

Briefing note

Continuing medical isotope shortages – the Environment Agency's position

We are aware of the ongoing problems with the supply of Technetium Generators. The limited worldwide availability of molybdenum-99 and dependence on ageing reactors means that for the foreseeable future the supply of technetium is likely to be problematic with intermittent periods of acute shortage.

There are several measures that hospitals have taken to adapt to the shortage of generators where the permits issued by us may impact. These include;

- The use of alternative isotopes, particularly thallium-201 for cardiac imaging
- The delivery of technetium-99m from another facility instead of a molybdenum/technetium generator
- The delivery of larger generators than normal, possibly incorporating depleted uranium shielding, when these are available

In order to help hospitals implement measures to deal with the shortages and minimise the impact on patient care we have published an enforcement position, outlined below. This is still in place and will continue to guide our approach to enforcement.

Since the enforcement position was written RSA '93 (the Radioactive Substances Act 1993) has been replaced by the Environmental Permitting Regulations 2010 (EPR 2010). Whilst the scope and nature of regulation is largely unchanged environmental permits issued under EPR 2010 will cover both open source use and waste disposal. When an application is made for a new permit or a major variation a consolidated environmental permit will be issued replacing the separate open source registration and authorisation. As in the near future most permit holders are likely to have separate open source registrations and authorisations this terminology is used when describing the enforcement position. Further information on the EPR 2010 can be found at <http://www.environment-agency.gov.uk/business/sectors/32481.aspx>

Enforcement Position

Registrations

We will not take enforcement action against registration holders who choose to respond to these circumstances by keeping an increased amount or range of radioisotopes – beyond that allowed by their registrations. This includes the holding of larger generators incorporating depleted uranium shielding, the delivery of technetium-99m (where the current registration only includes Mo/Tc generators) and the use of alternative isotopes such as thallium-201

customer service line

08708 506 506

incident hotline

0800 80 70 60

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0845 988 1188

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If you are a registration holder:

- You should keep suitable records.
- You need not contact your local regulator unless the change in arrangements is permanent.

Authorisations

We will not take enforcement action against authorisation holders who respond to these circumstances by disposing to sewer an increased amount or range of radionuclides – beyond that allowed by their authorisation – providing that the overall radiological impact of those disposals is not greater than that of the disposals allowed by their authorisation. We would expect that, in many cases, an increase in the disposal of other isotopes such as thallium-201 will be compensated for by a reduction in technetium-99m.

If you are an authorisation holder:

- You should carry out a review of the radiological assessment made in support of your application for authorisation, to determine whether the disposal of alternative isotopes will increase the radiological impact of your site. Where you are able to confirm that there will be no increase in radiological impact you should provide a brief summary of your conclusions to your local regulator - he or she will then write, confirming our approach to enforcement. You need not make an application to vary your authorisation unless this change is permanent.
- Your proposals may mean that you wish also to increase the amount and type of radioactive waste accumulated as well as the time during which you will accumulate that waste. You should review your arrangements to ensure that you can manage this additional waste safely and provide a summary to your local regulator. Their response will confirm our approach to the enforcement of limits and conditions about accumulation.
- Where you propose to increase the solid waste consigned for off-site disposal, and your contractor confirms that they can collect this additional waste you should once again inform your local regulator. He or she will then write, confirming our approach to enforcement on this issue.

This enforcement position is intended to apply when temporary or ad hoc measures are in place. We expect permit holders to resume their compliance with all the limits and conditions of their permits once the period of acute shortage is over. Where a permanent change in arrangements has resulted from the problems with the technetium supply, for example the regular delivery of a higher activity generator or routine use of an alternative isotope, then it would be appropriate to apply for a variation to the registration or authorisation. In this case sites are advised to consult their local regulator. Where a variation is required the local regulator may agree to the above enforcement position whilst the application is determined.

We suggest that permit holders begin now to consider how best their permits and their radioactive material and waste management arrangements might accommodate future interruptions in supply.

Hospitals must of course ensure compliance with other relevant legislation such as the Ionising Radiation Regulations 1999, the Ionising Radiation (Medical Exposure) Regulations 2000, and the Medicines (Administration of Radioactive Substances) Regulations 1978.

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Should registration or authorisation holders wish to discuss this Environment Agency response to the shortage of medical isotopes, they should contact: Kate Griffith - RSR Technical Specialist (0115 982 8384)

Bob Russ

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Environment and Business

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