

# Association of Imaging Producers and Equipment Suppliers (AIPES), Transport Group

## Anomalies and challenges of the IAEA regulations that effect the transportation of radiopharmaceuticals

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Association of Imaging Producers and Equipment Suppliers  
Nuclear Medicine and Molecular Healthcare

# AIPES

- European Interest/trade group for the manufacturers of Nuclear Medicine products, equipment suppliers and contrast media for x-ray.
- set up originally due to the constraints of normal pharmaceuticals against radiopharmaceuticals



# AIPES Working groups

- 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

# Recent challenges to radiopharmaceuticals supply

molybdenum 99 shortage due to Reactor availability

Mo-99 daughter product Tc-99m used in millions of diagnostic procedures annually.

- old equipment requiring major maintenance
- new machines not coming on line

**position stable but fragile.**



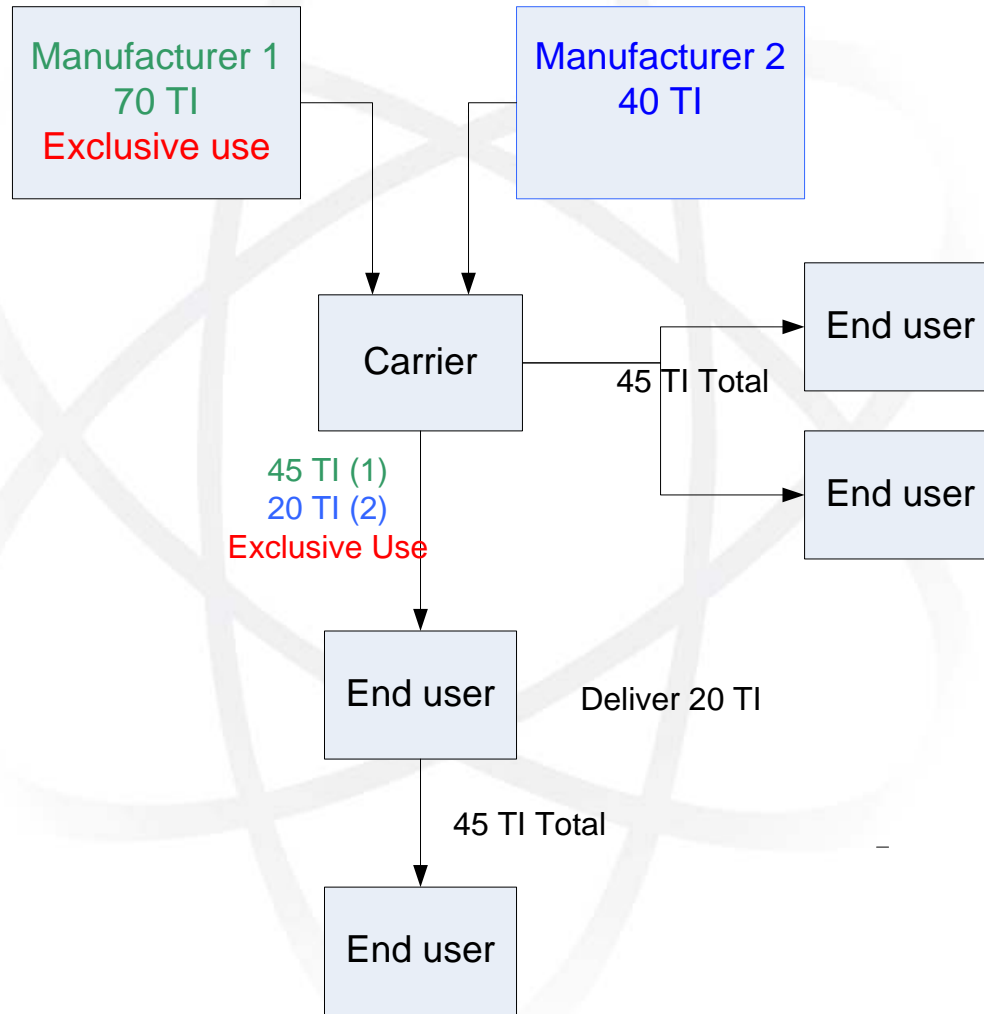
# Exclusive use anomaly?

- exclusive use for TI is in TS-R-1 for conveyances and freight containers
- exclusive use is

*221. Exclusive use shall mean the sole use, by a single consignor, of a conveyance or of a large freight container, in respect of which all initial, intermediate and final loading and unloading is carried out in accordance with the directions of the consignor or consignee.*



# Some of the problems



# Radiation protection programme

- Radiation Protection Programme (RPP) introduced into TS-R-1
- requires a system for control through the transport process
- monitoring of doses and control limits



# RPP does it work?

- by audit within Europe, the doses have been seen to reduce over a number of years.
- in Europe the maximum allowed dose is now 20mSv/a
- mechanical systems have been employed by carriers to help reduce doses
- work by manufactures to help handling





# Bunkers



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# Lead at the vehicle bulkhead



# Control of movement of the load



# Lead lined vehicle, quick load



# Other changes



# Hang on from the old regulations

- need to look at TS-G1.1 para 566.1 (a)

(a) To prevent the creation of higher than acceptable radiation levels as a result of the additive effects of radiation from the individual packages. For consignments not carried under exclusive use, this is done by placing a limit on the total number of TIs. The theoretical maximum dose rate at 2 m from the surface of a vehicle carrying 50 TIs was historically calculated as 0.125 mSv/h, and considered to be equivalent to 0.1 mSv/h since the maximum was unlikely to be reached. Experience has confirmed the acceptability of these values.



# AIPES Position

- exclusive use for conveyances no longer required with RPP in place
- dose limits are in place for road vehicles for surface dose and dose at 2 metres and RPP for drivers dose
- exclusive use is used by some authorities as a conveyance limit, this can cause denials or use of extra vehicles
- segregation distances are in use on conveyance for air and sea mode
- exclusive use to stay for packages (individual package over 10TI)
- **AIPES Transport Group believes the exclusive use requirement for conveyances should be removed, It would simplify the regulations with no decrease in safety**



# 20% increase in SDR after testing

- industry would like to move to more green solutions for packaging, this can be a problem for liquids when dropped from 9 metres or the puncture test.
- 20% increase for the surface dose rate after testing for category I and II packages is in reality a very small increase in dose
- for a 30cm square package it is shift of the source of only 1.4cm



# AIPES Proposal

for Category I and II packages

- should stay within the package category +20%
- inner components must not come out of the outer packaging after testing





Thank you

Any questions?

