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Cyclotron production of Tc-99m - radionuclidic impurities profile and compatibility with commercial kits

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Cyclotron production of Tc-99m via Mo-100(p,2n) reaction seems to be viable alternative to Mo-99/Tc-99m generators. It is already known that 1) one cyclotron is able to cover daily consumption of large metropolitan area (up to 1.7 GBq at EOB), 2) target processing and separation of Tc-99m as pertechnetate is more or less solved problem including recycling of Mo-100, 3) enough high enrichment of Mo-100 (> 99.5 %) that reduces formation other Tc radioisotopes to acceptable levels is available, 4) time schedule of the separation and quality control seems to comply with Tc-99m half-life and estimated period of validity, 5) economical aspects of the cyclotron production of Tc-99m do not seem to be as disadvantageous in comparison with reactor-based production of Mo-99/Tc-99m generators as originally thought. Anyhow, there are still several open questions that are thoroughly discussed today. Among them, question of radionuclidic impurities impact on both radiation burden and specific activity of cyclotron-produced Tc-99m plays and important role.

In contrast to generator-produced Tc-99m, cyclotron-produced Tc-99m does not in principle contain any highly radiotoxic and long-lived impurities. However, its production results in formation of technetium radioisotopes, mainly Tc-93 (2.75 h), Tc-94 (4.88 h), Tc-95m (61 d), Tc-95 (20.0 h), Tc-96 (4.28 d) and Tc-97m (91 d). Our recent measurements of their production rates [1] makes possible to predict their relative percentage in the product as function of Mo-100 isotopic composition and irradiation & cooling times. The highest increase of radiation burden is due to Tc-95 and Tc-96. Anyhow, we have estimated total increase of patient radiation burden due to all present Tc radioisotopes in the most widespread Tc-99m-based radiopharmaceuticals based on calculations performed with use of RADAR and ICRP data [2,3]. They clearly showed that radiation burden increase due to co-produced Tc radioisotopes can be in order of a few percents related to administered dose of Tc-99m itself, even for relatively high beam incident energies.

Co-production of long-lived Tc-99g and Tc-98g that is negligible from dosimetry point of view, lowers specific activity of cyclotron-produced Tc-99m. Several authors have expressed misgivings concerning this parameter [4]. We have, therefore, tested many kits for preparing majority of Tc-99m based radiopharmaceuticals for compatibility with Tc-99m prepared by irradiation of Mo-100 with 24MeV protons. We have never noticed any problem with labelling yield or radiochemical purity. It should be noted that slight "carrier-addition" may even improve labelling yield, since substrate is usually present in large surplus (many orders of magnitude) in comparison with chemical amount of pertechnetate.

Quality of cyclotron-produced Tc-99m pertechnetate was tested by established Pharmacopoeia methods, if applicable. In a few particular cases, alternative methods were employed. No significant qualitative difference between cyclotron-and generator-produced Tc-99m was observed. Also quality control of reconstituted commercial kits with cyclotron-produced Tc-99m has shown no difference to generator-produced Tc-99m up to now. Such results strongly support viability of cyclotron production of Tc-99m as daily supply to hospitals both in emergency cases or regularly.

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References

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