IRSN
INSTITUT DE RADIOPROTECTION
ET DE SÛRETÉ NUCLÉAIRE

afppe
ASSOCIATION FRANÇAISE DU PERSONNEL PARAMÉDICAL D'ÉLECTRORADIOLOGIE

sfro
Société Française de Radiothérapie Oncologique

AFQSR

sfpm
SOCIÉTÉ FRANÇAISE DE PHYSIQUE MÉDICALE

GUIDE FOR INTEGRATING A TECHNICAL OR MATERIAL CHANGE IN RADIOTHERAPY

2021

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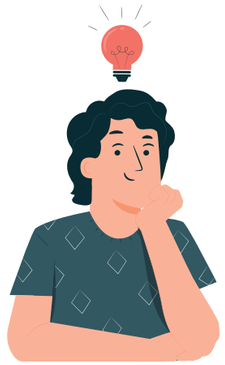


FOREWORD

The lessons learned from significant radiation protection events have enabled the French Nuclear Safety Authority (ASN) to identify that technical or material changes in external radiotherapy can potentially weaken the safeguards established to secure the treatment process. For this reason, since 2016, ASN has focused part of its inspections on the implementation of techniques or practices. Analysis has revealed that the risk of compromising the care process associated with such changes is not systematically evaluated before modifications are implemented.

ASN has therefore asked Institute for Radiation Protection and Nuclear Safety – IRSN to develop, in collaboration with radiotherapy professionals, a simple, operational document to assist radiotherapy centres in integrating material and/or technical changes.

This guide, which does not fall within a regulatory framework, was thus developed by an operational working group led by IRSN and composed of representatives from professional associations: AFPPE for radiation therapists, AFQSR for quality experts, SFPM for medical physicists and SFRO for radiation oncologists, as well as evaluation officers at IRSN.

The project was monitored by a steering committee comprising representatives from ASN, the Generale Directorate of Health Care Provision – DGOS, the French National Cancer Institute – INCa, IRSN.

The following people participated in the drafting of this guide:

Representatives from professional associations:

- Isabelle Barillot (SFRO),
- Jean-Michel Hannoun-Levi (SFRO),
- Philippe Le Tallec (AFPPE),
- Élise Leroy (AFQSR),
- Albert Lisbona (SFPM),
- Vincent Marchesi (SFPM),
- Nicolas Pourel (SFRO).

Evaluation officers (IRSN):

- Magali Édouard,
- Aurélie Isambert,
- Valérie Vassent.

International medical physics experts for the English version :

- Sébastien Gros (LUMC, USA),
- Alain Guemnie Tafo (UPMC, USA).

INTRODUCTION

External radiotherapy is part of a complex socio-technical system: it combines advanced technologies with human activities characterised by multiple interactions between different professions. Beyond the technical skills required, radiotherapy activities demand a high level of collaboration, or even synchronisation, among the various actors in the care process, both within the radiotherapy department and externally, such as with other departments (e.g. chemotherapy, surgery, etc.).

In this context, any material or technical change (such as installing an additional accelerator, replacing a machine, upgrading/extending the capacities of an already installed device, implementing a new technique, or deploying a new treatment planning system, or *Record & Verify*, etc.) represents a potential source of instability, in particular for treatment workflow and work practices by introducing complexity into the system. While some disruptions can be apprehended *a priori,* others are more difficult to anticipate and are discovered as the change is implemented. They may then result in the inappropriate use of the new technique or changes in the workflow that gradually weaken certain safeguards. These instabilities can ultimately cause risks for patients. Adopting a material or technical change therefore raises questions about the security of the entire care process.

Aim

This document is a guide to support radiotherapy teams in integrating material or technical changes, contributing to the delivery of safe treatments. It is intended for all actors involved in such change, both at managerial and operational levels. This French guide is independent of existing tools for project management and risk management, such as the data sheets proposed by HAS[1], or the recommendations made in the context of GPMED[2], and can be used in addition to those. It does not replace the regulatory requirements associated with radiotherapy. This guide has also been designed so that every radiotherapy department, regardless of size, status or organisation, can rely on the non-exhaustive recommendations provided as food for thought or action, and adapt them according to its needs and specificities, depending on the nature of the change considered.

This guide has been developed based on lessons learned from clinical professionals regarding the implementation of technical and material innovations. The recommendations and examples of questions included in this guide are intended to support centres in facilitating the integration of technical or material changes by radiotherapy professionals.

It is supplemented by lessons learned from Human and Organisational Factors (HOF) which inform the recommendations presented in this guide. An approach based on the role of HOF in risk management emphasizes consideration of the various determinants of an activity, such as organisation, management, rules, work groups, techniques, and individuals to better understand the factors that ensure safety. An HOF approach promotes a holistic understanding of the activity and enables action on these factors, either directly or through their interactions, to maintain the required level of safety.

1. HAS : French National Authority for Health: https://www.has-sante.fr/jcms/c_1239410/fr/mettre-en-oeuvre-la-gestion-des-risques-associes-aux-soins-en-etablissement-de-sante.

2. GPMED : ASN's Advisory Committee of Medical Experts: https://www.asn.fr/Informer/Actualites/Nouvelles-techniques-en-radiotherapie-et-pratiques-associees.

Document **structure**

This document is organised into four chronological steps consistent with the different phases of a project for radiotherapy material or technical change.

Each of these steps is carried out according to the following arrangement:

- **recommendations** concerning the organisation, the resources to be allocated (human, financial) and the actions to be carried out to facilitate the integration of the technical or material change by teams;
- **questions** to guide reflection and the implementation of solutions in accordance with the recommendations.

THE STEPS OF THE PROCESS

The **"Initiate"** step corresponds to initiation of the project. It includes the choice of the most suitable technical solution available for the context and needs.

The **"Prepare"** step refers to the preparation for the clinical deployment of the technical or material change. It involves, in particular, technical implementation of the change.

The **"Deploy"** step corresponds to the clinical deployment of the technical or material change.

The **"Consolidate"** step focuses on the actions to be implemented in the medium and long term to ensure the integration of the technical or material change, as well as an assessment of the completed project.

Explanatory **inserts** provide a **human and organisational factor (HOF)** perspective to shed light on the role of various determining factors for the activity when it comes to integrating changes and securing care.

"The science of planning consists in preventing difficulties at execution."

— Vauvenargues —

A technical or material change must first align with a medical project and be integrated, as early as possible, into a comprehensive approach involving all relevant stakeholders. It is also essential to consider the context in which the change will be implemented, analyse the needs, assess the associated costs, and evaluate the available resources. These elements will help determine the feasibility of the project, justify its relevance to decision-makers and select the most appropriate technical solution.

