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)

D4.3: Workshop Proceedings as Part of the Draft Final Report

31 October 2024

Start date of project:	1 January 2023
Duration:	24 months
WP4 lead:	C. Prieto Martín
WP4 co-lead:	N. Pourel
Authors:	C. Prieto Martín, N. Pourel, G. Paulo, D. Akata, C. Kelly, J. Johansen, M. Hierath, N. Peld
	Review by all consortium members
For the attention of:	European Commission, Directorate General for Energy, G. Simeonov

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This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.880751.

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List of Abbreviations

BSSD	Basic Safety Standards Directive (Council Directive 2013/59/Euratom)
DG ENER	Directorate-General for Energy
EANM	European Association of Nuclear Medicine
EC	European Commission
EIBIR	European Institute for Biomedical Imaging Research
EFOMP	European Federation of Organisations for Medical Physics
EFRS	European Federation of Radiographer Societies
ESR	European Society of Radiology
ESTRO	European Society for Radiotherapy and Oncology
EU	European Union
HERCA	Heads of the European Radiological Protection Competent Authorities
IAEA	International Atomic Energy Agency
ILC	Incident learning committee
ILS	Incident learning system
SAFRON	IAEA Safety in Radiation Oncology system
SAMIRA	Strategic Agenda for Medical Ionising Radiation Applications
SGQS	SAMIRA Steering Group on Quality and Safety
WP	Work package
WP MED	Article 31 Working Party on Medical Exposures

1. Introduction

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 includes 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

The deliverable contains detailed session summaries and conclusions from the discussions held during the project workshop of September 2024 at the BluePoint Brussels and online. The workshop was intended to present and validate the results of the work carried out under work packages (WPs) 1–3 and discuss issues relating to reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine, and interventional and diagnostic radiology. The target groups, dissemination, organisational arrangements, online streaming platform and attendance are also described.

Workshop date: 5–6 September 2024

Workshop format: in-person meeting, 1.5 days

Venue: BluePoint Brussels, Belgium

Target countries: EU27, Norway, Switzerland

2. Background

The workshop came near the conclusion of the project, providing an opportunity to present the consortium's achievements since beginning in January 2023. WP1 constructed a portrait of the status quo in Europe by developing, deploying and analysing a survey and conducting expert interviews on the implementation of ILSs in Europe in all areas of the use of ionising radiation in medicine, as a consequence of BSSD. This was complemented by the formulation under WP2 of general technical and practice-specific guidelines on reporting and learning from patient-related incidents and near misses in the relevant clinical areas. The workshop constitutes a major portion of the crucial stakeholder feedback prior to the adoption and implementation of these guidelines in the final form, which is the focus of WP3, which consulted with the relevant Member States' competent authorities and European professional organisations to refine the guidelines prior to the workshop.

The workshop gathered the consortium's crucial stakeholders such as its Advisory Board, Article 31 Working Party on Medical Exposures (WP MED), and SAMIRA Steering Group on

Quality and Safety (SGQS) as well as regulatory authorities and medical professionals and patient advocacy groups. Their feedback is essential to the finalisation and implementation of the consortium's guidance. Confirmed workshop participants received a copy of the draft consensus guidelines in the latest version available at the time ahead of the workshop.

Detailed briefings were distributed to moderators, and rapporteurs were assigned for each session to summarise the main items presented by the speakers as well as conclusions and recommendations from the discussions, ensuring that workshop feedback is integrated into the final version of the consortium's consensus guidelines. In addition, a session featuring a panel discussion to present recommendations for each clinical area and statements from the relevant European professional societies will also contribute to implementation of these guidelines.

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

3. Dissemination

3.1 Target Groups

The following groups were represented at the workshop.

- 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
- SGQS and WP MED

3.2 Dissemination

A venue for the workshop in Luxembourg or Brussels was sought as soon as the date of September 5–6 was settled with the EC in October 2023, after which the consortium also agreed to submit the programme in January so a final version can be a part of the 3rd progress report in June 2024. After selecting a venue, a save-the-date message was distributed in January to the consortium and Advisory Board members with relevant information available at that time.

The draft programme was posted to the MARLIN website in March, after which invitations to register were distributed to the consortium partners for early registration of their members. Speakers, moderators, rapporteurs and Advisory Board members were formally

invited in April, followed by similar invitations to the WP1 survey participants. The EC was forwarded an invitation to distribute to HERCA, SGQS and WP MED members, and target societies were approached to nominate representatives of their leadership and national member societies. In mid-June, reminders were sent to the relevant European societies and invitations were extended to the ESR EuroSafe Imaging group and participants in a recent webinar series by the i-Violin project, which deals with the optimisation and harmonisation of oncological imaging procedures in Europe. The European Institute for Biomedical Imaging Research (EIBIR) office consulted with its consortium members and the partner societies to collect their travel information, arrange hotel reservations and notify them of the reimbursement scheme. By mid-June, all moderators, rapporteurs and speakers had confirmed their participation in the workshop.

