Contribution ID: **86** Type: **Oral presentations**

Gallium-68 –a candidate for use in clinical routine

Wednesday, 3 February 2010 11:35 (25 minutes)

The 68Ge/68Ga radionuclide generator (68Ge, T1/2 = 270.95 d) is an excellent cyclotron-independent source for the positron emitter 68Ga which is successfully used in clinical PET. Nevertheless there remain open problems in the routine use related to the applicability of the technique in clinical environment and legal aspects. An effective application of the generator produced 68Ga can be limited by poor chemical and pharmaceutical quality of the generator eluate. Thus traces of metals, as a consequence of the use of metal oxide based matrixes; rather large volume and high acidity lead to suboptimal conditions of the radiolabelling reaction and can decrease the reproducibility in the routine preparation of 68Ga-radiopharmaceuticals. In order to extend the shelf-life of the generator systems, high initial activities of the 68Ge are used. A long-term utilization of the generator systems in non-gmp environment can cause, however, decreasing of pharmaceutical quality and conflict with legal aspects of in-house radiopharmaceutical production. Finally, users face the problem of the generator utilization, since long-lived 68Ge can not be declared as decay waste.
In this context we propose a novel "metal free"68Ge/68Ga radionuclide generator system dedicated for production of high quality gmp grade 68Ga preparations. The concept includes an effective 68Ge management and improved logistic for the routine utilization of the radionuclide generator system in clinical environment.

Please submit a short bio (max 1500 characters)

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Session Classification: Session 2: Radioisotopes in diagnostics and therapy

Track Classification: Radioisotopes in diagnostics and therapy