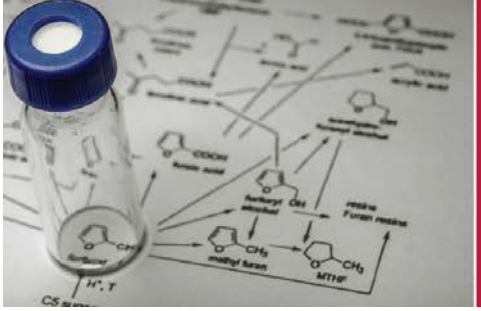

Industrial Hygiene Method Validation

Novi Laboratory

Maxxam Analytics (Maxxam) offers a range of validation protocols that allow us to meet client requirements based upon air monitoring needs and method performance criteria. We are experienced in providing validation in accordance with US-based OHS agencies including OSHA, NIOSH, and US EPA TSCA requirements. Validation in accordance with European guidelines (EN Standards) or any client specified protocol is also available, accommodating specific corporate OHS criteria.

In general, validation protocols include studies that assess analytical method performance, media recovery performance, air sampling collection and/or retention efficiency, and sample storage stability on media. Methods are typically validated over a range corresponding to 0.1 to 2 times the target occupational exposure limit (OEL), covering what is usually considered to be the potential field sampling scenario. Validating method performance down to 0.1 times the target OEL, or below, offers more flexibility in field sampling to accommodate situations where a full shift, 8-hour sampling period is not convenient or appropriate.

Three example validation protocols are described on the following page, including the routine validation elements for each protocol. The number of levels and replicates are easily modified to suit client needs for the level of statistical significance required. We will be happy to incorporate any suggestions or changes to the protocols and prepare a specific technical proposal, tailored to suit your monitoring situation.

Scheduling and Turnaround Time

Maxxam understands that method development and validation can require short turnaround times. Because scheduling is a key component for the timely completion of projects, we request advance scheduling to ensure we can meet client's time requirements. General turnaround times are shown in Table 1 for the various validation protocols illustrated.

Pricing

Exact pricing will depend on the particular compound, the occupational exposure limit (OEL), the anticipated analytical technique, and the scope of validation elements desired. Due to the many variables involved, costs for method validation can range from $5000 to over $30,000. The lower price figure would correspond to an abbreviated validation protocol similar to Protocol 1 in Table 1 where the validation approach is amenable to routine GC or HPLC analytical techniques. The higher price range would correspond to more rigorous validation protocols where the validation approach requires analytical techniques with mass spectrometry detection (GC/MS or LC/MS/MS).

Table 1: Example Industrial Hygiene Method Validation Protocols

Routine Validation Elements	Protocol 1	Protocol 2	Protocol 3
Analytical Calibration Range	5 – 6 Points (over the target validation range)	5 – 6 Points (over the target validation range)	5 – 6 Points (over the target validation range)
Analytical Precision	3 Levels with 6 Replicates	5 – 6 Levels with 6 Replicates	5 – 6 Levels with 6 Replicates
Media Selection [a]	Preliminary media selection evaluations may be required to determine the optimal air sampling media based upon recovery and collection/retention performance under the target sampling conditions.		
Extraction/Desorption Efficiency (Media Recovery)	3 Levels with 3 Replicates	4 Levels with 6 Replicates	5 Levels with 6 Replicates
Collection and/or Retention Efficiency [b]	3 Levels with 3 Replicates	4 Levels with 6 Replicates	5 Levels with 6 Replicates
Stability on Media	None	2 Levels with 3 Replicates over 3 time periods and 2 storage conditions (3, 7, 14 days)	2 Levels with 3 Replicates over 4 time periods and 2 storage conditions (3, 7, 14, 28 days)
Turnaround Time	3 – 5 weeks	6 – 8 weeks	8 – 12 weeks
Price Range [c]	$5,000 - $35,000		

[a] Media selection evaluation applies in cases where multiple filter or sorbent materials may be suitable for the analyte of interest and the best performing media is chosen for purposes of validation.

[b] Collection/retention efficiency studies are performed under simulated air sampling conditions that are appropriate for the collection media and the anticipated field sampling environment. Air sampling studies are performed at levels over the target validation range for TWA and/or STEL exposure monitoring. Evaluations can be performed under controlled temperature and humidity conditions to simulate specific environmental conditions.

[c] Exact pricing will depend on the particular compound of interest, the occupational exposure limit (OEL), the anticipated analytical technique, and the scope of validation elements desired. Due to the many variables involved, costs for method validation can range from $5000 to over $30,000.

Validation Report

A formal report is generated for validation projects with method summary information and performance data. The final report typically contains the following items. Additional information can be included upon request.

- Sampling and method performance summary
- Analyte definition (name, CAS No., molecular weight, chemical/physical properties)
- Listing of reagents, equipment/apparatus, and supplies
- Analytical procedure (includes the preparation of standard solutions, preparation of media spikes, sample extraction, and analytical conditions)
- Description of calibration procedure and representative calibration curve
- Example calculations of final air-borne concentration results from instrument results
- Validation study results and discussion, including statistical calculations
- Representative chromatograms of calibration standards, media spikes, and media blank

Protocol 1: Analytical / Media Proficiency Screening

The key assumption in applying this protocol is compound stability. Analytical/media proficiency is applicable to existing analytical methods that appear capable of meeting target levels, but may not have been applied to IH sampling or the requested analyte. Analytical methodology is developed if existing methods are not available. The validation scope is limited to analytical method performance and abbreviated media performance.

Protocol 2: Typical Analytical and Sampling Method Proficiency

This protocol provides a defensible IH methodology on the basis of a “reasonable care” philosophy. Validation is performed in accordance with OSHA and NIOSH criteria. Analytical methodology is developed if existing methods are not available. Analytical method performance, media recovery performance, air sampling collection or retention efficiency, and storage stability on the media are evaluated.

Protocol 3: Extensive Method Validation Program

This protocol provides a peer-review, defensible IH methodology with greater statistical significance. The scope of validation is more rigorous and may include, a broader target validation range, collection/retention efficiency evaluation under TWA and STEL sampling scenarios, or collection/retention evaluation under specified temperature and relative humidity environmental conditions. Extended storage stability on the media evaluations are performed with four time points over a period of 28 or 60 days.