communication skills of health care providers and radiation protection professionals – involve both technical and communication experts, in collaboration with patient associations, in a concerted action to develop clear messages tailored to specific target groups”.

-“Strengthen collaboration in relation to education and training among education providers in health care settings with limited infrastructure as well as among these providers and international organisations and professional societies”.

### **Level of stakeholder involvement**

With the aim to foster an improved radiation benefit risk dialogue technical and communication experts are envisioned in collaboration with patient associations to improve the risk communication in develop clear and adequate messages for the best communication towards specific interest groups. In the view of the need for a holistic approach it is considered the “*partnership of national governments, civil society, international agencies, researchers, educators, institutions and professional associations*” and the harmonization and coordination of procedures at international level. Moreover a closer cooperation is foreseen between different area of radiation protection and including professional societies and patient associations to strengthen the culture of radiation protection in health care.



## **HERCA Report - CT Manufacturers Stakeholder Involvement. November 2017.**

### ***Key words***

The following key words were searched:

- stakeholder(s)
- patients
- member of the public
- engagement/involvement

### ***Definitions and requirements***

On 3 March 2017 COCIR and EFOMP signed A Memorandum of Understanding, by COCIR and EFOM, regarding five elements, including: -the promotion in the use technology in imaging, therapy and the increase of awareness of public authorities regarding the aging of medical equipment; -the mutual promotion in educational and scientific activities as far as allowed by the societies' rules.

Annual face to face HERCA-COCIR meetings allowed reporting the level of the actions and multi-stakeholder meetings were an opportunity to exchange view with a number of key stakeholders, with the focus to ensure an optimized balance between image quality and dose.

To describe the role of CT manufacturers and other stakeholders in education and training a HERCA Position Paper: "The process of CT dose optimisation through education and training and role of CT Manufacturers" was published in October 2014.

### ***Motivation***

In this document HERCA evidence that "all stakeholders involved in the radiological process should be part of this important initiative to reduce patient dose" and this in view of need for action against the increasing trend to higher medical exposures. In particular, HERCA considered the CT manufacturers to be one of the most important stakeholders in the field of medical radiation protection and consequently the HERCA working group medical applications created a subgroup "Work Package Stakeholder Involvement of CT Manufacturers".

Note that CT is a very high developed technology accompanied by high increase in its use. It is a benefit to patients and society as a whole, however it has led to a large increase in medical exposure (as in DDM2, CT contributes for about 57% of the collective dose from all x-ray radiological procedures). As result of the process, the COCIR CT manufacturers were willing to underline their responsibility on patient dose reduction and commit themselves to actions towards this goal. CT manufacturers and HERCA acknowledged the need for raising the awareness at education and training level via the involvement of other stakeholders in CT dose optimisation and the ALARA principle in daily operational practice.

### ***Level of stakeholders***

The stakeholders who participated in these meetings, this Report is dealing about were COCIR which represents the radiological, electromedical and healthcare IT industry in Europe, professional organisations (ESR, EANM, ESTRO, EFRS, EFOMP, ISSRT) and international organisations IAEA, WHO, EC and IRPA participated as observers.

In the related multi-stakeholder meetings emerged that the manufacturer training programs are not always adapted to the needs of the relevant professionals and COCIR accepted to collaborate with

EFOMP and EFRS on this issue. The collaboration between HERCA and COCIR is considered very beneficial to both parties for the good outcome.

As result of the process, the COCIR CT manufacturers were willing to underline their responsibility on patient dose reduction and commit themselves to actions towards this goal, including:

- the development and implementation of a standardized benchmark for CT system,
- the implementation of dose reduction in CT,
- the implementation of dose management and reporting tools, and
- the provision of specific training curricula.

The initial formulation of this commitment started in 2011 with the aim, from the CT manufactures part, “ to provide transparency and easily understood values that attempt to characterize system performance through standardized test methods and conditions.”

**Lefebvre, G., Kettunen, E., Godet, J-L., Olerud, H.M., Sánchez, M., Trueb, Ph. Stakeholder Involvement in Medical Practices. Report of the HERCA Working Group 5. Participating countries: Belgium, Finland, France, Norway, Spain, Switzerland.**

#### **Keywords**

Not applicable (the entire document was dedicated to stakeholder involvement).

#### **Definitions**

Stakeholders in medical practices are defined as “someone who is (or should be) entitled to have an interest in radiation protection in medicine” (pp. 1). They are split in three categories, according to their relevance to justification of medical practices (stakeholders involved before a procedure is carried out); optimisation (stakeholder involved at the time of carrying out the procedure) or general.

The stakeholders linked to justification are i) medical doctors, medical societies and associations; ii) patients, patient organisations; iii) the legislator.

The stakeholders linked to optimisation are i) Medical doctors, medical physicists, technicians, other medical staff ; ii) Manufacturers and suppliers, staff undertaking installation and maintenance; iii) Hospital directors.

The category ‘general’ includes i) Patients and their relatives; ii) Patient ombudsman; iii) Members of the public; iv) Insurance ; v) Legislator and authorities.

#### **Motivations and goals**

The documents states that “only a close collaboration between all the stakeholders will allow this dose increase [from medical exposures] to be understood and kept under control” (pp. 1).

It is also argued that “The authorities should take the lead to bring stakeholders together to solve today’s challenge in a concerted manner”, the document emphasizing that challenges relate to situations where “different professional groups work together on new technologies and/or new processes”.

The goals of stakeholder involvement are further detailed using the categorisation: justification, optimisation and general (pp. 2-pp.3).

In relation to justification, the goals include creating awareness of medical doctors and dentists of the ICRP principle of justification of practices (ICRP 103 is referred to), the application of good practices and informing the patients of the risks and benefits of radiology.

