Project title: Implications of Medical Low Dose Radiation Exposure

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Call identifier: NFRP-2016-2017

Topic: NFRP-9

Deliverable D6.3

Second Stakeholder Board Annual Report

Lead partner: IRSN

Author(s): Jacques Repussard, Jean-René Jourdain

Work Package: WP6

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Dissemination level: Public

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This report summarizes the activities of the MEDIRAD stakeholder board for the period May 2018-May 2019. It is mainly based on the outcomes of the second stakeholder board meeting held on 28 March 2019 in Vienna, Austria.

Agenda of the second MEDIRAD stakeholder board meeting:

13:00-13:15	Opening of the meeting and adoption of the agenda (J. Repussard)
13:15-13:30	Approval of minutes from previous meeting in Rome (J. Repussard)
13:30-14:00	Brief update on MEDIRAD project progress (J.R. Jourdain)
14:00-15:00	Setting up the Stakeholder Forum (J. Repussard, J.R. Jourdain, F. Vanhavere) - Report on the initial step of invitation of potentially interested organizations - SHB recommendation towards the finalization of SF composition - Presentation of the IT infrastructure for SF operations (if useful)
15:00-16:45	MEDIRAD Recommendations (J. Repussard, F. Vanhavere) - Update on ongoing Task 6.3 - Discussion on the general approach towards elaborating the recommendations including a timeline for successive steps (views from WP6.3 & input by SHB Members) - Discussion on a first questionnaire to engage dialogue with SF members (on the basis of a draft to be established in advance of the meeting)
16:45-17:00	AOB, next meeting, closure of the meeting (J. Repussard, J.R. Jourdain)

Participants:

- Members of the SHB: Jacques Repussard (Chair), Sisko Salomaa (MELODI), Željka Knežević (EURADOS), Maria del Rosario Perez (WHO), Virginia Tsapaki (EFOMP), Anders Widmark (EFRS), Gerhard Glatting (EANM), Christoph Hoeschen (EURAMED).
- MEDIRAD WP representatives: Elisabeth Cardis (WP1), Guy Frija (WP1), Monika Hierath (WP1), John Damiliakis (WP2), Glen Flux (WP3), Rob Coppes (WP4), Isabelle Thierry-Chef (WP5), Jean-René Jourdain (WP6, Task 6.1), Filip Vanhavere (WP6, Task 6.3), Shane Foley (WP6, Task 6.3), Antonella Rosi (WP6, Task 6.3), Cinzia De Angelis (WP6, Task 6.3).

Apologies were received from Viktoria Fonsou (EPF), Reinhard Loose (ESR), Wolfgang Doerr (ESTRO).

1. Approval of the meeting agenda

Jacques Repussard gave a brief presentation of the draft agenda of the meeting that participants then approved.

2. MEDIRAD WP6 progress overview

Jean-René Jourdain presented a summary of progress made in MEDIRAD WP6 since the first stakeholder board meeting.

He reminded the central objectives of the MEDIRAD WP6 which are:

- To formulate a series of science-based policy recommendations built upon results of WPs 2-5, for the effective protection of patients, workers and the general public;
- To organize a web-based consultation of a wide range of stakeholders *via* two structures: Stakeholder Board and Stakeholder Forum, in order to contribute to the development of the MEDIRAD recommendations;
- To disseminate the MEDIRAD results to broader communities interested in radiological protection.

The structure of MEDIRAD WP6 is as follows:

- Task 6.1: Setup and management of Stakeholder Board and Forum ***(Lead: IRSN*)**;
- Task 6.2: Setup and operate the MEDIRAD consensus formation infrastructure ***(Lead: SCK•CEN)*;**
- Task 6.3: Develop of recommendations to enhance radiological protection of patients, doctors, medical physicists, and radiographers ***(Lead: SCK•CEN*)**;
- Task 6.4: Promotion and dissemination of MEDIRAD results among relevant stakeholders ***(Lead: EIBIR).***

The objectives of MEDIRAD WP6 for the first reporting period (M1-M18) were:

- Identify the MEDIRAD stakeholder board members and organize their first meeting (Task 6.1);
- Appoint the Chair of the stakeholder board via a call for tenders (Task 6.1);
- Write the terms of reference for the MEDIRAD stakeholder interface structure (Task 6.1);
- Write the first annual activity report of the stakeholder board (Task 6.1);
- Constitute the MEDIRAD stakeholder forum (Task 6.1);
- Setup of an interface and password protective site devoted to the activities of the stakeholder board and stakeholder forum (Task 6.2);
- Start the process toward the development of a series of recommendations based on MEDIRAD scientific WPs findings by notably writing a document describing the MEDIRAD recommendation development process (Task 6.3).

