Cod: PO198

RADIOPHARMACEUTICALS PRODUCTION: VALIDATION PROCESS APPLICATION

S. Romani[1], L. Lodi[1], L. Uccelli[1], D. Farina[1], S. Bertelli[1], D. Bortolotti[1], E. Govoni[1], S. Zaccaria[1], E. Zappaterra[1], C. Cittanti[1], L. Feggi[1]

[1]Nuclear Medicine Unit, S. Anna Hospital, Ferrara, Italy

BACKGROUND-AIM

The mission of Nuclear Medicine should be to provide effective and time sparing modalities according to validated procedures, complying to regulations issued on the operator, patient protection and quality. Most of the diagnostic nuclear medicine procedures involve the use of radiopharmaceuticals in form of lyophilized obtained from commercial kits, which are reconstituted with radionuclide of interest, usually Tc-99m. High quality and safety standards allow to avoid unnecessary patient radiation exposure and to obtain the best diagnostic efficacy. A pivotal aspect to ensure the product pharmaceutical quality is to keep the radiopharmaceutical at the temperature indicated by the manufacturer. The use of isolators for the production and the presence of heat sources may compromise this condition. The purpose of this work was to apply the validation method of the process to evaluate the impact of storage temperature on the quality of radiopharmaceuticals. The “validation” is the statement of the process ability to provide reproducible results in order to obtain targeted requirements. This certification should be issued after an analysis of the whole process aimed to identify the critical points and the measures to be taken into account to ensure the imposed results, and the tests.

METHODS

The first step was the settlement of the team appointed for the risk analysis: a multi-professional group consisting of 3 Nuclear Medicine Unit operators. The analysis was conducted using the FMECA (Failure Mode, Effects and Criticality Analysis) method applied as follows: mapping of processes; failure modes for each mapped task; definition of priority index of risk (PIR score) i.e. result of the product between severity, probability and detection; analysis of barriers; analysis of causes that break barriers; identification and definition of potential actions and corrective measures able to reduce the risk of error. Each member of the working group evaluated the questions “what can happen?” “what we have to do to prevent the error?”. Then, for each activity, error probability, detection and gravity were scored using standardized scales. The PIR score for each identified failure mode was subsequently calculated. The average scores assigned to each critical phase were calculated for both the near misses and occurred accidents. The phase “Stability of Radiopharmaceuticals” has proven to be the “phase of process” at major risk. All radiopharmaceutical preparations were subjected to a series of quality controls from the time of preparation to the end of the period of stability as defined by manufacturer. The temperature was measured using a calibrated thermometer, and the quality controls were performed as specified by the manufacturer.

RESULTS

The application of the validation method at the process of conservation of radiopharmaceuticals has allowed us to demonstrate the absence of adverse events.

CONCLUSION

The FMECA technique can be effectively adopted before the drafting of the “validation protocol” of a process for the identification of critical parameters to be checked during a validation process.