In relation to optimisation, the goals refer to technical aspects such as the use of state-of-the-art equipment, quality assurance and maintenance, optimised procedure for examination, availability of radiation protection resources, as well as organisational or safety culture related issues such as regularly trained staff, definition of responsibilities, feedback culture.

In the category general, goals of stakeholder engagement are formulated in terms of “care” of radiation protection from the side of manufacturers and organisations preparing standards, awareness of radiation protection among public and patients, and “well-accepted authorities, who inform, coach and train all users”.

The document details on the role of different actors:

- it argues that “there is no doubt that important benefits can result from interactions between stakeholders and regulatory authorities” (pp. 3) and that the interaction vary depending on the situation.
- it states that drafting of regulation should be done in consultation with stakeholders: “to get commitment from stakeholders for the regulation it is useful to prepare basic regulations using consultation with stakeholders” (pp.4). Key stakeholders are “experts from professional activities”.
- it recommends that guidance for operators should be prepared with attention to the needs of licence holders and specialists in the field. It is argued that “this is also to get better mutual understanding of the common goals in radiation protection and to prepare proper guidance”. It suggests involvement of specialists involved in the actual practices.
- in relation to communication it recommends that all radiation users should be provided with “general information on radiation protection”, by email and through the www-pages of the authority; regular discussions and meetings should be organised with different specialists and organisations; risk communication should be prepared together with stakeholders such as medical doctor organisations, hospital directors, patient organisations, press bodies; and communicated proactively (booklet), as well as after an incident/accident.
- it mentions that “information transfer between stakeholders is important part of learning process in radiation protection”, for instance by creating discussion forums.
- it is suggested that the radiation protection authority could act as a “trainer of trainers”, e.g. “for leaders of stakeholders”;
- it suggests that surveys with stakeholder groups are done to evaluate the present level of radiation protection and discuss further the findings.

### **Level of stakeholder engagement**

The document lists a number of “purposes and expected outcomes of the involvement”: “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, emergency prevention, preparedness, and response”.

The document states that it adheres to the recommendations concerning stakeholder involvement formulated during the 10th European ALARA Network Workshop in what concerns the role of regulatory bodies as facilitators of stakeholder involvement: “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.”

It further argues for wide stakeholder involvement –“whenever acceptable” (from a security viewpoint) and “manageable”, and for the need that regulatory authorities establish “structural mechanisms” for “consultation with stakeholders”.

Involvement of patients is mainly framed as providing information about the risks and the benefits of radiology.

### **Any other observation that may be relevant to the study**

The documents identifies priorities for stakeholder involvement, among which to increase awareness of the general public and some medical professions, to organise consultations with a broad range of stakeholders (including patients), to establish platform for discussion and analysis open to stakeholders, and to make the information available for all stakeholders.

Some good practices are mentioned:

- Finland: Implementation of Clinical Audit in Finland
- France: Notification of events in radiotherapy and information of public in France
- Switzerland: Introduction of Diagnostic Reference Levels
- Spain: Permanent Forum concerning Radiological Protection in the Medical Field
- Norway: A national program on Quality Assurance in Radiotherapy (KVIST) initiated as part of the national cancer plan
- Belgium: Cooperation between health authorities and radiation control authorities

### **Conclusions**

Although the focus of the document is on the involvement of experts and professionals in the field of medical exposures and regulators, the document argues in general for wide stakeholder involvement (including patients). Involvement is tailored to a justification, optimisation or general purpose. It proposes various levels of involvement, from information, collection of information and communication, to consultation and dialogue. It notably recommends upstream involvement (of experts from professional activities or radiation users) through e.g. stakeholder consultation in the development of regulations and guidance, and inclusion of their suggestions in the guidance. It also highlights the role of the radiation protection authority as facilitator for stakeholder involvement, notably by establishing structural mechanisms for consultation with stakeholders.

Motivations for stakeholder involvement are diverse, ranging from increasing awareness and application of good practices, to mutual learning through information exchange (e.g. between radiation users), and up to collaboration and joint problem solving aimed at addressing the increase of dose from medical exposures.

Involvement of patients is mainly framed as providing information about the risks and the benefits of radiology. However, the document argues for wide involvement whenever acceptable (from a security viewpoint) and manageable. It also states that the regulatory authority should encourage participation of interested parties, e.g. by public meetings, which can be seen as opportunities for dialogue.

The document refers to and adheres to ICRP 103 and the recommendations of the 10<sup>th</sup> ALARA workshop.

## 9.4.2. Emergency preparedness and response

### **Preparedness And Response For A Nuclear Or Radiological Emergency, GSR, Part 7, IAEA, 2015**

Jointly sponsored by FAO, IAEA, ICAO, ILO, IMO, INTERPOL, OECD/NEA, PAHO, CTBTO, UNEP, OCHA, WHO, WMO.

#### ***Key Words***

Public, public in preparedness for a nuclear or radiological emergency, workers, emergency workers, members of the public and, as relevant, patients and helpers in an emergency, public who are affected or are potentially affected. There is no use of word stakeholder in the document, but instead the term interested parties is used.

#### ***Definitions and requirements***

Requirement 10: Providing instructions, warnings and relevant information to the public for emergency preparedness and response: The government shall ensure that arrangements are in place to provide the public who are affected or are potentially affected by a nuclear or radiological emergency with information that is necessary for their protection, to warn them promptly and to instruct them on actions to be taken. That include permanent population, transient population groups and special population groups or those responsible for them and special facilities within the emergency planning zones and emergency planning distances.

