Cod: PO165

STUDY FOR DEFINING FREQUENCY IN ROUTINE ANALYTICAL CONTROL IN RADIOLABELLING PROCESS

F. Ria[1], F. Ria[1], G. Albini[1], S. Battista[1], S. Valentino[1], R. Messere[1], P. Gandolfo[1], R. Armonino[1], S. Papa[1]
[1]Nuclear Medicine – Diagnostic Imaging Department, CDI Centro Diagnostico Italiano, Milan , Italy

BACKGROUND-AIM

Aim of the study is to define a new frequency criteria in radiolabelling process routine analytical control.
The Italian D.M. March 30th, 2005 (Norme di Buona Preparazione dei Radiofarmaci) requires that quality control must be performed on each preparation. However, the EudraLex Volume 4 EU GMP Annex 17 provides parametric release of the preparation under certain quality conditions. Furthermore, the guidelines PIC/S Guide to good practices for the preparation of medicinal products in healthcare establishments provide as "the extent to which quality control tests are performed should take into account stability information and physical properties and should be defined on the basis of a risk assessment.".
This study defines new criteria on the frequency of analytical controls on radiopharmaceuticals out of kits, also ensures high standards of safety and reduces costs related to quality control and worker exposure to ionizing radiation.

METHODS

Radiochemical purity during the preparation of radiopharmaceuticals out of kits, essentially depends on the following three factors:
• manual skill workers;
• radioactivity concentration in bulk;
• total radioactivity contents in the bulk.
Three hundred and thirty one preparations have been examined, of three different radiopharmaceuticals labeled with Tc99m are (DTPA-Tc99m Pentetate Injection, HDP-Tc99m Oxidronate, Myoview-Tc99m Tetrofosmin for Injection) between September 2012 and August 2013.
On that basis it has been analyzed:
• temporal trends of radiochemical purity values;
• potential correlation between radiochemical purity values and total radioactivity contents of the preparation;
• potential correlation between radiochemical purity values and radioactivity concentration of the preparation.
The worker exposure was estimated with a TLD dosimeter used only during the execution of routine analytical controls.

RESULTS

The analysis shows how there is no relation between percentage of radiochemical purity of radiopharmaceuticals and total radioactivity contents of the preparation and that there is no relation between the radiochemical purity values and radioactivity concentration in the final bulk solution. Moreover, the one year analytical controls executed on each preparation, allowed to determine how the analytical values do not depend on an inter-operator dependency and there is not evidence of particular temporal trends in time.

CONCLUSION

The study allows to determine how it is possible to reduce quality control frequency on the radiolabelling operations without reducing the level of safety preparations. This would substantially reduce costs and worker exposure to ionizing radiation.
Finally, this study may be the basis for risk assessment in order to define the frequency of analytical control in radiolabelling operations.