Comparison of 1R6F and 3R4F Smoke and Tobacco Filler HPHC Means and Standard Deviations

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Reference Cigarettes

- Used for numerous purposes including:

  - Quality control monitors

  - Model cigarette systems

  - Analytical method development tools

  - Interlab study samples

- We used the 3R4F cigarette as our primary quality control monitor from 2015 to early 2021

- Because of limited remaining quantities of 3R4F, we transitioned to 1R6F as our primary quality control monitor in early 2021

- Both 1R6F and 3R4F were manufactured over several days and are subject to normal day-to-day manufacturing variation

  - Analyte levels can be somewhat different on different days of manufacture so comparisons can modestly differ depending on which batches are being compared

Blend and Design Information

Component	3R4F	1R6F
Flue Cured	35.4%	34%
Burley	21.6%	24%
Maryland	1.4%	0%
Oriental	12.1%	12%
Reconstituted Tobacco	29.6%	20%
Expanded FC	0%	7%
Expanded Burley	0%	3%
Glycerin	2.7%	1.7%
Propylene Glycol	0.0%	1.0%
Isosweet (Sugar)	6.4%	6.3%

Characteristic	3R4F	1R6F
Cigarette Length	84 mm	83 mm
Tobacco Rod Circ.	24.8 mm	24.8 mm
Tobacco rod Length	57 mm	56 mm
Filter Length	27 mm	27 mm
Tobacco Weight	0.783 g	0.640 g
Cigarette Weight	1.06 g	0.887 g
Total RTD	128 mm	107 mm
Plug RTD	115 mm	99 mm
Ventilation	30%	30%
Paper Permeability	24 CU	46 CU
Paper Citrate	0.60%	0.60%
Cigarette Paper	Non-Banded	Banded
Manufacture Period	Dec 2006	Mar 2015

Tar Nicotine and CO comparison

	Analyte	1R6F Mean	3R4F Mean	1R6F Std	3R4F Std	1R6F N	3R4F N
Non-Intense ISO 3308	CO	10.0	10.7	0.64	0.61	263	159
	Nicotine	0.72	0.73	0.03	0.03	263	159
	TPM	10.3	10.1	0.43	0.46	263	159
	Tar	8.8	8.5	0.35	0.39	263	159
	Puff Count	7.88	8.32	0.24	0.24	263	159
	Water	0.80	0.85	0.08	0.09	263	159
Intense ISO 20778	CO	28.6	31.0	1.61	1.73	267	160
	Nicotine	2.00	2.00	0.09	0.11	267	160
	TPM	47.9	46.7	2.84	2.73	267	160
	Tar	29.2	28.5	1.54	1.52	267	160
	Puff Count	9.09	10.43	0.38	0.42	267	160
	Water	16.7	16.3	1.51	1.62	267	160

Methods Using 3R4F/1R6F as a Monitor

Filler/Tobacco Methods*	Smoke Methods
Ammonia	Aromatic Amines
Nicotine and minor alkaloids	Carbonyls
TSNAs	B(a)P
B(a)P	VOCs
Metals	TSNAs
Nitrate/Nitrite	

* Filler methods were based on large ground composite samples.

Parallel Testing Scheme

- For smoke runs

  - 2 ports each 3R4F and 1R6F per 20-port linear smoke run

  - Non-intense (ISO 3308) and Intense (ISO 20778)

