European Journal of Nuclear Medicine and Molecular Imaging (2026) 53:6661–6669
https://doi.org/10.1007/s00259-026-07973-5

ORIGINAL ARTICLE

Incident learning systems to improve patient safety in nuclear medicine across Europe: results of the MARLIN study

Carlos Prieto[1,2] · Ana Geao[3,4,5] · Stephan G. Nekolla[6] · Erik Björn Mille[7] · Ora Israel[8] · Gianfranco Brusadin[9] · Jonas Andersson[10] · Maeve Kearney[11,12] · Andy Rogers[13,14] · Deniz Akata[15] · Nicolas Pourel[16] · Graciano Paulo[17,18] · Olivier Pellerin[19] · Barry Hallinan[20] · Monika Hierath[21] · Nathan Peld[21] · Colin Kelly[22]

Received: 18 March 2026 / Accepted: 26 May 2026 / Published online: 30 May 2026
© The Author(s), under exclusive licence to Springer-Verlag GmbH Germany, part of Springer Nature 2026

Abstract

Purpose To enhance patient safety in nuclear medicine (NM) across Europe by operationalising MARLIN recommendations for implementing incident learning systems (ILSs), including barriers/enablers and practical implementation guidance.

Methods A mixed-methods study (combining a survey, semi-structured interviews, and a targeted literature review) was performed within the MARLIN project. This was a 24-month initiative conducted under the European Commission's Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) Action Plan, involving European organisations such as EANM, EIBIR, ESTRO, and EFOMP. Surveys were distributed to Clinical Facilities (CFs), Competent Authorities (CAs), and professional societies (PSs). Interviews were used to explore implementation barriers and examples of good practice. Data were analysed using descriptive statistics and thematic analysis.

Results The study revealed significant variability in the criteria for defining and reporting significant radiation events in NM across Europe. While all surveyed countries had designated authorities for managing reported events, only 11/23 had specific criteria for NM. The study identified key enablers and barriers to ILS implementation, including the need for a just culture to encourage reporting without fear of punitive measures. The guidelines recommended criteria for significant radiation events in NM and the organisation of ILSs.

Conclusion The MARLIN study provides a comprehensive framework for the systematic implementation of ILSs in NM, highlighting the importance of standardised reporting criteria in several categories, multidisciplinary involvement, and a culture of safety. Addressing the identified barriers and promoting a coordinated effort among stakeholders are crucial for enhancing patient safety in NM across Europe.

Keywords Incident learning system · Nuclear medicine · Patient safety · Radiation protection · Quality management

Introduction

The use of ionising radiation for medically justified exposures has expanded substantially across Europe in recent decades [1]. The rapid growth in both diagnostic and therapeutic nuclear medicine (NM) procedures over the past decade underscores the increasing importance of patient safety within this field [2]. This expansion, driven by greater access to modern equipment and the continuous development of new techniques, underscores the growing relevance of Incident Learning Systems (ILSs) in this specialty. In NM, potential reportable events may occur at different stages of the clinical workflow, including radiopharmaceutical preparation, activity calibration, patient identification, administration of radiopharmaceuticals, and the use of hybrid imaging procedures such as PET/CT or SPECT/CT. ILSs serve as an essential tool for identifying and addressing process failures and enabling corrective actions that enhance patient safety.

Despite their importance, literature on the specific use of ILSs in NM remains sparse, and their comprehensive implementation in this field is still rare. Additionally, the number of publications on ILS use in NM is limited compared to those available on external beam radiotherapy. For

Extended author information available on the last page of the article

example, SAFRON [3], the voluntary ILS developed by the International Atomic Energy Agency (IAEA) in 2012, was initially limited to external beam radiotherapy events. Therapeutic NM was only added in 2020. However, guidance literature [4–6] has been published for ILSs in NM, and some publications detail their specific characteristics and applications [5, 7–13].

RP-208 [14] provides valuable insights and recommendations of the MARLIN (Medical Applications of Radiation – Learning from Incidents and Near Misses) study to support the systematic implementation of ILSs in clinical NM practice, as mandated by the EU basic safety standards directive (BSSD) [15]. The BSSD requires member states to take all reasonable measures to minimise the probability and magnitude of accidental or unintended patient exposures. Article 63(c) further stipulates that undertakings must implement an appropriate system for recording and analysing events involving or potentially involving unintended medical exposures, proportionate to the radiological risk posed by the practice. In this context, these recommendations aim to support the establishment of structured systems for incident reporting, analysis, and organisational learning in NM practice across Europe. Given the higher radiological risks associated with treatments compared to diagnostics, dedicated efforts to establish systems tailored, at minimum, to therapeutic NM procedures are essential.

