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Title: Anomalies and challenges of the IAEA regulations that effect the transportation of radiopharmaceuticals

Charlie Carrington, Distribution Manager, Quality and Transport Regulations, GE Healthcare
Eugenie Roelofsen, Transportation Compliance Manager, Covidien Pharmaceuticals
Members of Association of Imaging Producers & Equipment Suppliers (AIPES) Transport Group.

Abstract

The IAEA regulations have since their inception ensured that the transport of radioactive material is safe. This is testified by the number of packages that are transported annually with no problem and with no safety issues to the public.
As the IAEA regulations have been updated to take into account changing technology and policies e.g. Quality Assurance, some of the older redundant requirements have not been removed.
One case is exclusive use shipment limits for normal radioactive material. For radioactive material the Radiation Protection Programme (RPP) covers the requirements for dose control to workers and to the general public. When the RPP was instigated within the modal regulations, the exclusive use requirements stayed as they were; they were originally in place as a simple protection programme to the workers and the general public. Now that the RPP has been in place for a number of years, the exclusive use limits to vehicles carrying normal RAM should be removed for conveyances. In some countries the exclusive use limit is used as a limit per vehicle and this can cause problems with the distribution of radioactive material.
The need to limit the Transport Index per road vehicle is not required as the vehicle dose limits must be measured and be within the regulatory requirements. Revoking this requirement would allow more flexibility in moving RAM, improve utilisation of vehicles and be more environmentally friendly.
The other change that would help the industry, help it to be greener with packaging and have no detrimental effect to the safety in transport is a review of the 20% increase in radiation level of any external surface for Type A packages after testing, paragraph 646 (b) TS-R-1.
This in reality is easy at high dose rates, for instance if the package has a starting surface dose rate (SDR) of 1500 μSv/h 20% is an increase of 300 μSv/h. At low levels SDR say 2 μSv/h the increase is 0.4 μSv/h, extremely difficult to measure. Our suggestion is that the SDR should be limited to an increase of up to the category level for Cat I and Cat II packages and 20% for Cat III packages.

AIPES

This paper is presented on behalf of the transport working group of the Association of Imaging Producers and Equipment suppliers (AIPES) http://www.aipes-eeig.org . AIPES is the trade group for the major radiopharmaceutical producers in Europe and the major equipment suppliers used in this branch of medicine. AIPES has several working groups for the promotion of nuclear medicine and molecular healthcare. These working groups include:

- The Nuclear Medicine awareness working group
- the reactor and isotopes working group (this includes associate membership of the main research reactors around the world)
- the regulatory affairs group that monitors regulations pertaining to drugs
- the new technologies working group

- the transport working group

The last two years, 2009/2010, have been difficult with supplies of Molybdenum 99 being in short supply due to breakdowns and essential maintenance of the aging major research reactors. Technetium 99m is the daughter nuclide of Molybdenum 99. The Tc-99m when mixed with inactive material is used routinely within medicine as a diagnostic tool for the diagnosis of cancer or differentiation of different diseases that present the same symptoms. This shortage and disruption in supply has meant big challenges for the manufacturers to ensure deliveries to the end customer, ultimately the patient. AIPES has taken the lead in ensuring that the supply worldwide has been shared evenly, even when the production only met approximately 10% of the world weekly requirement.
The AIPES transport group was set up to produce minimum standards for the radiopharmaceutical industry when preparing packages and transporting radioactive material by all modes. The AIPES transport group interfaces with European Union Standard Working Group, the World Nuclear Association (WNA) and AIPES also have contact with Council on Radionuclides and Radiopharmaceuticals (CORAR) the US equivalent to AIPES. We have worked with these groups on topics such as the regulations, and denials of shipments.

The AIPES transport group have looked at the regulations and have two suggestions to help improve the transport of radioactive material with we believe no loss of safety.
The first is the exclusive use requirements for radioactive material; these requirements have been in the regulations for some considerable time and certainly pre-date the requirements for the Criticality Safety Index (CSI) and for Radiation Protection Programmes (RPP). When the CSI and requirements were introduced into the TS-R-1, the exclusive use tables for TI and the CSI were split into Table 9 for TI and 10 for CSI. With the advent of the RPP the exclusive use requirements do not seem to have been reviewed for conveyances and the TI limits are still in place. We are only talking about the limits set out in Table 9 all the other exclusive requirements should stay. Reasoning behind our statement is that since the advent of the RPP the carriers with the manufacturers have worked to reduce the doses received in the delivery of radioactive material. At the same time the dose requirements in Europe have been changed with the maximum allowed dose reduced from 50mSv to 20mSv/year.