- For tobacco runs

  - 2 or 3 reps of 3R4F and 1R6F in each tobacco sequence

  - Both fillers were from homogenized batches

- Data were collected for each method for at least 10 months

3R4F/1R6F Filler Comparisons
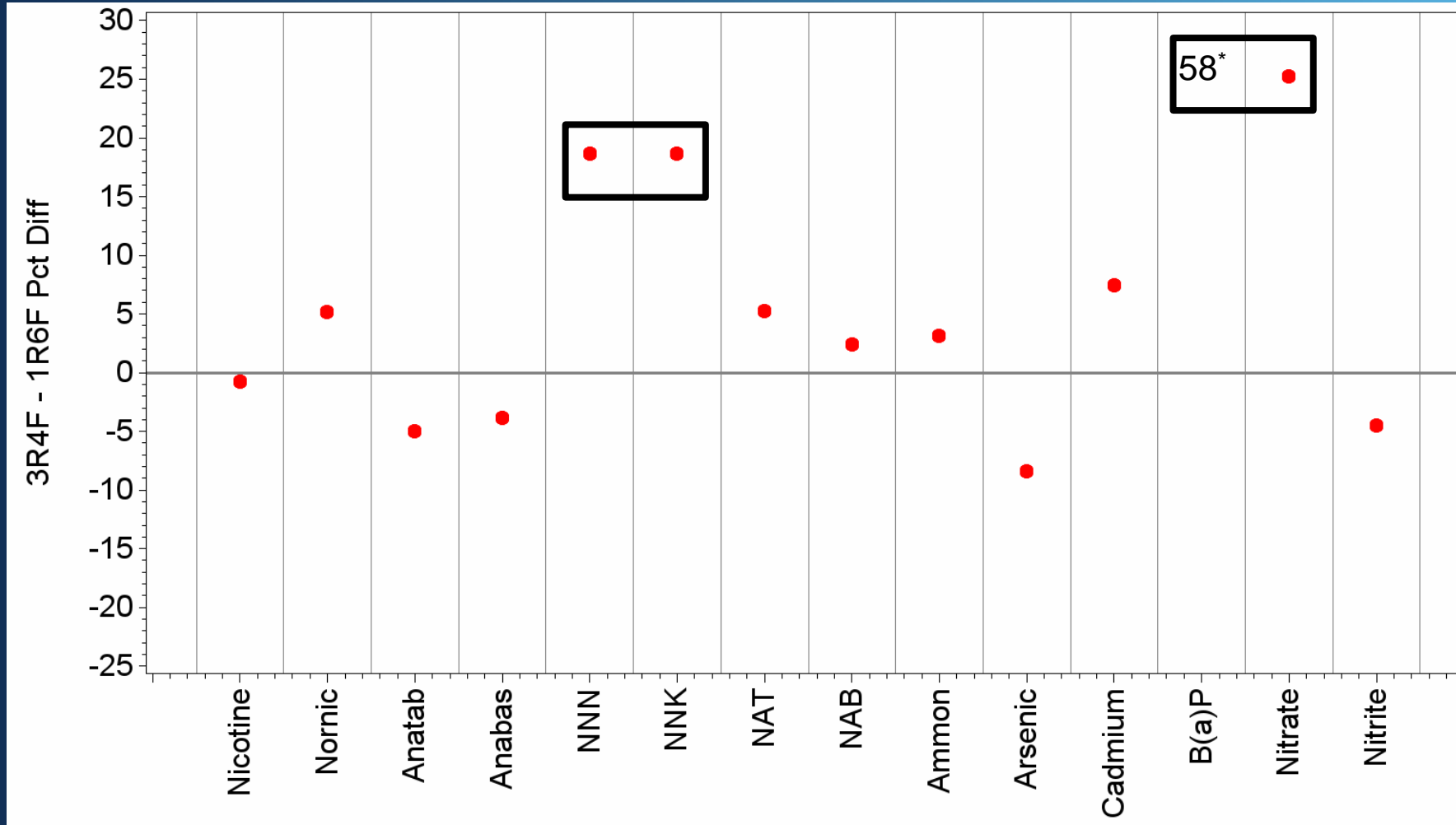
3R4F/1R6F Filler NNN
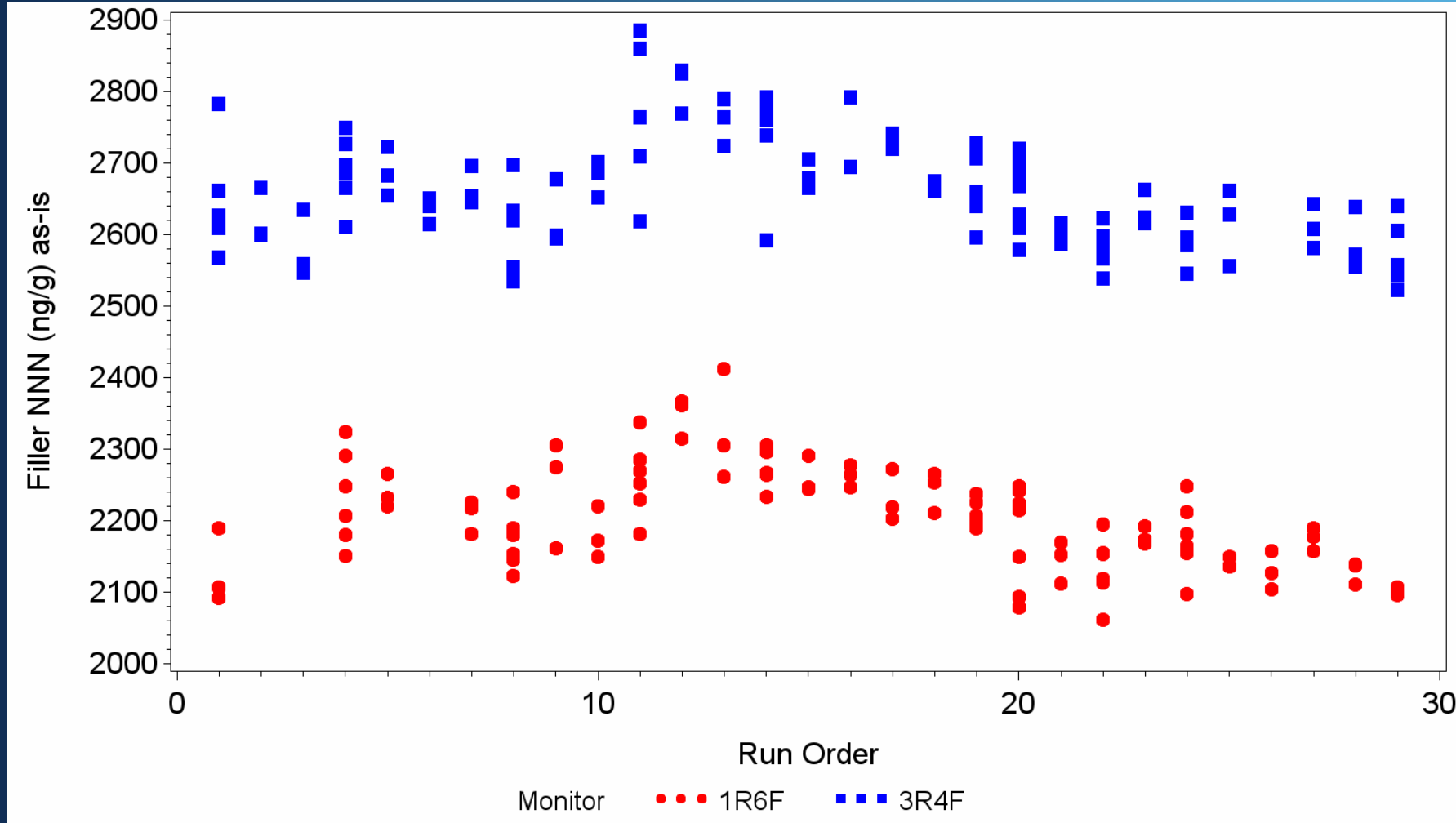
The cigarettes were made more than 8 years apart and TSNAs are known to show large year-to-year variability.

