# Environment Agency permit variation - the use of IRAT2 to evaluate doses to critical groups in a tricky

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#### Background.

The Royal Marsden NHSFT based in Sutton, Surrey, is a large molecular radiotherapy (MRT) centre with an expanding portfolio of MRT clinical trials, thus variations to the Environment agency (EA) permit [1] are increasingly frequent.

The sewage from the Royal Marsden NHSFT Sutton drains to the Hogsmill Sewage treatment works (STW) which then returns clean water to the Hogsmill River (78%) and Beverley Brook (22%). These are both small tributaries of the Thames and this combined with our numbers of MRT treatments can lead to large doses to critical groups resulting in difficulties in the inclusion of additional radiopharmaceuticals to Schedule 3 of the permit.

#### Methods.

A variation of the Environment Agency permit was requested in 2023 to remove Y-90, increase Lu-177, and include Ac-225 for clinical trial work. The Initial radiological assessment tool 2 (IRAT2) was utilised to calculate the doses per annum to critical groups and minimise these by adjusting the aqueous waste limits for other radioisotopes, prior to entering discussions with the EA.

#### Results.

The variation of the permit as stated above would result in an increase to critical groups of 0-22% and an increase of 53% in the river angler family dose for consumption of fish and water, and an increase in the dose rate to wildlife of 50%. The food doses for the angler family and the irrigated food consumer family dose are both above the 20  $\mu$ Sv per annum limit which triggers the involvement of the UK Food Standards Agency in any permit variations.

Thus, it was decided to reduce F-18, Tc99m, Ra-223, Th-227, and the categories: total beta/gamma emitting radionuclides and total positron-emitting radionuclides. Other more commonly used radioisotopes were listed separately such as I-123 and Se-75 on advice from the Environment Agency. This resulted in a reduction in the dose to all critical groups except the farming family dose which had an increase of 41%, and an increase from food consumption of 47%. These were mostly due to the separate inclusion of Se-75, prior to this the contribution to the farming family dose from I-131 was 91%, with the inclusion of Se-75, this was reduced to 65% from and the contribution from Se-75 was 30%. The EA then proposed a reduction in the annual limit for I-131 which resulted in a reduction of doses to all critical groups.

#### Discussion.

IRAT2 is a useful tool to allow the minimisation of doses per annum to critical groups. Actual discharges in 2023 led to much lower dose rates to critical groups than those calculated from the permit limits.

Water sampling and habit studies are a requirement of the RMH Sutton permit. These are performed regularly to ensure discharges are sufficiently low and that there is no change in behaviour of critical groups.

The reduction of the annual limit for I-131, while maintaining the monthly limit, allows the administration of high activity I-131 mIBG treatments to be performed but closer scrutiny of the monthly discharges is required.

#### Conclusion.

Permit variation granted in 2023 thanks to the use of IRAT 2 and the co-operation of the Environment Agency.

#### Key references.

1. The Environmental Permitting (England and Wales) Regulations 2016, UK Statutory Instruments, 2016 No, 1154

# Refinement of IRAT2 – 'Up Sewage Works Creek'

# Aims and background

The Royal Cornwall Hospital discharges via a sewage works on a tidal river.

A proposed change to our discharge limits was evaluated using the Initial Radiological Assessment Tool 2 (IRAT2). This indicated annual doses to Anglers in the region of 1200  $\mu$ Sv (well above the screening criterion of 20  $\mu$ Sv per year) and a sewage treatment works (STW) worker dose of 33  $\mu$ Sv per year. The model needed to be refined to fit reality and ensure that doses to exposed persons were actually (as common sense suggested) below the screening threshold.

# Methods:

The aqueous discharge of P-32 (the main culprit) was reduced by three quarters through the use of annual (as opposed to monthly) discharge limits, but the dose to Anglers was still high at 470  $\mu$ Sv per year.

