Alliance for Pharmacy Compounding

Compounding the Joy of Living®

January 27, 2025

Anne Sodegren, Executive Officer
Seung Oh, President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear President Oh, Director Sodegren, and Members of the California State Board of Pharmacy:

We submit these comments on behalf of the Alliance for Pharmacy Compounding and our members. Thank you for another opportunity to provide input on the proposed regulations regarding compounded drug preparations, hazardous drugs, and radiopharmaceuticals, as outlined in Title 16, California Code of Regulations. We appreciate the Board's efforts to update and clarify these regulations and your consideration of public comments during this process.

We continue to have serious concerns regarding the pathway outlined in the proposed regulations for compounding with active pharmaceutical ingredients (APIs) included in FDA's Interim Category 1. While the pathway appears to establish a mechanism for compounding, the associated testing and documentation requirements you propose create significant barriers that make compounding for all necessary dosage forms and strengths impractical under the revised proposed regulations.

Stability Studies and API Testing Requirements

1. **Stability Studies**:
    - **USP Standards**: USP does not require full stability studies for sterile compounding under **Category 1 or 2**. Instead, USP aligns required tests with the beyond-use date (BUD) assigned to the compound. Full stability-indicating studies are only required for **Category 3**, which pertains to larger-scale compounding (typically batches of 250 units).
    - **California's Proposed Rules**: The requirement for full stability studies in all cases goes far beyond USP and FDA standards. Stability studies are expensive, costing **$10,000–$30,000 or more per formulation**.
    - **Impact on Pharmacies and Patients**: This requirement would force pharmacies to limit the formulations they produce, focusing only on the most common ones that justify the cost of stability studies. For example, a pharmacy might conduct a

study for **glutathione 200 mg/mL multi-dose vials**, which serve the largest number of patients (IV, IM, and inhalation use, even though preservatives should not be inhaled). However, more specialized formulations, such as **an NAC/glutathione inhalation combination** or **preservative-free individual inhalation vials**, would become financially unviable.

2. **API Testing Requirements**:
    - California proposes additional testing requirements for APIs that exceed what is required by USP or FDA.
    - These tests could be performed by the manufacturer, repackager, or wholesaler, but initial reviews suggest that these tests are not typically listed on Certificates of Analysis (COAs). This means pharmacies would likely need to perform the tests themselves, incurring additional costs and delays.

USP Chapters Above 1000

USP chapters numbered above 1000, such as **Chapter 1097** (which is referenced by the testing required for API in FDA's interim category 1), are intended for informational purposes and are not enforceable unless explicitly adopted. They contain no mandatory tests, assays, or requirements for compliance. Board member's claim that they are "just listing the tests required by USP" is inaccurate. While the state does have the authority to enforce requirements from chapters above 1000, doing so would make it an exception among the states.

Request to Align with National Standards

To ensure patient access to compounded medications while maintaining safety and quality, APC respectfully requests the Board to align its regulations with national standards:

1. **Treat APIs on FDA's Interim Category 1 List Consistently**: Allow pharmacies to compound under USP **Category 1 and 2** standards, as permitted in all other states, avoiding the need for full stability studies.
2. **Do Not Mandate Compliance with USP Chapters Above 1000**: Recognize these chapters as guidance, not enforceable regulations, to avoid imposing unnecessary burdens on compounding pharmacies. USP's General Notices plainly state that chapters numbered between 1000 and 2000 are for informational purposes only.

Additional Comments and Attachment

To illustrate the financial burden, we are attaching a **stability study quote of $40,000** for a commonly requested **NAC/glutathione combination**, used for its antioxidant effects to protect lung tissue from damage caused by free radicals and oxidative stress. This serves as a concrete example of how the proposed regulations would limit access to customized, specialized formulations that patients rely on.

We are also concerned about certain documentation requirements in the proposed regulations. For example, to use API in FDA's interim Category 1, the prescription must document the "clinical circumstances" that require the use of these medications. It would be helpful if examples of what appropriate documentation looks like to make sure that both pharmacies and inspectors know what to expect. Additionally, we respectfully request a Q&A or greater specificity regarding the documentation requirements for pharmacists to demonstrate verification of the need for a change to a compounded prescription under the "essentially a copy" sections of the proposed regulations. While FDA guidance calls for "documentation," the proposed California regulations require "verification." The addition of "verification" suggests the Board is looking for an additional level of accountability. Providing clear and satisfactory examples of acceptable documentation would greatly assist in ensuring compliance with these requirements.

