

Guidance on the transfer of ^{99m}Tc generator eluates and the sharing of $^{99}\text{Mo}/^{99m}\text{Tc}$ generators between different hospitals

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The strategic report published by ARSAC *A Review of Supply of Molybdenum-99, the Impact of Recent Shortages and the Implications for Nuclear Medicine Services in the UK* outlined a number of recommendations. The aim of this guidance document is to provide advice on Recommendation 7: *'We recommend that the Department of Health, with other government departments and agencies, address options regarding transfer of radioactivity, radiopharmaceuticals and generators between different hospitals, with a view to issuing clear guidance'*.

This guidance is restricted to the two following scenarios:

1. Transfer of generator eluates (from product licensed generators) between Radiopharmacy Units for the preparation of technetium radiopharmaceuticals

This maybe undertaken by Radiopharmacy Units that operate under a) Section 10 exemption of the Medicines Act or b) hold a Manufacturer's 'Specials' Licence for the preparation of radiopharmaceuticals.

2. Sharing of product licensed technetium generators between Radiopharmacy Units of separate NHS Trusts for the preparation of technetium radiopharmaceuticals

This maybe undertaken by Radiopharmacy Units that operate under a Section 10 exemption of the Medicines Act.

The transfer of a product licensed technetium generator by the holder of a Manufacturer's 'Specials' Licence (where there is no pharmacist present) is considered a wholesale dealing activity and would normally require a Wholesale Dealer's Licence. However it is recognised that it would not be practicable for all Radiopharmacy Units (who are unable to operate under a Section 10 exemption) to obtain a Wholesale Dealer's Licence solely for this purpose. If a Radiopharmacy Unit holds a Manufacturer's 'Specials' Licence (and has no pharmacist present) the transfer of the generator would need to involve the hospital pharmacy department so it can supply (virtually) under a Section 10 exemption of the Medicines Act. The physical transfer of the generators can still be from one Radiopharmacy Unit to another, but the responsibility and quality assurance aspects will need to involve a pharmacist to meet the Section 10 exemption.

There should be a risk assessment in place to ensure that adequate controls are in place and that products are adequately labelled, sterility assurance maintained and the transportation arrangements do not present any risk to the product.

This guidance is given specifically in relation to the emergency transfer of licensed technetium generators and their eluates between Radiopharmacy Units for the preparation of technetium radiopharmaceutical kits during a molybdenum shortage and does not cover usual routine practice or planned future clinical services.

In addition his guidance does not cover Environment Agency or other transport issues that may arise as a result of the above two scenarios. The transfer of generator eluates and sharing of technetium generators all carry an increased liability for Trusts and such practices undertaken during a molybdenum crisis must be approved by Trusts.