EANM Reply to the Radioactive Waste and Radioactive Shipments Directives Evaluation – Call for evidence

As the largest non-profit medical organisation dedicated to nuclear medicine in Europe and bringing together nuclear medicine professionals from a range of medical specialties, the European Association of Nuclear Medicine appreciates the opportunity to give input through this consultation.

Legislation applying broadly to radioactive waste, such as the Directives at hand, should consider the specificities, characteristics and legislative landscape pertaining to nuclear medicine to ensure that the legislative framework governing such products and devices is coherent. Overly restrictive rules could delay patient access, increase the organizational and financial burdens of hospitals without safety gain and slow down the uptake and progression of innovative treatments. In addition, coherence with other EU legislation such as the Basic Safety Standards Directive, the General Pharmaceutical Legislation, and the Medical Device Regulation are required to avoid regulatory fragmentation.

The number of patients eligible for nuclear medicine therapies is expected to increase significantly in the coming years, as is the use across indications. Therefore, hospitals are increasingly using radioactive isotopes for diagnostic and therapeutic applications, with most of the hospital's radioactive waste being generated in their department of Nuclear Medicine. The growing application of radiopharmaceuticals results in an increased demand for efficient treatment and disposal of the associated radioactive waste. Rising concerns about radioactivity have led to increasing awareness about the risk associated with improper management of radioactive waste and the need to implement strategies for safe and sustainable methods of waste disposal.

It should be emphasised that medical radioactive waste is fundamentally different from waste from nuclear energy or isotope production, including in waste volume, the kind of radionuclides, the order of magnitude of radioactivity, and associated risks. Most radionuclides used in medicine for therapeutic purposes have relatively short half-lives (i.e. typically less than 10 days but may be up to 100 days), while most used for diagnostic purposes have completely decayed (i.e. fallen below the exemption limit) in less than one day, latest after a week. Hospitals, therefore, usually segregate waste according to the required decay time. Full use of on-site decay methods should be utilised so that waste can be disposed of at the authorised clearance levels, based on risk assessment. After decay, the waste can be treated as regular (i.e. non-radioactive) hospital waste.

The short half-life and characteristics of medical radionuclides also needs to be taken into account for cross-border shipment requirements, which should remain proportionate to risks present and avoid delays that could compromise usability of radiopharmaceuticals.

It should also be noted that nuclear medicine physicists, physicians and technologists are well trained to appropriately handle radioactive waste management and each nuclear medicine department across Europe follows national rules to ensure its efficient and safe management.

EANM supports high standards of radiation protection, environmental safety and responsible radioactive waste management as well as shipment across the European Union. Any future revision should maintain a coherent, and proportionate framework that is based on an appropriate risk assessment and reflects the specific characteristics of radioactive waste generated in nuclear

medicine and avoids creating unnecessary barriers to the delivery of healthcare and the continued development of innovative radiopharmaceutical applications.

Key recommendations:

- Explicitly recognise medical radioactive waste as a distinct category
- Enable decay-in-storage as the primary approach
- Avoid applying disproportionate transport/shipment requirements to short-lived radionuclides
- Ensure consistency with BSSD and other relevant EU legislation