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Practice Guidelines

Strengthening incident learning in radiotherapy practice: insights from the MARLIN study

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ABSTRACT

Background and purpose: Incident Learning Systems (ILSs) are central to patient safety in radiotherapy, enabling learning from adverse events and near misses. Despite EU regulatory requirements, substantial variability persists across Europe in the implementation and effectiveness of ILSs in radiotherapy. This paper presents radiotherapy-specific recommendations derived from the MARLIN study to support harmonised, risk-informed implementation of ILSs.

Methods: The 24-month MARLIN study, conducted under the SAMIRA Action Plan, employed a structured literature review, an online European survey of clinical facilities, competent authorities and professional societies, expert interviews, and a multi-stakeholder consensus workshop. Survey data from 172 respondents in 28 countries were analysed to identify current practices, barriers and enabling factors for ILS implementation in radiotherapy.

Results: Although all responding countries reported transposition of the Directive, substantial variability was observed in criteria for reporting significant radiotherapy events, feedback mechanisms and use of international databases. Fear of punitive actions, limited resources, lack of training in incident analysis, and insufficient dissemination of lessons learned were identified as key barriers. External-beam radiotherapy showed more mature ILS implementation than brachytherapy. Findings from the MARLIN study informed recommendations on category-based event classification, radiotherapy-specific taxonomies, multidisciplinary incident-learning committees, and collaboration between clinical facilities, competent authorities and professional societies.

Conclusion: The MARLIN recommendations provide a practical framework to strengthen ILS implementation in radiotherapy, promote a just culture, enhance learning from incidents and support regulatory compliance, ultimately improving patient safety and quality of care across Europe, while the broader RP-208 report extends these principles to all medical fields using ionising radiation, supporting cross-disciplinary harmonisation.

Introduction

The use of ionising radiation in medicine has expanded significantly across Europe [1]. Radiotherapy is a major application, with approximately 50% of cancer patients receiving it during their treatment pathway [2]. Advances in treatment planning, imaging and delivery have improved precision in dose delivery.

Radiotherapy is generally considered safe, with low residual risk. Increasing attention to patient safety has led to the adoption of structured risk-reduction strategies, including Incident Learning Systems (ILSs), which support reporting, analysis and learning from incidents and near misses [3–8]. These systems enable departments to detect vulnerabilities in clinical workflows and implement targeted corrective and preventive actions.

The MARLIN (Medical Applications of Radiation – Learning from Incidents and Near Misses) project, conducted under the European Commission's SAMIRA [9] Action Plan and involving ESTRO alongside regulatory authorities and professional societies, was established to support harmonised implementation of Article 63 of Directive 2013/59/Euratom (Basic Safety Standards Directive, BSSD) [10]. The BSSD requires Member States to ensure that all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of patients undergoing medical exposure. Article 63(c) of the Directive also stipulates that undertakings implement an appropriate system for the record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice. Although the Directive outlines the necessary requirements, it offers limited guidance on implementation, resulting in varied approaches to the deployment and use of ILSs across Member States. RP-208 [11] serves as a valuable resource to enhance patient safety across all contexts. It provides a framework for establishing consistent objectives throughout Europe, while still accommodating differing realities on the ground.

For ESTRO and the wider radiotherapy community, ensuring that regulatory requirements translate into effective, learning-oriented safety systems is of direct relevance to clinical practice. This paper presents radiotherapy-specific recommendations derived from the MARLIN study and provides a framework for radiotherapy departments, professional societies and regulators to standardise the use of ILSs.

While RP-208 provides comprehensive recommendations for

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reporting and learning from patient-related incidents across medical applications of ionising radiation, the paper complements it by focusing specifically on the radiotherapy context. Drawing on data generated within the MARLIN project, it examines how these recommendations are implemented in practice, identifies influencing factors, and highlights radiotherapy-specific aspects and variability across European countries. This approach supports the ongoing development and optimisation of ILSs in radiotherapy.

Methods

The 24-month MARLIN study aimed to develop comprehensive guidelines on the implementation of ILSs across all clinical domains, including radiotherapy. The consortium included representatives from ESTRO, EFOMP, and EIBIR. It was built upon the work conducted under the Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) Action Plan and related initiatives [9].