The achievements made during the first reporting period were:

Identification of MEDIRAD stakeholder board members & organization of the 1st meeting

- **MS9 - Composition of the MEDIRAD SHB (submitted on 15 May 2018):** Prof. Sisko Salomaa (MELODI), Dr. Zeljka Knesevic (EURADOS), Prof. Reinhard Loose (ESR), Prof. Wolfgang Doerr (ESTRO), Prof. Gerhard Glatting (EANM), Dr. Anders Widmark (EFRS), Dr. Virginia Tsapaki (EFOMP), Prof. Christoph Hoeschen (EURAMED), Ms. Victoria Fonsou (EPF), Dr. Maria Perez (WHO, special advisor).
- **First meeting of the SHB:** 13 April 2018, Rome, Italy

Appointment of the Chair of the SHB: Jacques Repussard (call for tenders organized in December 2017, appointment confirmed in January 2018).

Writing the terms of reference for the MEDIRAD stakeholder interface structure: the ToR of the MEDIRAD stakeholder interface structure has been approved by the MEDIRAD SHB members on 11 May 2018 and published on the MEDIRAD project website.

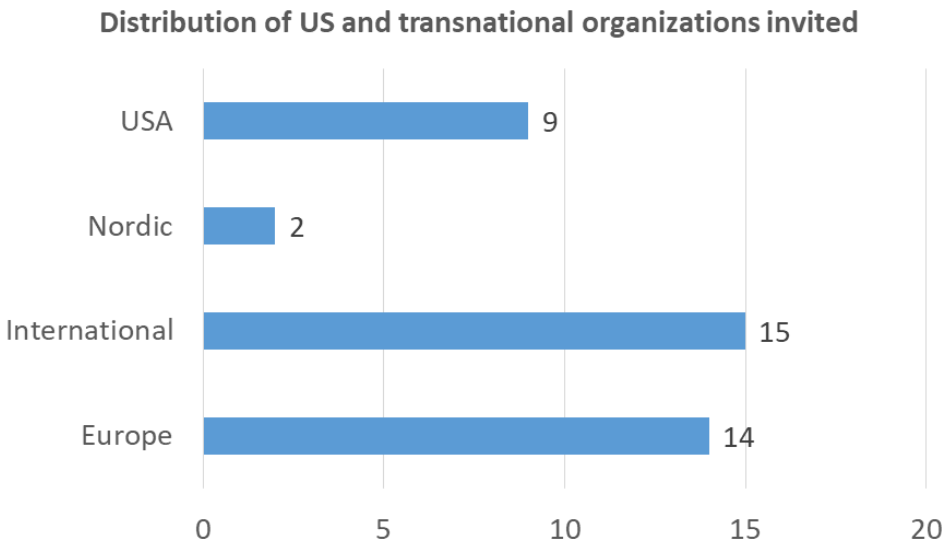
D6.1 - Writing the first annual activity report of the stakeholder board (submitted on 28 May 2018).