The model was refined for river flow rate, fish consumption and working behaviour of sewage treatment workers. The first of these involved investigation of the tidal patterns at the discharge point of the STW and conversations with CEFAS (Centre for Environment, Fisheries and Aquaculture Science). IFCA (Inshore Fisheries and Conservation Authority) advised on the consumption of fish by local anglers and finally South West Water kindly engaged with the physics team regarding working habits of their employees. This work also involved various site visits to the picturesque rivers and shorelines (and STW) of Cornwall.

This information was used with the Environment Agency (EA) guidance on IRAT2<sup>(a)</sup> to tailor the calculation model for the specifics of the discharges from the Royal Cornwall Hospital.

### Results:

After extensive finessing, the maximum dose to any person of interest was below the screening criterion of 20  $\mu$ Sv per year.

# Discussion:

IRAT2 is a screening tool and as such is designed to provide a conservative assessment. Making changes to the model is sometimes necessary, however this is not a straightforward process.

### Conclusion:

Awaiting verdict from EA.

# Key words:

Initial radiological assessment tool, IRAT, Environment Agency, Permit amendment

(a) Initial Radiological Assessment Tool 2: part 2 methods and input data, EA 2022 <u>https://assets.publishing.service.gov.uk/media/63528573d3bf7f1943006c60/Initial radiol</u> <u>ogical assessment tool 2 - part 2 methods and input data.pdf</u> accessed March 24

# Revising the Natural Resources Wales (NRW) open source permit for Withybush Hospital: A day (year!) in the life of a budding RWA!

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Environmental legislation exists to protect the public and the environment from the discharge and disposal of radioactive waste. The keeping and use of radioactive materials, and the accumulation and disposal of radioactive waste are detailed in site-specific permits issued by the UK Environment Agencies.

A change of radiopharmaceutical supplier was required at Withybush Hospital due to a planned shutdown of their aging radiopharmacy facility. This change required a review of their Natural Resources Wales (NRW) open source permit in accordance with The Environmental Permitting Regulations (England and Wales) 2016 (2018).

It was necessary to remove Molybdenum-99 (Mo-99) as a Tc-99m generator would no longer be on-site and to add Technetium-99m (Tc-99m) to the open source category. Permit revisions are lengthy and costly so we also revised the Tc-99m and Selenium-75 (Se-75) disposals to sewer. We completed the Environment Agency (EA) initial radiological assessment tool (IRAT2), which assess radiation doses to people and wildlife resulting from proposed discharges of radioactive waste to the environment. The spreadsheet uses pre-calculated dose per unit release (DPUR) factors.

We also updated our Best Available Techniques (BAT) assessment and the summary of arrangements for off-site transfer of low-level waste.

Our application was duly made in September 2023. A draft version of the permit was shared where we had the opportunity to change the wording around the receipt of radioactive waste. This supported our Carriage of Dangerous Goods (CDG09(19) compliance in the event of a transport incident. The permit was successfully determined in November 2023.

#### Radioactive Waste Adviser (RWA) Certification: The long road to success

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Radioactive Waste Advisers (RWAs) are specialists in radioactive waste disposal and environmental radiation protection. The current provision of certified experts within NHS Wales is the lowest in the UK with only four registered RWAs. The need for additional support is everincreasing with the Welsh Government's commitment to develop high quality, effective and sustainable services in Wales as published in their Statement of Intent for Diagnostic Services<sup>1</sup>.

A person wishing to act as such must gain a certificate of core competence from an assessing body recognised by the UK Environment Agencies (RPA2000) and deemed *suitable for appointment* by the employer.

A portfolio of evidence is prepared and must cover both the basic underpinning knowledge for RWAs and demonstration of practical competence and workplace experience. The basic syllabus was covered by attending the RWA Training Course (RWATC) hosted by The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research. They also offered an optional assessment, which was passed successfully.

The practical competence and workplace experience included a chapter publication on radiation safety, waste management and transportation, annual Pollution Inventory (PI) reporting, a permit revision and a radionuclide facility decommissioning report.

