

Position Paper on the Ban on Lead for the Transport of Radiopharmaceuticals



The European Chemicals Agency's (ECHA) 11th recommendation to include lead metal in the REACH Authorization List* raises significant concerns within the Nuclear Medicine community

While the intention behind such regulations is undoubtedly to enhance safety and environmental protection, it is crucial to consider the potential challenges and consequences that may arise from the implementation of this ban.

*(<https://echa.europa.eu/-/echa-recommends-eight-substances-for-reach-authorisation>)

Key points

- Nuclear Medicine Europe recognizes the urgent need to reduce lead usage but emphasizes the nuclear medicine community's ongoing commitment to **maintaining stringent safety measures** during lead use, ensuring no direct contact with individuals.
- The European Chemicals Agency proposes **banning lead metal**, while raising concerns for the Nuclear Medicine community.
- Lead plays a **crucial role in radiation shielding**, ensuring safety during **transport of radiopharmaceuticals**.
- Existing lead production installations may become obsolete, leading to **delays or shortages, and increased costs**.
- Alternatives pose very **complex practical and economic challenges**.
- Recommendations include **exemptions for nuclear medicine**, advocating for a circular economy, engaging with legislators, and collaborating with patient associations to ensure safety and accessibility.

CHALLENGES AND CONSIDERATIONS

1. Critical Role of Lead in Radiation Shielding

Lead has been a cornerstone material in the nuclear medicine industry for its unparalleled efficiency in shielding against radiation, ensuring the safety of both professionals and the environment.

The ban on lead for transport may compromise the industry's ability to uphold rigorous safety standards during the transportation of radiopharmaceuticals.

Furthermore, a potential ban of lead usage in nuclear medicine and a replacement by other materials may increase complexity of transport and use of radiopharmaceutical products. Ultimately such decision and norms may prevent patient access to a large array of diagnosis and therapies across Europe.

2. Longevity of Existing Lead Installations

Many facilities within the nuclear medicine community have invested in lead-lined walls, machines, and packages, designed to last for decades without posing any risk to individuals. Implementing a lead ban could render these existing installations obsolete, necessitating replacements or modifications, leading to extensive delays in providing radiopharmaceuticals to patients.

3. Impact on Treatment Costs

The prohibition of lead for transportation could lead to drastic increased costs associated with the treatment of patients, as alternatives may be more expensive or less efficient in ensuring the necessary protection during transport.

4. Practicality and Viability of Alternative Materials

Alternative materials such as steel or concrete are often impractical due to their bulkiness, making regular transport to hospitals much more challenging.

Tungsten, while effective, is extremely scarce and expensive, posing economic challenges for widespread adoption in the industry.

Materials like depleted uranium, while having shielding properties, introduce concerns regarding radioactivity, creating a new set of safety, regulatory and environmental issues.

POSITION AND SUGGESTIONS

1. Exception or exemption for nuclear medicine

Given that the use of lead in the nuclear medicine industry accounts for only a small percentage (1 to 2%) of the total lead consumption, we propose that this specific community be granted an exception or complete exemption from the lead ban.

This exception could be based on the industry's commitment to **maintaining and enhancing safety standards** through other means, such as advanced packaging technologies or additional safety measures during transport.

2. Advocacy for a circular economy

The nuclear medicine community actively pursues a circular economy approach, emphasizing **the smart use of lead-containing packages**.

Implementing effective recycling programs for lead-based shielding materials ensures environmental sustainability while mitigating the impact of a potential lead ban on the industry.

3. Engagement with Legislators

Every national association related to nuclear safety must **engage with national legislators** on radiation protection, articulating the concerns and challenges posed by the proposed lead ban. By fostering open dialogue, the nuclear medicine community can work collaboratively with regulators to find practical solutions that balance safety, environmental responsibility, and economic viability for the benefit of the patient.

4. Collaboration with Patients' Associations

The radiopharmaceuticals associations should actively **collaborate with Patients' Associations** to ensure that any regulatory changes do not compromise the accessibility and affordability of treatments.

Inclusion of patient perspectives in discussions can provide valuable insights into the real-world impact of proposed regulations on the patient experience.

CONCLUSION

Nuclear Medicine Europe's Members are committed to prioritizing safety and environmental concerns while safeguarding accessible patient care. Striking a delicate balance between these priorities, Nuclear Medicine Europe remains dedicated to collaborative efforts with legislators, Patients' Associations, and regulatory bodies.

The Nuclear Medicine community's focus on innovation and patient-centric care stand resolute in the commitment to advancing nuclear medicine while placing patients' well-being at the forefront of every decision and action.