Requirement 13: Communicating with the public throughout a nuclear or radiological emergency: The government shall ensure that arrangements are in place for communication with the public throughout a nuclear or radiological emergency. Arrangements shall be made for providing useful, timely, true, clear and appropriate information to the public in a nuclear or radiological emergency, with account taken of the possibility that the usual means of communication might be damaged in the emergency or by its initiating event (e.g. by an earthquake or by flooding) or overburdened by demand for its use. Arrangements shall be made so that in a nuclear or radiological emergency information is provided to the public in plain and understandable language. The government shall ensure that a system for putting radiological health hazards in perspective in a nuclear or radiological emergency is developed and implemented with the following aim: to support informed decision making concerning protective actions and other response actions to be taken; to help in ensuring that actions taken do more good than harm; to address public concerns regarding potential health effects.

Requirement 16: Mitigating non-radiological consequences of a nuclear or radiological emergency and of an emergency response: The government shall ensure that arrangements are in place for mitigation of non-radiological consequences of a nuclear or radiological emergency and of an emergency response.

Requirement 18: Terminating a nuclear or radiological emergency: The government shall ensure that arrangements are in place and are implemented for the termination of a nuclear or radiological emergency, with account taken of the need for the resumption of social and economic activity. Adjustment of protective actions and other response actions and of other arrangements that are aimed at enabling the termination of an emergency shall be made by a formal process that includes consultation of interested parties. The termination of a nuclear or radiological emergency shall be based on a formal decision that is made public and shall include prior consultation with interested parties, as appropriate.

Requirement 22: Coordination of emergency preparedness and response: The government shall ensure that arrangements are in place for the coordination of preparedness and response for a nuclear or radiological emergency between the operating organisation and authorities at the local, regional and national levels, and, where appropriate, at the international level. Arrangements for communication with the public;

Requirement 24: Logistical support and facilities for emergency response: The government shall ensure that adequate logistical support and facilities are provided to enable emergency response functions to be performed effectively in a nuclear or radiological emergency.

Arrangements for continued communication with the public, and for monitoring of public opinion and the reaction in the news media; Arrangements for consultation of interested parties.

### ***Aspirations***

The IAEA GSR Part 7 provide comprehensive provisions which could assure engagement of stakeholders and members of the public in different phases of emergency management: in preparedness phase, emergency itself and in the post emergency phase. However, the IAEA GSR is based mainly on provision of information by the responsible institutions. The consultation is also mentioned but it is related to existing exposure situation.

### ***Motivations***

In the IAEA GSR Part 7 communication with the public is basic with some provision of information on the key topics, and in addition to some communication/consultation for the limited areas. The engagement of public in this process is not described, but it is stated that the government (the state) shall provide arrangement for fulfilment of requirements. It could be assessed that the motivation of the participation is mainly normative as it responds to a certain principle.

### ***Level of stakeholder engagement***

The level of stakeholders' engagement is mainly limited to provision of different information for EP&R topics from preparedness, emergency, termination and post emergency. For post emergency also beside communication and information also consultation is required. In this document there is no definition what these could mean.

## **ICRP 2009. Application of the Commission's Recommendations for the Protection of People in Emergency Exposure Situation. ICRP Publ 109. Ann. ICRP 39 (1)**

### ***Key Words***

The following key words were searched:

- Public
- Stakeholders
- Emergency workers/workers
- Involvement/Engagement
- Participation

### ***Definitions***

The document was prepared to provide advice on the application of the last ICRP Recommendations (ICRP Publ 103) in the preparedness for and response to all radiation emergency exposure situations.

It is considered that an emergency exposure situation may evolve, in time, into an existing exposure situation (this part is object of ICRP Publ. 111, 2009). It is indicated that the change from an emergency exposure situation to an existing exposure situation will be based on a decision by the authority responsible for the overall response and that the transfer should be undertaken in a co-ordinated and fully transparent manner, and should be understood by all parties involved.

In the area of preparedness for and response to all emergency exposure situations, the last ICRP Recommendations (ICRP Publ 103) have evolved in some significant ways from the previous Recommendations (ICRP Publ 60), for example, 'rather than assessing the potential benefits of individual protection options, the approach is now to consider all exposure pathways and all relevant protection options when deciding on the optimum course of action in the context of an overall protection strategy. The objective is the best possible overall response under the circumstances; something that was difficult to ensure when considering individual actions in isolation.'

Definitions:

Exposure situations: 'situations that may occur during the operation of a planned situation, or from a malicious act, or from any other unexpected situation and require urgent action in order to avoid or reduce undesirable consequences'.

The document considers the protection of all those at risk of exposure as they are directly involved in mitigating actions, emergency 'workers', regardless of whether or not they are routinely exposed to radiation as a result of their normal employment, or simply in need of protection as 'the public'. Emergency workers may include radiation workers (e.g. employees of registrants and licensees) and people who are not normally occupationally exposed to ionising radiation, such as police, rescue personnel, fire fighters, and medical personnel.

The stakeholders involved in an emergency response situation will vary with the type of situation/facility being considered, the scale of the emergency exposure situation being considered, and the time phase of the emergency exposure situation being addressed.

The stakeholders referred in the document include many different types of people and organisations, e.g. the public affected by the emergency, the authority responsible for the emergency response, the licensee of the facility or activity causing the emergency exposure situation, the regulatory authority licensing the facility or activity causing the emergency exposure situation, local public officials within

and perhaps near the areas affected by the emergency exposure situation, emergency workers including first responders, and others.

‘It is essential that all aspects of the plan are consulted with relevant stakeholders, otherwise it will be more difficult to implement them during the response.’

### ***Motivations***

The exposure of workers responding to an emergency can generally be seen as deliberate and controlled, although this is not always the case; thus, some flexibility is required.

There may be a need to take protective actions promptly during an emergency, necessitating exposures for some workers higher than the dose limit for planned exposure situations.

In such cases, it may be acceptable for emergency workers to receive, on the basis of informed consent, doses that exceed the occupational dose limits normally applied. Such doses should be optimised.