While the Directive sets out clear requirements, it offers limited guidance on implementation, resulting in significant variations in how member states adopt and utilise ILSs. This variability is not inherently negative, as it accommodates national differences and diverse applications of ionising radiation. Regardless of these disparities, RP-208 provides a valuable framework for improving patient safety across all areas and fostering a more consistent approach across Europe.

This paper focuses on specific NM-related recommendations from the MARLIN study, offering a structured approach for NM departments, professional societies (PSs), and regulators to optimise the use of ILSs. Ultimately, the goal is to support NM professionals and stakeholders in enhancing patient safety, ensuring compliance with regulatory requirements, and promoting the systematic reporting and learning from radiation events. Through improved dissemination of information and the development of safety measures, the study aims to enhance the overall quality and safety of NM services across Europe.

Materials and methods

The 24-month MARLIN study aimed to develop guidelines for implementing ILSs across all areas, including NM. The consortium included the European Institute for Biomedical Imaging Research (EIBIR), the European Society for Radiotherapy and Oncology (ESTRO) and the European Federation of Organisations for Medical Physics (EFOMP). EIBIR had 11 shareholders including the European Association of Nuclear Medicine (EANM). Building upon the work conducted under the Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) Action Plan and related initiatives [16], the MARLIN study aimed to provide practical guidance on the implementation of ILSs, identify barriers to their adoption, and promote a culture of safety and continuous learning in all areas, including NM. This article synthesises MARLIN outputs into NM-specific operational recommendations.

The study faced several NM-specific challenges, including:

- Assessing the current use of ILSs in NM across Europe.
- Defining clear criteria for what constitutes a significant radiation event in NM.
- Recommending an organisational structure within both NM departments and competent authorities (CAs) for managing reported events.
- Clarifying the role that PSs should play in supporting reporting, analysis, and dissemination of lessons learned.

To achieve its objectives and tackle these challenges, RP-208 incorporated the following key elements:

- Survey, Interviews, and Literature Review: A targeted literature review was conducted before the survey to prevent redundancy, ensure comprehensive coverage, and guide survey design. The search focused on publications and guidance documents addressing incident learning systems, patient-safety event reporting, accidental or unintended exposures, and radiation-safety learning in medical radiation practices. The databases searched were Scopus and Web of Science, complemented by targeted searches of relevant organisational and regulatory sources, including IAEA, European Commission, HERCA and professional society guidance. The search covered the period from 2010 to 2023 and used combinations of terms including “incident learning system”, “nuclear medicine”, “patient safety”, “radiation protection”, “accidental exposure”, “unintended exposure”, “near miss”, and “significant event”. Retrieved records were screened for relevance to nuclear medicine, medical radiation-event reporting, incident analysis, and ILS implementation. The review informed the questionnaire structure, the interview guide, and the development of the MARLIN recommendations. The project team then carried out a survey on the implementation of European legal requirements for reporting and learning from patient-related radiation incidents and near misses.

In-depth interviews with experts were conducted with regulatory authorities and hospital representatives to identify good practices and implementation gaps. Semi-structured interviews were conducted with representatives from five competent authorities and four hospitals. The relevance of their expertise was primarily confirmed from the survey results, which identified respondents and institutions with direct involvement in ILS implementation, oversight, analysis, or use. Interviews were conducted online and, when possible, in person, using a semi-structured interview guide addressing implementation barriers, enablers, examples of good practice, reporting culture and feedback mechanisms. These efforts provided a comprehensive understanding of the current status of ILSs in Europe and served as the foundation for guideline development. Nevertheless, response rates varied across stakeholder groups and countries. Results should therefore be interpreted as descriptive in nature.

- Guideline Development: General and practice-specific guidelines [14] were developed to support reporting and learning from patient-related incidents and near misses across all areas, including NM.

The questionnaires were tailored to CFs, CAs, and PSs to reflect their distinct roles within ILSs and to capture complementary perspectives at local, national, and professional levels. This approach enabled the collection of practice-based data (CFs), regulatory and organisational information (CAs), and cross-cutting expert insights (PSs), ensuring a comprehensive and triangulated assessment of ILS implementation across Europe, in line with the requirements of the BSSD. The full set of questionnaires for each stakeholder group is provided in the Supplementary Appendix.

The online survey gathered insights from key stakeholders, including CFs, CAs, and PSs. It included questions on national legislation governing ILSs, the existence and scope of ILSs, types of incidents reported and criteria for classifying significant events, as well as operational effectiveness and evidence of functioning systems, among other aspects. A total of 56 questions were posed to CFs, 41 to CAs, and 22 to PSs.

In total, 172 valid responses were analysed after data cleaning (removal of duplicates and incomplete submissions): 55 responses from CFs (from 19 countries), 23 responses from CAs (from 23 countries), and 94 responses from PSs (from 28 countries). Quantitative survey data were analysed descriptively. Qualitative material obtained from free-text survey responses and semi-structured interviews was analysed thematically. Responses were reviewed to identify recurring concepts related to ILS implementation, including reporting culture, organisational learning, feedback mechanisms, training, resource constraints and reporting criteria. Themes were then grouped into broader categories of barriers and enablers and used to inform the development and refinement of the MARLIN recommendations.

