**SAMIRA Study on Reporting and Learning from Patient-Related Incidents and Near Misses in Radiotherapy, Interventional Cardiology, Nuclear Medicine and Interventional and Diagnostic Radiology**

**MARLIN**
*(Medical Applications of Radiation – Learning from Incidents and Near Misses)*

**Draft Workshop Programme**

The 24-month MARLIN project will support the implementation of Council Directive 2013/59/Euratom, specifically articles 63c–e and 104.5, by providing a comprehensive description of the current status of incident reporting. It is important that the use of ionising radiation in the diagnosis and treatment of diseases is carefully monitored and measures are taken to minimise both the frequency and harm caused by accidental or unintended exposures to patients, according to the relevant articles of the Basic Safety Standards Directive (BSSD). The use of incident learning systems (ILSs), notification systems where incidents and near misses can be investigated and possible flaws in a process can be identified and rectified, will be studied with regard to their compliance with the BSSD and other regulatory requirements and their role in improving patient safety.

To achieve the specific objectives, the project will include the following elements.

- A survey on the implementation of the European legal requirements on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, diagnostic and therapeutic nuclear medicine, as well as interventional and diagnostic radiology
- General and practice-specific guidelines on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, diagnostic and therapeutic nuclear medicine, as well as interventional and diagnostic radiology
- Consultations on the draft guidelines with the relevant Member States’ competent authorities and European professional organisations
- Project workshop

**Workshop date:** 5–6 September 2024 (beginning 13:00 on Sept. 5 and ending at 16:00 the next day)

**Workshop format:** in-person meeting, 1.5 days

**Venue:** BluePoint Brussels, Belgium

**Target countries:** EU27, Norway, Switzerland
Workshop goals:

- Presentation of the MARLIN project and its results
  - Project objectives and SAMIRA context
  - Presentation of the relevant BSSD requirements and underlying issues and perspectives from important organisations and stakeholders
  - Status of implementation of the BSSD requirements on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and diagnostic and interventional radiology in EU Member States, Norway and Switzerland (WP1)
  - Member-State field reports and good-practice examples (WP1)
  - Presentation of the general guidelines and recommendations, including methodology of development and consensus procedure (WPs 2 and 3)
  - Presentation of practice-specific guidelines and recommendations (WP2)
- Receive feedback from stakeholders
- Receive feedback from target groups
- Reach consensus on the guidance document and further actions needed
- Prepare proceedings of the workshop, consisting of session summaries and main conclusions and recommendations

The groups intended to be represented at the workshop include the following.

- National competent authorities
- National health authorities
- European and national professional societies
- European and international bodies such as the European Commission (EC) and Heads of the European Radiological Protection Competent Authorities (HERCA)
- European and international experts in the field
- Patient representatives
- Industry
- SAMIRA Steering Group on Quality and Safety and Euratom Article 31 Working Party on Medical Exposures

Workshop Programme
Thursday, 5 September 2024

Session 1  Opening and Background
Moderator: C. Prieto Martín
Rapporteur: EIBIR Office

13:00–13:10 Welcome by the EC and consortium
13:10–13:40 Introduction to the MARLIN project and overview
  - The project and its rationale
  - SAMIRA context
13:40–14:00 Presentation of the underlying issues
14:00–14:30 Perspectives of European and international organisations
  - HERCA, IAEA
14:30–14:40 Perspectives of patient organisations
14:40–15:10 Coffee break
**Session 2**  
**Status of Implementation of BSSD Requirements on ILSs [WP1]**  
Moderator: J. Andersson  
Rapporteur: G. Paulo  
15:00–15:50 Survey methodology and results of questionnaires and expert interviews  
15:50–16:30 Member-State field reports and good-practice examples  
  France  
  Germany  
  Belgium  
16:30–17:15 Discussion  
17:15–17:25 Conclusions and recommendations  
17:25–17:30 Wrap-up, Day 1

**Friday, 6 September 2024**

09:00–09:10 Welcome to Day 2 and introduction of programme

**Session 3**  
**Presentation of the General Guidelines and Recommendations Including Methodology of Development and Consensus Procedure [WPs 2, 3]**  
Moderator: M. Kearney  
Rapporteur: D. Akata  
09:10–10:00 Presentation of general guidelines and recommendations, including methodology  
10:00–10:30 Coffee break  
10:30–10:50 Discussion  
10:50–11:00 Conclusions and recommendations

**Session 4**  
**Presentation of the Practice-Specific Guidelines and Recommendations [WP2]**  
Moderator: N. Pourel  
Rapporteur: C. Kelly  
11:00–12:00 Panel presentation of guidelines and recommendations:  
  Experts from the relevant clinical areas  
12:00–13:00 Lunch break  
13:00–13:20 Statements of European professional societies  
13:20–14:20 Discussion  
14:20–14:30 Conclusions and recommendations  
14:30–15:00 Coffee break

**Session 5**  
**Summary**  
Rapporteur: J. Johansen, ESTRO Office  
15:00–15:35 Final discussion on guidelines and recommendations per project task  
15:35–15:50 Next steps in the project  
15:50–16:00 Closing