

STUDY CASE N° 24: ANALYSE OF UNINTENDED OVEREXPOSURE DURING PALLIATIVE TREATMENT AND THE DEVELOPMENT OF A CRITICAL INCIDENT REPORTING SYSTEM IN SWITZERLAND

European ALARA Newsletter: Issue 22

□ Legal provisions

In Switzerland, the use of ionising radiation in medicine is regulated by several ordinances. Whilst the Radiological Protection Ordinance gives a general framework, more detailed requirements are specified in technical Ordinances, such as the “Use of unsealed sources”, the “Use of sealed sources in medicine” and the “X-ray” Ordinances. The Ordinance on medical accelerators is particularly relevant to radiation therapy, and in particular, requires overdoses to be notified to the surveillance authorities (Art. 27) (as is also required in Germany – see ALARA Newsletter Issue 21, October 2007).

□ Incident summary

In 2006 an incident took place in a radiation therapy unit whereby an elderly patient was overexposed during a palliative treatment. The incident was discovered shortly after the final dose fraction had been administered, whilst undertaking routine checks of calculations. As required by law, the surveillance authority (SFOPH – Swiss Federal Office of Public Health) was informed by the medical physicist in charge.

The circumstances which led to the incident were investigated and fully clarified. An error was made in the hand-calculation whereby the fraction dose was not divided by the number of fields (2 fields: pa/ap), resulting in the wrong number of monitor units. None of the staff involved in the treatment noticed the unusually high number of monitor units. Fields are normally thoroughly checked one day after treatment starts. However, this treatment consisted of 3 fractions and, due to a lack of time, the monitor units were not re-calculated before the end of the final fraction which was 2 days after the start of treatment. As a consequence, the patient received a dose higher than intended.

Following the incident the overexposure of the patient was investigated; the calculation mistake had resulted in the patient being treated with 30 Gy instead of 15 Gy. It was decided to closely observe the patient during their palliative care. Sadly, the patient passed away a few weeks later. A post-mortem was undertaken, and the cause of death was found to be multifactorial with several findings unrelated to the overexposure.

□ Lessons learned / Measures

Several measures were identified in order to avoid such mistakes in the future:

- The definition of a stop-dose in the record and verify (R&V) system, which halts further treatment after the first session until the calculation check is performed,
- The calculation check has to be signed, and thus documented,
- The used data parameters, which are important for monitor unit calculation, correct delivery and documentation, have to be verified and listed prior to the second treatment.

□ Radiation therapy critical reporting system

Following discussions with relevant professional bodies, a working group comprising members of the Swiss Society of Radiobiology and Medical Physics (SSRMP) and the Swiss Association of Radiation Oncology (SASRO) was brought together to analyse future cases and propose measures in order to avoid future incidents. This group has been working on a CIRS (Critical Incident Reporting System) with the aim of making such a system available to each radiation therapy department in Switzerland. In collaboration with the SFOPH, they have been defining rules and content of this national CIRS database called ROSIS_CH. One issue specific to Switzerland relates to the use of different languages in different areas and it is planned to include the ability to enter the text of the input in the local language in the local expandable database with a translation to the different languages appearing in the national database, thus avoiding speculations about the source of the data. It is hoped the system will be available sometime in 2008.