# SAFRON

SAFety in Radiation ONcology

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

## Updates on Patient Safety in Radiotherapy

August 2018

Safety and Quality in the use of Intensity Modulated Radiation Therapy

## What is Intensity-Modulated Radiation Therapy and how is it used?

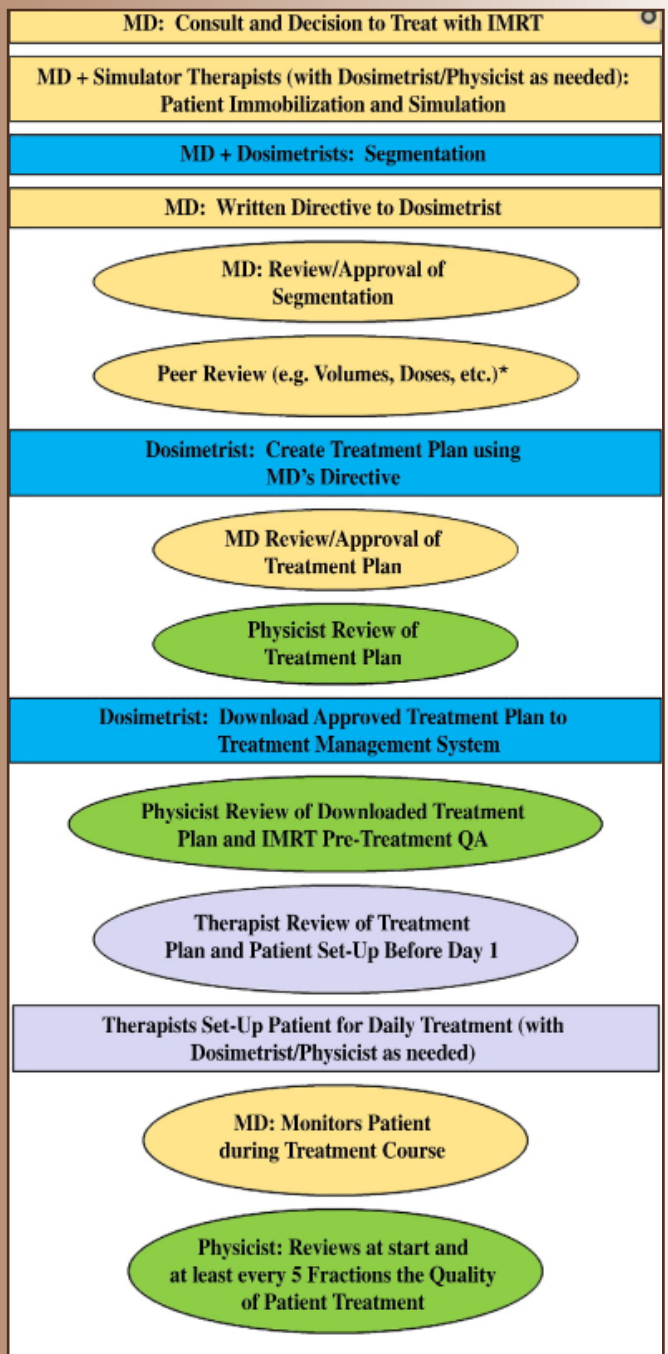
Intensity-modulated radiation therapy (IMRT) is an advanced mode of radiotherapy that uses computer-controlled linear accelerators to deliver precise radiation doses to a malignant tumour. The advantages of IMRT is the ability to conform more precisely to the three-dimensional (3-D) shape of the tumour by modulating — or controlling — the intensity of the radiation beam in multiple small volumes with higher doses of radiation, thus achieving better tumour control.

The objective with IMRT is to use a combination of multiple intensity-modulated fields coming from different beam directions to produce a custom-tailored radiation dose. The dose is maximized to the tumour volume while minimizing the dose to adjacent normal tissues. When successfully administered the patient's, response is improved and the side effects of radiation therapy minimized.

Errors in treatment delivery can occur at any of the process steps, from calibration, patient imaging, treatment planning and treatment delivery. Medical physicist need access to calibration and quality assurance equipment designed for IMRT. The treatment unit must perform with precise accuracy. Treatment planning is complex and even simple variations can produce unexpected results, including missed treatment targets. Treatment set up must be accurate and correct, even small variation could produce poor outcomes on increased side effects.

In the 2011 publication "Safety considerations for IMRT: Executive summary" the following process steps (see on the right) were described for a patient undergoing IMRT. At each of these steps there is a potential for an error or errors to occur. Safety systems or barriers need to be in place such that errors are identified early in the process before they reach the patient.

Quote:
"The physician has the overall responsibility for the IMRT program."
Bisham Chera




Adapted from: Safety Consideration for IMRT https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3808751/

## Evaluation of SAFRON events

Once a failure is identified whether or not the failure reached the patient; the facility should look to improve the system to minimizing the risk of future patient harm. An incident learning system such as SAFRON can be used to identify safety system weakness. The objective of an incident learning system is to minimize the risk of patient harm in the future due to a repetition of the observed failure mode. To reach this objective, it is necessary to identify the causes of the failure, and to initiate appropriate changes in the procedures or the quality management system.