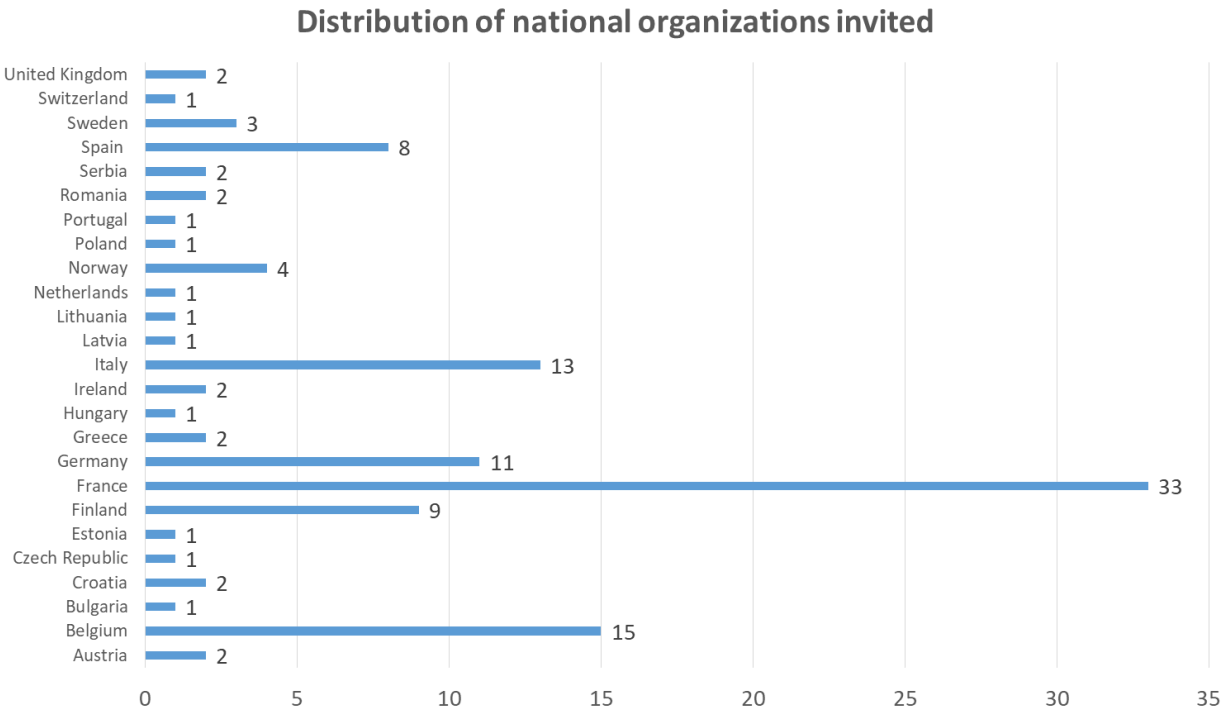
Setup and operate the MEDIRAD consensus formation infrastructure

- **MS11** entitled "Development of stakeholder survey (WP6)" has been delivered on 31/1/2018 (M8) as foreseen. The milestone reports on the actions towards setting up a stakeholder survey, instead of having the survey ready
- The Stakeholder Board/Stakeholder Forum Sharepoint® workspace has been set up and a user manual has been created. This is reported in the public **Deliverable D6.2** submitted 31/5/2018 (M12).
- Update of the GDPR compliance of the workspace before launching the call for SHF membership is in preparation. Indeed, privacy law has changed, and this has some impact on the design and use of the workspace.

Constitution of the MEDIRAD stakeholder forum

- As of 27 March 2019, 160 invitations were sent to organizations proposed by MEDIRAD partners and SHB members to be possibly part of the SF, with the following geographical distribution.
- **From the 160 invitations, 70 nominations were received so far:**


Distribution of US and transnational organizations invited
USA
9
Nordic
2
International
15
Europe
14
0
5
10
15
20


