



SAFRON

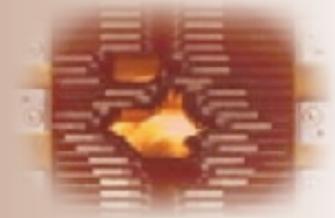
SAFety in Radiation ONcology

<https://rpop.iaea.org/SAFRON/Default.aspx>

Updates on Patient Safety in Radiotherapy

May 2020

Launch of SAFRON for Radionuclide Therapy



Launch of SAFRON for Radionuclide Therapy

The IAEA recently launched an incident learning system to collect information from radionuclide therapy events.

The use of radionuclide therapy is increasing worldwide and there are newer radionuclides that have had a positive impact on the management of cancer and other diseases. Radionuclide therapy can be administered in many ways. The chemical properties and safety challenges can vary based on radionuclide and the disease process, the complexity of the treatment itself can lead or could lead to medical events or unintended exposure pathways for the patient, worker or the public. There are environmental challenges with unsealed sources of radioactive material that make it uniquely different than radiotherapy. The process steps, safety systems and barriers are also unique.

The SAFRON radionuclide therapy incident learning systems does share some basic software architecture with radiotherapy but has been designed to meet the needs of medical professional providing this service.

This system is in response to a 2018 Technical Meeting and “Guidance on prevention of unintended and accidental radiation exposures in nuclear medicine” (1). A consultancy meeting was held in late 2018 to develop the registration information, process steps, safety systems, safety barriers. This information was then provided to IAEA IT staff who constructed the system.

Though there are internal incident reporting systems for radionuclide therapy, there are no known available incident learning systems, that would allow the sharing information on these events with a broader



medical community. SAFRON NM was designed to be an internal incident learning system and at the same time share information with a larger community anonymously, therefore allowing others to identify potential safety issues that could be implemented in their clinic to prevent an event.

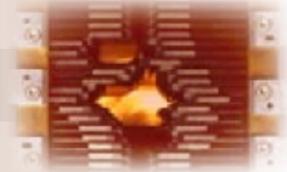
As an internal incident learning system, all data for the clinic can be reviewed and evaluated for types of events, improvements over time and provide information on trending within the clinic.

How to register for SAFRON Radionuclide Therapy Incident Learning

Registered contributors using SAFRON will be able to collect and analyse their reports to track, trend and benchmark activities within their centres and with other SAFRON participants in radiotherapy and radionuclide therapy.

You will need to register with [Nucleus](#) to access [SAFRON](#).

Find the detailed instructions [here](#).



E-learning - Safety and Quality in Radiotherapy now available in Spanish

The popular IAEA e-learning course - Safety and Quality in Radiotherapy is now available also in [Spanish](#).

The course provides continuing education to radiotherapy professionals on safety and quality in radiotherapy. The e-learning offers participants from all around the world the opportunity to improve their understanding of safety in radiotherapy, learn techniques to reduce and avoid radiotherapy incidents and understand the value and use of incident learning systems.

Throughout this e-learning course, the participants are expected to:

- Improve their understanding of safety in radiotherapy;
- Learn techniques to reduce and avoid radiotherapy incidents;
- Understand the value and use of incident learning systems;
- Learn about useful sources of information to enhance safety in radiotherapy;
- Gain insight into improving safety culture in medical clinics/facilities.

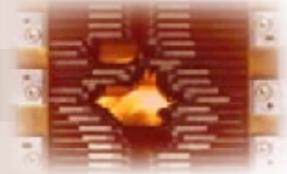
You can see more information on [RPOP website](#). So far, more than 3100 people took the [English version](#) of the online course. To access the Spanish version, please click [here](#).

Are we doing enough to make sure that radionuclide therapy is safe?

One way to find out is to collect information on events that reached the patient or could have reached the were unintended or accidental. This can help to determine if we have adequate safety systems in place and help identify the effectiveness of safety barriers.

SAFRON has been designed to do just that. It's an easy system to add events that can improve safety in all clinics. Some of the type of events that might be included in the incident learning system are errors in the patient preparation, patient identification and administration of the radionuclides.





