

	Performance Qualification Protocol Table of Contents ONLY For Website	Page 1 of 2
		Document No. / Revision No. PQ-WEB-TOC, Rev. 1
		Revision Date / Initials 18-Jan-14 / RDN

Performance Qualification Protocol

Table of Contents ONLY

For Website

Contents, design and layout of this document are the CONFIDENTIAL property of
Ardien Consulting Services LLC.
Any dissemination, distribution, or copying in its entirety or partially is strictly prohibited.

Table of Contents

	Title Page.....	1
	Table of Contents.....	2
1.0	SIGNATURE LOG.....	3
2.0	PROTOCOL REVIEW AND APPROVAL.....	4
3.0	PURPOSE.....	5
4.0	SCOPE.....	6
5.0	DEFINITIONS.....	7 – 12
5.1	Acronyms.....	7 – 10
5.2	Terms and Definitions.....	11 – 12
6.0	SYSTEM DESCRIPTION.....	13
7.0	POINTS TO CONSIDER.....	14
8.0	EQUIPMENT AND MATERIALS.....	14
8.1	Equipment.....	14
8.2	Materials.....	14
9.0	PROCEDURE STEPS.....	14
10.0	DELIVERABLES.....	14
11.0	ATTACHMENTS.....	14
12.0	REFERENCES.....	15 – 17
13.0	PREREQUISITES AND APPROVAL TO PROCEED WITH PROTOCOL EXECUTION.....	18
14.0	PARAMETERS THAT AFFECT VPHP BIODECONTAMINATION EFFICACY.....	19
15.0	RATIONALE.....	20 – 26
16.0	CYCLE PARAMETERS AND SETTINGS.....	27 – 31
17.0	LOAD CONFIGURATION AND CHALLENGE LOCATIONS.....	32 – 43
18.0	PROCEDURE.....	44 – 97
18.1	Document Execution.....	44
18.2	Document Completion.....	44
18.3	Test Procedure.....	44
18.4	Test Plan 1 - Isolator Instrument Calibration Verification.....	45 – 50
18.5	Test Plan 2 - Test Instrument Calibration Verification.....	51 – 54
18.6	Test Plan 3 - Material Verification.....	55 – 58
18.7	Test Plan 4 - Biological Enumeration.....	59 – 61
18.8	Test Plan 5 - Pre-Operation Checklist.....	62 – 67
18.9	Test Plan 6 - Cycle Run Checklist.....	68 – 72
18.10	Test Plan 7 - Temperature Results.....	73 – 77
18.11	Test Plan 8 - Chemical Indicator Results.....	78 – 80
18.12	Test Plan 9 - Biological Indicator Results.....	81 – 97
19.0	CHANGE REQUEST LOG.....	98
20.0	LIST OF ATTACHMENTS.....	99
21.0	PROTOCOL COMPLETION LOG.....	100
22.0	PROTOCOL EXCEPTION REPORT.....	101 – 102
	Protocol Exception Report List.....	103
	Change Record.....	1 of 1