Distribution of national organizations invited
United Kingdom 2
Switzerland 1
Sweden 3
Spain 8
Serbia 2
Romania 2
Portugal 1
Poland 1
Norway 4
Netherlands 1
Lithuania 1
Latvia 1
Italy 13
Ireland 2
Hungary 1
Greece 2
Germany 11
France 33
Finland 9
Estonia 1
Czech Republic 1
Croatia 2
Bulgaria 1
Belgium 15
Austria 2
0
5
10
15
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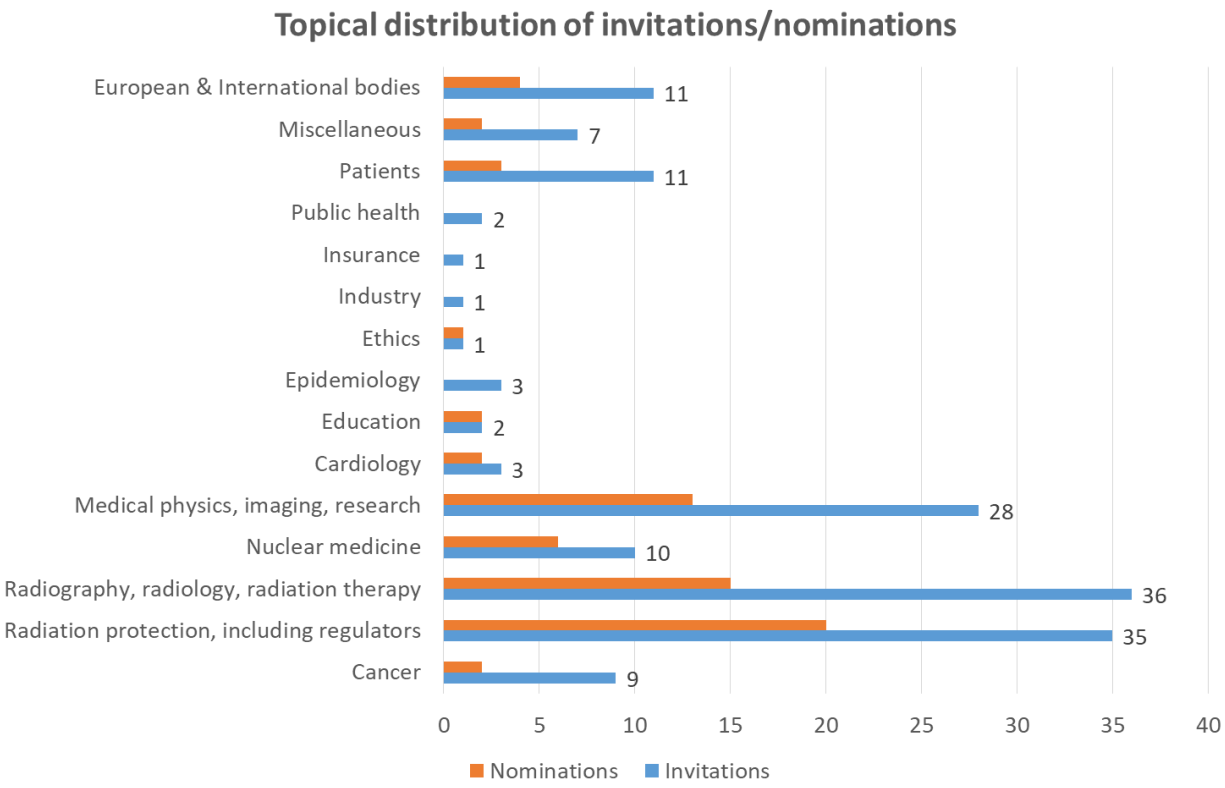
25
30
35



Development of MEDIRAD recommendations

- The recommendations will target 4 different audiences:
    - Development of recommendations to promote standardized procedures for patient data repositories;
    - Development of recommendations on patient RP towards the medical communities;
    - Development of recommendations on patient and worker RP towards policy makers and competent authorities;
    - Development of recommendations on future RP research towards research communities.
- Most of the activities of Task 6.3 are situated further in the MEDIRAD project timeline, because it is really focussed on the development of the recommendations. **However, preparatory consultations have already resulted in the elaboration of terms of reference and proposed composition of a single working group that will prepare the recommendations (whereas it was originally planned to develop recommendations through several WG's according to the type of target audience). There has also been interaction with Task 6.1 to clarify the role of Task 6.3 working group with the Stakeholder Board and Forum, and to define a general strategy to draft the recommendations.**
- In addition to this, WP6 members agreed on a document describing the MEDIRAD recommendation development process.

The deviations from the work plan are as follows:

DEVIATION #1:

Deviation title:

- Delay in the completion of **MS21** entitled "Stakeholder Forum - Online forum operational with publicly available participant list" (Task 6.2).

Reasons for the deviation:

- MS21 has not been submitted on 31/5/2018 as foreseen, because the list of SF potential members has been finalized later than scheduled in December 2018. The final participant list will be known only after entities consulted on a proposed participation in the stakeholder forum have had time to respond.
- The workspace that SHF members will use is online and a user manual has been developed, but whether there will be a publicly available list of participants will depend on the acceptance of the individual members of the SHF, taking into account the GDPR.