The study addressed radiotherapy-specific objectives, including an assessment of current ILS use across Europe, definitions of significant events, organisational structures for incident management, and the role of professional societies.

A mixed-methods approach was used, combining a literature review, a European survey, and stakeholder interviews.

A structured literature review was conducted to inform the study design, ensure coverage of existing evidence on ILSs and support survey and interview development. Details of the methodology are provided in the Supplementary Appendix.

An online European survey was developed to assess implementation of Directive 2013/59/Euratom. Separate questionnaires for clinical facilities (CFs), competent authorities (CAs) and professional societies (PSs) covered reporting criteria, investigation practices, feedback mechanisms, training, and barriers. Survey questions are provided in the Supplementary Appendix.

The survey was distributed through European professional and regulatory networks (including ESTRO, EFOMP and HERCA), with European societies disseminating it via national member organisations and quality and safety committees to ensure broad geographic coverage. Among professional society respondents, representation included radiation oncologists, medical physicists, radiation therapists, and other stakeholders (e.g. quality assurance professionals), although the distribution varied across countries. CFs were identified through these national professional societies, which disseminated the survey to selected hospitals and relevant quality and safety groups, complemented by direct contact from project experts to include centres reflecting both good practices and implementation challenges.

Responses were screened for completeness and duplicates prior to analysis. 172 responses were included in the final analysis: 55 from CFs (19 countries), 23 from CAs (23 countries), and 94 from PSs (28 countries). Data were analysed using descriptive statistics, with results reported in aggregated form to ensure confidentiality.

Semi-structured interviews were conducted with selected representatives from clinical facilities and competent authorities to explore implementation challenges and good practices. Interviews were analysed thematically. Interview guides are available in the Supplementary Appendix. The qualitative data obtained were used to support interpretation of survey results rather than for statistical inference.

Findings from all components were used to support the development of MARLIN guidelines [11] through iterative stakeholder consultation and a final consensus workshop involving regulators, professional societies, healthcare professionals and other stakeholders. The guidelines were subsequently endorsed by ESTRO, EFOMP, EFRS, EANM, and ESR.

Results

All responding European countries (n = 23 out of 27 countries) have transposed the BSSD and identified a national or regional authority responsible for managing reported significant events involving ionising radiation, highlighting a clear framework for handling such events.

However, substantial heterogeneity was observed in the operationalisation of Article 63. Although 16 of 23 CAs had issued specific criteria for defining significant events in External Beam Radiotherapy (EBRT) and brachytherapy, variation remained in thresholds and scope between countries, potentially affecting reporting rates. France reported the highest number of significant events for EBRT (621) and brachytherapy (51) during 2018-2022, whereas 11 of 23 countries had zero notifications for EBRT and 16 of 23 countries for brachytherapy. Clinical consequences (actual or potential) were the most commonly used reporting criterion. Other criteria included dose deviation, number of patients affected, wrong patient or site, and additional factors (Table 1). Differences were also observed in definitions, dose thresholds (5–25% of prescribed or planned dose), and dissemination mechanisms. The prescribed dose reflects the clinical intent defined by the radiation oncologist, whereas the planned dose represents its implementation in the treatment planning system. In clinical practice, deviations from the prescribed dose may arise either from deliberate planning trade-offs or from unintended factors. In particular, discrepancies between prescribed and planned dose may reflect prescription-related issues (e.g. incorrect specification or communication of the prescription) or planning and delivery variations. Introducing this distinction is important for interpreting dose deviations and identifying whether events are attributable to prescription errors, planning limitations, or delivery inaccuracies. Eleven countries reported complementary dose-related criteria, such as deviations in single fractions, systematic errors, or exceeding dose constraints. Additional criteria included wrong patient or tissue (10 countries), unintended fetal exposure (5), and equipment malfunctions (4).

Among professional society respondents, 15 of 32 reported initiatives to promote safety through ILSs. While CAs indicated a role in dissemination, 26 of 32 PSs considered that information on significant events should be shared more systematically.