The EC was regularly notified of the registration total and participants, resulting in guidance to devise a policy for onsite and online invitations and promote broad representation among the EU member states. The two Advisory Board members based outside Europe were offered virtual participation, necessitating a hybrid format. Registrants for the recent i-Violin webinar series were invited, and the members of scientific and quality and safety committees of the relevant European professional societies were offered online participation, bringing in many from outside Europe and key experts.

Registrants received the deliverable D2.3 so they could familiarise themselves with the draft guidelines and recommendations. In the week before the workshop, the EIBIR office posted the final programme on the MARLIN webpage, sent summaries of the panel and European society statements to the EC for review, and distributed welcome emails to all registrants. The EIBIR office used its social media channels during and after the workshop to publicise the sessions and tag the consortium partners for wider promotion.

3.3 Participation

Total participation, including speakers, moderators and panellists, amounted to 99, with 64 onsite and 35 online. A table of the represented countries and number of representatives follows.

Table 1: Summary of workshop representation

Austria	3	Lithuania	1
Belgium	12	Luxembourg	2
Bulgaria	1	Netherlands	3
Croatia	3	Norway	3
Cyprus	1	Poland	3
Czechia	4	Portugal	8
Denmark	2	Romania	2
Finland	3	Slovakia	1
France	6	Slovenia	1
Germany	3	Spain	5
Hungary	1	Sweden	4
Ireland	7	Switzerland	3
Italy	2	Other non-EU	15

4. Workshop Programme

Thursday, 5 September 2024

Session 1 Opening and Background
Moderator: C. Prieto Martín
Rapporteur: N.D. Peld

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

13:00–14:00 Discussion
(Discussion facilitator: N. Pourel)

14:00–14:20 Statements of European professional societies
EANM (M. Koole)
EFOMP (A. Rogers)
EFRS (A. England)
ESR (B. Brkljačić)
ESTRO (U. van der Heide)

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

14:30–15:00 Coffee break

Session 5 Summary
Rapporteur: J. Johansen

15:00–15:35 Final discussion on guidelines and recommendations (C. Prieto Martín)

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

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

5. Session Summaries

Day 1, September 5

5.1 Session 1: Opening and Background

Aims of the session

- To introduce the MARLIN project, its objectives and the work done to date
- To describe the role of the project in EC programmes for radiation and patient safety and treatment quality
- To present perspectives on the project from key international organisations and patient groups

Key points

- The MARLIN project is an EC-funded study that seeks to improve reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology.
- The project primarily focuses on the development and use of ILSs to implement the BSSD requirements for incident reporting and learning.

- Throughout the project, important international organisations and patient groups have provided guidance on its outputs, particularly the draft guidelines and recommendations.

Summaries of the presentations

1. Welcome by the EC and consortium

G. Simeonov opens the workshop with a welcome to all participants onsite at the BluePoint Brussels and online. The representatives of European and national professional societies and radiation protection/health competent authorities are welcomed as important contributors. The role of the project as part of the SAMIRA action plan is described, and its focus on patient-related incidents and near misses is intended to support the development and use of systems for learning. The medical uses of radiation are very safe, as there are not a large number of incidents, but incidents draw significant public attention. MARLIN started in January 2023 under EIBIR, EFOMP and ESTRO. The WP MED supports the EC in developing this project among others, and appointed reviewers have given regular guidance. The project will close at the end of 2024.

The programme is dense, including the main outcomes of the project, national experiences, views of professional societies and discussion.

C. Prieto Martín thanks the consortium members for the contributions to the work, Advisory Board for their feedback and EC for their guidance. Variations in incident reporting and learning across the EU made the project a difficult task. EIBIR is thanked for their help in project management. C. Prieto introduces the programme, with the first day to present the background research and the second to present the draft guidelines and recommendations.

A picture of the earth as a pale blue dot taken by the Voyager 1 spacecraft relates the scale of the galaxy with the specific work of the MARLIN project within the broad field of patient safety. The house rules are presented to inform the participants of how the discussions will take place. The programme for today is reviewed, and some statistics of registration are given.

2. The project and its rationale

C. Prieto Martín explains the project supports the implementation of the BSSD. MARLIN seeks to integrate the perspectives of clinical facilities, professional societies and competent authorities. The ACCIRAD project provided a background in ILSs and risk analysis for EBRT, while MARLIN adds a focus on ILSs in four clinical areas: radiotherapy, interventional cardiology, nuclear medicine, and interventional and diagnostic radiology. The partners and duration are introduced. The interrelations of the WPs are described. MARLIN seeks to improve learning from the inevitable occurrence of errors.

