

ANALYSIS OF CALIBRATION DISCREPANCIES IN LUTETIUM-177 RADIOPHARMACEUTICALS IN RADIOPHARMACY

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Introduction :

Lutetium-177 radiopharmaceuticals are used in targeted radionuclide therapies such as the treatment of metastatic castration-resistant prostate cancer and metastatic gastroenteropancreatic neuroendocrine tumors. Although doses are calibrated with a $\pm 10\%$ tolerance, discrepancies between declared and measured activities are frequently observed.

Aim :

Evaluate calibration discrepancies in ^{177}Lu radiopharmaceutical doses between laboratory-reported and measured values

Methods :

Analyze doses of ^{177}Lu -based radiopharmaceuticals of 8 radiopharmacies between January and December 2024

Comparison between measured activity (in MBq) and certificate reference activity



Data collection:

- date/time of calibration
- date/time of measurement
- day of delivery
- date of production
- production site



Results :

N = 1040 vials

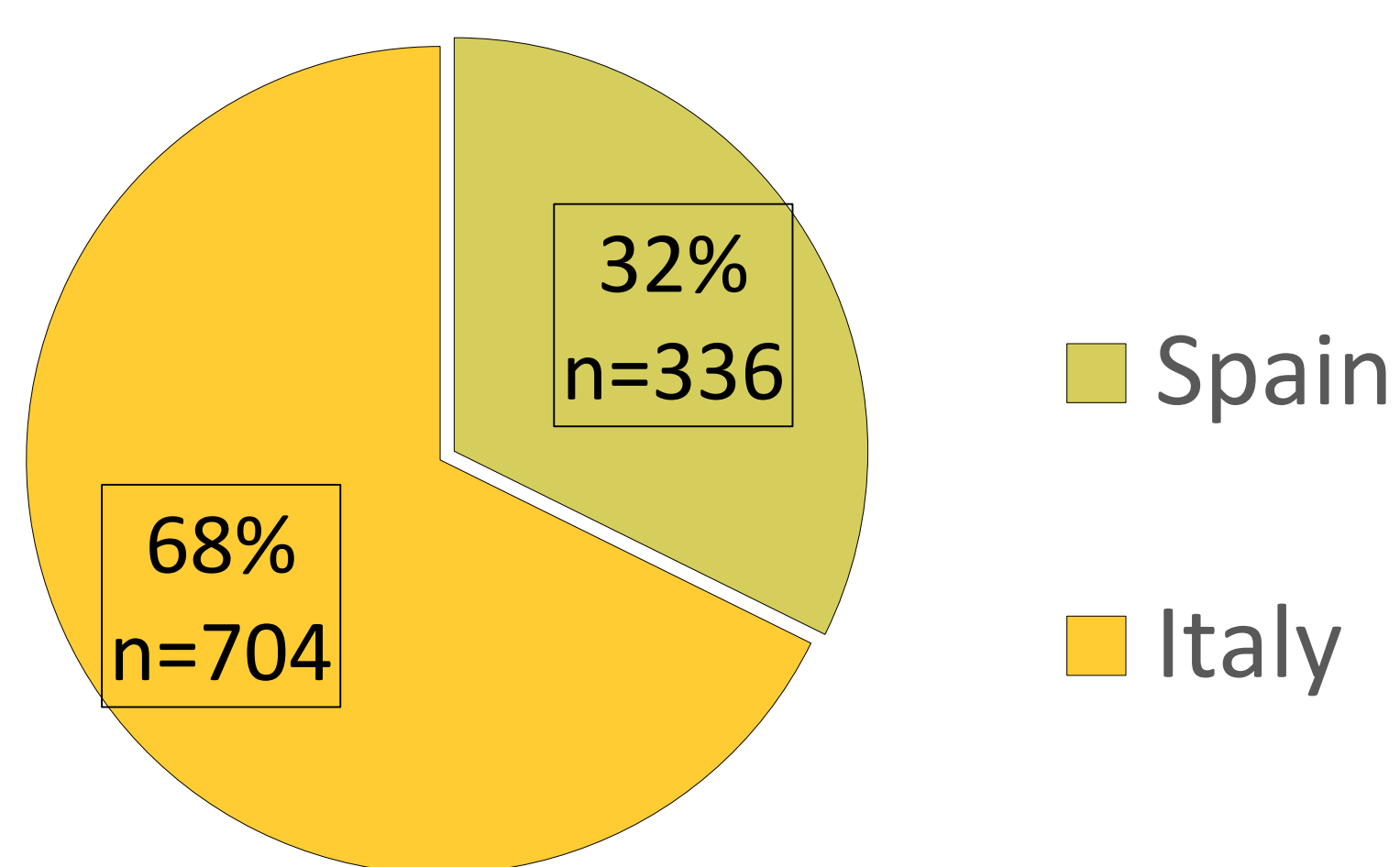
- ^{177}Lu -PSMA n=754
- ^{177}Lu -oxodotreotide n=286