1.

Initiate: **Initiation of the project and technical solution selection**

Collectively define a project consistent with the needs and context

To define a project and work toward its success, involving frontline actors in the planning process enables the identification and better consideration of their needs and the constraints of their professions.

▶RECOMMENDATIONS

1. **Define the project objectives**, especially clinical objectives.
2. **Ensure** the consistency and integration of the project with the multi-year investment plan.
3. **Collect and formalise** the needs (technical, clinical, and medical) and constraints in the field through collaborative discussions, particularly among radiation therapists, radiation oncologists[1], medical physicists, management, and quality experts.
4. **Define the technical characteristics** of the project (specifications or equivalent).

1. Guide Recorad - chapter "Démarches d 'amélioration de la qualité et gestion des risques en radiothérapie" ("*Improvement approach for quality and risk management in radiotherapy*" - Recommendations drawn up by the French Society of Radiation Oncologists - SFRO - 2016 edition).

▶QUESTIONS

What are the objectives of the project: maintain, enhance, or expand the care offering (treat more patients, develop innovative techniques, etc.)?

—

What is the expected benefit for patients?

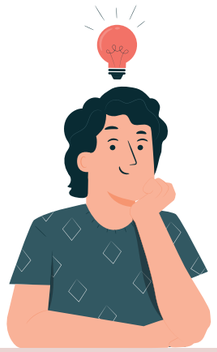
—

Is the schedule chosen for developing this project truly suitable or has it been accelerated due to constant pressure to innovate?

What resources can be utilised to gather information on the needs and constraints of frontline actors?

—

Which radiotherapy centres that have undertaken similar projects in comparable contexts can be consulted, and what lessons can be learned from their experience?



"One change, even minor *a priori,* can destabilise the entire system"

Radiotherapy is part of a complex socio-technical system consisting of various components: the physical and technological environment, individuals, professional groups, organisation and management, regulations and procedures. Each of these components influences the activity, both individually and through their interactions. Any change to one of these elements has the potential to disrupt this system's balance, leading to more or less significant consequences on the overall performance, particularly regarding safety. In this context, a technical or material change in radiotherapy, regardless of its scale, requires a comprehensive analysis of the socio-technical system to assess its potential impacts hollistically.

Assign
a working group to the project

To ensure an effective and dynamic organisation of a project, it is essential to assign a "working group"[1] and appoint a leader at the earliest possible stage.

▶RECOMMENDATIONS

1. **Entrust** steering of the project to a manager, formally designated (for example via a letter of engagement detailing the scope, duration, allocated time, available resources , and expectations). This manager will be in charge of coordinating the working group and oversee project progress.

2. **Set up** the working group by integrating representatives from various professions (radiation therapists, radiation oncologists, medical physicists, dosimetrists, management, quality experts, etc.).

3. **Appoint**[2] "discipline" referents from within the working group who will be in charge of monitoring and implementing the project. Their role should align with expertise and field experience to assess the impacts of the new development, from both a technical perspective and in terms of organisation and professional practices. They will also be tasked with supporting their peers during the clinical deployment of the change and facilitate the acquisition of new skills.

4. Formally **assign** roles to working group members (e.g. via an engagement letter) and ensure that dedicated time is allocated for them to fulfil their responsibilities.

5. **Identify and provide** the appropriate resources to enable the project lead to carry out their mission effectively.

6. **Anticipate** project management training for the lead, based on their initial skills, ensuring it is scheduled within a timeline compatible with the project deadlines. Otherwise, the lead must have a dedicated or adapted method[3] to guide their work effectively.

7. **Associate** support functions with the working group (biomedical engineers, secretarial staff, IT specialists, technical and logistics services, etc.).

8. **Rely** on the quality expert for their expertise in leading changes, organising processes (e.g. risk assessment, document management) and their knowledge of the interactions between the different system components.

1. In this guide, the term "working group" refers to a group made up of representatives of the various professions involved in implementing the change. Additionally, other professionals may participate in the project on an ad hoc basis without being explicitly part of this "working group".

2. Some of the representatives of the working group may also be referents.

3. Example of project management support tools:
- Hugues Marchat, 2008, *« La gestion de projet par étapes - Analyse des besoins, 1re étape »* Éditions d'Organisation ;
- Alain Asquin, Thierry Picq 2007, *« Manager un projet pour la première fois, De l'idée à la réalisation »*, Éditions d'Organisation ;
- Roger Aïm, 2011 *« Les fondamentaux de la gestion de projet »*, éditions AFNOR.

▶QUESTIONS

Which stakeholders should be included in the working group? Radiation oncologists, radiation therapists, medical physicists, IT specialists, dosimetrists, managers, biomedical engineers, other staff (such as those addressing patient hospitalisation constraints, or teams in charge of maintenance)?

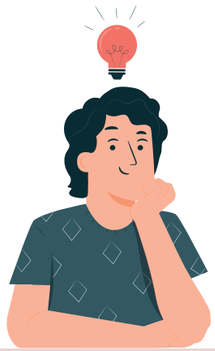
—

What is the expected role of the quality expert in the change project beyond methodological support, particularly in leveraging their knowledge of interactions between processes? How can they be provided with the appropriate information to fully understand the project objectives? What resources will be provided to support their efforts in guiding the change?

How can clinical activity be reorganised to allocate the time needed for referents to fulfil their responsibilities?

o Can certain tasks be delegated or transferred?

o Can schedules be adjusted (e.g. the number of scheduled consultations for radiation oncologists or radiation therapists to make them more available)?



"A co-built project involving future users"

Users possess information, including knowledge and expertise, that is invaluable when assessing the impact of a change on professional practices. They can effectively contribute to identifying relevant characteristics of the new development in relation to their activity. Their participation from the early stages of the change project is, therefore, highly beneficial.

The early involvement of users in the project also encourages their future involvement, and facilitates their contribution to knowledge transfer among their peers. Integrating users from the early stages of the change project helps create favourable conditions for the successful adoption of the new development.

Needs assessment and the associated costs of the change

Before validating the project, it is important to assess the centre's ability to meet the various needs (time, resources, skills, staff) and associated costs.

▶RECOMMENDATIONS

1. **Define the minimum requirements** (e.g. space, technical and human resources) for successful implementation of the project.

2. **Define the main steps** of the project and the expected deliverables for each step:

o providing flexibility in project milestones to ensure that expected actions at each step can be completed, under favourable conditions, before moving to the next step;

o not underestimating the time required by the medical physics team to perform necessary measurements and quality controls before the clinical implementation of new equipment.