The MARLIN draft guidelines underwent several rounds of consultation with relevant stakeholders. The draft guidelines were also presented at a two-day workshop attended by national CAs, health authorities, PSs, European and international bodies, professionals, patient representatives, and industry representatives. Through these consultations, consensus guidelines were developed. The final guidelines were endorsed by EANM, ESTRO, EFOMP, EFRS, and ESR.

Ethical considerations were addressed before data collection. The study did not involve patients, patient data, biological material, or clinical intervention, so it is exempt from formal ethics committee review and did not require ethical approval. Participation in the survey and interviews was voluntary, and interview participation was based on informed agreement to take part.

Results

All 23 European countries that responded to the survey had transposed the BSSD and confirmed the existence of a designated national or regional authority responsible for managing reported significant events involving ionising radiation. This indicated the establishment of a clear framework for handling such events, within the participant countries.

Among the responding competent authorities, 11/23 had specific criteria for defining significant events in NM, with considerable variation across countries. This disparity may contribute to differences in reporting rates. Between 2018 and 2022, the highest numbers of significant events in therapeutic NM were recorded in Germany ($n = 26$) and France ($n = 21$), while 10/15 responding countries reported no notifications during this period. In the same timeframe, Finland reported the highest number of significant events in diagnostic NM ($n = 824$), followed by France ($n = 552$). Among the 15 responding countries, only one had no notifications during the same timeframe.

The most commonly applied reporting criterion was based on clinical consequences, whether actual or potential. Other criteria used in certain countries included deviation in administered activity, the number of patients affected, events involving the wrong patient or radiopharmaceutical, and unintended fetal exposure, among others. Table 1 summarises the criteria applied across countries.

The threshold for defining a significant event depends not only on the administered activity but also on the individual metabolism, which influences radiopharmaceutical distribution, target accumulation and elimination, and radiobiological factors, which in turn affect the impact of exposure. Since

Table 1 Non-clinical criteria used for reporting significant events in NM to CAs in European countries. Many countries apply multiple criteria for event notification

Criteria	Countries
Administered activity (deviation from planned)	
30%	1
25%	2
20%	4
10%	4
+10 mSv (diagnostic NM)	2
+20 mSv (diagnostic NM)	1
+100 mSv (diagnostic NM)	1
≥1.5 times intended activity (diagnostic NM)	1
≥2 times intended dose (diagnostic NM)	2
≥20 times intended dose (diagnostic NM)	1
Systematic deviation in the activity > 15%	1
Number of patients affected	3
Wrong patient identification	10
Any event deemed significant by the operator	2
Wrong radiopharmaceutical or wrong route	3
Multiple non-notifiable incidents of a similar nature	1
Unintended exposure to the embryo or fetus	7
Breastfeeding not checked	2
Image not acquired after administration because of equipment failure	1

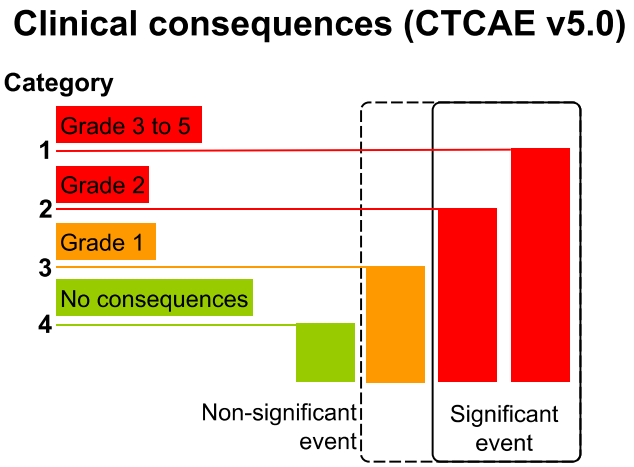

Fig. 1 Classification of nuclear medicine events by clinical consequence according to CTCAE v5.0, adapted from RP-208. Category 1 corresponds to severe consequences (CTCAE Grade 3–5), Category 2 to moderate consequences (Grade 2), Category 3 to mild consequences (Grade 1), and Category 4 to events without clinical consequences. Categories 1–2 are considered significant events, Category 3 events (orange) may be designated significant at the discretion of competent authorities, whereas Category 4 events are considered non-significant

administered activity deviation is a poor indicator of radiation energy absorbed in different tissues, its predictive value for treatment outcomes is limited [17]. Although absorbed dose in organs at risk as well as in the target would be a more meaningful reporting metric especially in therapeutic NM, it