The procedures for the implementation of protective actions to be justified and optimised during an emergency, should be agreed in advance in order to facilitate their acceptance by the public during the emergency. ‘Scientifically based recommendations for implementing protective and other measures need to be accompanied by an explanation that enables the decision maker to understand and consider them, and also to explain them to the public.’

The engagement with stakeholders is an important component of justification and optimisation of protection strategy in emergency exposure situations. It is recognised important that part of emergency response planning should be the development and implementation of processes and procedures to inform and involve stakeholders once the most urgent protective actions have been implemented.

When the emergency exposure situation requires urgent protective measures, ‘the ‘reflex’ use of pre-planned protection strategies will be necessary with no or very little stakeholder involvement beyond the emergency response authorities and those responsible for the site, facility, or source that is causing the emergency exposure situation’. Inappropriate involvement of stakeholders or excessive review of the detailed effectiveness of such ‘reflex’ protective actions is likely to reduce their effectiveness by delaying their implementation, and this should be avoided. However, ‘as the emergency exposure situation progresses, it will become increasingly beneficial to involve stakeholders in discussions leading to protection decisions.’

### ***Level of stakeholder engagement***

‘To incorporate stakeholder input appropriately into decisional processes, it is essential that structures, processes, and procedures, and perhaps legislation and regulation, are appropriately tuned to allow and encourage such participation.’

An iterative process is considered involving stakeholders in the optimisation of the protection strategy in planning. In this process the proposed protective measures are individually optimised and the robustness of optimisation is important since the detailed circumstances of the emergency cannot be known in advance: ‘the process of constrained optimisation is iterative with respect to individual measures and the overall protection strategy, with respect to time and stakeholders’

Considering that there may be international consequences in large-scale emergency, stakeholders are not limited to those groups affected in the country, since there would be the perceived need for protective measures in other countries, the need to harmonise the response across country borders;



and the need for authorities to ensure the safety of their nationals and to deal appropriately with people from an affected country crossing their borders.

It is recognised as important that national authorities ensure effective international communication with authorities and the advantages in co-ordinating the response as much as possible.

The active participation of stakeholders has the recognised advantage to bring relevant local knowledge, experience and values to decision-making processes. Appropriate training of the relevant staff of government bodies dealing with the emergency is required considering the social and interpersonal aspects of stakeholder involvement.

It is important to involve, wherever possible, relevant stakeholders in discussions regarding termination of protective measures, and to consider to return to evacuated areas and the termination of protective measures implemented at a later stage.

**ICRP PUBLICATION 111. Application of the Commission's Recommendations for the Protection of People Living in Long-term Contaminated Areas after a Nuclear Accident or a Radiation Emergency. ICRP Publ 111. Ann. ICRP 39 (3)**

***Key Words***

The following key words were searched:

- Public/people
- Stakeholders
- Emergency workers/workers
- Involvement/Engagement
- Participation

***Definitions***

The document is aimed to provide guidance for the protection of people living in long-term contaminated areas resulting from either a nuclear accident or a radiation emergency and it considers the effects of such events on the affected population.

The document recognises 'the complexity of post-accident situations, which cannot be managed without addressing all the affected domains of daily life, i.e. environmental, health, economic, social, psychological, cultural, ethical, political, etc.'

The document emphasises 'the effectiveness of directly involving the affected population and local professionals in the management of the situation, and the responsibility of authorities at both national and local levels to create the conditions and provide the means favouring the involvement and empowerment of the population.'

Existing exposure situation. The transition from an emergency exposure situation to an existing exposure situation is characterised by a passage from strategies driven by urgency to decentralised strategies to improve living conditions and reduce exposure.

It is implicit with this decision (from emergency exposure situation to existing exposure situation) the ability to provide people with protection against the potential health consequences of the radiation, and sustainable living conditions, including respectable lifestyles and livelihoods.

The decision on justification to allow people (who wish) to live permanently in long-term contaminated areas is taken by the authorities, and this indicates the beginning of the post-accident rehabilitation phase.

Optimisation of protection strategies is the process of developing the strategy's form, scale, and duration. In this process of selecting strategies for protecting people living in contaminated areas, the participation of relevant stakeholders is essential.

A 'practical radiological protection culture' within the population is recognised a key to the success of protection strategies in the long term.

### ***Motivation***

From past experience of long-term contamination it is demonstrated the effectiveness of the direct involvement of inhabitants and local professionals in management of the situation. It is the responsibility of the authorities to favour the involvement and empowerment of the population, by taking into account local social and economic living conditions with the aim to help individuals to regain control of their lives.

'The aim of the authorities should be to help individuals to regain control of their lives, in which radiation protection against the existing contamination is a factor to add to several other factors affecting the rehabilitation of living conditions'.

In long-term contaminated areas the inhabitants are recognised to take their own actions called 'self-help protective actions', such as by monitoring their own exposure and the exposure of the people for whom they have responsibility, e.g. children and elderly, and by adapting their way of life accordingly to reduce the exposure.

Forums are foreseen to allow sharing info and favour common assessment of the effectiveness of strategies. The local forums should be facilitated by authorities and representatives of the affected population together with relevant experts are involved. Since protective actions are implemented by the inhabitants themselves, they must be informed and trained in order to take informed decisions with net benefit, by taking into consideration from one side the desire to improve the situation, and on the other side the possible burden induced by the implementation of protective actions.

### ***Level of stakeholder engagement***

'Mechanisms for engaging with stakeholders are driven by national and cultural characteristics and should be adapted to the circumstances.'

The local population is in a position to manage the intake of radionuclides by avoiding or reducing consumption of products with higher levels of contamination. Groups of the population considered more sensitive, e.g. children, pregnant or breastfeeding women, people with poor health are advised to avoid or reduce consumption of certain types of food with high levels of contamination.

