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| **Identified legal provision for stakeholder engagement** |

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| **Abstract**  The report on identified legal provisions for stakeholder engagement related to the three fields of investigation in the frame of ENGAGE project is the result of first analyses performed upon collected legal framework and other international guidance and recommendations. It is the milestone in the WP1 Rationales and frameworks for stakeholder engagement in radiation protection and provides the inputs for the WP2 Stakeholder engagement in practice.  The report presents the outcomes from the documents, which were analysed by using a common form for reporting on legal requirements and recommendations for stakeholder engagement related to ionizing radiation use in medicine, in emergency preparedness and response and in activities related to indoor radon. The investigation included related directives and conventions, safety standards, requirements and recommendations from international organisations and other associations. The results of analyses prove that the legal requirements for stakeholder engagement are mainly basic and assure provision of information from responsible to the involved stakeholders. The motivation for participation in primarily instrumental, applied to secure the end points, with some evidences to be also normative, e.g. “it is the right thing to do”, it responds to a certain principle. The level of participation is involvement and participation in the decision making, although it is mainly formalised and limited to certain steps in the process. Other documents, which are not part of the legal framework, like recommendations and guidelines of international organisations or associations, address the stakeholder engagement broader and provides evidences that it is important to maximize interactions with different groups of stakeholders in activities on ionizing radiation.  The report will be transformed in the deliverable 1.1 after the completion of the other parts of the research. |

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# Introduction and WP1 overview

The ENGAGE project, funded under the H2020 CONCERT, aims at *ENhancinG stAkeholder participation in the GovernancE of radiological risks* (ENGAGE, 2017)*.* It is a two-year project that started on November 20th, 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 project aims are:

1. to assess why, when and how stakeholders engage in radiation protection;
2. to develop novel approaches to analysing stakeholder interaction and engagement, and provide guidance to meet the challenges and opportunities identified in response to (a);
3. 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
4. to build a joint knowledge base for stakeholder engagement in radiation protection.

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

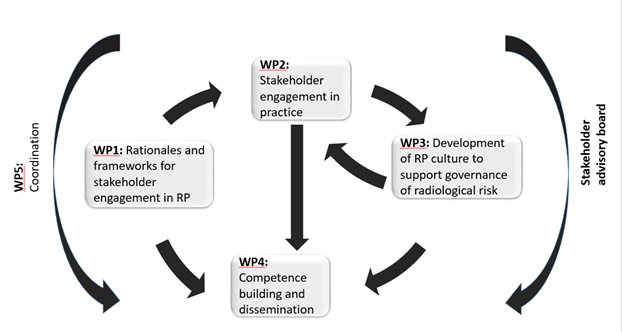


Fig. 1 Interaction between ENGAGE work packages

ENGAGE WP 1 on *Rationales and frameworks for stakeholder engagement in radiation protection* will clarify 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). WP1 will examine institutional and non-institutional stakeholders (e.g. EU bodies, national governments, responsible decision makers, responsible organisations, nuclear lobby, civil society organisations and other groups), what their attitudes and involvement are in relation to public participation into radiation protection issues, and finally if and how these positions can be aligned with the demands of Aarhus and other conventions, EU directives, international and national guidelines, bottom-up guidelines (e.g. from Citizen Science organisations), and general demands for public participation.

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

* 1. formulated in EU policy discourse (e.g. Responsible Research and Innovation, past and on-going research),
  2. 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,
  3. mobilised by different actors at national and international level in the radiation protection field (examples: organised regulatory authorities as in ENSREG and HERCA, NTW, technical RP platforms and other).

The investigation will be focused on the participation analyses at macro-level and will look at the European and international discourse for stakeholder engagement, what is prescribed and required, how these prescriptions are transposed at national level in participating countries and what is the extent and justification for stakeholder engagement. Based on the obtained information and analyses within the WP1, the conceptualization of the frameworks in which stakeholders are engaged in radiation protection will be developed.

WP1 is divided in 4 tasks, where three tasks (1.1, 1.2 and 1.3) correspond to three radiation protection contexts as for the whole ENGAGE (respectively medicine, emergency preparedness and indoor radon), and the fourth one (1.4) is the methodological and also comparative task. The research methods to be used are document analysis of all publicly available material related to legal requirements and recommendations for stakeholder engagement in three fields of radiation protection, and interviews with relevant actors in the participating countries and at the international level (EU level and international organisations such as NEA and IAEA). Task 1.4 will draw on results from other three tasks to assess differences and commonalities between stakeholder engagement in different exposure contexts. In addition, it will analyse transversal European discourse promoting inclusiveness and stakeholder engagement in science policy.