SAFRON collects information on different types of treatment methods in effort to learn about the types of events reported and identify prevention methods. There are 20 events in SAFRON associated with IMRT treatment method, 18 of these events reached the patient, only 2 events were identified as near misses or near events. Information on the events are provided at the end of the update. There was one critical event and 3 serious events while the remaining were minor events, potential serious events or no information provided. (see Table 1)

Table 2 indicates that radiation therapist at the treatment unit identified 9 of the 20 events, unfortunately many of the incidents do not indicate how the incidents were discovered but where information is provided the most common is the use of chart checks (3), use of quality control equipment (1), clinical review of the patient (1) in vivo dosimetry (1) and portal imaging (2). The remaining events indicate the error was discovered at a later stage during patient treatment (6).

## Did you miss the RPOP Webinar: IMRT QA – A Physicians Perspective?

You can now listen to a rebroadcast of the event: https://www.iaea.org/resources/video/imrt-safety-and-qa-a-physicians-perspective

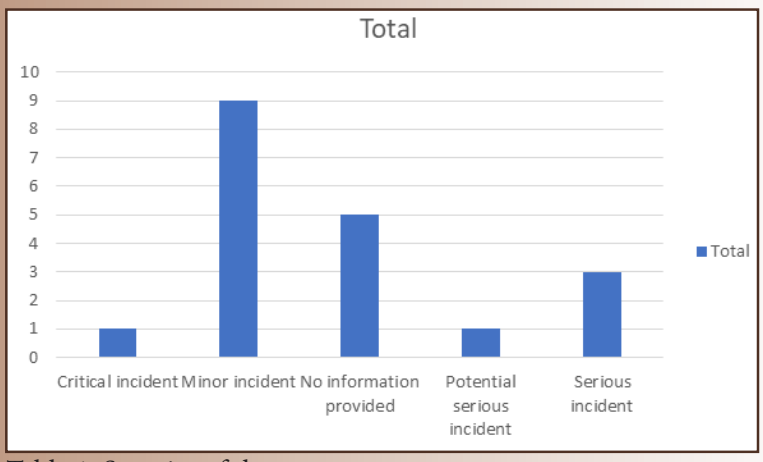



Table 1: Severity of the events

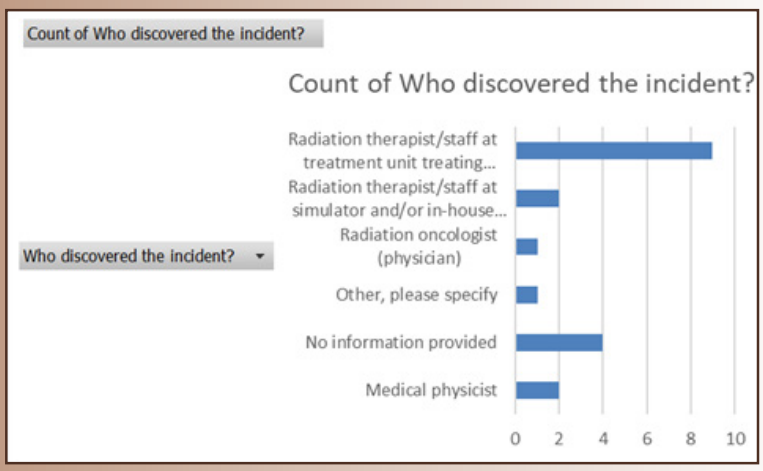



Table 2: Who discovered the incident?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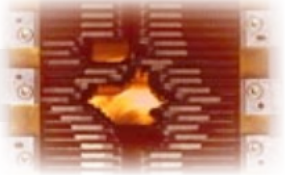
By reviewing the use of safety barriers in those cases one can identify the barriers that failed to detect the error, the barriers that detected the error and the barrier that might have detected the error, with this information we can begin to see how these barriers can be used to prevent errors. The IMRT reported events on the next page provided information on the use of safety barriers. How many of these safety barriers are being used in your facility?

To understand the table (please see next page), the barriers that failed to detect may have failed because they were not used or improperly used, the barrier that did detect the error may have been in place to limit the replication of the error where the patient could be harmed. A safety barrier is any component that mitigates risk of a dangerous situation. They can be physical barriers such as locks or interlocks or soft barriers such as procedures or checklists. A safety barrier may be no more than a planned activity such as time out that takes a pause and reflects on the patient setup before turning on the machine.