The responsibility is of authorities at both national and local levels to create the conditions (e.g. making the equipment available or doctors or pharmacies who are trained to take measurements) for the empowerment of the population, e.g. in the management of contaminated foodstuffs, and in evaluating the efficiency of changes in their diet.

On the basis of experience in stakeholder engagement and related lessons learned, it is recognised that processes and tools are considered in view of their applications to situations where the views and input of stakeholders could improve the quality of protection.

A decrease in the local economy and market losses may occur due to consumer concerns for supplies even for non-contaminated food, with choices that may not be justified in terms of dose reduction. In these cases, it is expected that decisions should be taken in close cooperation with local stakeholders.

‘As such foods will be subject to market forces, this will necessitate an effective communication strategy to overcome the negative reactions from consumers outside the contaminated areas.’

Justification of protection strategies goes far beyond the scope of radiological protection. The social and political values in reducing exposure and in limiting inequity in the exposure are needed to be included in justification of protection strategies, with attention to economic, political, environmental, social, and psychological consequences. It is recognised that such non-radiological factors require expertise, other than radiological protection, and could dominate decisions regarding protection strategies.

Optimisation of protection is central for existing exposure situations. In relation to its judgemental nature, it is recognised a strong need for transparency in the process of optimisation, with attention that all relevant information is provided to the involved parties and on the traceability of the decision-making process.

### 9.4.3. Radon

#### **WHO Handbook on indoor radon. A public health perspective. WHO, 2009**

##### **Key Words**

Stakeholder, involve\*, dialogue, consult\*, engage\*, include\*

##### **Definition**

A definition is not provided, but different categories of stakeholders are mentioned throughout the document: “stakeholders involved in *radon control* such as the construction industry and building professionals”; “building professionals and other stakeholders involved in the *implementation of radon prevention and mitigation*”; stakeholders that should provide *input on measurement protocols* “including researchers, radon measurement providers, builders, and officials who are responsible for implementing regional and national health guidance”; beneficiaries of *radon communication services* implemented through the development of a radon programme: “the public and other stakeholders”

P ix; The handbook is intended for countries that plan to develop national programmes or extend their activities regarding radon, as well as for stakeholders involved in radon control such as the construction industry and building professionals.

P xi: Key elements for a successful national programme include collaboration with other health promotion programmes (e.g. indoor air quality, tobacco control) and training of building professionals and other stakeholders involved in the implementation of radon prevention and mitigation.

#### 2.2 Measurement protocols

It is important to seek input on these protocols from stakeholders including researchers, radon measurement providers, builders, and officials who are responsible for implementing regional and national health guidance.

#### 6. National radon programmes

P 83: The development of a radon programme involves the setting-up of a clear organisational structure and a range of components in order to monitor radon levels, facilitate prevention and mitigation, and provide radon risk communication services to the public and other stakeholders.

P 84: 6.1 Organisation of a national radon programme

On pp. 84, the handbook lists different stakeholders, that should provide “input for the implementation of an effective radon programme implementation of an effective radon programme aimed at protecting the public against indoor radon exposures”: national, regional and local organisations responsible for public health and radiation protection; other agencies, entities or experts such as geological survey institutes, public and/or private radon measurement laboratories, building engineers and scientists, the construction industry and agencies that implement and enforce building regulations or building codes that should provide expertise; “governments that should promote a national radon programme of coordinated actions and designate one organisation or agency to take the lead in driving and coordinating it”.

The next page gives more details:

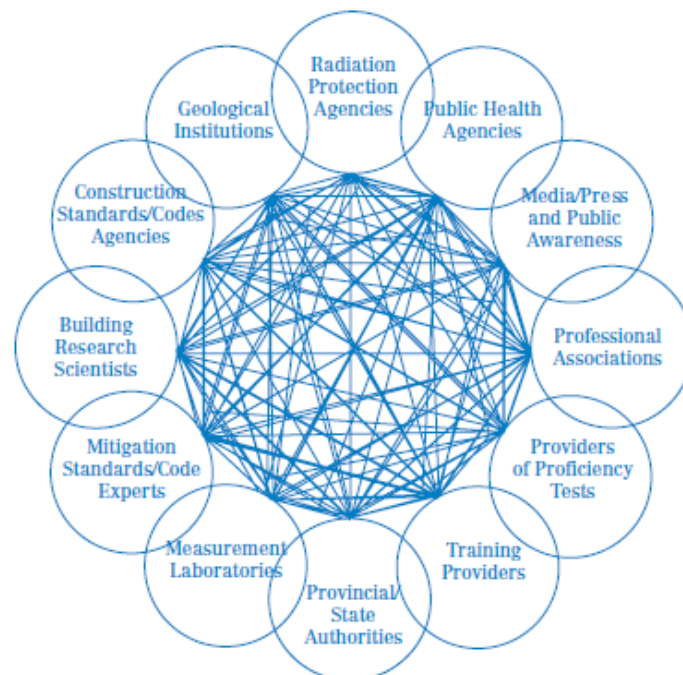


Figure 10. National agencies and other stakeholders may involved in radon programmes

**Engagement:**

P 75 The communication channels and the approaches to be used should be a combination of passive (information is provided without the ability to have a dialogue with the provider) and active (information is provided and the recipient can interact and have a dialogue) engagement techniques (WHO 2002).

**Concern**

P 89 Public awareness campaigns should encourage householders in these areas to test their homes for radon. These strategies could target organisations and professionals concerned with public health and with housing, such as builders, architects, regional and local government authorities and the medical community.

**Motivation**

Motivations are: implementation of an effective radon programme, through provision of input and expertise, enforcement of building regulations and codes, promoting coordinated actions.