3. **Define the additional resources and skills** needed:

o assess the resources and skills available and necessary for implementation of the project and the use of the new equipment or processes;

o define a strategy for acquiring resources and skills by assessing the advantages and disadvantages associated with different possibilities:

- consolidation of the internal team by increasing its professional staff (fixed-term or permanent contract) and/or by additional training if necessary,
- use of external resources (subcontracting) for the implementation of the project (staff and skills) or for support.

4. **Assess** the financial impacts by integrating the costs related to implementation of the project and use of the new technique in routine:

o works, purchasing of specific equipment;

o resources and skills needed;

o possible reduction in the number of patients treated due to the longer treatment time, longer controls, etc.

▶QUESTIONS

Does the radiotherapy department have all the skills necessary to carry out this project? What additional training beyond that provided by the manufacturers should be considered?

—

How can we most accurately assess the necessary human resources (for example, for medical physics)?, external feedback, internal collegial reflection, etc.?

—

In the case of subcontracting[1]:

o have the internal needs of the radiotherapy department in terms of means and skills to prepare, manage and validate the service been assessed and anticipated?

o are the skills expected of the service provider well defined and verified? Are the roles and missions of the service providers well defined in the contract?

o how can the potential difficulties encountered by the radiotherapy team be limited and handled as they integrate the subcontracted activities?

How can the project schedule be established (duration of each step and total duration of technical implementation) to take into account the specificities of the centre and possible contingencies, in particular related to the installation phase or any work?

—

What are the elements to consider in order to define the time required for each stage of the project (for example, acceptance of the new equipment) and not anticipate starting treatments too quickly, which would unnecessarily strain the schedule?

—

If the material or technical change introduces a complexity or puts the "routine" duties under pressure, what are the associated additional needs (staff, time, tools, modification of the organisation of work, etc.)?

1. Avis IRSN sur la sous-traitance en radiothérapie (*IRSN opinion on subcontracting in radiotherapy*): https://www.irsn.fr/FR/expertise/avis/2021/Documents/fevrier/Avis-IRSN-2021-00025.pdf

Analyse the relevance and feasibility of the project

An *a priori* analysis of the project's relevance and feasibility considering various aspects is (clinical, financial, human, and organisational) essential for project validation.

▶RECOMMENDATIONS

1. **Assess the relevance of the project** in meeting clinical objectives.

2. **Evaluate the feasibility of the project** as a whole, in economic and technical terms with regard to the needs and costs assessed previously.

3. **Evaluate the feasibility of the project** at the organisational and human level, in particular taking into account the potential introduction of complexity, in terms of practices and organisation.

▶QUESTIONS

Are the conditions for implementation of the project favourable:

o is integration compatible with ongoing projects?

o are there enough patients considering the financial commitment of the project?

o are the necessary human resources and skills available?

o is the schedule realistic?

o is there sufficient space on the premises?

o are there sufficient technical resources (computer, network, measurement tools, etc.)?

—

Is there significant turnover for certain professions of the radiotherapy team? If so, could this call into question the feasibility of the project?

—

Are there any potential interactions of the project with other projects under development in the institution that could introduce organisational difficulties causing time delays and pressure or lack of availability of certain professionals?

—

In order to assess the feasibility of the project, is there a provision for calling in professionals from other centres?

Report the results of the analysis and validate the project

An analysis of the project that integrates various aspects (medical, financial, organisational) provides decision-makers with a comprehensive overview of the project before approval.

▶RECOMMENDATIONS

1. **Present the project to decision-makers** (top management and financial managers) for validation:

o justify the project from a medical point of view, the associated needs (technical, human);

o present a budget to financial decision-makers, including an estimated cost and an assessment of revenues or savings;

o present the project support organisation (roles and responsibilities, the working group) and the main milestones.

2. **Present the validated project to stakeholders** (medical staff, quality experts, biomedical engineers, secretarial staff, etc.) to inform them and explain its purpose.

Choose the technical solution

Once the project has been validated, it is essential to review and select the technical solution available on the market that best meets the identified needs.

▶RECOMMENDATIONS

1. **Examine** the solutions available on the market (technical characteristics, associated training and support, etc.), drawing, if possible, on the experience of professionals who know the needs and constraints of the field:

- consult with manufacturers,
- ensure that there is real consistency between the solutions available and the clinical objective,
- anticipate any compatibility problems between the new technique and the digital tools used in the centre by contacting the IT department.

2. **Remain vigilant** of technical requirements related to specific internal constraints, such as the need to work remotely or between different sites which would require the reliability of electronic data transfers between institutions (for example, 3D complex data transfer).

3. **Negotiate** with manufacturers:

- the training courses (identify in advance the training courses adapted to the objectives) and the associated schedule;
- support from the manufacturer;
- the technical means necessary for the use of the new technique/machine (phantoms, measurement means, etc.).

4. **Explain** the choice of the working group to decision-makers following the review of all available solutions.

5. **Have the solution formally validated** by decision-makers.

6. **Present** the solution to stakeholders (medical staff, quality experts, biomedical engineers, secretarial staff, etc.) to keep them informed.

▶QUESTIONS

What are the relevant key points to negotiate regarding training?

- o should training be delivered in the official language of the country?
- o is the trainer qualified to address the needs of radiotherapy teams?
- o what training methods will be used (e.g. hands-on support with teams during the initial treatments, small group sessions, or follow-up visits by the trainer after the team has gained experience with the new technique/machine)?
- o what should the training content include?
- o what is the optimal duration of the training?
- o how should the training schedule be designed to consider the availability of the medical team and manufacturers? Etc.

What constraints of this particular centre could require specific technical requirements?

—

If subcontracting is used to carry out the implementation of the technical or material change chosen, is the service provider trained in the specificities of the solution selected?