3. SAMIRA context

F. Maksan introduces the legal obligations for incident reporting according to the Euratom Treaty as well as articles 63 and 96 of the BSSD. SAMIRA activities consider medical equipment and clinical audit. Education and training activities include INTERACT-EUROPE on inter-speciality cancer care training and EU REST on the current state of the radiology workforce with projections and recommendations. The SAMIRA preparatory joint action PRISMA supports member states in implementation of SAMIRA outputs and will be followed by a full joint action in 2026, which could include implementation of MARLIN outcomes.

4. Presentation of the underlying issues

C. Prieto Martín presents the identified issues to be resolved by the project's work. MARLIN studies ILSs, integrating the risk-assessment outcomes of the ACCIRAD project. The project identified ILSs at the local, competent authority and national or international levels. The former tend to be mandatory, while the latter tend to be voluntary. Many other

attributes were also considered. Two example structures of reporting and learning among the various levels of ILSs are described. The typical circumstances to be considered by ILSs at each level are also given. Variations among the member states must be considered in terms of BSSD transposition, safety culture, experiences, resources and regulations in addition to variations due to the different medical fields. To conclude, the use of ILSs contributes to improving safety and building a safety culture, the BSSD serves as a framework despite barriers to implementation, and the MARLIN project aims to overcome barriers.

5. Perspectives of HERCA

A. Craig introduces herself and HERCA, which was founded in 2007 with a goal of contributing to a high level of radiation protection throughout Europe by serving as a platform for the competent authorities to identify issues and develop common approaches. 56 competent authorities from 32 countries comprise the group. The structure is given, and the working groups are named. As it is the most relevant to the MARLIN project's objectives, the responsibilities, main interests and prominent achievements of the Working Group on Medical Applications are listed. The background of a long-standing lack of a standardised approach to reporting accidental and unintended exposures and legal framework of the BSSD are central to the aims of MARLIN. HERCA produced a position paper in 2017 based on a series of surveys and a multi-stakeholder workshop on BSSD requirements, and its key findings and seven key messages are described. HERCA's comments on the MARLIN project objectives are given.

6. Perspectives of the IAEA

O. Holmberg relates the support of the IAEA for the objectives of the project, as they agree with the general safety requirements, particularly requirements 3 and 41, of the International Basic Safety Standards. The survey results are useful for many types of organisations. The Safety in Radiation Oncology (SAFRON) system is described as an open-access international incident reporting system developed from ESTRO's ROSIS system and maintained by the IAEA that depends on information contributed by registered users. It collects 1.5 million page views per year. A newsletter is distributed to publicise featured incidents and safety-related documents, and SAFRON contributes to international training courses and workshops on radiotherapy incident prevention. In a published study of SAFRON incidents, the most significant reported causes are inadequate communication and not following standard procedures. A relevant international conference on radiation protection in medicine will be held by the IAEA in 2025 to formulate a strategy for the next decade.

7. Perspectives of patient organisations

S. Ebdon-Jackson notes his perspective as a patient and from long-standing interest in the area. The bargain between the patient and professionals in terms of trust exchanged for ethical, professional and vigilant treatment is described. A comparison with airplane passengers and operators is made. Ethical behaviour includes honesty and transparency. Confidentiality and communication are also primary components. Communication is key to comforting patients in case of accidents. Patients may accept the accident. Patients tend to want to control confidentiality, often seeking publicity out of altruistic concern, and all desire to be treated as individuals who matter rather than statistics. Organisations must be prepared in advance of incidents, including communications with media and other medical staff, and patients should be sure these measures are in place. Wording is extremely important. Regarding the draft guidelines, no-blame culture is a popular topic, but negligence should be given an appropriate response. 2nd and 3rd victims regarding an organisation that has created an error should be reconsidered, as patients tend not to accept this terminology. Organisations and staff need to learn but not at the expense of patients. Determining whether learning has been successful is a key question and may be related to verified communication.

Summary of the discussion

G. Simeonov asks regarding the SAFRON system if reporting is sourced from national systems or direct entry. O. Holmberg replies that 90% are done by direct entry. Furthermore, how expensive is implementation. O. Holmberg replies that migration between IT systems was > € 100 000, but the system requires little operation oversight and maintenance. P. Papírník advises that the border between negligence and malevolent action should be emphasised more in the discussion of no-blame culture. Also, ILSs are given the appearance of a form of software, but their primary benefit is to provide learning to users and practitioners.

C. Prieto Martín asks if there is an alternative suggestion for 2nd/3rd victims. E. Oymak asks if patients would like to know the end results of learning by the healthcare team, e.g., months or years after an accident. S. Ebdon-Jackson replies that the degree of detail is less important to the patient than the propagation of the lessons learned. Groups affecting patients affected by systematic errors have given evidence that they welcome details on the implementation of a plan for prevention of recurrence.