Consequences of the deviation:

- No consequences for the project itself in the sense that we will still be able to achieve the web-consultation in a timely manner with respect to the timeframe of the recommendation development process.

Proposed corrective action:

- Update of the GDPR compliance of the workspace before launching the call for SHF membership is in preparation.

DEVIATION #2:

Deviation title:

- The series of 4 MEDIRAD recommendations won't be developed by 4 working groups as originally foreseen in the work plan (Task 6.3).

Reasons for the deviation:

- Each of the 4 working groups were supposed to be composed of 10-15 persons, both from inside and outside the MEDIRAD consortium.
- Such a heavy structure was considered too cumbersome, with little added value in reaching recommendations.
- Multiple WG's could present a risks an increase in incoherence and lack of focus during the process of recommendation drafting.

- External input to the recommendation process is will nevertheless occur through interactions with the Stakeholder Board and Forum.

Consequences of the deviation:

- No consequences for the project itself in the sense that we will still be able to achieve the development of the MEDIRAD recommendations.

Proposed corrective action:

To set up a unique working group for the whole of Task 6.3, which will consist of ~11 persons. Such a group would be able to meet more often and be more effective in making real recommendations. The group would be composed of Task 6.3 partners, including one representative from each platform, as well as the Scientific and Clinical coordinators of MEDIRAD.

Jean-René Jourdain then presented the first conclusions from the EC review meeting held in February 2019, noting that some of the comments are of direct interest for the WP6 work plan:

Significant results linked to dissemination, exploitation and impact potential:

- "Project will likely provide results with significant immediate or potential impact in the next reporting period (even if not all objectives mentioned in the Annex 1 to the GA were achieved.)"
- ***"The time planned within the project plan for stakeholder engagement, formulation of recommendations and dissemination of results, for the size of the project, is very limited, and for the relevant work-package (WP6) to meet this timescale will be challenging."***

Recommendations concerning the period covered by the report:

- "Consideration should be given to an appropriate extension of patient recruitment for the EARLY-HEART study (Work-package 4, Subtask 4.1.1) to allow the number of patients included in the original proposal to be achieved."
- ***"Consideration should be given as to how the timescale for dissemination of results, stakeholder engagement and formulation of recommendations can realistically be met."***

Other comments:

- "The project remains highly relevant and has the potential to provide important scientific evidence in the field of medicine. ***It should assist in informing policy and improving radiological protection."***
- "The expected impact of the project on clinical practice, policy and potentially also regulation is significant. The project will provide important scientific evidence on the impact of the use of ionizing radiation in medicine, both in therapy and diagnosis."

3. Discussion on the development of MEDIRAD recommendations

As a result of the abovementioned proposed corrective actions, MEDIRAD Task 6.3 partners proposed to set up a task force in charge of the recommendations' development. This task force will comprise the following members:

- EFOMP: Anja Almen
- EFRS: Graciano Paulo
- ESTRO: Rob Coppes
- EANM: Michael Lassmann
- ESR: Guy Frija
- MELODI: Elisabeth Cardis
- EURADOS: Merce Ginjaume
- ISS: Antonella Rossi
- UCD: Jonathan McNulty
- IRSN: Marc Benderitter
- SCK•CEN: Filip Vanhavere

WP6 leader (Jean-René Jourdain) and SHB Chair (Jacques Repussard) will also follow this work and participate in meetings where needed.

The first meeting of the working group is scheduled on 29 March 2019. The first tasks of this WG will be to review and refine the recommendation development process and timeline, and to prepare a template for recommendations.