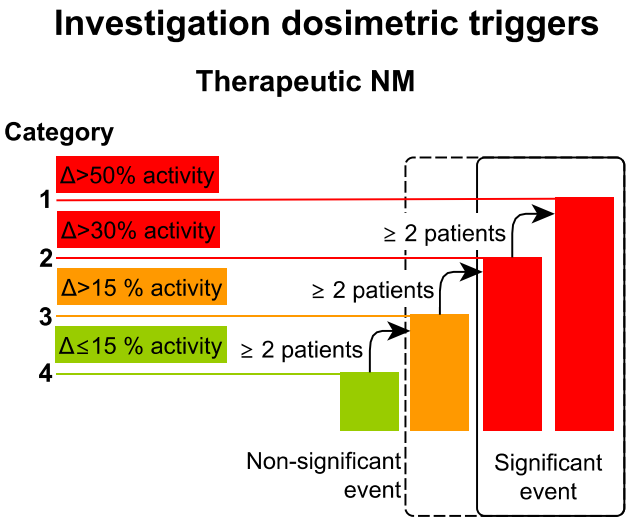

Fig. 2 Dosimetric triggers for investigation in therapeutic nuclear medicine, adapted from RP-208, based on deviation (Δ) in the target administered activity and the number of affected patients. Category 1 includes deviations Δ > 50%; Category 2, Δ > 30%; Category 3, Δ > 15%; and Category 4, Δ ≤ 15%. Events affecting two or more patients are escalated to a higher severity category. Categories 1 and 2 are considered significant events. Category 3 (orange) may be considered significant at the discretion of competent authorities, while Category 4 events are generally considered non-significant

is neither routinely available nor standardised across Europe for all procedures. Consequently, administered activity remains the practical basis for defining significant events. It is important to note that both over- and under-administration can compromise patient safety. Uncompensated underdoses may lead to poor disease control, making them as problematic as overdoses. Figures 1, 2, 3 and 4 summarise the criteria for defining significant events in NM.

The exposure of a pregnant patient as part of a justified and optimised NM procedure is not considered an unintended exposure event under RP-208, provided that the pregnancy has been identified before the procedure. However, restrictive investigation thresholds (Fig. 4) are recommended for events leading to embryo or fetal exposure due to higher radiosensitivity of embryos and fetuses, extended lifespan (increasing long-term risks) and heightened emotional sensitivity, particularly regarding unborn infants. These thresholds may also be applicable to breastfeeding patients undergoing NM procedures.

A total of 22 NM societies responded to the questionnaire. Among them, 36% reported undertaking initiatives to enhance safety through ILSs. Additionally, 82% expressed that the CA should adopt a more systematic approach to sharing information about significant radiation events, a view echoed by several CFs. Meanwhile, CAs acknowledged their responsibility for disseminating relevant safety information.

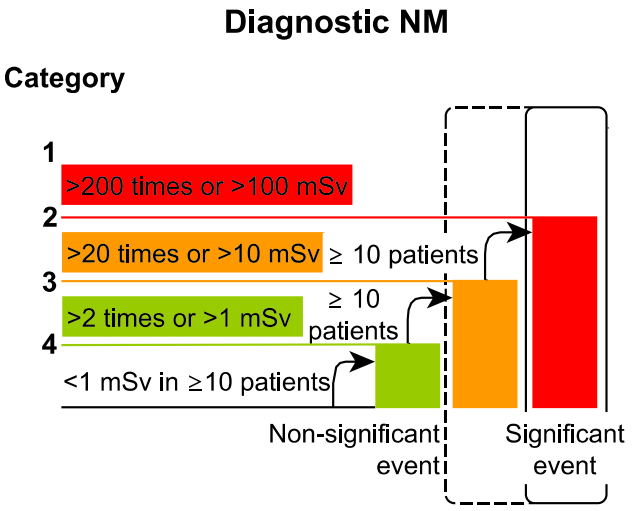

Fig. 3 Dosimetric criteria for investigating unintended exposures in diagnostic nuclear medicine, based on deviation from the target administered activity or the effective dose, and the number of affected patients, as defined in RP-208. There are no Category 1 events in diagnostic nuclear medicine, except in cases classified as such due to clinical consequences. Category 2 includes unintended exposures > 200 times the target administered activity or an effective dose > 100 mSv; Category 3 includes exposures > 20 times the target administered activity or > 10 mSv; and Category 4 includes exposures > 2 times the target administered activity or > 1 mSv. Events affecting ten or more patients are escalated to a higher severity category. Category 2 events are considered significant. Category 3 (orange) may be considered significant at the discretion of competent authorities, while Category 4 events are generally considered non-significant