Conclusions from the session

The session provided the background of the project, its contribution to EC programmes and how it intends to satisfy its objectives, leading to the next session on how the consortium collected data and testimony to use for the formulation of its guidelines and recommendations. Insight into how the consortium has been advised was also given.

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

Aims of the session

- To be aware of the 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
- To learn about good-practice examples from some EU Member-States

Key points

The MARLIN survey showed:

- That all EU Member States have transposed the BSSD, regarding incident reporting of significant events involving ionising radiation for patients, into their legislative framework
- That all the countries have a national/regional authority specifically designated as a competent authority for the management of declared significant events, involving ionising radiation
- That despite the positive aspect of the transposition and the fact of the existence of a competent authority, there are huge heterogeneities regarding:
  - The number of events reported
  - The kind of events reported
  - The role of competent authorities in managing reported significant events
- That only in some cases, professional societies were involved in the process of revising the legal provisions

- That amongst health professionals (and also managers) there is lack of:
  - A safety culture
  - Education and training
  - Financial resources

Summary of presentations

1. Survey methodology and results of questionnaires and expert interviews (J. Andersson)

J. Andersson gave an overview on the results from the questionnaire, which provided a clear picture of the situation across the EU, with the view from the national CA, professional societies and individual hospitals, with the main focus on the legal provisions established for the implementation of regulatory ILSs for significant events after the BSSD transposition.

2. Member-State field reports and good-practices examples – France

C. Rousse of the French Nuclear Safety Authority gave an overview about success factors for deploying a reporting and feedback system: the French experience, with a special focus on:

- The characteristics of the French reporting and feedback system
- Some key figures
- What does feedback mean?
- Success factors for deploying a reporting and feedback system

The French system was set up in 2007, in the context of a serious radiotherapy accident, with a strong health ministerial support and the involvement of all stakeholders, that was considered as the key aspect for the success of the implementation in France.

3. Member-State field reports and good-practices examples – Germany

E. Mille of the German Federal Office for Radiation Protection gave an overview about the German incident reporting system organized at Federal and State level, its structure, with a special focus on the set of definitions and criteria for significance.

The algorithm decision (workflow – practitioner's view) on the presence of an event was also shown.

4 Member-State field reports and good-practices examples – Belgium

A. Vaandering of Cliniques Universitaires Saint Luc gave an overview about the PRISMA-RT in Belgium: a common methodology to analyse all (near)-incidents in radiotherapy.

The Belgian national regulatory body, the Federal Agency for Nuclear Control, made:

- Mandatory notification of all significant events in radiology, nuclear medicine, interventional radiology and radiotherapy
- Voluntary notification of events that are of potential interest to other departments

In the context of the Belgian 2010 National Cancer Plan, a national platform for incident reporting and learning was developed and put in place, the PRISMA-RT platform.

The experience shows that establishing a common methodology of analysis has served as a uniting factor in the Belgian radiotherapy quality management community.

Summary of the discussion

Discussion with workshop participants focused essentially on the following aspects.

- The risks of overregulating and putting in place complex legal frameworks at the national level, which may jeopardise the implementation of ILSs
- The lack of existence of a common taxonomy, which would contribute to a better understanding across Member States
- The reasons that would explain the huge heterogeneity in reporting significant events amongst Member States

Conclusions from the session

The majority of the countries have transposed the EU directive; however, the way legislation is implemented at national level is quite diverse.

The fact that professional societies are not involved in drafting the provision seems to be one factor contributing to low levels of ILS development.

Evidence shows lack of collaborative work between competent authorities, professional societies and hospitals.

Education and training and lack of safety culture appear as two of the main barriers for implementing ILSs, both at the local and national level.

The good-practice examples shown are very important and should be used as examples to other Member States.

The type of actions that the national competent authorities take have a huge impact on reporting.

Member States interpret differently the concepts of the BSSD, mainly on how to implement specific measures. Therefore, clear guidance should be given to Member States, and MARLIN outputs will be of paramount importance.

Day 2, September 6

5.3 Session 3: Presentation of the General Guidelines and Recommendations Including Methodology of Development and Consensus Procedure [WPs 2, 3]

Aims of the session

Over recent decades, the benefits of ionising radiation have significantly advanced both in therapy and diagnostics. Our primary objective as professionals is to minimize harm and accidents while fostering a strong safety culture.

Key points

1. Critical steps for ILSs
    - **Reporting:** Should be straightforward and accessible in clinical settings.
    - **Recording:** Must be efficient and user-friendly.
    - **Analysis:** Needs to be thorough to identify errors and enhance care.
    - **Learning and redesign:** Essential for reducing errors and improving processes.

2. Establishing a just and safe culture:

    - Unlike a no-blame culture, a just culture encourages open and honest reporting while holding the system accountable.
    - **Standardisation:** Use standardized terminology and procedures.
    - **Efficient data collection:** Ensure data collection is streamlined.
    - **Analytical feedback:** Provide constructive feedback based on analysis.
    - **Focus on improvement:** Emphasise solutions and enhancements.