Mean deviation : $-7.2\% \pm 2,9$

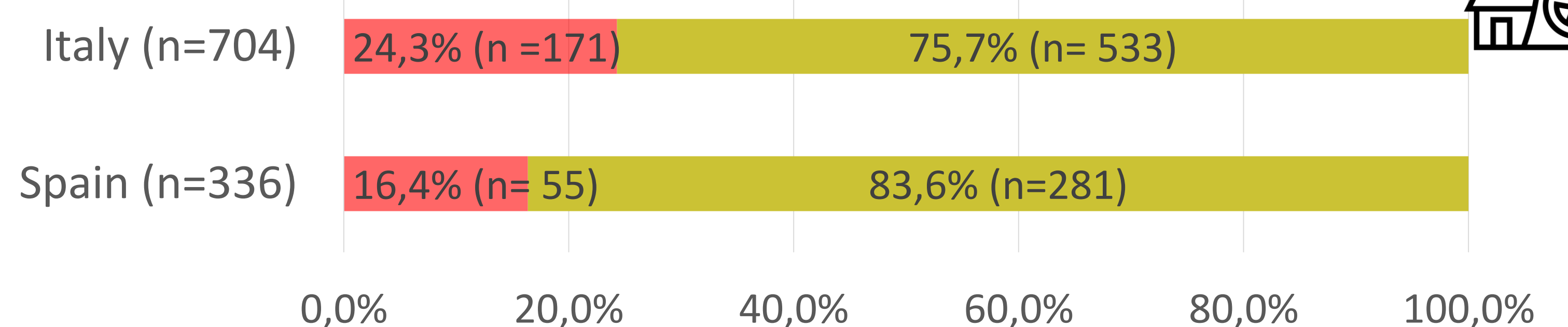
- 21.7% vials calibrated** beyond tolerance of $\pm 10\%$
- 73.8% vials exceeded 5% of deviation



Vial production site



>10% Deviation according to production site



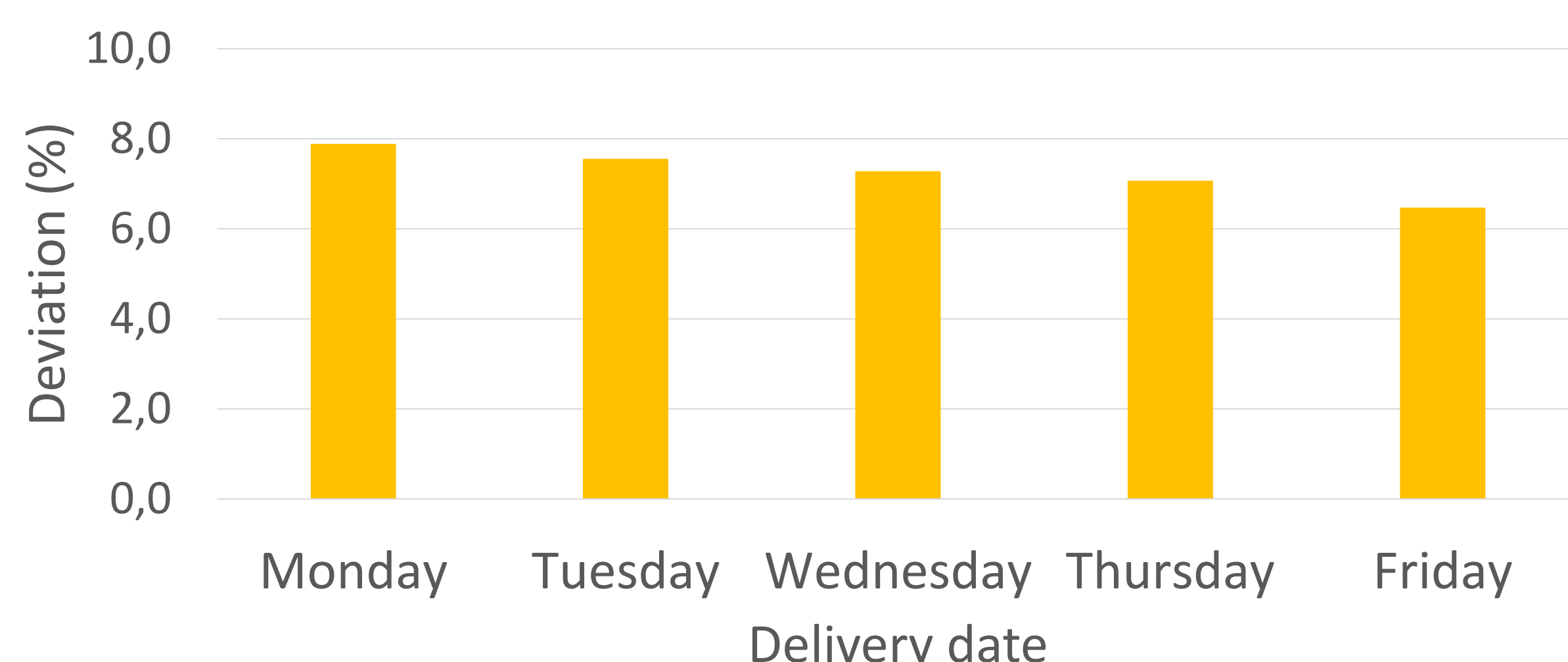
	Spain (n=336)	Italy (n=704)
% vials non compliant	16,4%	24,3%
% vials compliant	83,6%	75,7%