3R4F/1R6F Filler Nicotine
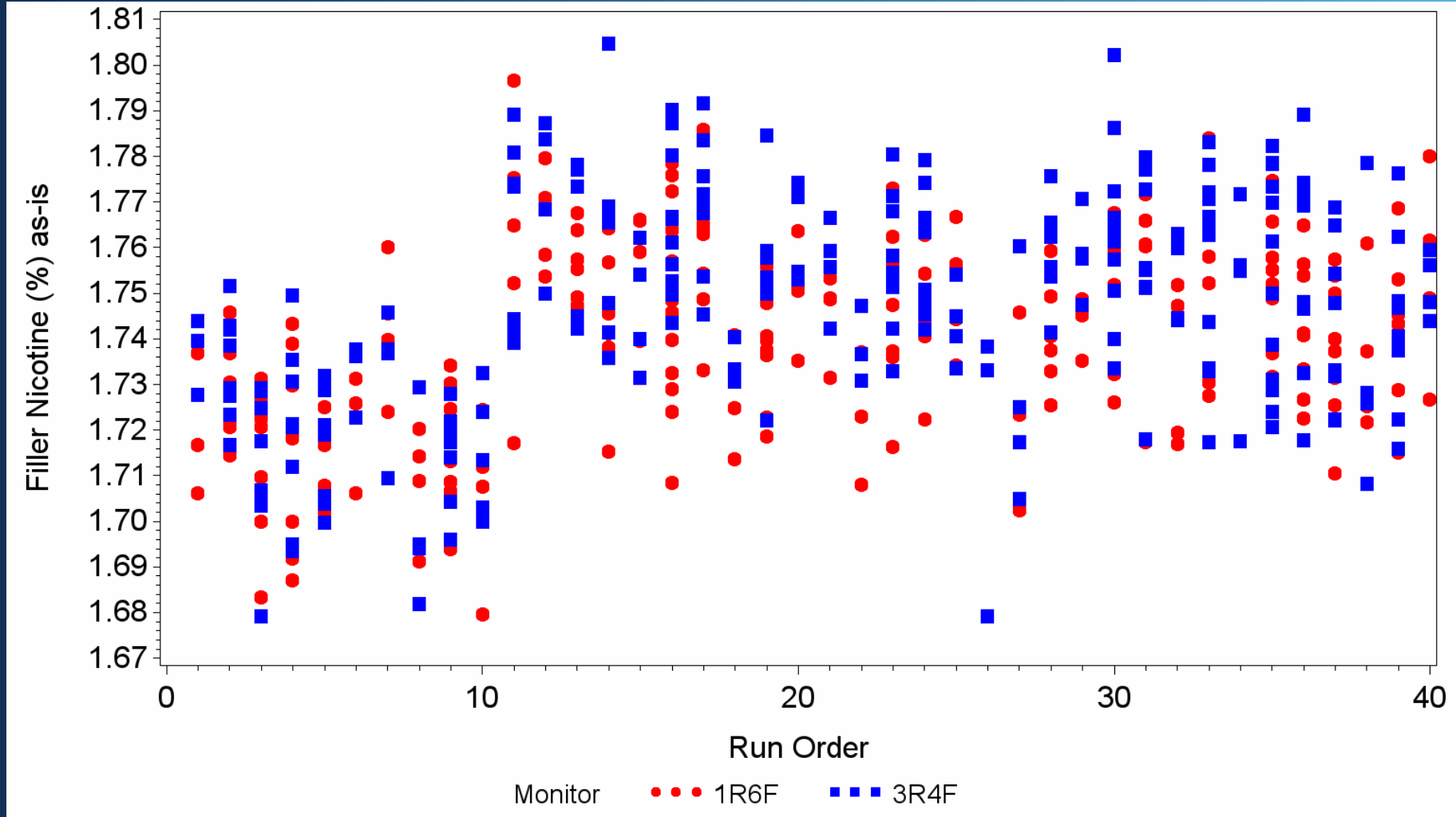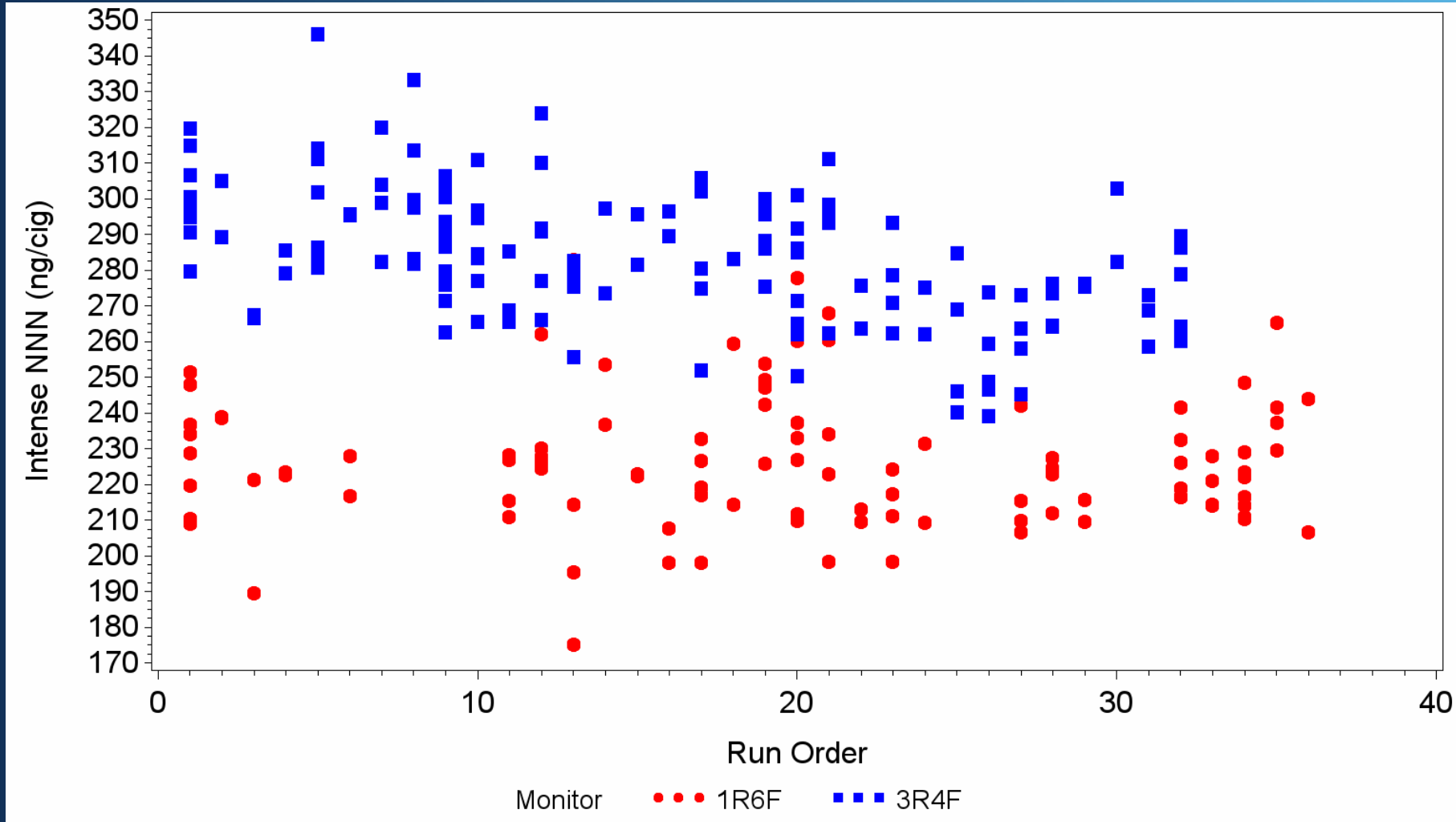