3. Golden rules for encouraging reporting

    - **Leadership support:** Ensure active support from leadership.
    - **Respect reporters:** Avoid blame policies to reduce litigation fears.
    - **Confidential reporting:** Implement confidential or anonymous reporting systems.
    - **Provide feedback:** Share lessons learned and improvements made.
    - **Follow-up:** Ensure corrective actions are implemented and tracked.

4. Collaboration with competent authorities

    - **Partnership:** Collaboration with competent authorities is crucial.
    - **Structure and responsibilities:** Understand the ILS structure and the role of medical radiation incident committees.
    - **Reporting significant events:** Report major events as per national criteria to avoid system overload, using a secure portal within a specified timeframe. The competent authority reviews these reports, including a detailed analysis and recommendations. The competent authority maintains a database, and clinical facilities support a national database for all events.

5. Open disclosure and patient engagement

    - Open disclosure is a critical component of ILSs in clinical settings.
    - The responsibility for disclosure rests with the incident learning committee (ILC) and the referring practitioner.
    - Communication with patients must be sensitive and supportive, using language that is easy to understand.
    - Patients should be kept informed about the progress of the analysis and offered the opportunity to participate and provide input.

Summary of the presentation

1. Presentation of general guidelines and recommendations, including methodology

M. Kearney provided a detailed explanation of the project methodology.

- **Stakeholder consultation:** Engaged with national competent authorities, professional societies, clinical facilities, and international and European organizations. Received 90 responses with a good geographical distribution.

- **Feedback integration:** Incorporated significant changes based on stakeholder feedback.

- **Executive summary:** Included an executive summary and a summary of recommendations in the project documentation.

- **Dose reference levels:** Removed as a criterion for triggering investigations due to problematic usage.

- **Significant events table:** Updated to better define categories and reflect clinical areas. Categories 1, 2, and 3 are now considered significant events, while Category 4 events can be reported if they are of particular interest from a patient safety perspective.

C. Kelly reviewed and refined definitions related to incident learning systems, including terms such as "critical event," "clinically significant event," "incident learning system," and others. Definitions were revised to align with the BSSD and to ensure consistency across the document. He highlighted that incident learning systems have been effectively

implemented in radiotherapy centres following major incidents. These systems are well-established and considered crucial for safety management. Experience shows that incident learning reduces the severity of incidents over time, promotes a safety culture, and encourages reporting.

C. Prieto Martín discussed the criteria for notification of significant events. He emphasised that dosimetric triggers by medical physics experts should only be reported if deviations from the expected outcomes are unjustified. Different dose thresholds apply across various fields such as radiotherapy, therapeutic nuclear medicine, and medical imaging. The main criterion for reporting is the clinical consequence of the event. He categorized events into three groups: Category 1 and 2 events are always reportable, Category 3 events should be reported as best practice, and Category 4 events are non-significant but reportable if of particular interest for patient safety.

Summary of the discussions

P. Papírník from the Czech State Office for Nuclear Safety recommends limiting compulsory initial reporting to category 1 and perhaps category 2. In the Czech approach, three categories are used, namely the immediate notification of category 1, notification within 1 month for category 2, and annual notification of category 3. The guidelines should focus on reporting events containing valuable lessons learned rather than minor regular events such as laterality error in radiography. C. Prieto Martín replies that the guidelines have been updated to emphasise discretion for the competent authorities within the mandate of the BSSD to notify of significant events as soon as possible as well as means for quick and easy notification. G. Simeonov recommends clarifying the difference between significant and reportable events as well as categories for the speed of dissemination of lessons learned. Also, the consortium should consider adding practical examples for competent authorities in an annex. L. Parent notes France requires every 7 years training in patient radioprotection with content designed by the professional society and competent authority, which has been found to raise awareness of the reporting system and asks why millisieverts was used for imaging despite the recommendation of flexibility in units elsewhere in the document. C. Prieto Martín replies criteria can be described as multiples of a normal dose or millisieverts, noting for some high-dose procedures multiples of a normal dose cannot be used. L. Parent recommends establishing a European registry for significant events to save costs and effort. G. Simeonov replies existing international systems such as SAFRON have worked well. E. Mille recommends legal guidelines and criteria should be precise enough to allow for application in practice and verification of compliance by competent authorities.

Conclusions

The benefits of ionising radiation in therapy and diagnostics have increased over the past two decades, and the goal of professionals is to uphold safety culture to minimise harm and accidents. Incident learning systems fundamentally rely on open and honest reporting, which can be supported through confidentiality and anonymity. Five steps for successful use of ILSs are reporting, recording, analysis, learning and redesign, all of which can be improved. There is also a strong recommendation for European legislation to enhance ILSs and protect healthcare professionals.

