

ERPAN Survey of Ra-223 Waste Issues

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Background

- Radium-223 dichloride (tradename Xofigo): used for the treatment of prostate cancer patients with bone metastases
- Radium-223
 - alpha-emitter, half-life 11.4 days, waste easily managed by storing until decay
- Product contains a level of contamination of the parent radionuclide Ac-227
 - beta-emitter, half-life ~22 years
- Nine hospitals licensed for Ra-223
 - One hospital has 106 half filled vials (clinical trials)

Background

- Each vial of Xofigo contains 14 MBq Ra-223
- Max content of Ac-227 at production: $\leq 0.004\%$ per MBq Ra-223 (560 Bq Ac-227 in each vial)
- Actual values are expected to be lower: 0.001% per MBq Ra-223 (140 Bq per vial)
- Exemption limit not specified in 1996 BSS
- UK exemption limit 1000 Bq/0.1 Bq/kg

Summary of ERPAN responses

■ Belgium

- Allows conventional disposal below clearance level (0.01 Bq/g)
- Otherwise waste is considered radioactive and disposed of via NIRAS (Belgian Agency for Radioactive Waste)

■ Spain

- Exemption limits of 1000 Bq or 0.1 Bq/g
- Segregate the Ra-223/Ac-227 waste from other wastes and manage disposal through ENRESA (National Radiation Waste Company)

Summary of ERPAN responses

■ Switzerland

- allow disposal via the conventional sewage system under certain conditions including
 - Exemption limits are not exceeded (weekly released activity concentration in the sewage system of the enterprise is lower than 1/50th of exemption limit (Bq/L))
 - Authorisation from the Federal Office of Public Health

■ Luxembourg

- preliminary arrangement to be reviewed this year
- allow 42 administrations (equivalent of 7 patients) per year and per hospital (4 in Luxembourg) unconditional disposal after 1 year of storage and validation of residual activity.

Summary of ERPAN responses

■ UK

- allow disposal as liquid waste (via the patient or directly to the sink).
- Any activity left in the solid waste (vials, syringes etc.) is considered as VLLW, now exempt waste.

Proposed Irish Approach

- Use (UK) Ac-227 activity exemption limit of 1000 Bq
- Hospitals store Xofigo vials and other waste from Xofigo procedures until complete decay of Ra-223 (minimum of 3 months).
- After the required period of decay for Ra-223, the residual liquid in the vial should be removed by syringe and disposed of via a dedicated sink that links directly to the conventional sewage system.

Proposed Irish Approach

- Ac-227 activity calculated based on the volume of residual liquid and it must be ensured that the exemption limit of 1000 Bq Ac-227 per day is not exceeded.
- Licensees must also obtain prior written approval from the relevant Local Authority as per current licence condition.
- Residual solid waste e.g. empty vials, syringes and other waste can be disposed of as normal clinical waste after the required period of decay for Ra-223.