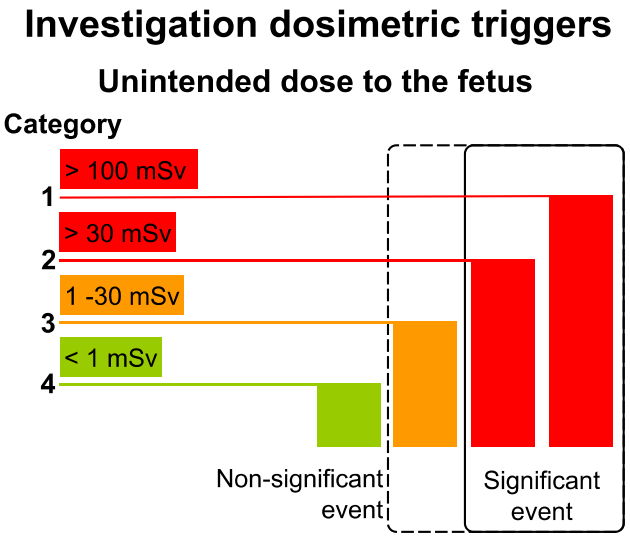

Fig. 4 Dosimetric criteria for unintended fetal exposure in nuclear medicine, as proposed in RP-208. Category 1 corresponds to doses > 100 mSv; Category 2, > 30 mSv; Category 3, 1–30 mSv; and Category 4, < 1 mSv. Categories 1 and 2 are considered significant events. Category 3 (orange) may be considered significant at the discretion of competent authorities, while Category 4 events are generally considered non-significant

Table 2 Key factors supporting the implementation of an ILS

Main supports in implementing an ILS	
Local Level	National Level
Quality department dedicated to safety, reporting, incident analysis, and dissemination of lessons learned, supported by MPEs	Legal provisions ensuring protection for reporters
A 'no blame, no shame' policy fostering a learning culture	Online and easily accessible reporting platforms
Staff education in reporting	Education and training in reporting and safety culture
An intuitive and user-friendly electronic reporting system	

Table 3 Key barriers to implementing an ILS

Main barriers in implementing an ILS	
Local Level	National Level
Fear of sanctions, litigation or repercussions for declaring significant events	Fear of sanctions, litigation, or repercussions for declaring significant events
Lack of safety culture and insufficient education in reporting	Lack of funding incentives to support ILSs
Limited time availability and the absence of user-friendly reporting systems	Lack of communication and feedback mechanisms from authorities
	Insufficient education and training in safety culture and reporting

The main supports and barriers to ILS implementation at local and national levels are summarised in Tables 2 and 3. Several CFs reported reluctance to report events due to fear of disciplinary action or negative economic consequences, highlighting the need for a just culture to encourage open reporting without punitive measures. Among 54 CF responses obtained from 19 countries, 17 responses (from 12 countries) provided data on events recorded in their local ILS for NM over a 5-year period. Event counts varied from fewer than 5 (in 11 CFs) to a maximum of 131 recorded in diagnostic NM and to a maximum of 6 events reported in therapeutic NM. Only 5 CFs (~10%) stated categorically that they did not regularly review reported radiation events. CFs that regularly review reported events involved key clinical personnel in the process, including medical physics experts (MPE) (65%), physicians (50%), radiation protection experts (50%), risk and quality managers (39%), radiographers (35%), and others. Of responding CFs, 26% involved department managers in these regular reviews.

Only 33% of the NM respondents provided staff training on event reporting and only 20% offered training in incident analysis methodologies, such as root cause analysis. The majority (85%) had systems in place to report information

and conclusions back to the NM department, either for all or selected events. The frequency varied, ranging from monthly to annual, with some centres reporting intermittently or as needed.

Key resource-related challenges include limited time for incident analysis, lack of training in investigation methodologies and the need for harmonised taxonomies. These findings underscore the importance of adequate funding and support for effective ILS implementation (see Table 3). Interviewees emphasised the need for a cultural shift to support and protect reporters. The qualitative analysis identified three recurring themes. First, participants emphasised the importance of a just culture, including protection of reporters and avoidance of punitive responses, as a prerequisite for open reporting. Second, participants identified limited time, staffing, funding, and training in incident analysis methodologies as major barriers to effective implementation. Third, respondents stressed the importance of feedback loops, including communication of analysis results to staff and dissemination of lessons learned beyond individual departments. These themes are reflected in the barriers and supports summarised in Tables 2 and 3.

Discussion

NM is distinct in that it encompasses both diagnostic and therapeutic procedures, and the opportunities for events span multiple domains: medication events, medical device malfunctions, radiation-related incidents, and more. In accordance with RP-208, a significant event is defined as an event that should be notified as soon as possible to the competent authorities, according to national regulatory criteria. In the context of NM, this term encompasses any unintended or unexpected occurrence during the preparation, handling, calibration, or administration of radiopharmaceuticals, as well as during associated imaging or therapeutic procedures, that could have implications for patient safety. This includes incidents and adverse events throughout the NM workflow, provided they meet the relevant national notification criteria.