5.4 Session 4: Presentation of the Practice-Specific Guidelines and Recommendations [WP2]

Aims of the session

A panel of experts from each of the identified clinical areas, radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology, present the consortium's guidelines and recommendations from chapter 5: Specificities in the Different Areas. The relevant European professional societies comment on the work on the project, the guidance in their clinical areas and their support for implementation.

Key points

- Although many similarities exist in the use of ILSs and dissemination of lessons learned across fields using ionising radiation, practice-specific considerations are an important element.
- The relevant European professional societies express their support for the project and welcome the publication of specific guidance for their members.

Summary of the presentations

1. Radiotherapy guidelines and recommendations

M. Kearney addressed the subject from the perspective of an expert in radiotherapy. She was speaking on behalf of ESTRO and currently works as a lecturer in radiation oncology and has previously worked for many years as a radiotherapist. She outlined that while radiotherapy is indicated for almost 50% of all cancer patents, it remains somewhat underutilised. Despite this almost 635 000 courses of radiotherapy are delivered in Europe each year. Radiotherapy is unique in that it deals with relatively high doses of radiation and the patient pathway is a complex process involving sophisticated equipment, complex IT systems and highly engineered machinery. Combined with multiple crucial human interventions this exposes the radiotherapy patient to the potential for serious unintended exposure. For these reasons ILSs are well developed and implemented in most radiotherapy centres and in general a good safety culture exists in the speciality. Maeve emphasised the importance of reporting of significant events to the competent authority and the usefulness of national and international databases. She also discussed the devastating impact that incidents have on staff and the importance of a just culture and the presences of supports for staff involved.

2. Therapeutic and diagnostic nuclear medicine guidelines and recommendations

A. Geão on behalf of the EFRS outlined changing dynamics in nuclear medicine as theranostics begins to overtake diagnostic procedures. Over 100 different procedures in nuclear medicine are recognised by European regulators and 10 million patients per year benefit from nuclear medicine procedures. The patient is at the centre of the nuclear medicine process. Nuclear medicine procedures are complex with many steps and involving many departments and staff throughout the clinical facility. This exposes the process to the potential for introducing human errors into the process. It is important to develop and consistently employ a common taxonomy for description of incidents. Ana emphasised the need for specific nuclear medicine expertise in designing ILSs and for the recording and analysis of incidents by the ILC.

3. Interventional radiology and cardiology guidelines and recommendations

A. Rogers, a medical physics expert nominated by EFOMP, outlined why interventional radiology has particular and specific characteristics. In general, in interventional radiology there are fewer incidents observed than in other specialities but there is a larger range of error. He outlined how in this setting ILSs can be used not only for incident learning but also for optimisation, leading to a reduction in patient dose from common procedures. He described how the use of an ILS in interventional radiology can identify dose outliers and lead to quality improvements. A. Rogers emphasised the need for common taxonomy and described the UK Health Security Agency common taxonomy system. In common with other speakers Andy emphasised the importance of the ILC but recommended the inclusion of representatives from other profession such as nurses and facilities in the ILC. He also spoke about the need for added resources to support ILSs in interventional radiology and highlighted the need for training and committed time.

4. Diagnostic radiology guidelines and recommendations

D. Akata presented a radiologist's view of incident learning in diagnostic radiology. Doses in diagnostic radiology are low compared to other specialities but scale is much larger. She illustrated how today over 80 million computed tomography scans are performed per annum in the USA compared to 3 million in 1980. Although this has resulted in significantly increased population exposure the health benefits are enormous. She illustrated not so appropriate uses of diagnostic radiology due to defensive medicine. This included the patients' insistence and desire for certainty, the rise in obesity and the increased use of computed tomography for procedures which may have been performed with ultrasound in the past, and the ordering of increased and medically unnecessary exams. She outlined how different protocols for the same or similar procedures can result in significantly different doses to the patient. She outlined how the reporting of events internally within ILSs or externally to the competent authorities can lead to significant quality improvements. She illustrated the differences in criteria for reporting of significant event across countries. She identified systematic failures affecting a number of patients and random events with single patient. She emphasised the importance in diagnostic radiology of misdiagnosis or misinterpretation leading to multiple additional scans and/or delays in treatment. She reiterated from the MARLIN guidelines that a specific diagnostic radiology ILS is not required within the clinical facilities, provided sufficient expertise is available to the clinical facility's ILC. She described the importance of patient–dose management systems and how optimisation and justification of exposures can be managed by implementing clinical decision support systems.

5. Statements of European professional societies

EANM: Michel Kolle

The use of the MARLIN guidelines in the nuclear medicine setting will require a culture change within the nuclear medicine community; however, the EANM strongly welcomes this work and encourages its members to collaborate and implement this welcome initiative

EFOMP: Andy Rogers

EFOMP strongly supports these guidelines. They understand and emphasise the extra resources required to fully implement this work. Undertake to work collaboratively with the professional societies and competent authorities in this regard.