Facilitators and barriers to ILS implementation at local and national levels, identified through the survey and complemented by insights from stakeholder interviews, are summarised in Table 2. At institutional level, 25 of 55 CFs from 14 countries provided quantitative data over five years, with reported events ranging from 0 to 253 in EBRT and from 0 to

Table 1
Criteria (apart from clinical consequences) used in some European countries for the notification of significant events in RT to the CA. Many countries have several of these criteria.

Criteria	Countries
Dose deviation: Whole treatment	
25% of the planned dose	2
20% of the prescribed dose	1
10% of the prescribed dose	3
10% of the prescribed dose and at least 4 Gy in the target volume	1
10% of the planned dose and the deviation is greater than 4 Gy	1
5% of the prescribed dose	1
Dose deviation: Other criteria	11
Any fraction: 20% of the prescribed dose	3
Any fraction: 50% of the prescribed dose	1
Systematic deviation exceeds 5% of the total dose	1
Stereotactic: 10% of the prescribed dose	1
Absolute dose deviation (3-4 Gy)	2
+10% of the dose restrictions for organs at risk	3
Potential dose deviation	3
Number of patients affected	3
Wrong patient/Wrong tissue/Volume deviations	10
Any event deemed significant by the operator	2
Malfunction of equipment leading to patient overexposure	4
Multiple non-notifiable incidents of a similar nature	2
Uncorrected fractionation	1
Deviation in total treatment time>1 week from planned	2
Re-irradiation without a medical assessment	1
Unintended exposure to the embryo or fetus	5

5 in brachytherapy. Although 90% of departments reported feedback mechanisms, reporting frequency and review processes varied, and 10% indicated events were not regularly reviewed. Multidisciplinary participation in incident review extends beyond a limited group of experts. Survey results indicate that the most frequently involved professionals are medical physicists (65%), radiation oncologists (50%), and radiation protection experts (50%). Other professional groups are also involved, although with lower reported participation, including risk and quality managers (39%), radiographers/radiation therapists (35%), department managers (26%), nurses (18%), as well as biomedical engineers and other staff where relevant. Eleven CFs reported reluctance to report events due to fear of disciplinary or economic consequences.

While 62% of radiotherapy respondents reported staff training in event reporting, only 26% provided training in event-analysis methodologies such as root cause analysis.

Most respondents (90%) reported having systems to provide feedback to departments, although frequency ranged from monthly to annual. Use of international ILSs [12,13] was limited, with only four facilities reporting participation. Similarly, dissemination of lessons learned beyond the institution was rare. Lack of dedicated time, limited training, and the need for harmonised taxonomies were identified as the key challenges (Table 2).

The literature review identified more publications on ILSs in EBRT than in other applications of ionising radiation, indicating more mature implementation in this field.

RP-208 [11] provides a framework for the organisation of ILSs, reporting criteria, dissemination processes, and stakeholder collaboration. It proposes a unified approach to under- and over-dosage, using dose deviation as a key reporting parameter. Figs. 1–3 summarise the classification of significant events based on clinical consequences and dosimetric triggers.

Significant events can be classified into three categories, with clinical consequences being the primary criterion. These consequences range from critical (Category 1) to minor (Category 3). As this is a clinical criterion, the categorisation of a significant event based on its clinical consequences must be determined by the radiation oncologist (RO). However, clinical consequences may take time to manifest, and it can sometimes be challenging to distinguish between normal post-procedure effects, interactions with other conditions, and failures resulting from treatment. Therefore, dosimetric triggers based on dose or volume deviations are also proposed for investigation. Event severity may be escalated when multiple patients are affected. Exposure of a pregnant patient during a justified and optimised procedure is not considered a reportable radiation event. However, restrictive reporting thresholds are recommended for events that result in unjustified exposure to the embryo or fetus. RP-208 [11] provides guidance to support national authorities in defining significant events.

Table 2
Main facilitators and barriers in implementing an incident learning system.