3R4F/1R6F Filler B(a)P
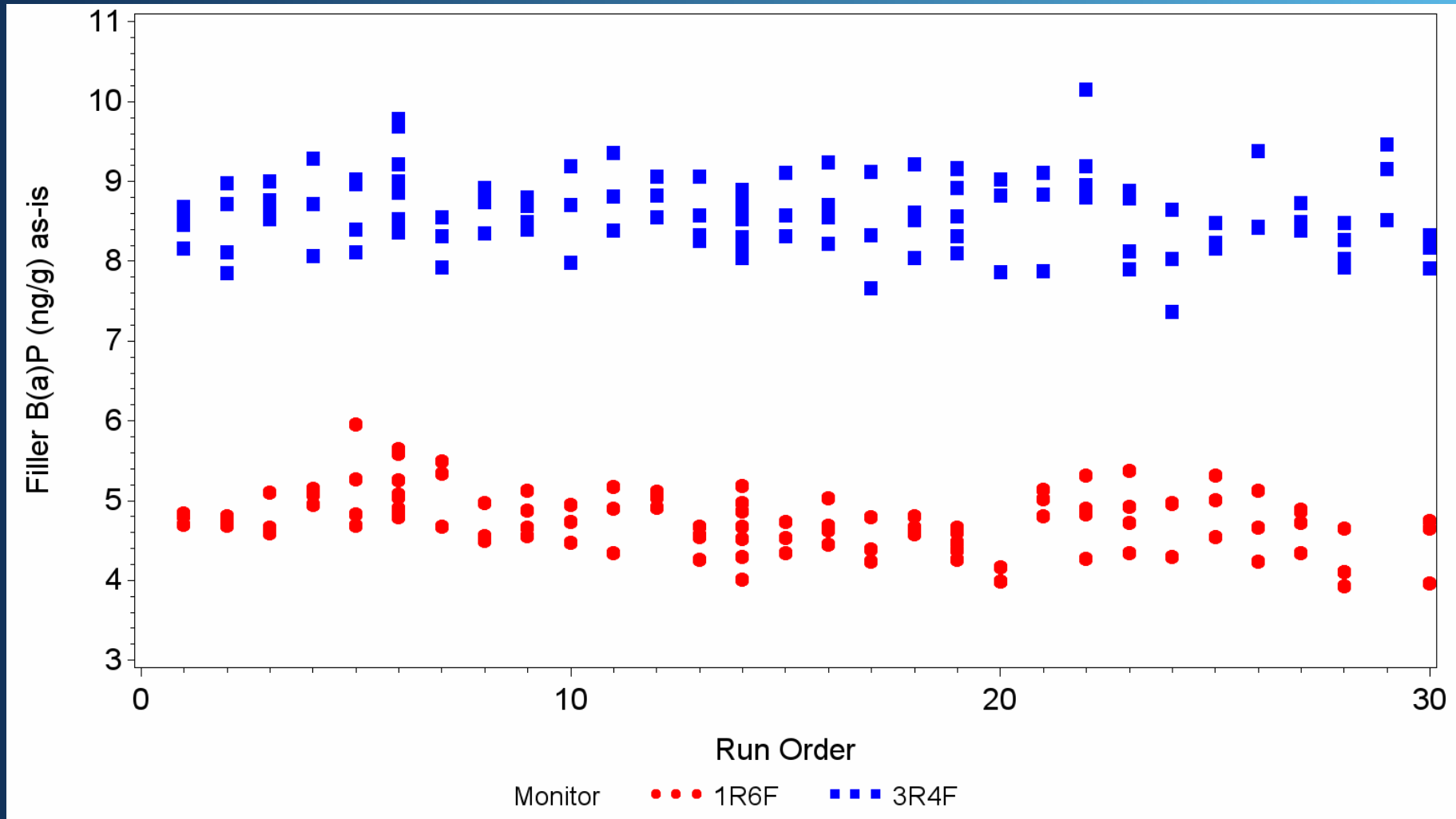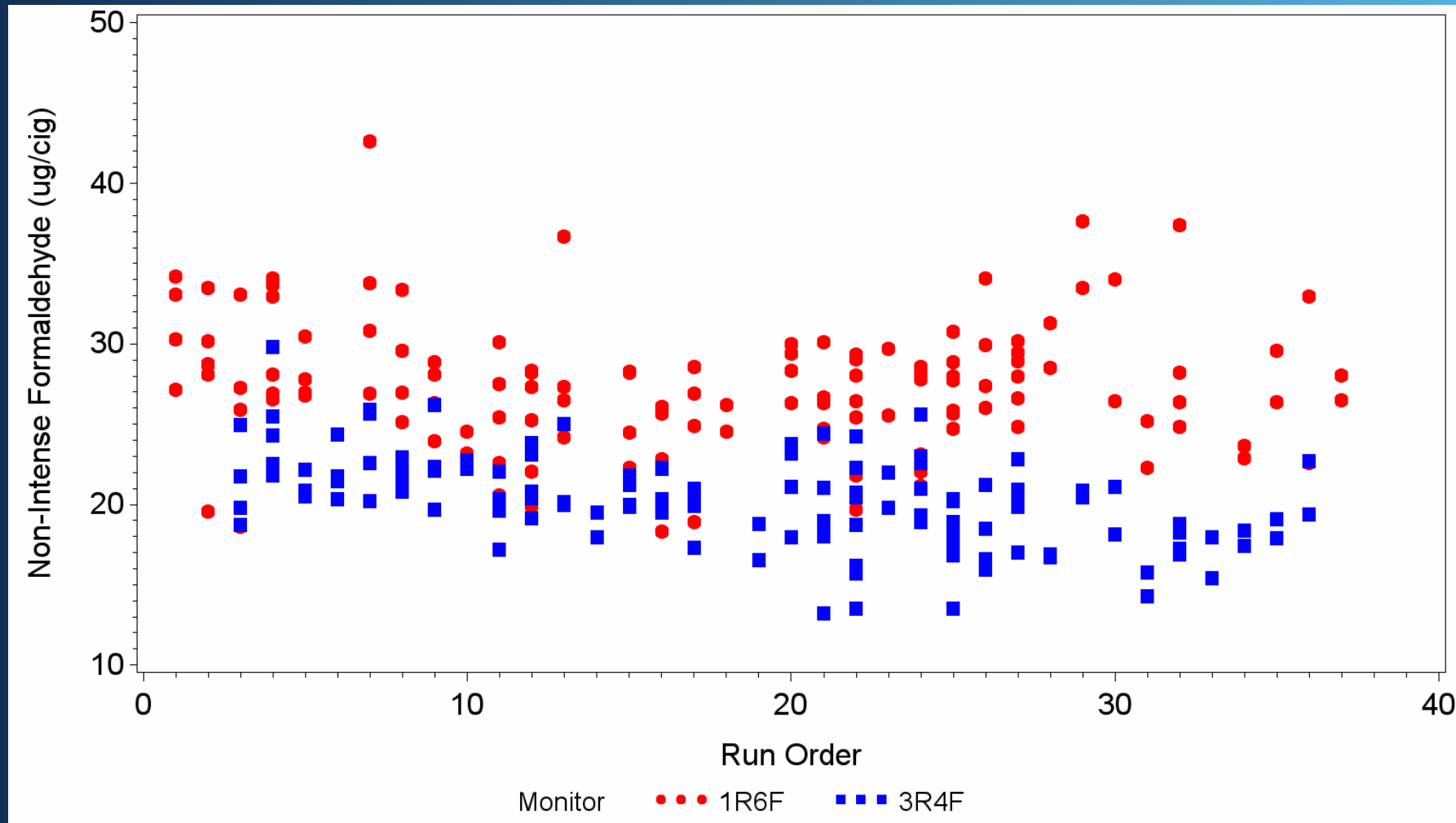
3R4F/1R6F Smoke Comparisons