EFRS: Andrew England

The EFRS represents almost 120 000 radiographers working throughout Europe. It commends the MARLIN project and supports its recommendations. The EFRS was delighted to see the crucial role of the radiographer in incident learning acknowledged and identified in the guidelines. EFRS however identifies some challenges in implementing the MARLIN guidelines. Amongst these is increasing numbers and complexity in the clinic and in this regard the EFRS would encourage a focus on simplicity and on the use of new technology to aid the increased use of incident learning in the clinic.

ESR: B. Brkljačić

ESR fully endorses the recommendation of the MARLIN consortium. The ESR will promote the recommendations through its organisation. It was also important to see the speciality specific recommendations outlined in the guidelines and welcomes this initiative. In particular the ESR acknowledges the usefulness of the guidelines and their use in the optimisation and justification of diagnostic scans.

ESTRO: U. van der Heide

ESTRO has long standing committed to quality and safety in radiation. ESTRO welcomes the outcome of the project and is committed to progressing the work through its

organisation. It welcomes the recommendations for safety committees within the professional societies working very much in a multidisciplinary environment. ESTRO as an international society will endeavour to support training and harmonisation of approach within national societies. It is important to acknowledge that incidents will happen, but it is important to learn from these.

Summary of the discussion

N. Pourel requests opinions on the composition of an ILC. C. Kelly recommends including the line managers, in line with his experience, to offer specialist knowledge and open discussion. General staff at his clinical facility receive an annual presentation on the process of incident analysis but are not part of the ILC. Quality managers, if applicable, are recommended to chair the ILC.

S. Ebdon-Jackson recommends for clinically significant event external experts, e.g., in clinical psychology, to disseminate lessons learned to patients and manage change with staff. A. England emphasises local control to improve radiation safety culture across departments and recommends expanding access to ILSs, which N. Pourel describes as the primary responsibility of quality managers in France. A. Craig appreciates clarifying the governance structure from the local level to the competent authority to ensure learning and oversight, and E. Mille adds that competent authorities can focus on corrective measures and verification of implementation. G. Brusadin notes frequent departmental meetings in radiotherapy in his clinical facility are organised by the quality risk manager to discuss significant events and align corrective measures, although the time required to change safety culture should not be underestimated.

An anonymous online participant advises that if the minimum size of an ILC is one person, a person with the highest qualification in radiation protection, in most cases the head of medical physics, is needed. The person should be informed about all radiation incidents and significant events and then involve all relevant persons and departments. Incidents could be divided into a minor category to be handled at the clinical level and a major category involving the competent authority. C. Kelly acknowledges that the line manager may not have the required expertise, and the recommendations for ILCs consider flexibility.

G. Simeonov recommends clarifying in the guidelines which dose triggers apply to various imaging techniques and nuclear medicine terminology among diagnostics, therapeutics and theranostics, while nuclear medicine ILCs should include radiopharmacy expertise and diagnostic imaging should consider computed tomography specifics. A. Geão notes radiopharmacists are not required in all nuclear medicine departments, but the guidelines advise including all relevant expertise. Also, theranostics combines diagnostic and therapeutic treatments. M. do Carmo Lopes recommends considering the latest developments in image-guided radiotherapy to determine whether dose reference levels still apply. A nuclear medicine physician recommends including guidelines for hybrid imaging and therapeutics, e.g., combining nuclear medicine and interventional radiology. C. Kelly notes an audit in his clinical facility found that more than half of reported incidents were reclassified by the ILC, but responsibility for classification remains with the reporter to encourage openness.

N. Pourel asks if unique taxonomies exist for a sole clinical area, and M. Vandecapelle replies the World Health Organisation’s taxonomy is used with some additions to develop a common list for incidents in radiology and nuclear medicine. C. Kelly reminds that taxonomies are generally compatible, and O. Holmberg notes SAFRON taxonomy is available without registering as a user. N. Pourel asks if a common modality for event analysis has been developed, and U. van der Heide answers that PRISMA-RT is commonly used in Belgium and the Netherlands. C. Rousse adds in-depth analysis is difficult, and a quality and risk manager with expertise in organisational and human factors is recommended, as they are often the cause of incidents, and E. Mille reports medical physics experts in Germany are receiving more training in root-cause analysis. S. Ebdon-Jackson

emphasises an external organisation can be contracted to write an incident report, which promotes transparency and confidence for patients.

Conclusions

During this session, a panel of experts shared the consortium's guidelines and recommendations as detailed in chapter 5: Specificities in the Different Areas. The discussions highlighted the importance of practice-specific considerations in ILSs across the four key domains: radiotherapy, nuclear medicine, interventional radiology and diagnostic radiology. Each speaker emphasised the unique challenges within their specialties and the need for some specific tailored recommendations. Furthermore, representatives from relevant European professional societies expressed strong support for the implementation of these recommendations, recognising their potential to enhance patient safety and optimize practice.

