$^{224}\text{Ra}$ standardization: radiopharmaceutical perspective

International Workshop on Standards and Measurements for Alpha Emitting Nuclides in Therapeutic Nuclear Medicine
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Radspherin

- **Current status:** clinical phase 2b trials - mid-2024
- Produced and analysed in **Oslo, Norway**
- Delivered ready-for-use to several sites in **Norway, Sweden, Belgium, Spain**, and expanding.
1) The dose calibrators on clinical sites can be of different models and vendors (Atomlab from Biodex, IBC-Lite/VDS from Comicer, VIK from Veenstra, etc.). They are diverse, but very typical.

2) Dial settings in clinics are set under Oncoinvent supervision. According to our standard, “All affirmative measurements should be found within 5% of the decay corrected activity”

3) In practice, the results are within 2,5%.
Calibration standard
Calibration standard
Analytical method: instrument
Analytical method: parameters

- Sample preparation
- Geometry
  - Sample size (volume)
  - Distance from detector
- Counting time
- Sample size (activity -> dead time)
- Interferences (e.g., $^{212}\text{Pb}$)
Analytical method: validation
Analytical method: validation

Quality control

Acceptance criteria:
Coefficient of correlation > 0.990

\[ y = 0.9932x - 7.3235 \]
\[ R^2 = 0.9999 \]

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Possible values</th>
<th>Acceptance criteria</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range, kBq/mL (2 days after HPGe measurements ≈ reference date and time)</td>
<td>502-1189</td>
<td>400-1400</td>
<td>314-1581</td>
</tr>
<tr>
<td>Range, kBq/mL (on HPGe measurements date)</td>
<td>735-1742</td>
<td>590-2090</td>
<td>461-2316</td>
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</tbody>
</table>
Analytical method:
true values – standardization – traceability
Complete chain of production, control and use

Patient

Clinics

Quality control

Production

Standardization

NIST
National Institute of Standards and Technology

NPL
National Physical Laboratory
Questions?