The MARLIN study, conducted under the SAMIRA Action Plan, reveals considerable variability in the criteria used across Europe for reporting significant events in NM. This inconsistency, further emphasised by the HERCA position paper [18], highlights the need for clear guidelines to establish consistent reporting criteria. To address this gap, RP-208 proposes a set of recommended criteria illustrated in Figs. 1, 2, 3 and 4. These criteria are designed to support countries that either lack established reporting frameworks or are considering updates to existing ones. RP-208 recommends adopting a categorisation approach for significant events rather than relying on a single threshold. This approach offers several advantages:

- Standardised classification enhances understanding of event severity or potential impact of events.
- Categorisation facilitates prioritisation and a more effective evaluation and communication of events.
- Establishing categories for significant events helps balance transparency with the need to avoid unnecessary alarm as it demonstrates that high-severity events (Categories 1 and 2) are typically rare.

Categories 1 and 2 should be mandatorily reportable, while Category 3 events may be considered significant at the discretion of CAs. Category 4 events, though less severe, still offer valuable learning opportunities and can be analysed locally. In line with Article 63.c of the BSSD, grouped analyses of events and near misses can further support learning and system improvement. CAs may also require facilities to conduct grouped analyses of Category 4 events. Additionally, CAs should encourage the optional voluntary reporting of incidents that, while not meeting mandatory criteria, may still hold potential patient safety significance. Communicating information about clinically significant unintended or accidental exposures (and the results of the analysis) to the patient and the referrer is a legal requirement that promotes transparency and trust.

In therapeutic NM, the classification of unintended deviation in administered activity depends on the magnitude of the deviation. For diagnostic NM, classification is based on the deviation from typical activity references, supplemented by effective-dose (see Fig. 3). Events affecting multiple patients suggest systemic issues and justify a higher severity classification. The proposed framework explicitly defines thresholds: two or more patients affected in therapeutic NM, and ten or more in diagnostic NM (see Figs. 2 and 3).

While CAs recognise their role in disseminating safety information, PSs and CFs call for more structured and systematic communication. A coordinated strategy involving CAs and PSs is essential for effective knowledge sharing and for ensuring that lessons learned are translated into practice.

RP-208 offers comprehensive recommendations for organisational structures, criteria for reporting significant events, collaboration between stakeholders, and mechanisms to facilitate effective ILS implementation. These recommendations support CFs, CAs, and PSs in strengthening their respective roles in event reporting, analysis, and dissemination of lessons learned.

The choice between generic and NM-specific ILSs depends on the national and local context, available infrastructure, and safety culture. Generic systems may offer

better information technology support and risk assessment tools, while NM-specific systems provide tailored metrics and processes. Regardless of the system used, both diagnostic and therapeutic NM procedures must be included, with therapeutic procedures prioritised due to their greater potential impact. In accordance with the BSSD, proactive risk analysis (e.g., Failure Mode and Effects Analysis or a risk matrix) is also mandatory in therapeutic NM.

A local ILS in NM should promote comprehensive reporting of all radiation-related incidents and near misses. This includes radiopharmaceutical administration events, equipment malfunctions, surface or personal contamination, and procedural deviations. ILSs should also capture non-radiation-related incidents, such as misdiagnoses or patient falls, to support a holistic approach to patient risk assessment in NM. At the same time, systems must allow filtering for radiation-specific events to enable focused analysis. Since radiopharmaceutical administration events closely align with medication events, which are managed through dedicated vigilance systems, coordination between these systems is essential for comprehensive incident management in NM.

A key recommendation from RP-208 is that incident reports should contain a structured minimum dataset. Each report should document: a description of the event; the stage of the process in which it occurred; severity or potential consequences; contributing factors; and the corrective or preventive actions taken. Standardised taxonomies should be used to enable pattern recognition, harmonised analyses, and cross-institutional learning. This structured dataset strengthens prioritisation, trend analysis, and targeted risk-reduction efforts, while allowing optional fields for more detailed investigations.

To advance global safety standards, NM professionals are encouraged to contribute to international ILSs such as SAFRON. Compatibility between national/local systems and SAFRON's taxonomy supports seamless reporting and facilitates cross-border learning.

To ensure effective oversight, a multidisciplinary Incident Learning Committee should regularly review incident data. This committee should include a NM specialist, a MPE and a radiographer, and may also include a nurse, a radiopharmacist, a radiation protection officer, a quality and risk manager, and administrative personnel, depending on staff availability and the type of event. RP-208 further emphasises that radiation-related incidents, whether reported through NM-specific ILSs or extracted from broader institutional systems, should undergo systematic local review to ensure timely corrective actions and organisational learning.