**Level of stakeholder engagement:** Involvement, information, elaborating national action plans together.

Among the key elements of a radon action programme, the following are mentioned: “provisions for inclusion of local and regional authorities”, and “programmes to inform the public and stakeholders about the radon issue and to include radon awareness”. (pp. 85)

In addition (see also above) several stakeholders (national authorities, professional organisations, experts and researchers) are expected to provide input and expertise and support the implementation of the national radon action plan.

The document also states that “when developing these [radon prevention and mitigation] guidelines and standards, it is important to consult radon mitigation contractors, building researchers as well as other building and construction professionals” (pp. 43)

For radon professionals training, “the training programme should be developed in consultation with building researchers, building contractors and construction workers. Universities, government and/or nongovernmental agencies may be included in the training.” (pp. 44)

The chapter on radon risk communication mentions that effective communication should “maintain an open dialogue” (pp. 72), and use a combination of passive and active “communication engagement techniques” (e.g. local “phone-in” sessions, use of third party networks (e.g. briefings and community group meetings), information hotline or helpline, meetings and public hearings, reporter interviews.

## Conclusions

While no definition for “stakeholders” is provided, the documents lists several categories of stakeholder and their roles. Although the public is mostly mentioned in relation to information provision and increasing awareness, the document makes reference to dialogue and “active communication engagement techniques”.

## **Annals of the ICRP. ICRP Publication 126. Radiological Protection against Radon Exposure. ICRP 2014**

### Key Words

Stakeholder, involve,

P. 16: Domestic radon exposure management should address a number of issues (e.g. environmental, health, economic, architectural, and educational) involving a wide range of stakeholders

P. 16: The strategy should be straightforward, appropriately scaled with other health hazards, supported and implemented on a long-term basis, and involve all stakeholders.

P19: (bb) The national radon protection strategy should be implemented through a national radon action plan established by national authorities with the involvement of relevant stakeholders. The action plan should establish a framework with a clear infrastructure, determine priorities and responsibilities, and describe the successive steps to deal with radon in the country. Depending on the exposure conditions, it should identify stakeholders, such as those who are exposed and those who should provide support or implement action; address ethical issues, particularly those associated with responsibilities; and provide information, guidance, support, and conditions for sustainability.

(cc) (cc) The national action plan should also deal with radon measurement techniques and protocols; radon surveys to identify radon-prone areas; methods for mitigating radon exposure and their

applicability in different situations; supporting policies, including information, training, and involvement of stakeholders; and assessment of effectiveness.

#### 2.4.1 Public health considerations

P 42: (45) Considering the ubiquity of radon exposure, and the multiplicity and diversity of situations and decision makers, a straightforward, realistic, and integrated radon protection strategy, addressing most situations with the same approach, is appropriate. It must be supported and implemented on a long-term, potentially permanent basis, and involve all the relevant stakeholders.

#### 2.4.2. Responsibilities of stakeholders (p 42)

This section (46) to (49) describes justification for a graded approach for the responsibility of different stakeholders for taking action against radon.

#### 3.3. Optimisation of protection

P. 48/49 (68): the involvement of the relevant stakeholders is described as important part of the optimisation process

#### 3.3.5. Graded approach (p54)

(90) Where a building has high radon concentrations, the response should include the involvement of, and communication with, relevant stakeholders, such as the building users.

#### 4.1 national action plan

(101) A national radon action plan should be established by national authorities with the involvement of relevant stakeholders. The objective is to reduce the collective risk of the population and the individual risk to indoor radon exposures by implementing the optimisation principle.

The national radon action plan should, as far as possible, be integrated in a manner consistent with other strategies concerning buildings, such as indoor air quality or energy saving, in order to develop synergies and avoid contradictions.

#### **Information**

P50: (...) so that general information should be, where possible, made available to enable individuals to reduce their doses.

#### 3.3.5. Graded approach

(87) The Commission now recommends that a graded approach should be applied for the control of radon exposures. In such an approach, the radon protection strategy should start with a programme aimed at encouraging relevant decision makers to promote self-help protective actions, such as measurement and, if needed, remediation. This process can be implemented through information, advice, incentives, practical assistance and, where necessary, more formal requirements. The level of enforcement of these various actions should be dependent upon the degree of legal responsibility for the situation, and the level of ambition of the national radon protection strategy.

(88) The radon protection strategy should include a programme of actions including provision of general information on radon behaviour and risk, campaigns aiming to increase awareness among the targeted public, campaigns of concentration measurements, and organisation of technical or financial support for measurements and remediation actions (see Section 4).

P59 (104) The action plan may contain both incentive-based and mandatory provisions. Given that responsibility for taking action against radon will often fall on individuals who cannot be expected to perform a detailed optimisation exercise, the action plan should provide appropriate information and support to those individuals to be able to address the radon issue themselves through self-help protective actions, such as self-measurement or access to appropriate measurement services, proper use of buildings, and simple remediation techniques.

P66: (137) The first step in securing support of a national radon strategy is the development of awareness, which appears to be very weak in many countries. Easily available information about radon, how it can be trapped inside enclosed spaces, related risks, and how to identify and mitigate high concentrations should be disseminated to the general population, notably through elected representatives, civil servants in administrative divisions, home owners, landlords, employers, children at school, etc.

(138) ... Appropriate information and training should also be provided to other concerned professionals (e.g. health, real estate).

### **Definitions**

There are no definitions given for the keywords mentioned above. This is interesting, especially in view of the important role “stakeholder” plays in this publication.

The term stakeholder is described and illustrated with examples as follows:

P 19) and p 59): stakeholders, such as those who are exposed and those who should provide support or implement action

P 42: individual householder; builder or the seller of a property towards the buyer, landlord towards the tenant, of the employer towards the employee, and, generally speaking, of the responsible person for any building towards its users; the individual, general population;

P 43: owner of a house, employers, manager of a school, the local authority, building users

### **Motivations**

Not clear.

