

> Experience feedback

Focus on an event notified to ASN

March 2020

Choice of dose calibrator preset

In 2019, errors in the choice of dose calibrator preset when preparing radiopharmaceutical resulted in the administration of incorrect activities doses and the overexposure of several patients.

The experience feedback from the two centres concerned by these events is shared to prevent that type of errors

> The significant events in brief

Failure to verify the dose calibrator preset of the syringe preparation enclosure when measuring the activity to administer for scintigraphic examinations (bone, cardiac and exploration of the parathyroid glands) with technetium 99m, led to the overexposure of 10 patients (up to 1.5 times the prescribed dose).

In another centre, but for the same reason, after the daily dose calibrator constancy check, selection of the wrong radionuclide for the preparation of syringes of 18-FDG led to the overexposure of 7 patients (6.5 times the prescribed dose). In this case the event was not detected until the 8th syringe was being prepared, when the lack of activity in the multi-dose container became apparent.

> Analysis of causes and influencing factors

Organisational and human factors

- > Disruption in the tasks of the operator responsible for preparing the syringes.
- > No verification of the calibration channel after the morning daily check (with the constancy source)
- > Selection of the wrong channel before preparing the syringes.
- > Un-adapted workstation ergonomics.

Technical factors

- > No connection between the dose calibrator and the radiopharmacy management software, preventing the display of alert messages if the wrong radionuclide is chosen.
- > No interface between the dose calibrator and the preparation automaton (consequently, selecting a radionuclide other than the one prepared is not a blocking error).
- > Poor ergonomics (configuration) of the dose calibrator control panel (keys for different radionuclides situated close together and/or of a similar colour, etc.) preventing good visual differentiation.



Barriers

> The medical devices vigilance declarations:

The medical devices vigilance declaration made to the ANSM (French Health Products Safety Agency) enabled the suppliers of the various devices (dose calibrators and software) to be informed so that they can propose solutions to upgrade devices that are not interoperable. The manufacturers have thus proposed interoperable solutions which some centres have already acquired to avoid this type of error.

> Useful actions identified to avoid this error occurring

The solutions presented below have been envisaged by the centres which have experienced this type of event. They are not binding in any way and must only be applied if they seem appropriate and suited to the organisation of a service.

1. Organisational solutions relating to radiopharmaceutical preparation:

- Before starting any preparation:
 - check the connections between the various software programs used in the preparation of the doses to administer: between the dose calibrator software and the shielded enclosure software, between the prescription / radiopharmacy software and the shielded enclosure software,
 - check the selection of the dose calibrator preset (^{18}F , $^{99\text{m}}\text{Tc}$, etc.) so that it matches the prescribed radiopharmaceutical,
 - check the selected pharmaceutical form (vial, syringe, capsule), so that it corresponds to the measurement actually taken.
- During preparation:
 - check the measurement parameters (with or without syringe shield),
 - do not override a dose calibrator alert message: daily quality control noncompliant, displayed activity significantly higher (or lower) than the prescribed activity, etc.
 - limit task disruptions when preparing radiopharmaceutical syringes*
- Following any electrical failure or malfunction that evidences a connection problem, re-check the calibration channels, or even repeat the quality control procedure.

2. Organisational solutions concerning training of the professionals:

- Increase and refresh the training of the professionals assigned to radiopharmaceutical syringe preparation.
- Perform cross-checks (for example radiopharmacist / radiographer / hospital pharmacy technicians) of the choice of dose calibrator, calibration radionuclide and the selected pharmaceutical form (vial, syringe, capsule) before starting the preparations (check-list).
- Tighten the syringe preparation procedures and operating methods (no advance preparation).
- Put in place audits of practices.
- Adapt the ergonomics of the workstation.

3. Technical solutions:

- Examine the possibility of connecting the dose calibrator to the automaton PC (radionuclide selection).
- Examine the possibility of moving the keys of certain radionuclides or disabling the keys of radionuclides that are not used.

*See the Patient safety newsletter "Safety of the radiopharmaceutical circuit in nuclear medicine". ASN March 2020



avec la participation de la HAS, l'IRSN et l'ANSM