



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)***

Workshop Programme

The 24-month MARLIN project will support the implementation of Council Directive 2013/59/Euratom (Basic Safety Standards Directive, or BSSD), 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 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 streamed via EIBIR Zoom, 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), Heads of the European Radiological Protection Competent Authorities (HERCA), and International Atomic Energy Agency (IAEA)
- 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: N.D. Peld, EIBIR office

13:00–13:10 Welcome by the EC and consortium (G. Simeonov, DG ENER; C. Prieto Martín)

13:10–13:40 Introduction to the MARLIN project and overview

- The project and its rationale (C. Prieto Martín)
- SAMIRA context (F. Maksan, DG ENER)

13:40–14:00 Presentation of the underlying issues (C. Prieto Martín)

14:00–14:30 Perspectives of European and international organisations

- HERCA (A. Craig)
- IAEA (O. Holmberg)

14:30–14:40 Perspectives of patient organisations (S. Ebdon-Jackson, ESR Patient Advisory Group)

14:40–15:10 *Coffee break*



Session 2 Status of Implementation of BSSD Requirements on ILSs [WP1]

Moderator: J. Andersson

Rapporteur: G. Paulo

15:10–15:50 Survey methodology and results of questionnaires and expert interviews (J. Andersson)

15:50–16:30 Member-State field reports and good-practice examples
France (C. Rousse, French Nuclear Safety Authority)
Germany (E. Mille, German Federal Office for Radiation Protection)
Belgium (A. Vaandering, Cliniques Universitaires Saint Luc)

16:30–17:15 Discussion (Discussion facilitator: G. Brusadin)

17:15–17:25 Conclusions and recommendations (G. Paulo)

17:25–17:30 Wrap-up, Day 1 (J. Andersson)

Friday, 6 September 2024

09:00–09:10 Welcome to Day 2 and introduction of programme (C. Prieto Martín)

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 (C. Prieto Martín; M. Kearney; C. Kelly)

10:00–10:30 *Coffee break*

10:30–10:50 Discussion (Discussion facilitator: M. Kearney)

10:50–11:00 Conclusions and recommendations (D. Akata)

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
Radiotherapy expert (M. Kearney)
Therapeutic and diagnostic nuclear medicine expert (A. Geão)
Interventional radiology and cardiology expert (A. Rogers)
Diagnostic radiology (D. Akata)

12:00–13:00 *Lunch break*

13:00–13:20 Statements of European professional societies
EANM (M. Koole)
EFOMP (A. Rogers)
EFRS (A. England)
ESR (B. Brkljačić)
ESTRO (U. van der Heide)

13:20–14:20 Discussion (Discussion facilitator: N. Pourel)

14:20–14:30 Conclusions and recommendations (C. Kelly)

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
(C. Prieto Martín; J. Andersson; M. Kearney; N. Pourel)

15:35–15:50 Next steps in the project (M. Hierath)

15:50–16:00 Closing (G. Simeonov, DG ENER; C. Prieto Martín)