### **Level of stakeholder engagement**

The level of stakeholder engagement is information, involvement, raising self-help-ability

### **Any other observation that may be relevant to the study**

In this document, the term “responsibility” plays an important role. It is a lot about involvement of stakeholders and working with stakeholders to achieve a better protection level and more actions taken against radon.

### **Protection of the Public against Exposure Indoors due to Radon and Other Natural Sources of Radiation. IAEA Specific safety guide 2015**

### **Key Words**

Stakeholder: no matches. Also no matches for other key words, except information and consultation.

S. 11: Provision of information on radon.

3.13. Requirement 50 of Ref. [2] states that: “The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors.”

S. 11, 3.14. The requirement to provide public information applies irrespective of whether or not radon measurements are being carried out or are planned.

3.17.: interested parties 3.17. If a national policy to control public exposure due to radon needs to be developed, the national authority should prepare information and make it available to all interested parties. This includes decision makers, medical practitioners, building professionals (including architects, engineers, quantity surveyors and builders) and the public.

Information should be provided clear and consistent.

Consultation p 18 3.37. When setting a reference level, the national authority should consult interested parties. Reference levels should be selected such that the resulting activities are seen to be practicable and manageable. For example, it would be impractical to set a reference level such that corrective actions would be necessary for the majority of existing dwellings. The percentages of dwellings that would require corrective actions under different reference levels should be considered in the choice of an appropriate reference level.

p. 24:

Monitoring the effectiveness of the action plan on radon

„The level of awareness may be evaluated on the basis of the number of requests for information or the number of requests for radon measurements to be made, or by means of market research surveys“

Cooperation:

P 23 3.54. The national authority should ensure cooperation with the authorities responsible for the regulation of the planning and construction of buildings when incorporating preventive measures for <sup>222</sup>Rn into national building codes. This includes those authorities responsible for addressing other aspects of indoor air quality and energy efficiency. Site inspection forms an important part of building regulation. Such building regulation should include communication with and training of both building inspectors and professionals in the construction industry

p. 24 3.59 Public awareness of the risks of exposure due to <sup>222</sup>Rn is low in many States. However, a radon reduction programme requires the cooperation of the public in order to be successful in reducing high activity concentrations of radon in dwellings. As part of any action plan on radon, the national authority should develop strategies to inform the public about the risks due to radon and about preventive measures and corrective actions. These strategies should also target bodies and professional groups concerned with housing and with public health, such as builders, architects and regional and local government authorities and the medical profession. Details are provided in Annex V.

Annex V

#### PUBLIC INFORMATION PROGRAMMES ON RISKS DUE TO RADON

e. g. V–4. Perhaps the most important group to be targeted by activities for awareness of radon are building owners, but other important groups include local authority staff, surveyors, builders, housing professionals, estate agents, solicitors, health and safety professionals and the medical profession. The



broad message to be conveyed is the same in all cases but the specified focus and the degree of detail and packaging needs to be tailored to their specific needs.

### **Definitions**

Description of “target group”: building owners, local authority, staff, surveyors, builders, housing professionals, estate agents, solicitors, health, and safety professionals and the medical profession.

### **Motivations**

This document reflects an instrumental motivation for “information”: public awareness should be raised by information.

### **Level of stakeholder engagement**

Level of stakeholder engagement in this document is information and “awareness raising”.

## **Radon in Homes. Factsheet for Decision Makers. IAEA**

### **Key Words**

Information, stakeholder: „What actions are required“ „National authorities need to provide relevant information to target groups - the public, local stakeholders, decision makers and building professionals.

### **Definitions**

No definitions. Only information, no engagement

Target groups: the public, local stakeholders, decision makers, and building professionals.

### **Motivations**

Describe the actions that are required.

### **Level of stakeholder engagement**

No information.

**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". EU level, legislation (directive)**

**Key Words**

To identify engagement aspects related to radon, the document was searched by the key words:

Radon, Information, Communication, Involvement, Participation, Public, Occupational, Operational, Interaction, Exchange, Stakeholder, interested parties, concerned parties, engagement, involvement, participation

Regarding occupational exposure, Article 54 Radon in Workplaces does not entail any word on stakeholder involvement nor information.

With respect to public exposure, Article 74 Indoor exposure to radon, paragraph 3 says "3. Member States shall ensure that local and national information is made available on indoor radon exposure and the associated health risks, on the importance of performing radon measurements and on the technical means available for reducing existing radon concentrations". This paragraph refers to information only, nothing is said about involvement, interaction. Interesting is that the text says "made available" and not for example "provide", which implies a more recipient oriented view, not only the view of information creators. Interesting is the diversification between exposure and risk information on the one side and more action oriented aspects "performing radon measurements" and "technical means for reducing radon concentrations" on the other side. Taken seriously, this would imply to think about how to empower specific groups to act (perform measurements, reduce radon concentration) and it would imply involvement in the transposition into national law. No target groups or potential recipients of that information are mentioned. Nevertheless, it will be duty of the member states to specify the target groups and potential recipients for those information.

The term "parties involved", related to existing exposure situations, is used in Article 102 Implementation of strategies, "1. Member States shall assign responsibilities for the implementation of strategies for the management of existing exposure situations, and ensure appropriate coordination between relevant parties involved in the implementation of remedial and protective measures. Member States shall provide as appropriate for the involvement of stakeholders in decisions regarding the development and implementation of strategies for managing exposure situations". Involvement is here used in the context of an overall approach to strategies for managing exposure situations. It does not specifically mention radon. But, interestingly, it requires stakeholder involvement.

ANNEX XVIII (5) "Assignment of responsibilities (governmental and non-governmental), coordination mechanisms and available resources for implementation of the action plan". However, the terms used imply the interaction with stakeholders.