What has been reported

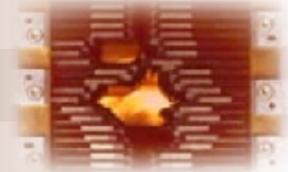
In published literature the following cases have been identified by Martin et al (1)

- Two ¹³¹I therapy capsules (4 GBq and 400 MBq) for separate hospitals, were delivered to the wrong hospitals. This resulted in the 4 GBq capsule being administered to the wrong patient without the activity being measured. See, as an example, a similar scenario described in Al Aamri et al.
- Two vials were delivered together to a NM department, vial 1 containing ¹³¹I and vial 2 ¹⁸F. Normally ¹³¹I would have been delivered at a different time of day. The technologist assuming both vials contained ¹⁸F labelled FDG, measured the activity levels with the ¹⁸F window setting on the radionuclide activity meter as 20.3 MBq and 1402 MBq. He injected the first patient with radiopharmaceutical aspirated from vial 1 and made up the required ¹⁸F activity with part of the contents of vial 2, resulting in an unnecessary thyroid dose of ¹³¹I. The error resulted from a lack of attention to the vial label, but the differences in the weight of the lead pot should have alerted the staff member to the difference. The availability of modern radiation protection instruments with gamma-spectrometric functions could also be helpful here.
- A slow injection of 1.2 GBq of ⁹⁰Y-Zevalin (ibritumomab tiuxetan) was given during treatment of a non-Hodgkin's lymphoma. Extravasation was noticed at the end of the procedure and was thought to have occurred during the flushing procedure at the needle puncture site. Erythema reported on day 2 extended over an area of 100 cm² and the likely dose that would be accrued was estimated as about 50 Gy. Following the development of dermatitis on the patient's elbow during subsequent weeks, analgesics, and non-steroidal and anti-inflammatory drugs were used to relieve pain. Five months later there was extensive cutaneous necrosis and plastic surgery was performed using an antero-lateral thigh free flap to cover the wound after debridement.
- An intravenous infusion of 11.1 GBq of ¹³¹I-metaiodobenzylguanidine was given for treatment of metastatic cancer. Although swelling was noted at the time the injection catheter was removed, this was attributed to an allergic reaction and not identified as being induced by radiation until 4 weeks later when the patient reported a rash on his arm measuring 50 cm². The amount of activity in the affected arm was estimated as 5 MBq one week after the injection, giving an estimated dose to the tissue of 12–16 Gy. The patient was followed up until the tissue damage resolved. In this case difficulty had been experienced in obtaining venous access, and the authors suggest that in such circumstance the access site should not be used to administer radionuclide therapy, and that a test be performed to ensure the absence of leakage at the site.



The US Nuclear Regulatory Commission requires licensee to report errors that have met a reporting error threshold. In 2018, they reported 3 radionuclide therapy events that were published in the report to Congress on Abnormal Occurrences Fiscal Year 2018(2). These can be viewed on the following [link](#).

SAFRON Radionuclide Incident Learning can help build a stronger and more robust safety system to reduce the unintended exposure to patients, workers and the public. To access SAFRON, [click here](#).



Importance of immobilization in radiotherapy

One of the most important steps in radiotherapy is the immobilization of the patient. The smallest movement of the patient or applicator can result in dose variation to the surrounding tissues as well as to the tumour to be treated. This is important in the advanced technologies where there are only millimetre margins of normal tissue in the treatment fields.

Patient comfort is important, if the immobilization is uncomfortable, the patient is more likely to try and move in the device. The immobilization device needs to be rigid enough to prevent this movement and be comfortable.

Fixation of the immobilization is critical high technology treatments where tumour margins are minimized. Reproducibility of treatment should be considered with any treatment setup. Poor fitting mobilization can have detrimental impact on patient treatment reducing control.

If we look at some of the cases in SAFRON, we can see where inappropriate immobilization has been identified as a contributor to events. A search of the term immobilization indicates that 14 events where immobilization was included in the description of the event or in the corrective actions.

Some of the errors are described below:

“The immobilization device was positioned by a new colleague centrally instead of laterally on the treatment couch. Therefore, one of the treatment fields was partially absorbed by the couch.”

“Risk of insufficient immobilisation not recognised. Needs of radiotherapy versus. diagnostic patients not distinguished. Communication incomplete and insufficient protocols. Immobilization requirements not documented.”

“A patient was treated for whole brain radiotherapy without an orfit shell. The patient was also receiving AP/PA lung treatment.”



“Due to the shape of the (short) immobilization mask the laser marks could not define the isocentre. Isocentre had to be found in every session by longitudinal shift.”

“Marks on left lateral orfit shell did not align to treatment field.”

What can we learn from this?

1. Immobilization must be adequate for the intended purpose. Especially in creating custom immobilization.
2. Immobilization needs to label correctly with instructions on the correct placement of lasers in the immobilization device.
3. Immobilization needs to be used, as described in the setup procedures.

How can we do this?

Most mobilization errors are random errors. Training and education become important, so that staff understand how the immobilization works and when it is positioned correctly. Consistency in how the immobilization devices are made and set up is done with mobilization from the creation of the mobilization, simulation and treatment setup. Standardization is key in high volume facilities. These procedures should be documented and understood by the entire treatment team.