■ % vials non compliant ■ % vials compliant

→ Moreover, 75.7% of vials showing a deviation of more than 10% came from Italy

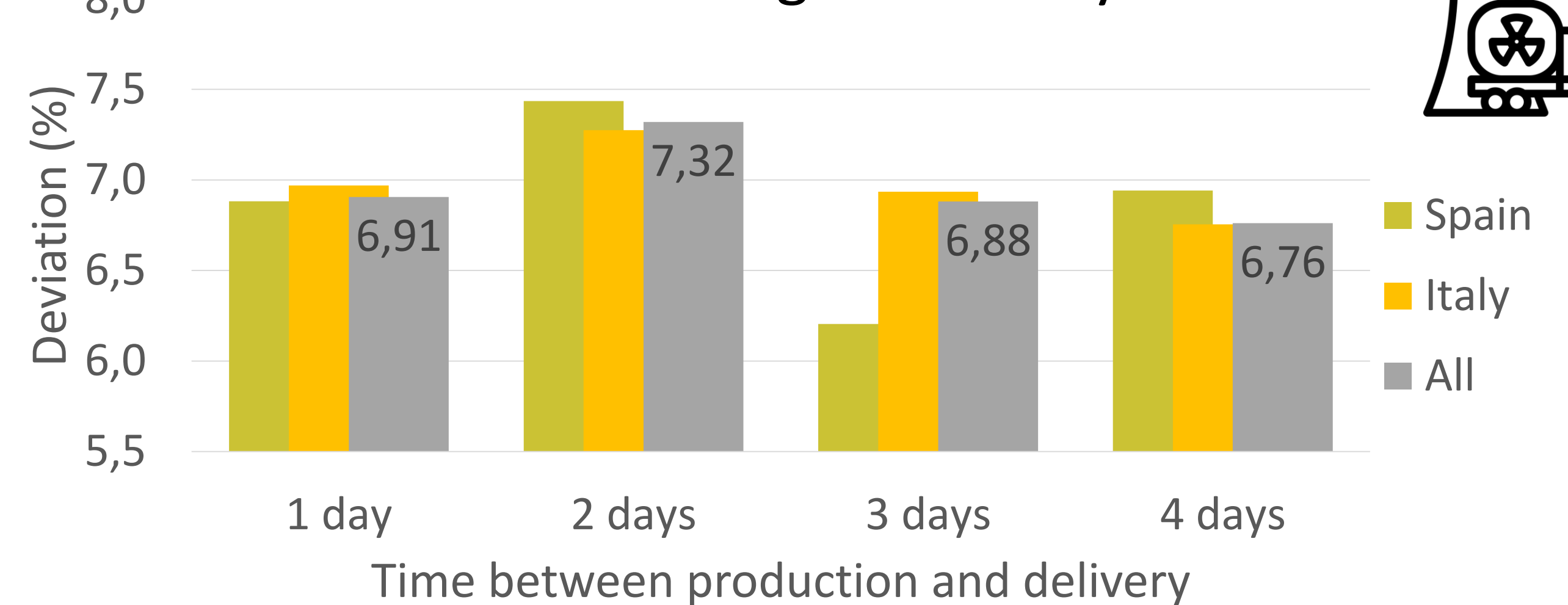


Deviation according to delivery schedules



→ Higher deviation observed for Monday deliveries

Deviation according to delivery time



→ No difference in activity deviation observed according to delivery delay (1-4 days)

Conclusion :

- Most doses remained within $\pm 10\%$ tolerance, but a **significant proportion** of ^{177}Lu doses showed **deviations greater than -5%**
- Both **origin** and **delivery** schedule influenced deviations
- Harmonization** of calibration procedures is needed at the European level