Jean-René Jourdain then presented the first ideas that MEDIRAD WP leaders suggested, towards the list of topics which could be addressed in MEDIRAD recommendations, noting that the list presented below results from an initial brainstorming exchange on this topic within MEDIRAD WP's, and requires further consideration:

Suggestions from WP2:

- Optimising medical staff protection during interventional procedures, by adequate choice and use of shielding equipment, considering their actual effectiveness and efficiency.
- Optimizing image quality / dose in CT scan, including in multimodality imaging procedures (e.g. SPECT-CT and PET-CT scans).
- Developing of patient dose and imaging European registries, with recommended appropriate quantities (effective dose, organ dose) for radiological examinations, for the purpose of:
    - patient radiation protection and information (multiple/repeated procedures),
    - further research, benchmarking of practice, development of DRL's

Suggestions from WP3:

- Proposing protocols for setting up optimised imaging systems for quantitative imaging of I-131 irrespective of camera make or model.
- Facilitating individualised patient care in nuclear medicine:
    - Procedures for evaluating patient-specific dose delivered to volumes and organs through activity uptake.
    - Modelling of patient dosimetry on an individual basis by highlighting the range of absorbed dose delivered from fixed administrations of activity, in order to evaluate the range of possible secondary effects, including long-term risks of secondary malignancies.
    - Consideration of individual biokinetics in patients with residual thyroid tissue or adjuvant disease, rather than reliance on models and values established for a healthy population.
    - Exploring of the potential of patient-specific radiobiology tests to assess the radiosensitivitiy of patients, in order to optimise the treatment prescription.
- Outlining a plan for a large scale and multisite epidemiological study to evaluate the effect of low absorbed doses of radiation through nuclear medicine imaging protocols in a population with an expected normal life expectancy.

Suggestions from WP4 & WP5:

- Developing and validating operational biomarkers predictive of patient exposure side or late adverse effects following repeated radiological examinations, or radiotherapy protocols, inter alias through implementing the research roadmap developed by Hall et al in the frame of the DoReMi EURATOM project.
- Optimising patient follow up care after radiation therapy and collecting valuable epidemiological data through a better bridging of medical professionals from relevant disciplines (e.g. for breast cancer, cardiologists and oncologists).
- Facilitating the development of large scale multinational epidemiological studies by proposing guidelines to help European countries to implement at the national level European regulatory requirements on ethics (including compliance with GDPR directive).

4. New timeline proposed for the implementation of MEDIRAD WP6 activities

As a result of decisions made along the MEDIRAD WP6 meeting on 26 March 2019, it is proposed to adopt a new timeline for the implementation of MEDIRAD WP6 activities, taking into account a possible 9-month extension of the project.

- **Task 6.1: M1-M57 (instead of M1-M48)**
    - Subtask 6.1.1: M1-M57 (instead of M1-M48)
    - Subtask 6.1.2: M1-M57 (instead of M1-M48)

- **Task 6.2: M5-M57 (instead of M5-M48)**
- **Task 6.3: M29-M55 (instead of M29-M45)**
  - Subtask 6.3.1: M29-M55 (instead of M29-M48)
  - Subtask 6.3.2: M29-M55 (instead of M29-M48)
  - Subtask 6.3.3: M29-M55 (instead of M29-M48)
  - Subtask 6.3.4: M29-M55 (instead of M29-M48)
- **Task 6.4: M47-M57 (instead of M35-M48)**

If adopted in a revised MEDIRAD work program the new implementation timeline of MEDIRAD WP6 for the period M23-M57 would be as follows:

- **APRIL 2019 (M23)**: Start of the survey development (expectations from recommendations)
- **OCTOBER 2019 (M29)**: End of survey development and distribution to SHB+SF
- **JANUARY 2020 (M32)**: Collection of answers to survey
- **APRIL 2020 (M35)**: Presentation of survey results to the MEDIRAD consortium
- **NOVEMBER 2020 (M42)**: SHB and Task 6.3 meetings (clear inputs from WPs required)
- **APRIL 2021 (M47)**: First draft recommendations available and start of SF consultation
- **JUNE 2021 (M49)**: End of SF consultation
- **SEPTEMBER 2021 (M55)**: Final draft recommendations available
- **OCTOBER 2021 (M56)**: Dissemination workshops

As a consequence, the delivery dates of MEDIRAD WP6 deliverables and milestones would be as follows (note that delivery date of D6.4 is postponed to M43 as the third SHB meeting is now planned in November 2020 instead of April 2020. As a consequence, it makes sense to postpone the third SHB annual report to December 2020):