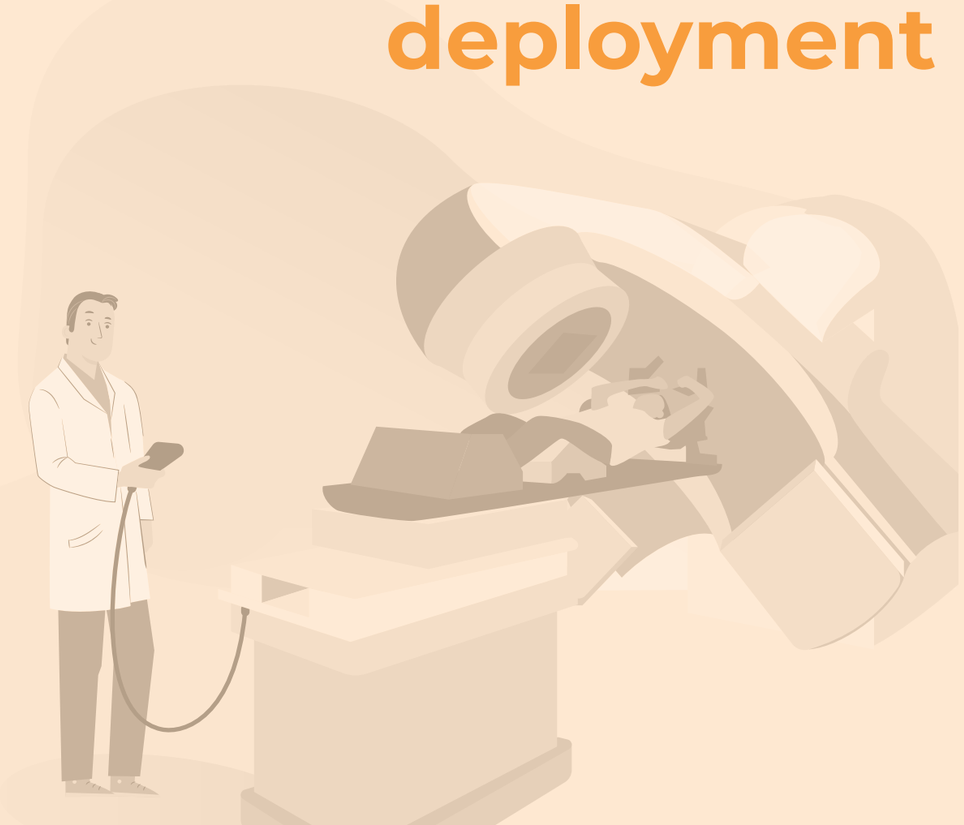
"Great things in business are never done by one person; they're done by a team of people"

— Steve Jobs —

Prior to clinical deployment, it is crucial to anticipate the impacts of the change on organisation and work practices, particularly in relation to treatment safety. Lessons learned from centres that have implemented similar techniques in comparable contexts, along with the experience of radiotherapy professionals, should be leveraged. The organisation must also facilitate the technical implementation and management of the new development while ensuring that project progress is regularly communicated to the entire radiotherapy department.

2.

Prepare: **Preparatory phase for technical deployment**



Collectively identify the effects of the change on work practices and the organisation

Multidisciplinary exchanges enable a clearer identification of the needs and constraints of the various professions affected by the change, allowing for better anticipation of its impact on their respective activities and their interactions.

▶RECOMMENDATIONS

1. **Encourage** exchanges with other centres.

2. **Organise** collegial reflection times between the members of the centre's radiotherapy team.

3. Collectively **identify** the effects of the change in connection with the new development and on the overall service by analysing *a priori*:

- Lessons learned (positive and negative) from other radiotherapy centres with similar facilities;
- the organisational changes to be implemented in the department to ensure treatments (evolution of the interdependencies and necessary interactions between different professions, need to synchronise activities within the department or with other departments, etc.);
- changes in practices (at individual and collective levels) for the various professions in the care pathway (temporary or permanent changes in assignments, new work methodologies, introduction of complexity, etc.);
- difficulties introduced or already existing which may be amplified by the change;
- the impact of the changes on patients which may introduce risks during treatment (e.g. maintaining an uncomfortable position, prolonged treatment session duration, low temperature in the treatment room required by the new equipment, etc.);
- the potential consequences on the flow of patients:
  - an increase in the number of patients to be treated as a result of a new treatment offer,
  - a temporary reduction in the overall capacity of the department in the number of patients who can be treated during the implementation phase of the change;
- the effectiveness of existing safety barriers[1] with respect to these changes, new barriers to be put in place.

▶QUESTIONS

What developments are likely to complicate the activity, or introduce new risks (technical development, introduction of new requirements for treatments, introduction of new interactions or interdependencies, presence of certain professionals required during treatments, additional steps in the preparation or delivery of treatment, increase in coordination, synchronisation between activities, increase in treatment time, increase in the direct or indirect workload on "non-medical" actors - secretarial staff, for example)?

—

Following the change, which phases can be identified as "sensitive" in the treatment process (need for increased concentration, need for activity continuity, introduction of technical complexity, strict time constraints on the organisation, etc.) and must therefore be particularly secured?

—

Are changes in practices or organisation - including minimal ones *a priori* - likely to impact the safety of the treatments?

To what extent are the effects of the change likely to constrain the implementation of all the department's activities (introduction of new steps in activities, distribution of patients on other machines, extension of schedules, disruption of the secretarial staff, etc.)?

—

What compensatory measures (formal or informal) could limit the risks associated with the technical or material evolution and help to secure the treatment process?

—

Which entities outside the radiotherapy department could be asked to participate in working group exchanges from time to time? Imaging department, chemotherapy department?

4. **Carry out** *a priori* risk assessment by integrating the identified effects of the change, in particular the organisational effects.

5. **Identify the actions to be carried out** and the working groups to be set up in order to address them.

1. Barriers are *"means of protecting the system against the occurrence of risks by preventing failures or, at least by allowing them to be identified and recovered before they occur"* according to Cuvelier L. & Falzon P. (2011). « Sécurité réglée et/ou sécurité gérée ? Quelles combinaisons possibles ? » *(Safety issues solved and/or safety issues managed? What combinations are possible?)*

Organise and carry out the technical implementation

The technical implementation phase must be allocated a dedicated, non-negotiable amount of time to allow teams to complete all the necessary controls and validations before beginning clinical deployment.

▶RECOMMENDATIONS

1. **Refine** the milestones defined during the initiation of the project by updating the needs in terms of dedicated time for the working group at the various stages: preparation, acceptance, implementation, monitoring, training and validation of the technical implementation, including the quality aspects.

2. **Develop** a participatory approach to the project at various levels: multi-professional working groups including support services (technical, human resources, training, works, finance, radiation protection, legal, etc.) and other services in interaction with the radiotherapy department.

3. **Free up** the time necessary for the working group to carry out its missions (identify the actions to be performed, carry out the technical implementation, share knowledge on the new development with peers, etc.)

4. **Adjust** the organisation and the resources (human, organisational) according to results of the assessment of effects caused by the change (see previous step on page 22).

5. Clearly **assign** tasks for technical and clinical implementation, in particular in terms of decision-making.

6. **Allow** the medical physics team to perform acceptance and commissioning of the medical devices without underestimating the necessary means in terms of time and resources.