Task 1.1 relates to stakeholder engagement in the medical field and is led by UMIL with participation of BFS, JSI (EIMV) and ISGlobal. The basic information will be collected from documents of European and international institutions and health care organisations (EC, ICRP, WHO, IAEA, HERCA). Also, consultations with different stakeholder groups will be performed with due attention for justification and optimisation in the framework of the informed consent processes. Stakeholders include patient representative organisations, medical doctors, medical physicists, radiographers, other medical staff, health authorities, scientific and professional bodies, manufacturers and suppliers. Contacts will be established with representatives of EURAMED, MELODI, EURADOS and WONCA.

Task 1.2 deals with stakeholder engagement in relation to emergency and recovery preparedness (EP&R) and response and is led by JSI (EIMV) with participation of SCK•CEN, ISGlobal and UMIL. Within this task an analysis of documents will be performed, such as BSS directive, OECD-NEA guidelines, ICRP publications, and other. In addition, lessons identified in the post-Fukushima context will be investigated along with requirements from Civil Society Organisations (CSOs) and NGO’s. Different groups of stakeholders will be consulted like authorities (nuclear, civil protection, local authorities), other involved services (rescuers, fire protections organisations, health professionals), the nuclear industry, TSOs, local population, CSOs &NGOs, citizens initiatives, NERIS and EURADOS platforms.

Task 1.3 investigates stakeholder engagement in relation to indoor radon exposures and is led by BfS with participation of SCK•CEN and JSI (EIMV). The basic document which will be analysed include EU BSS directive, recommendations and guidelines from IAEA, HERCA and ICRP, publicly available material related to legal requirements and international recommendations for stakeholder engagement in relation to indoor radon exposure, recent policy documents that are now calling for Member States to make arrangements for public involvement in relation to radon exposures. The obtained results will be supported by interviews with relevant actors.

Task 1.4 on transversal issues and specifics of different exposure situation will first develop a protocol for the analysis to be carried out in Tasks 1.1, 1.2 and 1.3. and then use the investigation and analysis of rationales and frameworks for the three exposure situations to analyse the transversal issues in terms of stakeholder engagement which could be synthesized as a general framework and the specifics of different exposure situations. Within the WP 1 two deliverables will be produced: report on rationales and frameworks for stakeholder engagement in radiation protection in the medical field, nuclear emergency and recovery preparedness and response and indoor radon exposure and report on stakeholder engagement in radiation protection: transversal issues and specifics of different exposure situations.

# Organization of work and methodology

The objective of analyses in WP 1 is to find out what are radiation protection (RP) communities[[1]](#footnote-1) being asked/expected to do with respect of engagement of stakeholders. That is, 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 for the year 1 as following:

* 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, press releases, 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 analyses of documents based on Protocol for analysis in tasks 1.1, 1.2 and 1.3 (Milestone 1.1, WP1) and Reporting template (annex 1) to prepare Legal provisions identified and provided as input to WP2 (Milestone 1.2, WP1);
* Further analyses of the documents and additional interviews with key actors identified in the investigation of documents;
* Reports on the results of investigation for three fields to be integrated as inputs for draft deliverable 1.1. with analyses and consultations to develop final deliverable.

The methodology for the investigation in the WP1 is presented in the Protocol for analysis in tasks 1.1, 1.2 and 1.3. The aim is to better understand why, when and how stakeholders are engaged in radiation protection. 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, document analysis and semi-structured interviews with key actors per field (e.g. policy makers, stakeholder group representatives) is planned.

The following questions and terms can be 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).

1. 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.
2. 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?
3. 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?
4. 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?

1. 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 ionizing radiation?
2. What else have you found, or should we be asking?

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

* **motivations for participation:** *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)[[2]](#footnote-2);
* **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* (Entman, 1993);
* **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[[3]](#footnote-3)

For the analysis of publicly available documents, collected for the research, the reporting format have been adopted (Annex 1) which propose the review template and allows for discussion of the above questions in the systematic way. It comprises the following information:

* the title of the document and the institution/organisation/association which adopted it,
* used keywords 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.

Until now following documents have been analysed to some degree:

* 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 RP communities (e.g. research platforms),
* Civil Society statements, press releases, other reports.