In conclusion, this session successfully illuminated the complexity and diversity in the application of ILSs across different clinical areas involving ionising radiation. The valuable insights shared by the experts and enthusiastic support from European professional societies underscore an important step toward cultivating a culture of safety in medical practices. As we move forward, collaboration and communication among all stakeholders will be essential to ensure the effective implementation of these guidelines and improve patient safety across Europe.

5.5 Session 5: Summary

Aims of the session

Through a final discussion on the guidelines and recommendations, the key points of discussion during the workshop were highlighted. In emphasising the presentations made, with the subsequent comments and dialogues, this session aimed to present an overview of the feedback received throughout this workshop and how they will be further assessed and adopted during the final stages of the MARLIN project.

Key points of the session:

- Importance of flexibility in the implementation of ILSs, without compromising the intent of the results of the project.
- The categories 2 and 3 of the criteria of notification are not considered significant enough to require initial notification to competent authorities.
- Importance of emphasising assessments of how learning following a significant event has occurred, with analysis, such as on the changes made, clinical audits, and inspections.
- The matter of confidentiality versus anonymity needs further elaboration, with a greater emphasis on the options of confidentiality and anonymisation after the analysis and investigation is complete.

Summary of the presentations

1. Final discussion and conclusions on guidelines and recommendations

The summary presentation by C. Prieto Martín provided an overview of the questions raised, and the work to be done through the final phase of the project.

The workshop saw the targets, responses, and application of the results of the survey on *implementation of the European legal requirements on reporting and learning from incidents and near misses* being presented in detail, allowing for significant feedback on its impact on the project. The guidelines developed and presented received discussions and

feedback for revising its final content. The criteria of notification of significant events were thoroughly discussed, implying that instead of presenting these criteria as legislation, they should rather be given in the form of guidelines, which more easily allow for later readaptation. With a discussion on the flexibility of implementation of ILSs, it was agreed that flexibility also needs to be further emphasised, acknowledging that the implementation of ILSs can vary between cases. The categories of significant events notification were particularly discussed as a key point requiring revision, with an agreement reached to potentially omit the initial notification of categories 2 and 3, as they are not considered significant enough for this requirement. The guidelines should also maintain flexibility in recognising that the composition of the incident learning committees should be recognised as often varying between the clinical facilities and countries, and that local circumstances requires different approaches.

Discussions were made on the used terminology, particularly that of 'no-blame and just culture'. The guidelines recognise 'just culture' as the preferred option. It acknowledges that 'no-blame' policy may be required as well, particularly as a starting point in the path towards a 'just culture'. Another point on terminology concerned the use of 'second and third victim'. The word 'victim' should be highlighted to be avoided in direct communication with the patient, although the terminology will be maintained in the guidelines. Furthermore, the importance of safety culture was acknowledged as an important aspect to be emphasised in the guidelines, particularly viewed through training, education support, and ILS analysis tools. It was agreed that it is key to recognise the importance of addressing how one can ensure if learning has happened following a significant event and its implementation.

With the conclusion of the workshop, the project will be assessing the points raised. The guidelines will need to acknowledge the importance of practicality, and that this varies from different countries and areas. Added accessibility to complement the tables of significant events will be achieved by incorporating specific examples with indicating the timeframes proposed for these examples. A lower emphasis on certain needs for reporting of minor events in the guidelines will be revised, with incorporating a specific guidance on what may be considered a significant event. It will take aim to support a paper on comparative significant events in different countries, which will complement the project survey, and contribution to the 2025 Conference on Radiation Protection in Medicine. Finally, it was stressed to maintain the understanding that improved safety is not for free, and that improvement in resources are necessary to achieve this, as a key message of this project.

2. Next steps in the project

M. Hierath describes the final outcomes, firstly making the workshop-related materials available. PDFs of the session presentations will be published on the EIBIR website, and the proceedings will be uploaded after approval by the EC. Workshop feedback will be integrated in October in a draft final report on the survey results, guidelines and recommendations. The consortium will hold a final meeting with the EC to discuss this and then prepare the text for a publication in the EC Radiation Protection Series. The study intends to close at the end of 2024.

3. Closing

G. Simeonov thanks the active participation of the audience and sees a general consensus on the consortium's guidance. Recommendations from the participants are welcomed to produce a final document, and the European professional societies are thanked for their statements and commitment. Project outcomes will be discussed with the Member States regarding implementation, and it is hoped the consortium members will remain available after the project ends. C. Prieto Martín also thanks the participants for their feedback. The final document is intended to contain useful guidance for a broad audience. The workshop organisers are thanked, and the workshop is closed.