To help reduce doses, the manufacturers have changed package designs to get the optimal activity against the shielding requirements with the minimum weight. This also helps with handling. Some of the changes made by the manufacturers for ease of handling has had knock on effects for the reduction in dose. For instance the minimum size for a hazard labelled package is 10 cm (paragraph 634) but to allow for the printing of the hazard labels and the labelling horizontally on the package with the label has meant that the minimum package size is actually15 cm, this has a dramatic effect on the surface dose rate of the package against the 10 cm minimum size. It has also been noted that the larger packages are less likely to be fully run over if dropped off a pallet.

Typical size of package that ensures label is on horizontally

The carriers have also changed the systems they use to carry radioactive material. For example, in small vans some of the carriers will add lead shielding behind the drivers seat and ensure that the loading is to the rear of the vehicle. If the carrier handles large number of packages they have shielded areas for sorting and preparing packages for onward shipment. For road transport loading, carriers will have mechanical means for moving pallets of packages without the need to have manual handling. This is also so with the air industry with packages loaded into unit load devices for loading onto aircraft by mechanical means. All these improvements and the requirements of the RPP have helped reduce doses to the transport workers with the(?)same TI going through the system.

Photo examples of radiation protection system for vehicles

Lead shielding in vehicle plus physical restraints across the rear wheel arches.

Slide out system for holding packages.

Lead shielded articulated lorry trailer with adjustable load bars.

When reviewing the regulations the AIPES Transport group asked the question is Table 9 now redundant? The 50 TI limit appears to come from 567.1 (a) using theoretical doses from a load of 50 TI. Freight containers and vehicles must meet the regulatory limits of 2mSv/h on the surface and 0.1mSv/ at 2 metres irrespective of the total TI, therefore the TI has now no bearing on the doses from the vehicles or containers.
The carriers used for the transport of radioactive material as well as having the RPP also have to be trained. Part of this training has to be for radiation protection and therefore loads above 50 TI will not cause problems to the handlers unloading the vehicles or freight containers. However, these limits can cause problems with transport. Some countries licence limit vehicles to 50 TI irrespective of size, this can mean a number of vehicles on the road rather than one. Paragraph 573.6 in TS-G-1.1 allows carriers to consolidate and become the consignor, this in reality is only a paper exercise and can lead to confusion. The segregation distances for air and sea take into account the TI and therefore the exclusive use limits are not required.
The AIPES transport group ask the IAEA that Table 9 exclusive use be reviewed in light of the RPP, we believe that the removal will have not be detrimental to safety .

The second is the 20% increase in the surface dose rate after testing as paragraph 646 (b) in TS-R-1. This can cause problems with packages that would normally fall into the two lower categories of I or II. The radiopharmaceutical industry would like to move away from expended polystyrene and other plastics to cardboard spiders or paper moulded formed inserts to hold the inner packaging. The regulations as written now will not allow an increase of dose above 20% on the surface of the package after testing.
For a 15cm square package, a shift of the source from the centre of the package of 7mm will give a surface dose rate (SDR) increase of 20%. For 30cm square package the shift of the source from the centre is about 14mm for a 20% increase on the SDR. These movements are not much compared to the size of the package.

Meeting these requirements by moving from expanded polystyrene to cardboard or to paper moulded forms gets more difficult with the 9 metre drop for liquid and the penetration test. These tests are much more demanding as during the testing the inner components are more likely to move if using spiders or formers. The inner packaging should still stay within the outer package but the SDR may well be above the 20% increase allowed.
Some theoretical examples are, for a category I package with a SDR of 3μSv/h, a 20% increase in SDR gives and increase of 0.6μSv/h, this is in reality not measurable. For a category II package with a SDR of 300μSv/h a 20% increase in SDR gives an increase of 60μSv/h and no increase in TI, staying at 0.2 due to rounding up.
Our suggestion is that for Category I and II packages the limit should be stay within the SDR of the category +20% at the limit, i.e. 6μSv/h for cat I and 600μSv/h for category II. The inner components of the package must not after testing come out of the outer package. This would give the designer of the package a better chance to design a package for smaller quantities of radiopharmaceuticals and meeting the requirements of Category I or II. The Safety implications would not be reduced as the packages in normal conditions of transport are seldom dropped subject to the test in transport. This would allow better use of material that can be easily recycled and the possibility to move away from plastic materials that are more difficult to recycle.

Conclusion
We would like the IAEA to consider a review of the requirements of exclusive use in light of the introduction of the radiation protection programme. We would also like the IAEA to review the requirements of the pass/fail criteria of packages especially in the I white and II yellow category.