In current milestone report, which is intended to be used as input for WP 2 Stakeholder engagement in practice, the results of analyses of EC directives and conventions are presented, and also main outcomes from the international communities related to stakeholder engagement in radiation protection. It serves as support to lead further investigation in WP2 on what is required and advised related to stakeholder engagement. All the other results of the analyses of collected documents and also the outcomes from the planned interviews with key actors will be included in the deliverable D1.1 Rationales and frameworks for stakeholder engagement in radiation protection. The information in the D1.1 will include overview of the following topics and countries as presented in Table 1.

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 | all | all | all |
| Related EC directives and other EU level adopted conventions (Aarhus, ESPOO,…) | all | all | all |
| Reports and guidelines from international organisations (e.g. IAEA, OECD-NEA, HERCA, ICRP, ENSREG,…) | all | all | all |
| 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) | all | all | all |
| Civil Society statements, press releases, reports | all | all | all |

# Directives and conventions

## 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.

### 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 organizations (NGOs)) there was no result.

### 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.

### 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.

### 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.

### 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.

### 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.

## 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.

### 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 organizations (NGOs)) there was no result.

### 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 it is provided in the corresponding article 2, it is clean 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 thatMember 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**.

### 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 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.

### 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.

### 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.

### Any other observation

The Nuclear Safety directive sets possibly advanced standards for the engagement of stakeholders. It could be linked to 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.

## 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.

### 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 organizations (NGOs)) there was no result.

### 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 understand 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.

### 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.

### 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.

### 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.

### 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.

## 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).

### 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 organizations (NGOs)) there was no result.

### Definitions and requirements

In the Information in radiological emergency directive there is 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 organization 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 organization 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.

### 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.

### 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).

### 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.

### Any other observation

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

## 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.

### Key Words

After the analyses of Early notification convention text, the following key word was 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 organizations (NGOs)) there was no result.

### 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;
* (0 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.

### 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.

### 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.

### 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).

### Any other observation

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

## EC EURATOM 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.

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.

### 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 organizations) there was no result.

### 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.

### 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.

### 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).

### 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.

### 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.

# Reports and guidelines from international organizations

Until now some reports, documents, recommendations and guidelines of different EU institutions, international organisations and associations have been analysed to obtain the frame under which the stakeholder engagement is proposed. Further analyses will be prepared for deliverable 1.1.



## 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 Nl, DK, UK, D, to a lesser extent in Fl. 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 organizations, 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).



## How are the stakeholders defined

Several documents of international organizations 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** document on “Stakeholder involvement in Nuclear Issues”, 2006, are stakeholders 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,
  + organizations and individuals.

In the IAEA terminology used in nuclear safety and radiation protection **(IAEA Safety Glossary**, 2007) 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 organization, 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 organization, 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 organization. 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** 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” 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 ionizing 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 ionizing 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” from 2012**, it is emphasized that the moto 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, 2017**: “Stakeholders are not only the ones who support your organization 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 [organizations] 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 organizations that represent the views of many individuals.

Three questions were prepared for three round tables performed during the **NERIS workshop in Dublin** on 25th of April 2018, however due to lack of time only the first two were addressed:

1. Who is (should be) a stakeholder in radiation protection in your experience?
2. Why should stakeholders be involved in emergency preparedness and response?
3. What are the strengths- weaknesses-opportunities and threats?

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

When answering the question “who is (should be) a stakeholder in your experience”, it is noteworthy that the members of the round table provide 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. Stakeholder 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 participation. 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 stakeholders 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 divers. 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 involved 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.

## Stakeholders and ionizing radiation in medicine

With respect to other field of exposure, the use of ionizing 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 ionizing 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.

ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. **ICRP Publication 103**, 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).

But (ICRP, 2006a) “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.’

Note that this 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).

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 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. 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.

HERCA, 2017, Report CT Manufacturers Stakeholder Involvement. The Meeting on Optimized use of CT scanners, Vienna 2017, promoted collaboration between stakeholders on the issue of education and training. The stakeholders included: COCIR, professional organizations (ESR, EANM, ISRRT, ESTRO…), international organizations (IAEA, EC, WHO, IRPA, …). This was the last meeting of a process initiated in 2010, between HERCA and the stakeholder COCIR. The initiative started from the conviction of HERCA that all stakeholders involved in the radiological process, and in particular the CT Manufacturers, should be part of the process towards the reduction of patient dose. 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 provision of specific training curricula. 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. Note that this is an example of a very productive initiative of involvement of different stakeholders motivated for a self-commitment and a 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.

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

While the term “stakeholder” is neither mentioned in IAEA EP&R Public Communication (2015) nor in IAEA GSR Part 7 (2015), IAEA guidance on public communication (2012) highlights their importance without clearly defining the term. Only in its publication on Stakeholder Involvement, 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.