	Local Level	National Level
Supports	Having a quality department supporting safety, reporting, events analysis and lessons dissemination, and having the expertise of medical physics experts to also support	Having specific provisions protecting reporters
	Having specific 'no blame, no shame' policy supporting learning culture	Online and easily accessible reporting systems
	Staff education in reporting	Education and training in reporting and safety culture
	Easy to use electronic reporting system	
Barriers	Fear of sanctions/litigations/ repercussions if declaring significant events	Fear of sanctions/litigations/ repercussions if declaring significant events
	Lack of safety culture and education in reporting	Lack of funding incentives
	Lack of time and 'easy to use' reporting systems	Lack of communication/ feedback
		Lack of education training in safety culture and reporting

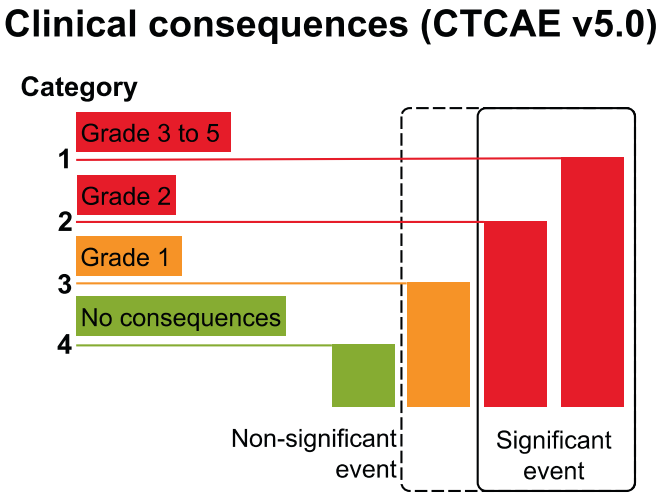

Fig. 1. Classification of radiotherapy events by clinical consequence according to CTCAE v5.0, adapted from RP-208. Category 1 corresponds to severe consequences (CTCAE Grade 3–5), Category 2 to moderate consequences (Grade 2), Category 3 to mild consequences (Grade 1), and Category 4 to events without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

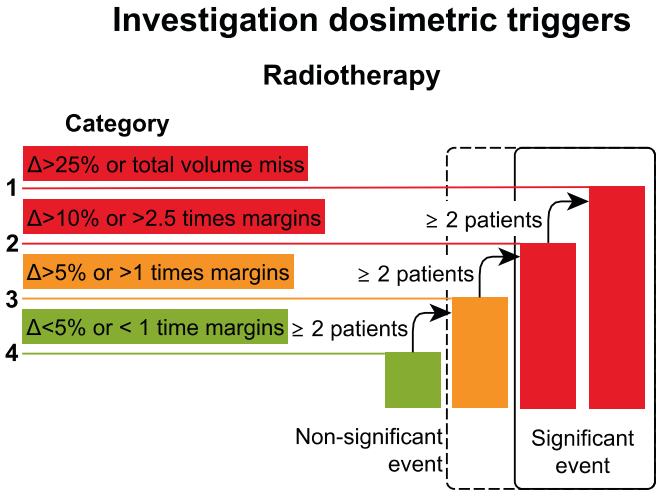

Fig. 2. Dosimetric triggers for investigation in radiotherapy, adapted from RP-208, based on dose deviation (Δ) or geometric miss and the number of affected patients. Category 1 includes deviations Δ > 25% or complete target miss; Category 2, Δ >1 0% or >2.5× margins; Category 3, Δ> 5% or >1× margins; and Category 4, Δ<5% or <1× margins. Events affecting two or more patients are escalated in severity category. Categories 1 and 2 are considered significant events. Category 3 (orange) may be considered significant at the discretion of the competent authorities, while Category 4 events are generally considered non-significant.

Discussion

This study indicates that, despite formal transposition of Article 63 of the BSSD across European Member States, its implementation in radiotherapy remains highly variable. Differences in the definition of