This study has several limitations. First, response rates varied across stakeholder groups and countries, and the findings should therefore be interpreted as descriptive rather than as a complete representation of all European nuclear medicine practice. In addition, a response bias is likely, as CFs, CAs, and PSs with a more developed safety culture, greater awareness of ILSs, or stronger engagement in radiation-safety activities may have been more inclined to respond to the survey. Consequently, the results may overestimate the level of ILS implementation, organisational maturity, and reporting culture across Europe. Second, the survey relied on self-reported information from CFs, CAs, and PSs, which may be affected by differences in interpretation of terminology, local reporting culture, and availability of national data. Third, the variability in national definitions of significant events limits direct comparison of notification numbers between countries. Fourth, although interviews and free-text responses provided important qualitative insights, the breadth and depth of qualitative data varied between participants. Finally, the study focused on the development of practical recommendations for ILS implementation; future work should evaluate the implementation, acceptability, and impact of these recommendations in clinical NM practice.

Conclusion

The MARLIN study demonstrates that, although the requirements for reporting and learning from unintended and accidental medical exposures are established in European legislation, their implementation in NM remains heterogeneous across Europe. The study identified substantial variation in national criteria for defining significant events, differences in reporting practices, and important barriers to effective incident learning, including limited training, insufficient resources, variable feedback mechanisms, and concerns about punitive consequences. At the same time, the findings highlight several key enablers: clear and harmonised reporting criteria, multidisciplinary review of events, systematic feedback to staff, involvement of CAs and PSs, and the development of a just culture that encourages reporting and learning.

From a clinical perspective, these findings underline the need for NM departments to move beyond simple event notification towards structured ILSs that actively support risk reduction and quality improvement. Practical implementation should include local mechanisms for reporting near misses and incidents, regular multidisciplinary analysis, staff training in reporting and root-cause analysis, and clear communication of lessons learned. Particular attention should be given to therapeutic nuclear medicine, where unintended deviations may have greater clinical consequences, while diagnostic procedures should also be incorporated into local and national learning systems. By translating the RP-208 recommendations into operational

practice, NM services, CAs, and PSs can strengthen patient safety, improve consistency in event classification and reporting, and promote a learning-oriented radiation safety culture across Europe.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00259-026-07973-5.

Acknowledgements The authors would like to acknowledge the valuable comments and improvements provided by the advisory board of the MARLIN project.

Funding This project has received funding from the European Commission under Service Contract No. ENER/2022/NUCL/SI2.880751.

Data availability The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval/Consent to participate This study did not involve patients, patient data, or biological material. It examined organisational practices related to incident learning systems through surveys and semi-structured interviews with healthcare professionals acting in their institutional roles. According to applicable national and institutional regulations, the study was exempt from formal ethics committee review and did not require ethical approval. Participation in interviews was voluntary.

Competing interests The authors have no relevant financial or non-financial interests to disclose, except that author Ora Israel is an editor for the European Journal of Nuclear Medicine and Molecular Imaging.

References

1. European Commission. Directorate-General for Energy. Radiation Protection No 180. Medical radiation exposure of the European population. Publications Office; 2015.
2. Lucignani G, Del Sole A. Nuclear medicine: What kind of quality would we want if we were the patient? Eur J Nucl Med Mol Imaging. 2010;37:2194–8. https://doi.org/10.1007/s00259-010-1595-x.
3. IAEA. SAFety in Radiation ONcology (SAFRON) [Internet]. [cited 2026 Feb 7]. https://rpop.iaea.org/RPOP/RPoP/Modules/login/safron-register.htm. Accessed 7 Feb 2026.
4. ARPANSA. Safety guide for radiation protection in nuclear medicine. 2008.
5. Marengo M, Martin CJ, Rubow S, Sera T, Amador Z, Torres L. Radiation safety and accidental radiation exposures in nuclear medicine. Semin Nucl Med. 2022. https://doi.org/10.1053/j.semnuclmed.2021.11.006.
6. Martin CJ, Marengo M, Vassileva J, Giammarile F, Poli GL, Marks P. Guidance on prevention of unintended and accidental radiation exposures in nuclear medicine. Journal of Radiological Protection IOP Publishing. 2019;39:665–95. https://doi.org/10.1088/1361-6498/ab19d8.
7. Bulot M, Rousse C, Thellier S, Sfez M. L'analyse organisationnelle au secours des CREX une expérience en médecine nucléaire. Congrès Lambda Mu 20 de Maîtrise des Risques et de Sûreté de Fonctionnement. INIST-CNRS; 2016. https://doi.org/10.4267/2042/61753.
8. Giannoula E, Panagiotidis E, Katsikavelas I, Chatzipavlidou V, Sachpekidis C, Bamidis P, et al. Quality & safety aspects of nuclear medicine practice: Definitions and review of the current literature. Hell J Nucl Med. 2020;23:60–6.
9. Kasalak Ö, Yakar D, Dierckx RAJO, Kwee TC. Patient safety in nuclear medicine: identification of key strategic areas for vigilance and improvement. Nucl Med Commun. 2020. https://doi.org/10.1097/MNM.0000000000001262.
10. Kearney N, Denham G. Recommendations for nuclear medicine technologists drawn from an analysis of errors reported in Australian radiation incident registers. J Nucl Med Technol. 2016;44:243–7. https://doi.org/10.2967/jnmt.116.178517.
11. Larcos G, Collins LT, Georgiou A, Westbrook JI. Nuclear medicine incident reporting in Australia: control charts and notification rates inform quality improvement. Intern Med J. 2015;45:609–17. https://doi.org/10.1111/imj.12758.
12. Martin CJ. A survey of incidents in radiology and nuclear medicine in the West of Scotland. Br J Radiol. 2005;78:913–21. https://doi.org/10.1259/bjr/20111483.
13. Rodrigues MDSB, Oliveira SM, De Sá LV. Development of a model for registration and notification of accidents and incidents in nuclear medicine. J Radiol Protect IOP Publish. 2021;41:59–78. https://doi.org/10.1088/1361-6498/abd913.
14. European Commission: Directorate-General for Energy. RP-208: Recommendations for reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology – Final report of the MARLIN study [Internet]. Publications Office of the European Union; 2026 [cited 2026 Feb 7]. https://doi.org/10.2833/7103627.
15. European Commission. Council Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom. 2014 p. L13/1–73.
16. European Commission. Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA). 2021.
17. Flux G, Bacher K, Chiesa C, Nijs R De, Kagadis GC, Lima T, et al. Physica Medica EFOMP policy statement No. 19: Dosimetry in nuclear medicine therapy – Molecular radiotherapy. Physica Medica. 2023;1–5. https://doi.org/10.1016/j.ejmp.2023.103166.
18. HERCA. HERCA Position Paper Accidental and Unintended Medical Exposures. 2017.