Thank you for your time, attention, and continued consideration of our comments. We look forward to further discussions on how to achieve a balanced regulatory framework that ensures patient safety while preserving access to essential compounded medications.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
scott@a4pc.org

Pharmacy – Glutathione / N-Acetylcysteine Stability Study Quotation

1/13/2025

Pharmacy
Address
City, St Zip
T: (XXX) XXX-XXXX
E: Pharmacy Representative Email
Attn: Pharmacy Representative

Dear Pharmacy Representative,

ARL Bio Pharma is committed to providing the industry's highest quality testing and customer service. We are FDA registered, DEA registered, and ISO 17025:2017 accredited (see certificate number 2992.01 for scope of accreditation). We offer both cGMP and non-cGMP services.

Please find the requested quotation attached. We appreciate the opportunity to provide this quotation and look forward to serving your needs. Please feel free to contact me with any questions about this proposal or any other services.

Thank you,

Technical Sales Representative
840 Research Parkway, Ste. 546
Oklahoma City, OK 73104
T: 405.271.1144
E: info@arlok.com

Project Scope

Pharmacy would like to demonstrate the stability of a Glutathione/N-Acetylcysteine inhalation solution. Pharmacy has asked ARL to develop and validate a stability indicating method for the quantitation of Glutathione and N-Acetylcysteine. After the method has been validated, ARL will evaluate the physical, chemical, and microbiological properties of the packaged product over a 90-day period. The testing requested by Pharmacy will be conducted under non-cGMP conditions.

Study Details

See tables below

- Table 1: Method Development and Validation Criteria
- Table 2: Stability Study Variables
- Table 3: Sample Requirements
- Table 4: Stability Study Pricing
- Table 5: Stability Study Specifications
- Table 6: Reference Standard Pricing
- Table 7: Summary of Charges

Table 1: Method Development and Validation Criteria[1]

Formula ID	Drug(s)	Concentration	Excipients
TBD	Glutathione	100 mg/mL	TBD
	N-Acetylcysteine	100 mg/mL	

[1]Enough drug and placebo must be provided by client for method development and validation. The exact amount will be determined by the project manager.

A stability indicating method will be developed and validated per USP <1225>. The validation includes Accuracy, Linearity, Precision (repeatability), Range, Specificity, and System Suitability. Specificity demonstrates non-interference from impurities and matrix components and involves stress studies/ forced degradation to demonstrate the method is capable of separating degradation products from the Active Pharmaceutical Ingredient (API).

Table 2: Stability Study Variables

Variable	Details
Drug Names and Concentrations	See Table 1
Dosage Form	Inhalation Solution, Single dose
Container Type(s)	3 mL Vials w/ 3 mL Fill
Secondary Packaging[1]	N/A
Storage Conditions	Refrigerated (5°C ± 3°C)
Lots	1
Time Points (Days)	0, 30, 60, 90

[1]The client is responsible for providing the necessary materials for any secondary packaging. If the client requests ARL to provide secondary packaging or additional labor is required due to the secondary packaging, ARL will contact the client about additional fees for materials and labor.

Table 3: Sample Requirements[1]

Test	# of Containers Designated per Test				# of Retains	# of Lots	# of Containers Requested per Test
	0	**30**	**60**	**90**			
Appearance	**	**	**	**	**	1	**
pH	3	3	3	3	3	1	15
Glutathione Assay	1	1	1	1	1	1	5
N-Acetylcysteine Assay	1	1	1	1	1	1	5
Sterility[2,3]	10	10	10	10	10	1	50
Endotoxin	1	1	1	1	1	1	5
Container Closure Integrity	11	11	11	11	11	1	55
Total # of Containers Requested							**135**

[1]The study samples will be supplied by the client. The sample requirements may be adjusted by the project manager.
[2]The client certifies that 10 articles of the finished product are required to satisfy USP <71> sterility testing requirements
[3]Requires suitability method. See summary of charges table for more information. Enough drug products must be provided by clients for method suitability. The exact amount will be determined by the project manager.
**Shared with the Stability test samples.

Table 4: Stability Study Pricing

Test	Method Type	Time Points[1] (Days)	# of Time Points	# of Lots	Total Units[2]	Unit Price	Total Price
Appearance	Visual	0, 30, 60, 90	4	1	4	$45	$180
pH	USP <791>	0, 30, 60, 90	4	1	4	$45	$180
Glutathione Assay	TBD	0, 30, 60, 90	4	1	4	$525	$2,100
N-Acetylcysteine Assay	TBD	0, 30, 60, 90	4	1	4	$525	$2,100
Sterility	USP <71>	0, 30, 60, 90	4	1	4	$190	$760
Endotoxin	USP <85>	0, 30, 60, 90	4	1	4	$110	$440
Container Closure Integrity	Vacuum Decay[3]	0, 30, 60, 90	4	1	4	$550	$2,200
						Total	**$7,960**

[1]The test dates will be determined from the date the stability samples are received. ARL will begin each test within 3 business days of the time point. The test results will be sent within 5 business days of completion.
[2]Total units = # of time points x # of lots
[3]If the client's sample is unable to be tested using ARL's current inventory of vacuum decay chambers, the client will be contacted for further quotation.