7. **Ensure** formal validation of technical implementation.

8. **Identify** the relevant key messages to be delivered to the various stakeholders (potentially beyond the radiotherapy department to optimise collaboration and coordination between departments).

9. **Communicate** the progress and key elements of the project to all staff ultimately concerned by the technical or material change.

▶QUESTIONS

How can the clinical activity be temporarily reorganised so as not to generate overload for the teams involved in technical and clinical implementation (radiotherapist oncologists, medical physics, quality experts, etc.)?

—

How can the activity of medical physicists be reorganised to give them the time objectively necessary for technical implementation of the technical or material change and guarantee they are sufficiently availability to support caregivers during clinical deployment?

—

Is the project schedule compatible, in terms of workload, with possible involvement of teams in other ongoing projects? If not, how do you manage priorities?

What type of information does it seem relevant to share with employees of the radiotherapy department who are not involved in the technical implementation of the project, depending on their activity, and in particular with a view to clinical deployment?

—

How can key messages be conveyed in a relevant way (presentation, documentation, discussion space, etc.)?

"Make sense for everyone"

Members of the collective around which radiotherapy is organised are involved at different levels in a material or technical change: For some, this change will result in a significant increase in their workload and the learning of new work practices, while others may be indirectly involved or not involved at all if they are not users of the change. In any case, because of the existence of a working group within the radiotherapy department, a change must be shared by the whole group, for two reasons in particular. First of all, a lack of information from part of the collective could lead to interpretations about the new equipment or technique, resulting in a misunderstanding of the change, the associated requirements (particularly human and organisational) and the impact on the working environment. In addition, limiting knowledge of the characteristics and implications of the change to only those directly affected could weaken the cohesion of the collective and undermine the existing collaboration mechanisms.

In the context of a change, it is therefore the responsibility of managers to share information with all employees, in particular to maintain team spirit and cooperation that contributes to safely providing care, and to preserve a sense of belonging to the project.

Thus, the involvement of all team members throughout the project makes it possible to develop the whole collective together, around a common objective and shared practices. Among the actions to achieve this objective, one example is the implementation of a communication plan for all staff (caregivers and non-caregivers), to inform them throughout the project of the objectives and effects of the technical or material change. Giving meaning to the project for all employees contributes to their motivation and commitment to the department's project, even when they are indirect stakeholders.

Provide support for learning
how to use the new development

Effective and efficient management of the change is based, in particular, on precise documentary support and training consistent with the reality of the situations encountered on the ground, as well as on the acquisition and transmission of good practices between professionals, in particular on the basis of the experience acquired by the referents.

▶RECOMMENDATIONS

1. **Collect,** before the start of the treatments, the lessons learned from other centres concerning management of the change, in particular the training that was completed and necessary.

2. **Organise** and monitor staff training:

- o define the necessary training for all professionals, without forgetting to identify the additional training required following organisational changes (for example linked to an expansion of missions or the redistribution of tasks or roles, etc.);
- o allow all teams to have the time necessary to complete the training before their first clinical use (for example by adapting the treatment schedules carried out during this phase).

3. **Identify** the documentary developments caused by the material or technical change to be carried out.

4. **Update** the applicable documentation to:

- o have clearly identified and optimised documentation (ensure that the proliferation of documents is limited);
- o ensure the adequacy of the documentation with the reality on the ground and its applicability;
- o delete obsolete documentation.

5. **Develop** support tools to assist with the use of technical developments (for example, the drafting of a "technical reference memo" specifying the new features).

▶QUESTIONS

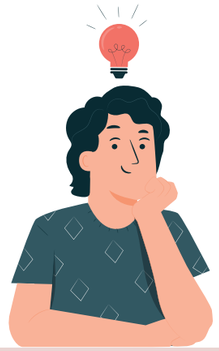
What documents must be available as *a minimum* from the start of treatment?

—

In the event of contingencies that do not allow certain professionals to complete the training (theoretical or practical) before the first treatments, what compensatory measures are to be provided to secure clinical implementation?

—

What features (new or modified) brought by the change may be sources of errors or difficulties?



"The ability of teams to adapt to the variability of situations helps to secure the care process"

The overall safety of a complex system, such as radiotherapy, is based on two complementary components: "regulated" safety, which is based on rules and procedures, and "managed" safety, which encompasses best practices, adjustments and standards implemented by teams in the field to address the variability of daily work situations (e.g. workload fluctuations, composition of the team) and unexpected events.

Managed safety depends on human expertise, proactive initiatives, the effective functioning of collectives, and organisations and management that are attentive to the realities of field work. It also requires fostering connections between different types of knowledge necessary to ensure safety. This approach demands adequate flexibility within the system to allow for adjustment. In practice, beyond the developments of documentation to support activities, it must be ensured that the change does not compromise the conditions for regulatory compliance.

Teams must also be given the time and flexibility to develop strategies adapted to unexpected situations.

"Time takes time"

— Miguel de Cervantès —

The deployment of new equipment or techniques must occur under favourable conditions to enable effective integration of the new development by all users to ensure patient safety. Achieving this objective requires, in particular, allocating sufficient time to the teams to adapt and facilitating the sharing of experiences among professionals. Particular attention must also be given to identifying situations or changes in professional practices that could compromise treatment safety.

3.

Deploy: **Clinical deployment**

Allow sufficient time for clinical deployment

Giving teams adequate time to adapt to a technical or material change is an investment in patient safety. This flexibility allows the teams to experience the change without time pressure and facilitate informal exchanges among professionals, regarding the use of the new technology or method.

▶RECOMMENDATIONS

1. **Ensure** the availability of key referents or professionals to:

- support and secure the first treatments (radiation oncologists, radiation therapists, medical physicists, etc.);
- have a dedicated clinical team to start the treatments with the new technique or machine;
- secure sensitive phases, in particular certain difficult treatment or scanner phases.

2. **Allow** the development of treatment schedules to:

- leave room for manoeuvre on the ground;
- enable informal inter-professional exchanges on practices;
- not constrain the caregiver's time;
- have peace of mind (limit work under pressure);
- free up time for communication on the project with all staff.

3. **Gradually introduce** new options in order to ensure favourable conditions (sufficient time, in particular) for their integration.

4. **Ensure** that the time allocated to staff to carry out their missions, in connection with the change, is compatible with the field requirements.

5. **Preserve** the need for concentration of the teams (no interruption of tasks for example) by setting up the appropriate organisational arrangements.

▶QUESTIONS

How can work be organised to free up time for the working group's referents during the clinical deployment phase?