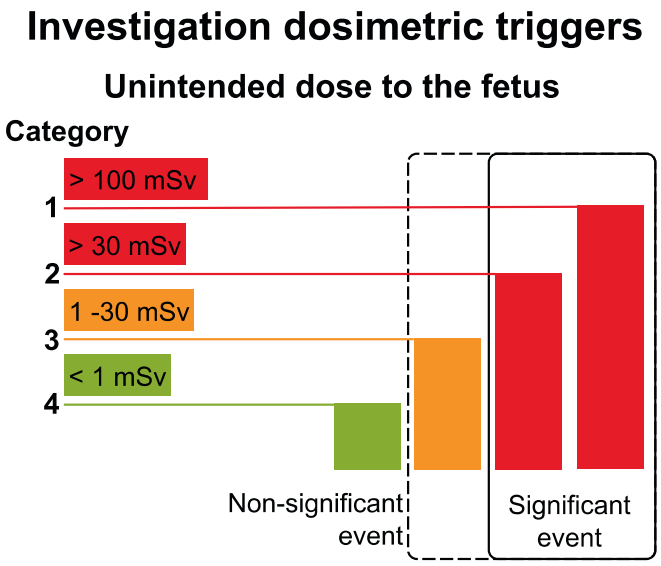

Fig. 3. Dosimetric criteria for unintended fetal exposure in radiotherapy, as proposed in RP-208. Category 1 corresponds to doses >100 mSv; Category 2, >30 m Sv; Category 3, 1–30 mSv; and Category 4, <1 mSv. Categories 1 and 2 are considered significant events. Category 3 (orange) may be considered significant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

significant events, particularly regarding dose deviation thresholds and reporting criteria, suggest that regulatory requirements are interpreted and operationalised in diverse ways. This variability is evident in the wide range of dose thresholds and the use of additional clinical and technical criteria, reflecting differing national approaches to risk perception and patient safety priorities.

Such heterogeneity has important implications for the comparability of reported events, the consistency of regulatory oversight, and the effectiveness of incident learning across countries. In line with the HERCA position paper [14], these findings support the need for clearer and more harmonised definitions of significant events. Previous analyses have identified gaps between regulatory frameworks and their practical implementation, particularly in relation to risk analysis and incident management processes [15], indicating that legislative alignment alone is insufficient without consistent translation into clinical practice. The MARLIN project, conducted under the SAMIRA [9] Action Plan with participation from ESTRO and other European bodies, was designed to address this gap.

RP-208 [11] supports harmonisation through a category-based classification of significant events. Categories 1 and 2 correspond to events with critical or potentially serious impact and are recommended for mandatory reporting under Article 63(e). Category 3 events, while less severe, are considered best practice for inclusion to maximise learning. Category 4 events, although generally minor, may still provide valuable insights, particularly when analysed in aggregate or when recurring patterns are identified.

This categorisation would facilitate prioritisation, improve communication, and provide clearer insight into event severity and impact. It would also support balanced transparency by showing that high-severity events (Categories 1–2) are expected to remain relatively rare in radiotherapy.

ILSs are well developed in radiotherapy and represent some of the most mature safety learning mechanisms. Their implementation has contributed to a strong culture of learning from incidents and near misses. A well-established safety culture is widely recognised as a cornerstone of safe patient care, and ILSs are an important mechanism to promote it in oncology [16]. Their use has been associated with reductions in incident severity over time [17]. Particular attention is needed for brachytherapy and advanced, high-precision modalities such as SABR, SRS and adaptive radiotherapy, where workflow complexity and hypofractionation amplify the impact of single-event deviations. Ensuring that ILS frameworks evolve alongside technological innovation is essential to maintaining patient safety [18].

A taxonomy that reflects the characteristics of EBRT and brachytherapy should be integrated into generic hospital ILSs. This need emerged from survey and interview findings, which showed variability in how incidents are categorised and analysed across CFs, and aligns with RP-208 recommendations. The absence of such a taxonomy in many systems may explain why some centres implement parallel, departmental ILSs. Regardless of the system used, radiotherapy-related incidents should be reviewed by a multidisciplinary local committee, including RTTs, MPEs, ROs, and risk or quality-management experts.

A multidisciplinary approach at the professional society level is feasible and demonstrated by structures such as the ESTRO Radiation Oncology Safety and Quality Committee (ROSQC). Close collaboration between national PSs and CAs can support the development of radiotherapy-specific methodologies and common classification systems [5,19] to reflect mandatory and voluntary reporting needs.