The IAEA Handbook on Nuclear Law 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 organizations 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 organizations 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 organizations (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 (2003) 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 organizations and the public, information on incidents and abnormal occurrences, and other information, as appropriate.*”

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) 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.

IAEA GSR Part 7 on Emergency Preparedness Response obliges the government in its Requirement 13 to “*ensure that arrangements are in place for communication with the public throughout a nuclear or radiological emergency*.” But it does not define “the public” or “members of the public”. GSR Part 7 does not recommend, which members of the public should receive prior information. 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.

## **Stakeholders and their engagement in indoor radon**

Radon in Homes. Factsheet for Decision Makers. IAEA: Information for stakeholder on what actions are required. National authorities need to provide relevant information to target groups - the public, local stakeholders, decisionmakers and building professionals.

Protection of the Public against Exposure Indoors due to Radon and Other Natural Sources of Radiation. IAEA Specific safety guide. 2015:

* 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.

Annals of the ICRP. ICRP Publication 126. Radiological Protection against Radon Exposure. ICRP 2014:

* 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, home owners, 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.

RADPAR Project. RADPAR FINAL SCIENTIFIC REPORT Radon Prevention and Remediation

* 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

* 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 organizational 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.
* Organization 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 organizations 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 organization or agency to take the lead in driving and coordinating it. National data should be gathered by this organization 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 organizations 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.

* 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.

# Conclusions

The current document presents the first results of the analyses from collected documents for the WP 1 Rationales and frameworks for stakeholder engagement in radiation protection. It deals with three fields of investigation: medical applications, EP&R and indoor radon. This report is also a milestone report intended as an input for WP2 which will address stakeholder engagement in practice. Therefore, it provides only results of the first investigation of more important legal frameworks, like directives and conventions, and in addition also reports like recommendations and guidelines from international organizations or associations. It will be in the future amended with more systematic description of the stakeholder engagement in international and national legal documents or other publications. The frames for stakeholder engagement will be also supported by positions and opinions of the main and key stakeholders in the area.

The results of analyses show that the legal requirements for stakeholder engagement are mainly basic and instrumental with some evidences to be also normative. The directives and also conventions which were adopted as directives, set a kind of basic requirements for stakeholder engagement. It is foreseen to mainly provide the information to stakeholders and to assure participation in decision making relevant to the different ionizing radiation fields. The level of participation is involvement and participation in the decision making, although it is mainly formalized and limited to certain steps in the process. Stakeholders are in different documents addressed differently, but most of them also include public, or general public, so all who are concerned or affected. Other documents, which are not part of the legal framework, like recommendations and guidelines of international organizations or associations, address the stakeholder engagement broader and provides evidences that it is important to maximize interactions with different groups of stakeholders in activities on ionizing radiation.

The other parts of the investigation which is described in the chapter 2 with further analyses of the documents and additional interviews with key actors identified in the investigation of documents will be developed according to the schedule of the project. It is intended to report on the results of investigation for three fields to be integrated as inputs for draft deliverable 1.1. with analyses and consultations to develop final deliverable.

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# 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***

# Annex 2: Extracts from directive and conventions



## Related extracts from BSS directive

***Preambule***

*(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/m3.*

*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*

1. *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.*

## 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 ionizing 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 ionizing 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.*

## Related extracts from Drinking Water directive

***Preambule***

*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 f****or the protection of the health of the* ***general public with regard to radioactive substances in water intended for human consumption. I****t 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 3 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.***

## 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:*

1. ***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;*
2. ***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 organization 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 organization 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 even****t; 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.* |

## 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 organizations (hereinafter referred to as "international organizations") of a notification received pursuant to sub-paragraph (a) of article 2; and*

*(b) promptly provide any State Party, Member State or relevant international organization, upon request, with (he 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;*

*(0 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.



## 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 matter****s 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 organization 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, organizations 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 organizations 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, organizations 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 organizations 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 organization meeting the requirements referred to in article 2, paragraph 5, shall be deemed sufficient for the purpose of subparagraph (a) above. Such organizations 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.*

1. RP community understood as an epistemic community (Haas 1992): “...a network of professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy relevant knowledge within that domain or issue-area.” [↑](#footnote-ref-1)
2. (see e.g.: <https://assets.publishing.service.gov.uk/media/57a08c6ce5274a31e00011ee/1052734439-stirling.2005-opening.pdf>) [↑](#footnote-ref-2)
3. Adapted based on The 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> [↑](#footnote-ref-3)