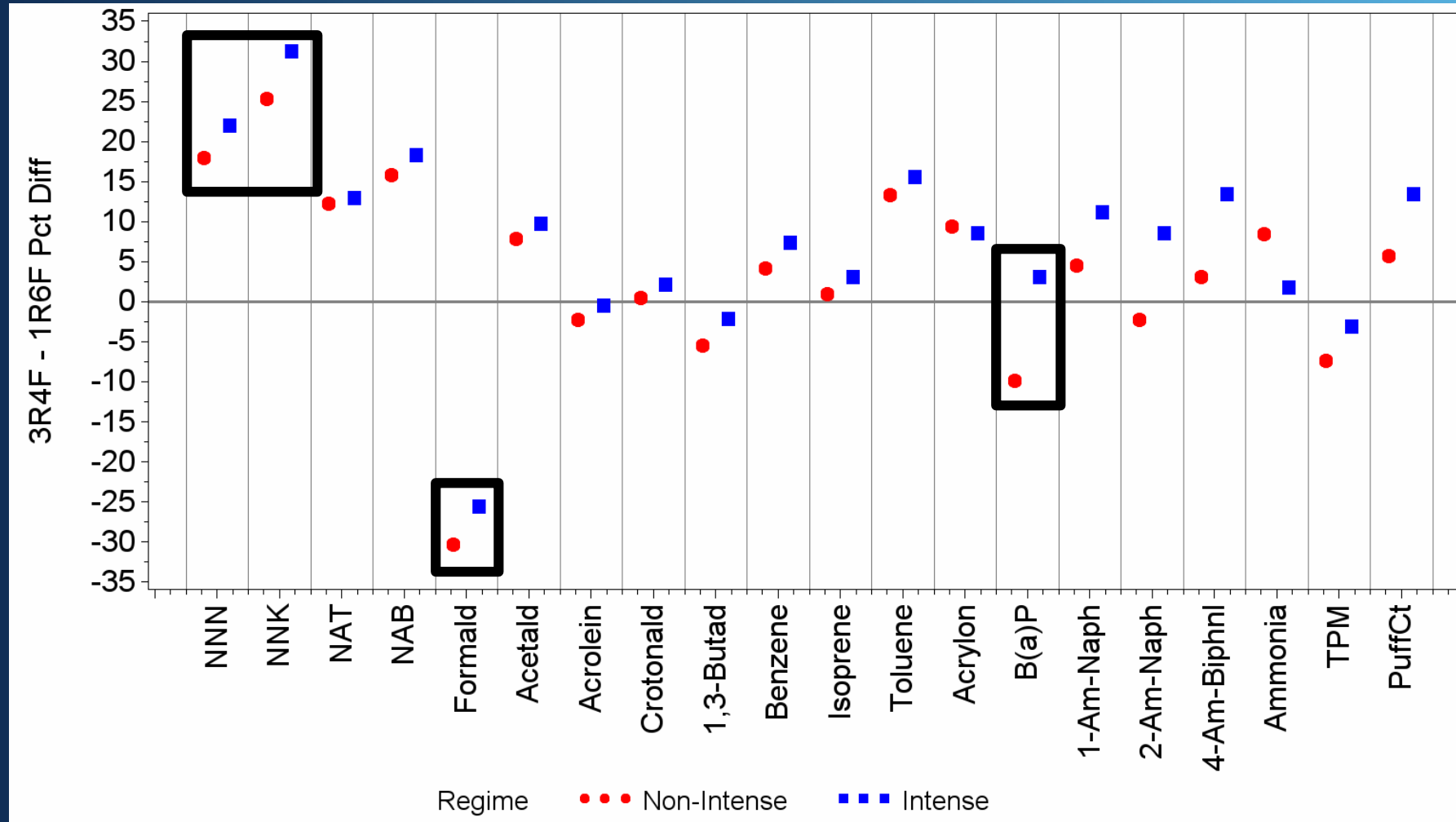
NNN and NNK show a similar trend as was seen with the filler