The definition of a significant event in radiotherapy cannot rely solely on dose-based thresholds. Clinical relevance depends on multiple contextual factors, including anatomical site, treatment intent, and patient-specific radiobiological sensitivity [5]. While dose deviation provides a practical basis for reporting, its interpretation varies depending on whether it refers to prescribed, planned or delivered dose. This complexity is amplified in hypofractionated treatments, where small deviations may have greater biological impact. The choice of dosimetric parameter (e.g. point dose, mean dose, or biologically effective dose) may also influence classification and comparability, supporting the need for context-aware approaches, as proposed in RP-208.

Although CAs reported involvement in dissemination, both PSs and CFs highlighted inconsistencies in communication practices. This emphasises the need for more coordinated and structured dissemination pathways, where PSs can play a key role.

Implementation of these recommendations may vary depending on resources and national context. Larger centres may sustain comprehensive local ILSs with detailed analysis and multidisciplinary review, whereas smaller centres may rely more on national or international systems (e.g. SAFRON or ROSEIS). At national level, CAs define significant event reporting requirements and ensure harmonisation, while CFs are responsible for local implementation. PSs play a complementary role in promoting safety culture, training and dissemination.

International ILSs such as SAFRON [12,20] and ROSEIS [13] provide platforms for global collaboration and improved safety in radiotherapy. To enable effective data sharing, national and local systems should align their structure and taxonomy with these platforms.

Differences in reported event numbers between countries (e.g. higher rates in France) likely reflect variations in reporting culture, resources and thresholds rather than intrinsic safety. Reporting frequency is therefore not a direct proxy for safety performance but may indicate maturity of safety culture and openness.

Cultural barriers remain important. Fear of consequences and limited safety culture were identified as key barriers to effective reporting and learning. This highlights the need to strengthen just culture principles, alongside training in incident analysis and implementation of corrective actions. Together with harmonised criteria and improved coordination between CAs, CFs and PSs, these measures are essential to improve the effectiveness of ILSs.

Finally, the adoption of a written, non-punitive policy (ensuring no action against reporters except in cases of reckless or intentional harm) is essential to reinforce trust and encourage open reporting within the radiotherapy community, and sustain a continuous, virtuous cycle of learning, feedback, and improvement.

Conclusions

Radiotherapy has been at the forefront of ILS implementation in medical ionising radiation applications. The MARLIN guidelines highlight the importance of ILSs, the existence of regulatory frameworks at European and national levels, the role of PSs in disseminating lessons learned, and the involvement of radiotherapy facilities in event reporting and analysis. This study revealed considerable variability in how Article 63 of the BSSD is implemented in practice. Differences in definitions of significant events, reporting thresholds, feedback mechanisms and dissemination processes limit the full safety potential of existing systems.

The MARLIN study, developed under the SAMIRA Action Plan with involvement of ESTRO and European stakeholders, provides a coherent framework to align regulatory requirements with clinical practice. By promoting category-based classification, risk-proportionate reporting thresholds, multidisciplinary review, improved dissemination, and just culture principles, MARLIN supports implementation beyond regulatory compliance and toward meaningful learning.

CRediT authorship contribution statement

C. Prieto: Writing – original draft, Methodology, Conceptualization. **C. Kelly:** Writing – original draft, Methodology, Conceptualization. **G. Brusadin:** Writing – review & editing, Validation, Methodology, Investigation, Conceptualization. **M. Kearney:** Writing – review & editing, Methodology, Conceptualization. **N. Pourel:** Writing – review & editing, Methodology, Conceptualization. **A. Rogers:** Writing – review & editing, Methodology, Investigation. **A. Geao:** Writing – review & editing. **D. Akata:** Writing – review & editing, Conceptualization. **J. Andersson:** Writing – review & editing, Validation, Methodology, Investigation. **G. Paulo:** Writing – review & editing, Validation, Investigation. **S.G. Nekolla:** Writing – review & editing. **E. Mille:** Writing – review & editing. **O. Pellerin:** Writing – review & editing. **O. Israel:** Writing – review & editing. **B. Hallinan:** Writing – review & editing. **N. Peld:** Project administration. **M. Hierath:** Project administration.

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Declaration of competing interest

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Appendix A. Supplementary data

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