The biggest challenge was not having a firm deadline for submission. A portfolio of evidence for the initial certification of competence to be a RWA was finally submitted in July 2023, nearly five years after the RWATC. The certificate of competence to be a RWA was granted in October 2023 and is valid for five years.

<sup>1</sup> <u>imaging-statement-of-intent.pdf (gov.wales)</u>

Radiation Protection Aspects of Radium-224 Diffusing Alpha Radiation Therapy (DaRT) Evelyn Shin, Bethany Gillett, Graham Whish, Cambridge University Hospitals NHSFT

### Background

Radium-224 Diffusing Alpha Radiation Therapy (DaRT) is a novel treatment developed by Alpha Tau Medical. Stainless steel seeds (hollow cylinders) are coated with radium-224 (<sup>224</sup>Ra, alphaemitter, half-life 3.7 days) and held along a suture for implantation as a brachytherapy source. Seeds are delivered pre-loaded in needle applicators, and can be left in permanently or removed after 14 days.

<sup>224</sup>Ra decays via a series of predominantly alpha and beta-emitting daughter nuclides to stable lead-208. However, once implanted in tissue, a proportion of the decaying <sup>224</sup>Ra atoms will recoil from the seed, resulting in the release of unsealed daughter nuclides into the tumour. Unsealed contamination in tissue is likely to be attributed to lead-212 (<sup>212</sup>Pb), as this has the longest half-life in the decay chain (10.6 hours).

This paper will discuss the radiation protection aspects of using <sup>224</sup>Ra DaRT seeds.

# **EPR Compliance**

Each seed is implanted with up to 185 kBq  $^{224}$ Ra at the time of treatment. Most treatments involve the implantation < 20 MBq  $^{224}$ Ra in total.

From clinical trial data, up to a quarter of the implanted activity that reaches the tumour can enter the blood stream where the majority of it will remain. A conservative estimate of approximately 4% of the administered activity is assumed to be excreted as <sup>212</sup>Pb.

The mean activity concentrations measured in blood and urine 96-hours post-implantation from previous patient data were 29.1  $\pm$  19.5 and 6.6  $\pm$  5.7 Bq/g <sup>212</sup>Pb respectively.

<sup>224</sup>Ra and <sup>212</sup>Pb solid waste arising from the therapy may be accumulated until they have decayed to out-of-scope levels or until disposal as very low level waste becomes possible.

Patients may be treated with DaRT as outpatients. Although it is unlikely that seeds will fall out, contingencies should be in place for any loose, or unaccounted for, seeds. When possible, loose <sup>224</sup>Ra seeds should be stored in water in a sealed container and returned to the treating hospital. An environmental impact assessment using the EA's IRAT2 model is needed for the loss of seeds into the environment, e.g. flushed into sewers.

### **IRR Compliance**

External doses are considered from gamma emissions from  $^{224}$ Ra (241 keV, 4%) and  $^{212}$ Pb (239 keV, 44%). A dose rate of 0.5  $\mu$ Sv/h per MBq is expected at 50 cm from the sources.

Rooms used for seed implantation and removal should be designated as Controlled Areas based on the likelihood of contamination from radioactive blood. Written contingency procedures for the loss of seeds should be provided to relevant groups, e.g. theatre staff, wards, and patients.

We have estimated that clinicians implanting and removing seeds will receive less than 50  $\mu$ Sv per procedure, and physicists involved in the assay, source accounting and waste management of <sup>224</sup>Ra/<sup>212</sup>Pb will receive less than 25  $\mu$ Sv per procedure.

Depending on the amount of activity implanted, some contact restrictions may be necessary to ensure family members do not exceed the annual public dose constraint.

### Summary

The use of <sup>224</sup>Ra DaRT seeds is simple and relatively easy to handle. These medical devices are novel with respect to their use as brachytherapy sources but with consideration of unsealed radioactive contamination once implanted.

Key references: AlphaTau Medical communications, 2018-19

Key words: Brachytherapy, Nuclear Medicine, EPR, IRR