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RADIOCHEMICAL PURITY QUALITY ASSURANCE ACCORDING TO THE NBP CODE OF GOOD PRACTICE: RESULTS ON 966 SAMPLES DURING THE FIRST 20 MONTHS AND OPERATIVE IMPLICATIONS

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BACKGROUND-AIM

Moving from the analysis of the results in 966 consecutive samples, our aim was to evaluate the “critical points” identified during the radiopharmaceutical preparations applying a systematic radiochemical purity assessment according to the NBP code of good practice, the potential causes of the “out of standard” results and the possible emeliorations.

METHODS

We retrospectively evaluated the daily radiochemical purity quality assurance performed in our department during the first 20 months after the application of the NBP code of good practice (from June 2012 to February 2014). Samples from 966 radiopharmaceutical preparations (10 of 99mTc-DMSA, 306 of99mTc- HDP, 131 of 99mTc-MAG3, 46 of 99mTc-DTPA, 160 of 99mTc-Tetrophosmin, 43 of 99mTc-Sestamibi, 79 of 99mTc-Nanocoll, 93 of 99mTc-Leukoscan, 63 of 99mTc-Lyo-MAA, 35 of 111In-Octreoscan) have been analyzed using Instant an Thin Layer Cromatography (ITLC) procedure, according with the technical modalities suggested by the manufacturer. Moreover, an assessment questionnaire (with 10 difficulty-level steps, from 1 very simple, to 10, very difficult) have been provided to the technical staff, in order to identify the subjective difficulties encountered during the preparations and with the aim to compare objective and subjective results.

RESULTS

7 out of 966 quality controls (0.7%) demonstrated a radiochemical purity lower than the standard value proposed by the technical sheet (5 cases of MAG3 – 4%- 1 case of HDP -0.3%-, 1 case of Tetrophosmin-0-7% -). In 4/5 cases, the MAG3 out-of-references results were related to a drop in temperature during boiling, in 1 case to the presence of air inside the preparation. In the all 7 cases of too-low radiochemical purity value, the labeling was repeated before injection. For all the radiopharmaceuticals, the critical points identified during the preparations were exactly corresponding to the difficulties subjectively declared in the questionnaire by the involved technicians. In particular, MAG3 was considered the more difficult radiopharmaceutical to label, with a “difficulty level” of 7.5; moreover, several critical points have been identified in all the preparation, including the more simple ones. Of course, a daily quality assurance of all the preparations has requested a new schedule in the daily routine organization of the department.

CONCLUSION

In our experience, a systematical assessment of the radiochemical purity before the administration, according to NBP, is essential to provide the better diagnostic information, to avoid an improper irradiation to the patient (due to the injection of a non-optimal radiopharmaceutical) and to perform a better operative schedule in terms of organization and time. Moreover, it’s also essential for clearly define the “critical points” of the preparation, with the aim to further reduce the out-of-references results and also to obtain a reference-point for technicians in training.