No	Description	Lead	Due date
D6.1	First stakeholder board annual report	IRSN	M12
D6.2	Report on the stakeholder forum: composition, content of the web-consultation, guidelines for the use of the stakeholder infrastructure	SCK•CEN	M12
D6.3	Second stakeholder board annual report	IRSN	M24
D6.4	Third stakeholder board annual report	IRSN	~~M36~~ M43
D6.5	MEDIRAD first recommendations (final draft)	UCD	~~M42~~ M55
D6.6	MEDIRAD second recommendations (final draft)	ISS	~~M42~~ M55
D6.7	MEDIRAD third recommendations (final draft)	SCK•CEN	~~M42~~ M55
D6.8	MEDIRAD fourth recommendations (final draft)	IRSN	~~M42~~ M55
D6.9	Report on the organization and findings of the two seminars organized within Task 6.4	IRSN	~~M48~~ M57

No	Name	Lead	Due date	Mean of verification
MS9	Stakeholder board established	EIBIR	M6	Publicly available member list and ToRs
MS11	Development of stakeholder survey	SCK•CEN	M8	Content of survey finalized
MS21	Stakeholder forum	SCK•CEN	~~M12~~ M25	On-line forum operational with publicly available participant list
MS31	Recommendation WG	SCK•CEN	M24	WG operational
MS51	Dissemination seminars	IRSN	~~M42~~ M56	Detailed agendas of seminars available and list of participants decided

5. Conclusions and next steps

In accordance with the second stakeholder board meeting conclusions, the following action plan has been decided:

Action	Responsible	Deadline
To ask stakeholder board members and MEDIRAD WP leaders to examine the current status of organizations proposed for the stakeholder forum and to suggest, if relevant, additional missing members/organizations	Monika Hierath	June 2019
To identify supporting documents presenting the scope, context and objectives of the MEDIRAD project that would be communicated to stakeholder forum participants	Monika Hierath	June 2019
To prepare a questionnaire directed to stakeholder forum participants aiming to collect their concerns and expectations related to the MEDIRAD recommendations towards better enhancing the radiation protection of public, workers and patients. The questionnaire should include a statement highlighting that contributions from the stakeholder forum members will not be interpreted as an endorsement by responders of MEDIRAD recommendations. With this regard, it was recommended to get benefit from the format of recommendations developed in the frame of recent European projects, such as SHAMISEN recommendations in the OPERRA project	Jacques Repussard & Jean-René Jourdain	June 2019
To hold a teleconference with MEDIRAD coordinators, WP1&6 leaders and SHB members to decide on the final composition of the stakeholder forum, and to validate the text of the questionnaire	Jacques Repussard & Jean-René Jourdain	July 2019
Once the content of the questionnaire validated, to send the questionnaire to stakeholder forum participants	Monika Hierath	July 2019
To develop with MEDIRAD WP leaders a list of topics to be addressed within the MEDIRAD recommendations, based on the likely findings of the MEDIRAD project and on available SF members response to the questionnaire	MEDIRAD stakeholder board members	October 2019
To ask MEDIRAD Task 6.3 partners to develop a template for MEDIRAD recommendations. Such a template may include a description of missions and scope of MEDIRAD (which will be generic for all recommendations), issues addressed by each recommendation, considerations underpinning the recommendations, including MEDIRAD results and	Filip Vanhavere	October 2019

justification in terms of addressing stakeholder concerns. The text of each recommendation would include in a first annex scientific evidences from MEDIRAD (and other projects) results, and a second annex comprising information on authors of the recommendations, as well as a disclaimer		
To collect comments of the stakeholder board members on the final list of topics proposed for the MEDIRAD recommendations and on the template proposed by MEDIRAD Task 6.3 partners	Filip Vanhavere	November 2019
To present at the third MEDIRAD consortium meeting to be scheduled the final list of topics and template for recommendations	Filip Vanhavere	April 2020

6. Next meeting

Taking into account the likely extension of the MEDIRAD project, it is anticipated that the next stakeholder board meeting will be scheduled in November 2020 at a location to be determined. This meeting will consist of a 3-day meeting that will include a 2-day MEDIRAD Task 6.3 meeting devoted to the preparation of the MEDIRAD recommendations.