## Evaluation of Safety barriers and their effectiveness

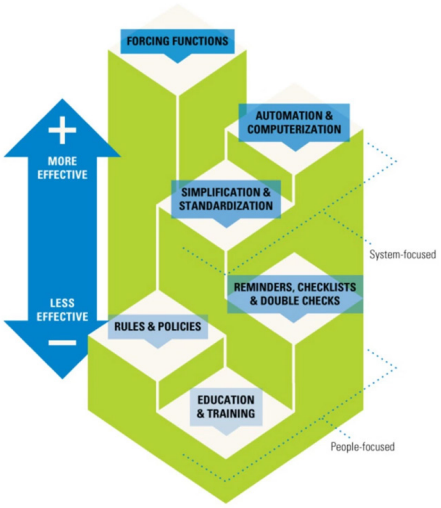
Below is the information on the events that contributed to the information on the safety barrier query.

| Incident summary | What safety barrier failed to identify the incident? | What safety barrier identified the incident? | What safety barrier might have identified the incident? |
|---|---|---|---|
| CBCT performed on the incorrect reference point. | Verification of patient ID<br>Verification that pre-treatment condition have been taken into account<br>Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)<br>Physician peer review<br>Review of treatment plan<br>Independent confirmation of dose<br>Verification of treatment accessories<br>Regular independent chart checks<br>Regular clinic patient assessment<br>Post treatment evaluations (evaluation of clinical and process)<br>Independent review of commissioning<br>Regular internal audit<br>Regular external audit<br>Regular equipment performance verification | Verification reference points<br>Image based position verification | Verification reference points<br>Time out<br>Use of record and verifying system<br>In vivo dosimetry<br>Intra-treatment monitoring |
| IMRT Brain treatment scheduled and treated on a non-licensed Elekta machine. | Review of treatment plan<br>Regular independent chart checks | Review of treatment plan<br>Use of record and verifying system | Time out |
| Physics staff did not see they had to do a IMRT plan QA and checks on this patient - patient delayed to allow time. | | Regular independent chart checks | |
| RE-inflating vac bag for 5# | Verification of treatment accessories | Image based position verification | |
| IMRT treatment Incorrect shift instruction led to most of the first fraction being delivered outside intended volume | Physician peer review<br>Review of treatment plan | | Time out |
| Patient received incorrect dose for 16 fractions because the dose per fraction and the number of fractions were reversed in the treatment plan and sent to the R&V system. | Review of treatment plan<br>Independent confirmation of dose<br>Time out<br>Regular independent chart checks | In vivo dosimetry | |
| The radiation therapist used a portal image treatment plan for another patient. | Verification that pre-treatment condition have been taken into account | | Verification that pre-treatment condition have been taken into account<br>Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)<br>Verification reference points<br>Physician peer review<br>Review of treatment plan<br>Time out |
| Missing the dose delivery of one of the treatment fields to one patient. | | Verification that pre-treatment condition have been taken into account<br>Review of treatment plan<br>Use of record and verifying system | In vivo dosimetry<br>Intra-treatment monitoring<br>Post treatment evaluations (evaluation of clinical and process) |
| Patient received one fraction from Verification site instead of treatment site. | | Verification that pre-treatment condition have been taken into account<br>Review of treatment plan | Post treatment evaluations (evaluation of clinical and process) |
| Missing the dose delivery of one of the treatment fields to one patient. | | Verification that pre-treatment condition have been taken into account<br>Review of treatment plan<br>Use of record and verifying system | In vivo dosimetry<br>Intra-treatment monitoring<br>Post treatment evaluations (evaluation of clinical and process) |
| Patient received one fraction from Verification site instead of treatment site. | | Verification that pre-treatment condition have been taken into account<br>Review of treatment plan | Post treatment evaluations (evaluation of clinical and process) |
| Patient was treated for 2 fractions in the same day on a tomotherapy machine. | Review of treatment plan<br>Independent confirmation of dose | | Time out<br>Use of record and verifying system<br>In vivo dosimetry<br>Intra-treatment monitoring |
| Elevated dose to unintended area due to an error in treatment planning. | Post treatment evaluations (evaluation of clinical and process) | | In vivo dosimetry<br>Intra-treatment monitoring<br>Regular clinic patient assessment |
| Error in dose fractionation | Review of treatment plan<br>Independent confirmation of dose<br>Use of record and verifying system | | |

## How effective are these barriers?

Research has indicated that the most effective barrier are those hard barriers that prevent the error from occurring. These prevent the user from performing an act. The table below demonstrate the most effective intervention.

Most of the corrective actions observed in SAFRON fall in the lower area of the diagram. When the error is repeated often from many different facilities is when we can share collected data with manufacturers to automate or force such activities in the equipment used in radiotherapy.




## Safety and Quality of IMRT

To safely use IMRT quality assurance steps and safety systems must be in place. Numerous articles address the need to safety barriers, safety checks and process to assure the radiation is administered correctly. IMRT is not recommended to be used without consideration of the potential hazards that exist. In addition to the safety barriers identified in the SAFRON data, facilities are encouraged to have standard operating procedures, adequate QA programs and assure that staff is adequately trained to perform IMRT. Commissioning of IMRT is different than traditional conventional radiotherapy and there is a need to validate the accuracy of treatment planning and delivery systems. Any deviation from the expected outcome should be investigated. These safety systems will only work in an environment where there is a strong safety culture that include the following:

- Employees trust in each other,
- Management support for safety
- Incident learning system that encourages “see something say something”
- Up to date operating procedures and policies
- Job descriptions that include responsibilities
- Strong communication among the team members; and
- Efforts to continually look to improve the system.

Facilities that subscribe to these recommendations are improving both the safety and quality of their radiotherapy treatments and assuring patient safety.