—

Which key players must be present, unconditionally, during sensitive phases? What organisational arrangements must be put in place to free up the necessary time for them?

—

How can time be allocated for users to allow them to have the optimal conditions for integrating the new development without otherwise restricting them in the performance of essential transversal tasks (tasks related to the preparation of tomorrow's cases, for example)?

What concrete provisions would make it possible to adapt the schedule to the different constraints? Introduction of buffer time slots? Breaks in response to an increased need for concentration? Limiting the number of patients to be treated per day? Definition of extended time slots to support specific treatments (long, complex, rare, restrictive for patients, etc.)?

—

Is the treatment schedule compatible with the potential extension of the duration of certain tasks, such as placement of the patient?

—

What organisational arrangements would make it possible to secure sensitive phases or complex treatment? For example, how can we ensure that these phases or treatments are not concomitant with team shift changes?

"The professional identity of caregivers must be preserved in the context of a technical and material change"

In radiotherapy, the practices of "care" (having someone's best interests at heart and doing what you can to maintain or improve their wellbeing) represent an essential part of the professional identity of caregivers, that is to say their own role in treating patients, experienced as a vocation, or self-actualisation. However, as "*care*" cannot be measured, it remains invisible at the organisational level, which is a difficulty, especially in the event of a reorganisation of care processes.

This is why, during a material or technical change, it is necessary that the time essential for "*care*" be preserved – that it does not serve as an adjustment parameter in case of delays for example – to obtain a global appropriation of the tool by the caregivers, respecting their total professional identity and promoting the delivery of treatments under more favourable conditions for professionals and patients.

Rely
on collective knowledge for support

Planning exchange sessions among different professions enables a better understanding of each individual's needs and constraints while facilitating the sharing of practices. These exchanges contribute to the adaptation of professionals to new developments and, thus, to the safety of care. They can be formal, when scheduled by the organisation, or informal, which requires the organisation to act as a facilitator by providing the necessary resources.

▶RECOMMENDATIONS

1. **Organise** formal and regular collective exchanges in order to capitalise on the feedback during the deployment of the project.

2. **Establish** conditions conducive to informal exchanges between the various professions of the radiotherapy department (dedicated spaces, wiggle room in the schedule, etc.).

3. **Encourage and facilitate** the development of a support tool by the working group describing best practices for the management of patients, particularly radiation therapists.

In the context of formal and informal exchanges:

1. **Identify the difficulties and the elements facilitating** the performance of the activity.

2. **Collectively identify the risks** associated with difficult treatments or "unusual" situations encountered, and define compensatory measures or actions to be taken to secure them.

3. **Discuss** the changes introduced by the new development, at individual and collective levels, new needs, organisational or practice difficulties encountered, and blocking points.

4. **Over time, identify** the new best practices (and alerts) based on actions developed on the ground to adapt to the new development and share them with all users.

▶QUESTIONS

How should formal exchanges be organised? For example, by holding a daily meeting of all staff regarding the patients of the day? Regular, short and multidisciplinary debriefings?

—

Does the organisation of work allow for regular informal exchanges between the various professionals? If not, what obstacles exist to these exchanges? How can we facilitate the implementation of time slots dedicated to these exchanges, spaces accessible to all that promote these exchanges between different professions?

How can we capitalise on the experience gained on the ground? For example, are there plans to create "best practice sheets" that can be developed as integration progresses (by profession and between professions)?

In the context of formal and informal exchanges, identify:

o how the new development contributes to the introduction of difficult treatments or unusual situations (for example: technique implemented, changes in practices, difficult treatment plans, long treatments likely to slow down the flow of patients, specific imaging, particular locations, tiring position for the patient, etc.).

o what constraints have been introduced for each profession or between the professions in the care pathway (collaborations, cooperations, etc.).

o what measures would make it possible to limit the difficulties introduced by the change (for example, mobilising additional resources, etc.).

o what is fundamentally different from the practices usually implemented for a given type of treatment.

o what requires special vigilance or a hold.

"Impacts occur at both individual and collective levels"

A material or technical change modifies both the individual and collective dimensions of the work. In order to facilitate integration, it is important that each actor in the radiotherapy department feels concerned by the change, as an individual but also as a contributor to a group of professionals representing different interacting fields.

Addressing the impacts of material or technical change at the level of collaborations, interdependencies between the professions, synchronisation needs, and a better understanding of the constraints that other professions are subjected to, makes it possible to evolve both individual and group practices. It also allows for arbitrations adapted to the needs on the ground for securing the care process.

In this regard, regular exchanges, formal or informal, between actors in the care process, in particular through the establishment of spaces for discussion, contribute to the individual and collective adoption of the new development and to the reliability of treatments.

Identify situations or changes in practices that could potentially impact the safety of care

Different constraints or requirements introduced by the new development may compel teams to change their working methods, and potentially lead to risky practices. It is therefore essential to identify and share warning signs of such situations, to collectively define limits of acceptable practices in relation to patient safety.

▶RECOMMENDATIONS

1. **Encourage** the different types of professions to report, as they go, changes in practices caused by the material or technical change that may generate risks in the long term (proven or potential).

2. **Identify** situations that could lead to "deviations[1]" in practices, for example, the use of a technical option that is not adapted to the situation or the return to a previous practice that is better mastered.

3. **Propose** golden rules (organisational and technical rules that are not broken under any circumstances), for example, not authorising the start of a treatment unless all planned measures contributing to safety of the treatment with the technical or material change have been finalised or if certain technical values are outside of defined tolerances.

1. Deviation in the HOF sense: gradual shift of practices towards the limit of what is acceptable from a safety point of view, under the effect of internal or external constraints

▶QUESTIONS

What collectively defined rules could protect against a shift in practices towards the limits of safety, which is not acceptable from the point of view of securing the treatments?

—

Is the training provided to users sufficiently comprehensive (including, for example, does it address technical options that will not be used immediately but may be used later)?

What changes in practice, previously considered insignificant, would ultimately be likely to lead to risky practices with regard to treatment?

—

What level of knowledge does management have of the reality on the ground, including the difficulties encountered and the potential risks associated?

"The impact of a material or technical change can gradually cause practices to drift towards the limits of safety"

Beyond the "normal" variabilities encountered daily by radiotherapy professionals, and to which operators respond with "normal" regulations, a change in the operational context that introduces new constraints can significantly complicate working conditions, without the expected performance necessarily being affected, particularly in terms of safety. In many cases, teams compensate for difficulties to reach the set objectives, at all costs, to preserve execution of treatments and patient safety, at a potentially high cost to their own wellbeing. These compensations lead, for example, to extended hours, or the acceptance of working under high pressure to comply with the treatment schedule. When the situation persists, we gradually see a shift in work practices towards the limit of what is considered safe, or even exceeding this limit. This is known as "deviations from practice". It is therefore essential that teams be able to recognise the warning signs of such migrations in practices.