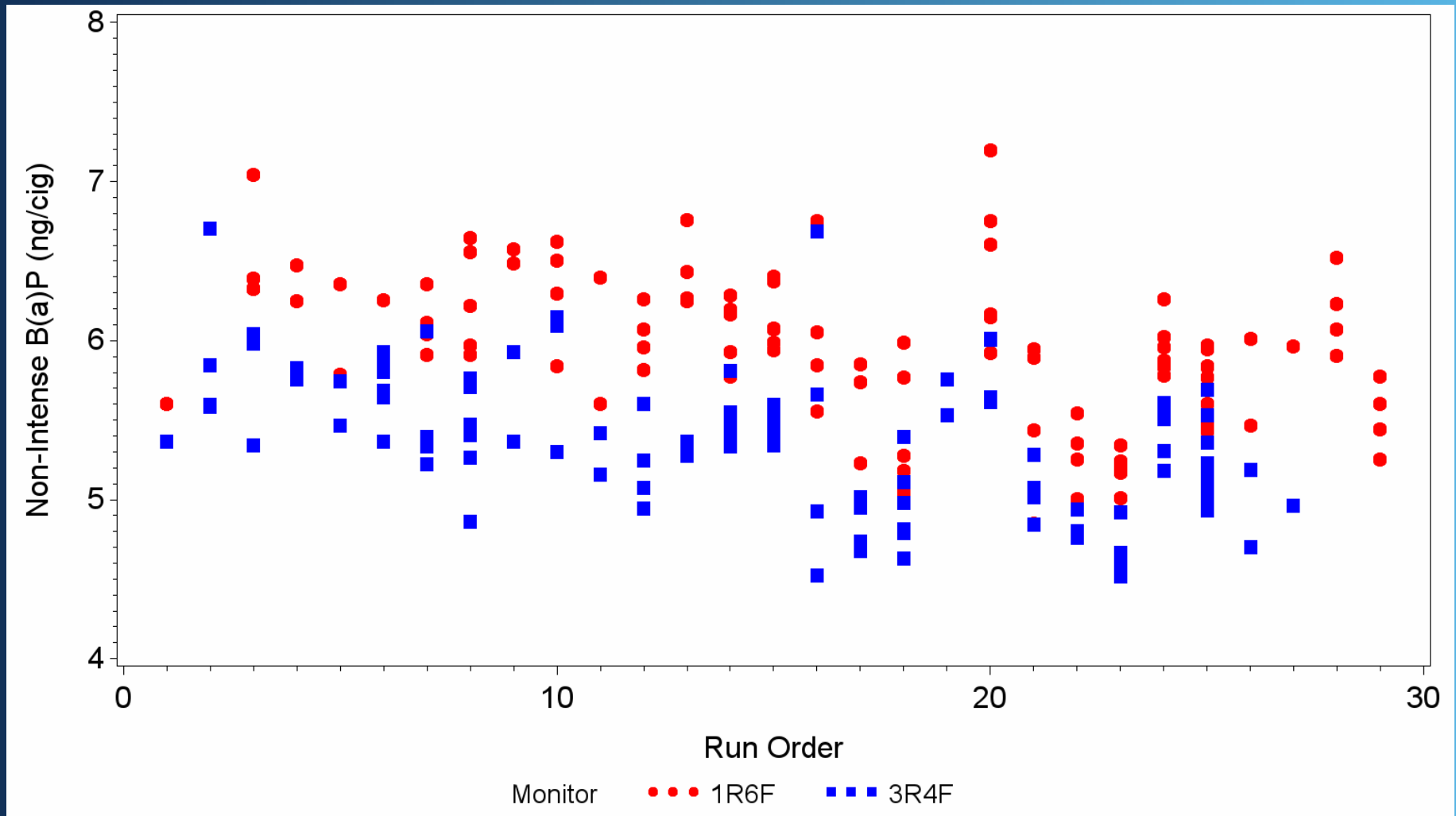The B(a)P difference is small despite the filler differences
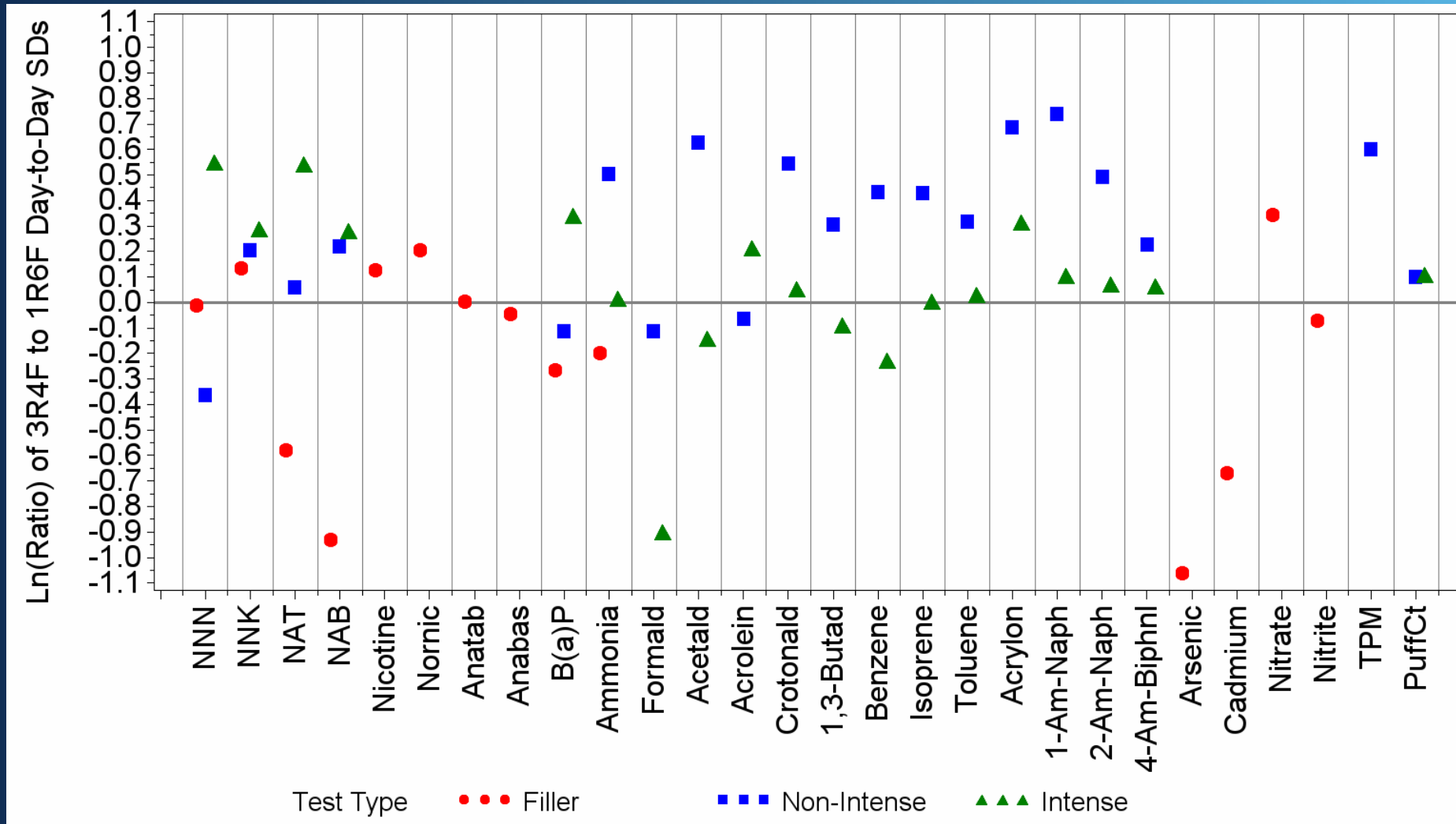
NNN in Smoke – Intense

