

# Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>7</b>
1.1	Background.....	7
1.2	Purpose.....	7
1.3	Scope.....	8
1.4	Rationale for the Third Edition .....	9
1.5	Benefits.....	9
1.6	Structure of This Guide .....	10
1.7	Key Concepts and Terms.....	10
<b>2</b>	<b>Test Environment .....</b>	<b>17</b>
2.1	General Aspects of the Test Environment.....	17
<b>3</b>	<b>Test Material.....</b>	<b>23</b>
3.1	Introduction .....	23
3.2	Selection of Test Material .....	23
3.3	Storage of Test Material .....	25
3.4	Handling of Test Material .....	26
3.5	Surrogate Descriptions .....	27
<b>4</b>	<b>Measurement of Airborne Particulate Matter and Surface Contamination.....</b>	<b>29</b>
4.1	Introduction .....	29
4.2	Airborne Particulate Matter Sampling .....	29
4.3	Surface Sampling.....	33
4.4	Sampling Strategy.....	33
4.5	Task Analysis of Most Probable Emission Points.....	34
4.6	Test Cycles/Runs .....	34
4.7	Recording Field Data .....	35
<b>5</b>	<b>Sampling Strategy.....</b>	<b>37</b>
5.1	General Principles.....	37
<b>6</b>	<b>Sample Analysis .....</b>	<b>45</b>
6.1	Introduction .....	45
6.2	Components of a Robust Sampling and Analytical Method .....	45
6.3	Laboratory Selection .....	46
<b>7</b>	<b>Analysis, Interpretation, and Documentation of Data.....</b>	<b>47</b>
7.1	Background.....	47
7.2	Establishing a Containment Performance Target.....	47
7.3	Comparing Air Sampling Results to the CPT .....	48
7.4	Analyzing Surface Sampling Results .....	52
7.5	Comparing Surrogate to API .....	52
7.6	How to Handle a Failed CPA.....	52
7.7	Retesting Equipment.....	53
<b>8</b>	<b>Report Writing.....</b>	<b>55</b>

<b>9</b>	<b>Appendix 1 – Calculating the Air Change Rate</b>	<b>61</b>
<b>10</b>	<b>Appendix 2 – Calculating the Required Sensitivity for an Analytical Method and the Minimum Sample Volume</b>	<b>63</b>
10.1	Sensitivity	63
10.2	Minimum Sample Volume	64
<b>11</b>	<b>Appendix 3 – Procedures and Examples</b>	<b>65</b>
11.1	Swab and Wipe Surface Sampling Procedures	65
11.2	Inhalable (IOM and DIS) Air Sampling and Analysis Extraction Procedures	67
11.3	Closed-Face Cassette (CFC) Air Sampling Procedure	70
11.4	Calculation of Airborne Concentration	71
11.5	Example Surrogate Material Certificate of Analysis	72
11.6	Sample Field Data Sheet	73
11.7	Occupational Hygiene Sampling Checklist	74
<b>12</b>	<b>Appendix 4 – Containment Equipment Test Protocols</b>	<b>77</b>
12.1	Protocol 1 – Generic Protocol	78
12.2	Protocol 2 – Single-Point Transfer System	79
12.3	Protocol 3 – Downflow Booth	82
12.4	Protocol 4 – Ventilated Enclosure with Downward Airflow, Air Curtain, and Containment Shield	84
12.5	Protocol 5 – Unidirectional Airflow Booth	86
12.6	Protocol 6 – Ventilated Enclosure	89
12.7	Protocol 7 – Isolator/Glove Box	92
12.8	Protocol 8 – Flexible-Film Enclosure	95
<b>13</b>	<b>Appendix 5 – Example Sampling Strategy</b>	<b>99</b>
<b>14</b>	<b>Appendix 6 – References</b>	<b>111</b>
<b>15</b>	<b>Appendix 7 – Glossary</b>	<b>113</b>
15.1	Acronyms and Abbreviations	113
15.2	Definitions	114