The organisation must therefore allow them to develop vigilance and awareness of the risk, to discuss it collectively and to sound the alarm. In this regard, regular sharing among professionals on the difficulties encountered during implementation of a material or technical change, and the associated potential risks, can help to identify the limits of safe practice, to characterise the signs of slippage in practice, to anticipate the potential impacts, and to put in place the necessary measures to preserve the safety of staff and patients. The organisation and management must also encourage reporting, over time, of practices introduced by the material or technical change that are likely to generate risks for the patients or teams.

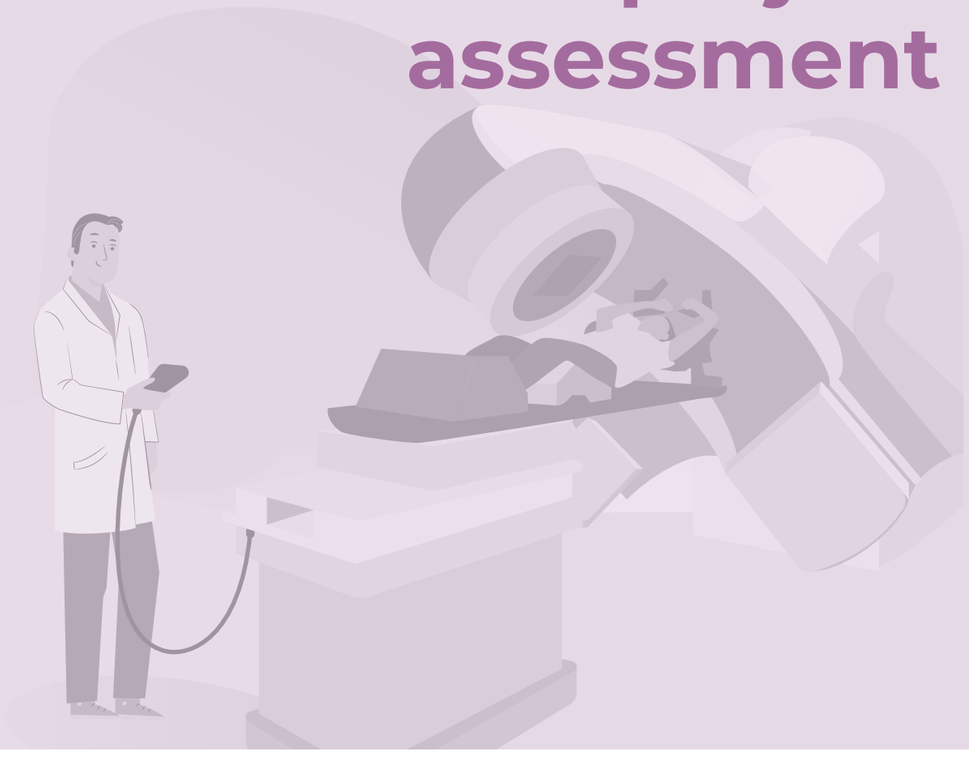
"One of our most difficult, but most necessary tasks is to fully comprehend that which is most familiar to us"

— Gérard Macé —

The integration of a change is a gradual process, extending beyond the completion of clinical deployment. It is essential to regularly organise long-term collective exchanges to review the impacts of the change and make adjustments as needed. A more comprehensive assessment of the project should be conducted in the long term with all stakeholders to optimise the conditions for implementing future material or technical changes.

4.

Consolidate: **Medium- and long-term integration, and project assessment**



Consolidate
integration

Once the technical or material change has been integrated into the clinical routine, it is important to regularly and collectively reflect on the work practices developed during its use. This reflection should focus, in particular, on the suitability of the practices and documentation available for addressing the situations encountered.

▶RECOMMENDATIONS

1. **Define** medium- and long-term milestones (after the ramp-up phase) to carry out formal assessments of implementation of the new technique or new equipment with all stakeholders.

2. **Analyse** regularly and collectively the differences in practices between professionals.

3. **Update** the applicable documentation regularly to:

- ensure that it is complete;
- adjust it to the reality of the work (update according to changes in practices);
- restrict the documents available to those that are applicable.

4. **Inform** professionals of the applicable documents.

▶QUESTIONS

On what basis is it relevant to define the milestones associated with the assessments: in terms of months or number of patients treated?

—

How can differences in practices between professionals be analysed?

- workshops to discuss scenarios based on lived or hypothetical situations?
- debriefing times focused on sharing between the different professions?
- exchanges between user teams from different centres to compare the practices and solutions implemented?

Overall assessment
with the various stakeholders

In the long term, an overall assessment must be carried out to evaluate what has facilitated or constrained, at the technical, organisational and human levels, the integration of the new development, and to identify the improvements needed for a future technical or material change project.

▶RECOMMENDATIONS

1. **Organise** a review of the project, with all stakeholders, in order to:

- identify and take into account any effects of the change not previously considered;
- develop, if necessary, the conditions for implementation of a future material or technical development.

2. **Analyse** the elements that have facilitated or constrained the integration of the new development by professionals during the project.

3. **Check** the suitability of the training and of technical and human resources provided compared to:

- the needs in the technical and clinical implementation phase of the project;
- the needs in the so-called "routine" clinical phase, in particular concerning the training of new users, updates to documentation, etc.

4. **Assess** the overall impact of the change on the organisation of the department and on care of all patients treated in the department.

5. **Ensure that** the risk map is regularly updated (at least annually).

▶QUESTIONS

Are the means necessary for the use of the technical or material change in the clinical routine available to ensure the safety of the treatments?

—

How do professionals feel about what has facilitated or complicated the implementation of the new development? For example: is the time allocated to various phases sufficient or excessively tight, flexibility or rigidity of the organisation, possibility of informal exchanges between professionals.

—

For a future project, what organisational arrangements could facilitate the integration of the new development by teams?

—

What effects of the change were not identified beforehand? What is the plan for integrating them on a future project?

CONCLUSION

The elements structuring this guide (recommendations and questions) are based on lessons learned from the humanities and social sciences, particularly organisational and human factors. They demonstrate that activity performance relies on factors such as organisation, management, the work situation, the collective work environment, and individual contributions.

Explaining certain recommendations through this perspective highlights the impact of organisational and human factors on the integration of change by teams, and ultimately, on treatment safety.