ANNEX XVIII (7) "Strategies for facilitating post construction remedial action" also implies exchange with concerned parties.

(9) Schedules for reviews of the action plan also implies interaction with stakeholders.

(10) "Strategy for communication to increase public awareness and inform local decision makers, employers and employees of the risks of radon, including in relation to smoking". Key words: communication, awareness, information.

**Definitions**

No definitions available.

With respect to EU BSS, stakeholders mentioned in the context of “radon” are the public, occupational exposed, relevant parties.

### **Motivations**

There is no description of motivation. It can be interpreted as a mixture between instrumental, normative and substantive motivation for stakeholder engagement.

### **Level of stakeholder engagement**

The level of “engagement” mentions in the BSS is mainly information. The terms involvement, cooperation and communication are used only once. Interestingly, information has to be made available”, not “to be provided”. To make it available seems to be a higher level of engagement.

### **Any other observation that may be relevant to the study**

For other cases, such as Emergency management, stakeholder involvement has a much larger role in the directive’s text than for example for radon.

The expression “make available” instead for e. g. “provide information” is used in several references.

## **RADPAR Project. RADPAR FINAL SCIENTIFIC REPORT Radon Prevention and Remediation**

### **Key Words**

Stakeholder:

P. 27: “For categories 1 and 2: A comprehensive strategy (developed with all stakeholders) has to be implemented by means of National Action Plans, involving also local authorities and expertise, and coordination with other related programs/activities (cigarette smoking, IAQ, energy saving) should be promoted.

S. 29: The dissemination of information on radon and its risks to the general population and other relevant stakeholders has been found to be the first step in the development of awareness of radon and on how to deal with it. Raising awareness should not, however, be seen as an end in itself.

Inform:

p. 30: The biggest problem the radiation protection community faces in dealing with public exposure to radon in existing dwellings appears to be apathy. It is very difficult to persuade members of the public to measure for radon in their homes. Even when informed that the radon concentration in their home is above a national reference level only a disappointingly low percentage of householders will decide to remediate. Knowledge on building protection is not shared enough with building professionals and it is needed to spread this information on building protection

Involve: Social marketing techniques have been used to persuade people not to smoke in public areas, to use seat belts, to follow speed limits etc. Social marketing is, unfortunately a skill not normally present in the skill set of radiation protection practitioners, epidemiologists, physicists or other scientific experts. Therefore just non radiation professionals such as architects, builders etc. play an important role in dealing with radon social marketing specialists should be involved in radon risk communication.

It is remarkable, that RADPAR is mostly about “informing”, persuading”, but not about „involving“

### **Definitions**

Stakeholder is used mainly for stakeholders of the RADPAR project, and only two times in the sense of stakeholders in the radon case itself.

No further description of stakeholder is provided.

### **Motivations**

Stakeholder engagement, or rather “information” or “persuasion” is used in an instrumental sense.

### **Level of stakeholder engagement**

The level of stakeholder engagement is information, raising awareness. Involvement is used in the sense, to involve other stakeholders in the radon risk communication

### **COUNCIL DIRECTIVE 2013/51/EURATOM of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption. EU-level, legal (directive)**

#### **Key Words**

No matches for involve nor engage; inform:

P 13, 9): The general public should be adequately and appropriately informed of the quality of water intended for human consumption.

P14, 4. Member States that have recourse to the exemptions provided for in paragraph 3(b) shall ensure that:

(a) the general public concerned is informed thereof and of any action that can be taken to protect human health from the adverse effects resulting from any contamination of water intended for human consumption;

#### **Definitions**

No definitions available. “General public” as target group.

#### **Level of stakeholder engagement**

Level of stakeholder engagement is “information”. No further descriptions.

### **“Common understanding and recommendations related of the BSS requirements on radon in workplaces”. HERCA 2016.**

#### **Key Words**

To identify engagement aspects related to radon, the document was searched by the key words:

Radon, Information, Communication, Involvement, Participation, Public, Interaction, Exchange, Stakeholder, interested parties, concerned parties, engagement, involvement.

The term “stakeholder” is mentioned twice in the HERCA paper on radon workplaces:

Rec. III, p 6: The national action plan should include preventive and educative actions developed for all employees, involving stakeholders such as Labour Unions and Employers Associations.

(Rec. III, p 6)

Rec. V., p7: Radon risk communication is a key aspect of any radon action plan. As a part of the action plan, customized information should be prepared for employers, employees and their representatives, and other stakeholders. Appropriate communication channels should be used, with particular attention given to small and medium-sized enterprises.

“Information” is additionally mentioned in two further recommendations.

„Participation” is mentioned in:

Rec VI. Mechanisms for worker participation in managing radon risk should be encouraged. That could be interpreted as stakeholder engagement.

Rec. VII. Is dedicated to risk communication: “HERCA draws national authorities’ attention to the radon risk management in workplaces with public access, particularly on the issue of risk communication. In a situation where the radon concentration remains above the reference level, even after optimization, risk communication should cover both the public and workers’ exposures. The communication should allow for the difference between the regulatory frameworks (existing exposure situation without dose limitation on the one hand and an existing exposure situation deliberately managed as a planned exposure situation under certain circumstances, with dose calculation, on the other hand). The elements for risk communication toward the workers and the public should be generally prepared in advance, particularly in schools and kindergartens”.

### **Definitions**

No definitions available. Examples are provided for stakeholder: “Labour Unions and Employers Associations”; “employers, employees and their representatives, and other stakeholders.” (Rec. V.)

### **Motivations**

There is no description of motivation. It can be interpreted as a mixture between instrumental, normative and substantive motivation for stakeholder engagement.

### **Level of stakeholder engagement**

The level of “engagement” ranges from information to communication to participation.

### **Any other observation that may be relevant to the study**

This reference is for occupational exposure, not for general public.