Formaldehyde – Non-Intense

B(a)P – Non-Intense

Day-to-day Variance Comparison

3R4F shows slightly more variability in non-intense smoke results

Overall, there is not a statistically significant difference in variability

1R6F Certified Values

- 1R6F has certified values and certified uncertainty

- The uncertainty around the certified values is intended to represent 95% confidence intervals around the _mean value_

  - The uncertainty is not intended to represent a 95% prediction interval for <u>individual test results</u>

- The <u>long-term average</u> of results in a lab should normally be within, or very near, the confidence interval, but <u>individual results</u> would be expected to sometimes fall outside the confidence interval

1R6F Averages Compared to Certified Values
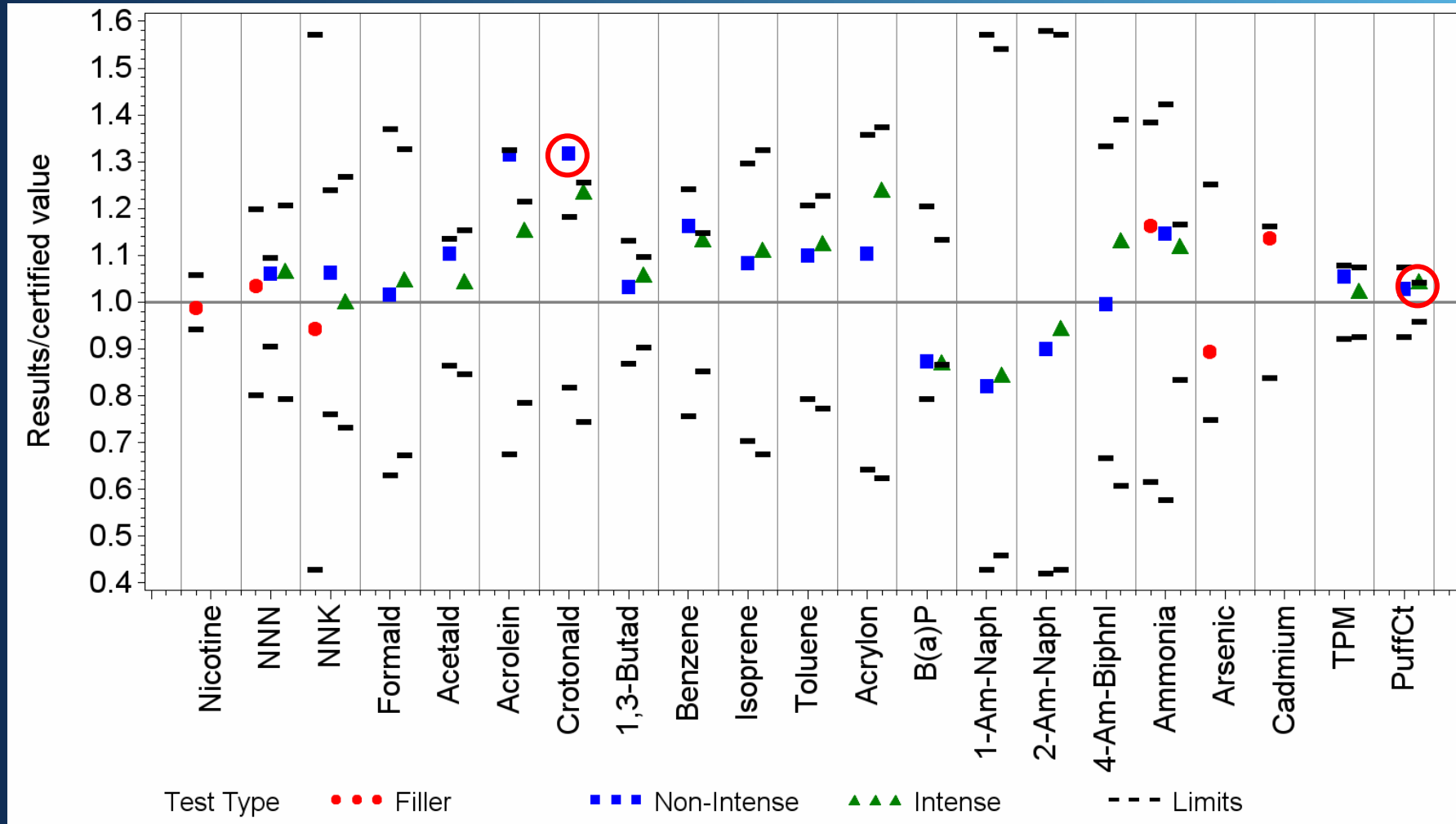
1R6F Individual Results Compared to Certified Values
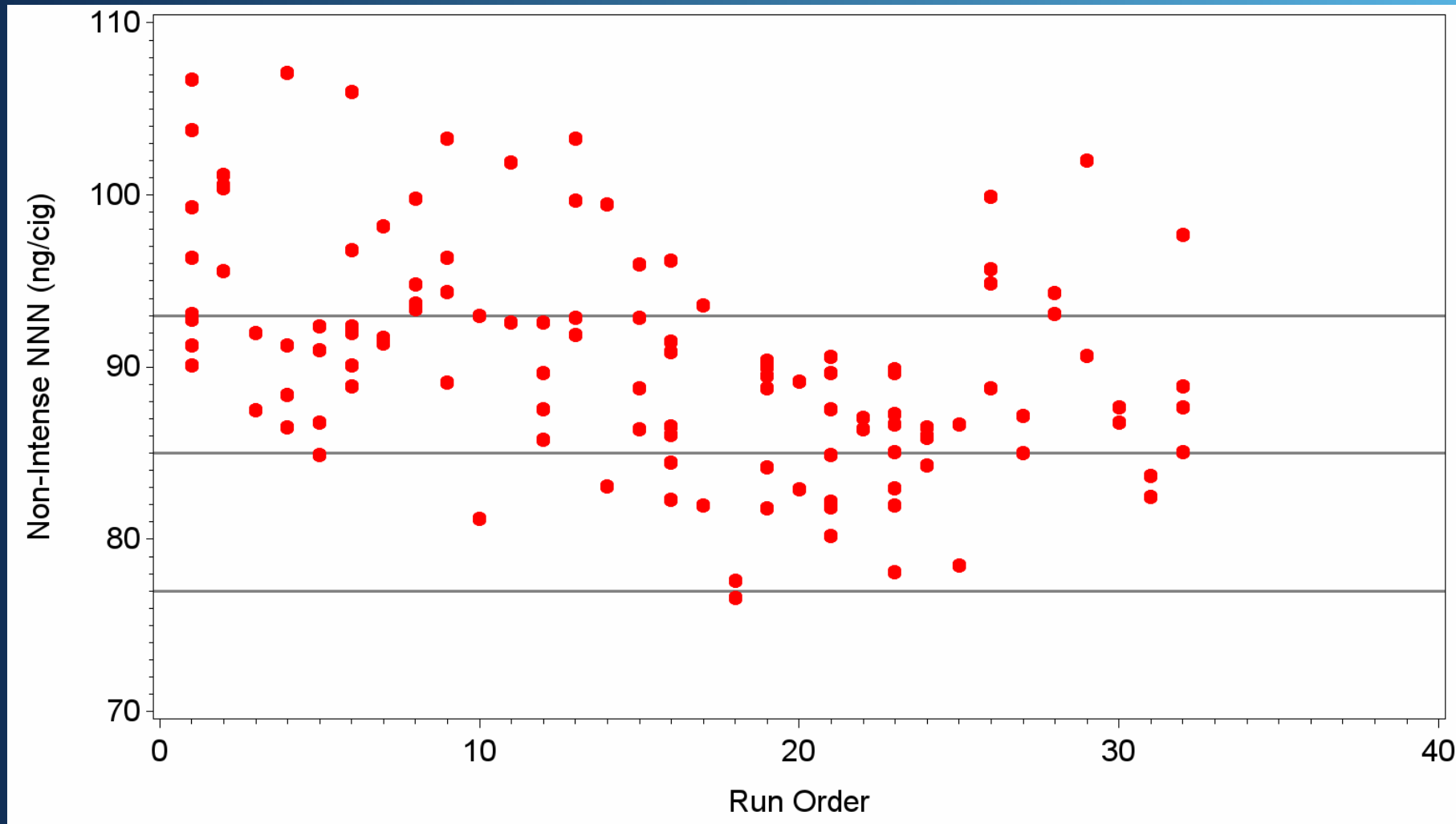
Even if the long-term mean is within the certified uncertainty limits, many individual data points can be outside those limits.

Summary and Conclusions

- A common use of reference cigarettes is as a laboratory QC monitor for method process control

- Our lab carried out this work prior to substituting 1R6F as a lab monitor to replace 3R4F

- There were several analytical differences between the two reference cigarettes, but 1R6F showed similar or reduced variability compared to 3R4F, so is a reasonable replacement.

- The average values of 1R6F in our lab fell within the certified uncertainty (with two exceptions)

- All should understand the certified uncertainty is related to a confidence interval about the <u>mean value</u>, not prediction intervals for <u>individual results</u>

Questions?
THANK YOU

More questions? Email us!
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