These factors particularly underscore that even minor changes can disrupt the entire department or affect noncare professionals (e.g. secretaries), and other departments interacting with radiotherapy such as chemotherapy or surgery. This approach also enables a better understanding of the impacts of technical or material changes on work practices, at both individual and collective levels. Such insight helps improve the integration of the new development and enhance patient safety.

This guide highlights the importance, during the implementation of a technical or material change, of:

- **involving** all staff concerned by the change;
- **taking into consideration** the context in which the change will be deployed (in particular, the human context);
- **anticipating** the impacts of change at the level of the organisation and work practices;
- **requesting** lessons learned from centres that have developed the same type of technique or material in a similar context and the experience of radiotherapy professionals;
- **facilitating** technical implementation and clinical deployment by establishing favourable conditions for the adoption of the change by all professionals;
- **identifying** risky situations or changes in practices in the long term.

Through recommendations and associated questions, this guide offers non-exhaustive assistance to radiotherapy teams for support during a technical or material change in order to facilitate the integration of the new development and thus the safety of care by taking into account organisational and human factors. This guide aims to be clear and easy to implement by radiotherapy teams. It draws on the experience of professionals who have participated in the identification of "essentials" for successfully integrating this type of change.

TO LEARN MORE ABOUT HOF

On the notions of a socio-technical system and context factors:

- *Résilience des Systèmes Sociotechniques Application à l'ingénierie système* (Resilience of Sociotechnical Systems Application to system engineering) Jean-René Ruault, Dominique Luzeaux, Christian Colas and Jean-Claude Sarron

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On the notions of regulated safety/managed safety:

- Comité d'orientation sur les facteurs sociaux, organisationnels et humains (COFSOH - orientation committee on social, organisational and human factors) - *Développer la sécurité - Synthèse des travaux du groupe de travail* (Developing safety - Working group summary) D - September 2019
- *Le risque d'accident peut-il se contrôler par des approches formelles ? (Can the risk of an accident be controlled by formal approaches?)* René Amalberti - Science & Devenir de l'Homme, 2010.

On the actual work and the consideration of professional initiatives:

- Institut pour une Culture de Sécurité Industrielle (ICSI - Institute for Industrial Safety Culture) – *Conviction n°22: « Pour améliorer la culture de sécurité, les managers doivent connaître les pratiques du terrain »* (To improve the safety culture, managers must be familiar with practices in the field) - July 2016 - www.icsi-eu.org

On informal dimensions and change:

- *Donner du sens à la conduite du changement : un facteur de maîtrise des risques,* (Giving meaning to managing change: a factor in risk management) Carine Hébraud, Thierry Morlet, IMDR – 20e Congrès de maîtrise des risques et de sûreté de fonctionnement (Congress on risk management and operational safety) - St-Malo - 11 to 13 October 2016

On sharing of the collective:

- *Produire la santé, produire la sécurité - Récupérations et compromis dans le risque des manipulatrices en radiothérapie,* (Producing health, producing safety - Risk recovery and compromises for radiotherapy manipulators) Adélaïde Nascimento and Pierre Falzon http://journals.openedition.org/activites/2225

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- *Comprendre la résistance au changement* (Understanding resistance to change) C. Dejours, D. Dessors, P. Molnier – INRS 1994

On discussion spaces:

- *Espaces de discussion, apprentissages et sûreté nucléaire,* (Discussion spaces, learning and nuclear safety) Violaine Bringaud, Olivier Guillaume, Nicolas Lot Éducation Permanente - n° 224/2020-3
- *Approche ergonomique de l'analyse des risques en radiothérapie : de l'analyse des modes de défaillances à la mise en discussion des modes de réussite -* (Ergonomic approach to risk analysis in radiotherapy: analysis of failure modes at discussion of modes for success).Sylvie Thellier, 2017. https://www.theses.fr/2017CNAM1159

On the concept of co-construction:

- *Une nouvelle voie pour réussir les changements technologiques : la co-construction* (A new path for successful implementation of technological change: co-construction) Philippe Bernoux, Yves-C. Gagnon Direction et Gestion | « La Revue des Sciences de Gestion » 2008/5 n°233 | pages 51 to 58 ISSN 1160-7742 https://www.cairn.info/revue-des-sciences-de-gestion-2008-5-page-51.htm

On the notion of integration:

- *La capacité d'appropriation, une capacité organisationnelle immatérielle négligée dans l'adoption des systèmes d'information et de gestion* (The capacity for integration, an intangible organisational capacity neglected in the adoption of information and management systems) Roxana Ologeanu-Taddei, Karine Gauche, David Morquin, Rodolphe Bourret De Boeck Supérieur | « Innovations » 2015/2 n° 47 | pages 79 to 100 https://www.cairn.info/revue-innovations-2015-2-page-79.htm

On the notions of migration and deviation of practices:

- *Résilience des Systèmes Sociotechniques Application à l'ingénierie système* (Resilience of Sociotechnical Systems Application to system engineering) Jean-René Ruault, Dominique Luzeaux, Christian Colas and Jean-Claude Sarron https://www.researchgate.net/publication/263855675_Resilience_des_Systemes_Sociotechniques_Application_a_l%27ingenierie_systeme
- *Migration de pratiques et sécurité en anesthésie : du flou de la prescription à la pratique illégale-normale des Auxiliaires Médicaux en Anesthésie Réanimation* (Migration of practices and safety in anesthesia: from the vagueness of prescription to the illegal-normal practice of Medical Auxiliaries in Resuscitation Anesthesia) Amrane, H., Zahi, C. (2017) – 52e congrès de la SELF – Présent et futur de l'ergonomie (Toulouse, 20-22 September) (SELF congress - Present and future of ergonomics)
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On the notions of migration of practices and achieving performance

- *Proposition d'architecture et de processus pour la résilience des systèmes : application aux systèmes critiques à longue durée de vie. (Proposed architecture and process for systems resilience: application to critical systems with a long lifespan.) Biomécanique [physics med-ph].* Jean-René Ruault. Université de Valenciennes et du Hainaut-Cambresis, 2015. French. NNT: 2015VALE0025.

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IRSN
INSTITUT DE RADIOPROTECTION
ET DE SÛRETÉ NUCLÉAIRE

31, avenue de la Division Leclerc
92260 Fontenay-aux-Roses
RCS Nanterre B 440 546 018

MAILING ADDRESS
B.P. 17
92262 Fontenay-aux-Roses Cedex

TELEPHONE
+33 (0)1 58 35 88 88

WEBSITE
www.irsn.fr

EMAIL
contact@irsn.fr
@IRSNFrance

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