Publisher's note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Springer Nature or its licensor (e.g. a society or other partner) holds exclusive rights to this article under a publishing agreement with the author(s) or other rightsholder(s); author self-archiving of the accepted manuscript version of this article is solely governed by the terms of such publishing agreement and applicable law.

Authors and Affiliations

Carlos Prieto[1,2] · Ana Geao[3,4,5] · Stephan G. Nekolla[6] · Erik Björn Mille[7] · Ora Israel[8] · Gianfranco Brusadin[9] · Jonas Andersson[10] · Maeve Kearney[11,12] · Andy Rogers[13,14] · Deniz Akata[15] · Nicolas Pourel[16] · Graciano Paulo[17,18] · Olivier Pellerin[19] · Barry Hallinan[20] · Monika Hierath[21] · Nathan Peld[21] · Colin Kelly[22]

✉ Carlos Prieto
carlprie@ucm.es; cprietom@salud.madrid.org

1 Facultad de Medicina, Universidad Complutense de Madrid, Madrid, Spain

2 Servicio de Radiofísica y Protección Radiológica, Hospital Universitario de La Princesa, Madrid, Spain

3 Nuclear Medicine Department, Hospital CUF Descobertas, Lisbon, Portugal

4 Higher School of Health of the Portuguese Red Cross, Lisbon, Portugal

5 Higher School of Health Technology, Polytechnic Institute, Lisbon, Portugal

6 TUM Klinikum Rechts Der Isar, Nuklearmedizinische Klinik Und Poliklinik, Munich, Germany

7 Bundesamt Für Strahlenschutz, Federal Office for Radiation Protection, Berlin, Germany

8 Rappaport School of Medicine, the Technion, Haifa, Israel

9 Quality and Risk Management Department, Institute Gustave Roussy, Cancer Campus Grand Paris, Paris, France

10 Department of Diagnostics and Intervention, Radiation Physics, Umeå University, Umeå, Sweden

11 Applied Radiation Therapy Trinity, Discipline of Radiation Therapy, Trinity College Dublin, Dublin, Ireland

12 Trinity St James's Cancer Institute, St. James's Hospital, Dublin, Ireland

13 Radiation Physics, Nottingham University Hospitals NHS Trust, Nottingham, UK

14 School of Medicine, University of Nottingham, Nottingham, UK

15 Department of Radiology, Hacettepe University School of Medicine, Ankara, Turkey

16 Radiation Oncology Department, Institut Sainte-Catherine, Avignon, France

17 H&TRC- Centro de Investigação Em Saúde E Tecnologia, ESTeSC, Portugal

18 Escola Superior de Tecnologia da Saúde de Coimbra, Instituto Politécnico de Coimbra, Coimbra, Portugal

19 Service de Radiologie Interventionnelle, Université de Paris, Paris, France

20 Imaging and Interventional Radiology Directorate, Beaumont Hospital, RCSI Hospital Group, Dublin, Ireland

21 European Institute for Biomedical Imaging Research, Vienna, Austria

22 St James's Centre, St Luke's Radiation Oncology Network, Dublin, Ireland