Note - Methods cited in USP general chapters or monographs are followed as directed. This includes system suitability or other inherent quality control tests that are specified in the cited method. Per 21 CFR 211.194(a)(2), users of analytical methods described in USP–NF are not required to validate the accuracy and reliability of these methods but merely verify their suitability under actual conditions of use. If additional suitability testing and/or validation is required that is not otherwise outlined in the test method cited please notify ARL.

Table 5: Stability Study Specifications

Test	Method Type	Specifications
Appearance	Visual	TBD
pH	USP <791>	Report Value
Glutathione Assay	TBD	TBD
N-Acetylcysteine Assay	TBD	TBD
Sterility	USP <71>	Sterile
Endotoxin	USP <85>[1]	See note below table
Container Closure Integrity	Vacuum Decay	Meets Test Criteria

[1]USP <85> can be cited if client provides Endotoxin limit or information to calculate MDV – average weight (kg), max dose/hour & route of administration.

Table 6: Reference Standard Pricing[1]

Reference Standard	Unit Price
Sigma Glutathione (PHR1359-500MG)	$167
Sigma N-Acetylcysteine (PHR1098-1G)	$154
Total	**$ 321**

[1]Additional reference standard units may be invoiced throughout the method work and the stability study. ARL will invoice for the reference standard at the time of purchase. ARL's fee for reference standard is calculated by adding tax, shipping, and handling to the vendor's list price. The fee in the table above reflects the current cost to client. If ARL's vendor changes their list price after the time this quotation was issued, the amount ARL charges the client will also change. If additional reference standards are required that have not been listed in this quotation, ARL will contact the client with a revised quotation.

Table 7: Summary of Charges

Item	Cost
Method Development and Validation x 2 APIs @ $15,825 each	$31,650
Reference Standards	$321
USP <71> Sterility Method Suitability[1]	$570
Stability Study (Table 4)	$7,960
Stability Study Summary Report	$500
Total	**$41,001**

[1]USP <71> method suitability based on a maximum batch size of 250 units.

Payment Milestones

- To accept this quotation, please return a signed copy.
- Method Development and Validation will be invoiced when a project manager is available. Payment is due upon receipt.
- USP <71> Sterility Method Suitability will be invoiced upon completion.
- Stability Study Time Points will be invoiced upon completion.
- Stability Study Summary Sheet will be invoiced upon completion.

Project Timeline

- The initiation and completion dates will be determined when client is ready to execute quote

Sending a signed copy of this quotation to ARL certifies that: (1) all information provided in this quotation is true and correct; (2) you have reviewed the Terms and Conditions attached to this quotation; (3) you agree to be bound by the Terms and Conditions; and (4) if you are submitting this quotation on behalf of a company or other entity, you have the authority to bind that company or entity to the Terms and Conditions.

ARL BioPharma, Inc.
840 Research Parkway, Suite 546
Oklahoma City, OK 73104
T: 405.271.1144 F: 405.271.1174
E: info@arlok.com
Submitted by:

Technical Sales Representative
Date: 1/13/2025

Pharmacy
Address
City, St Zip
T: (XXX) XXX-XXXX
E: Pharmacy Représentative Email
Accepted:

_____
Pharmacy Representative
Date: _____

1. Interpretation.
1.1 For the purposes of these Terms and Conditions; "Client" shall refer to any person or entity engaging ARL's services whether or not subject to a Quote, "Quote" shall refer to an agreement of custom services and fees negotiated and executed by ARL and the Client.
1.2 These Terms and Conditions shall control over all clients. These Terms and Conditions shall control to the extent they do not conflict with any terms within a Quote. To the extent any terms herein conflict with a Quote, the Quote shall control.

2. Conduct of the Services. ARL Bio Pharma, Inc., an Oklahoma corporation ("ARL") will perform testing, prepare a Certificate of Analysis, and all other services agreed to by ARL and Client (collectively, the "Services") in accordance with generally prevailing industry standards of professional conduct. For non-compendial testing, the specification(s) are for informational purposes only. For analytical testing, the analyte is reported as it was calculated to derive the result. Client shall verify that the specification and analyte reported are correct for the formulation. For Services to be performed pursuant to a Quote, ARL will perform the Services in accordance with the standards set forth in the Quote. For cGMP Services, a Quality Agreement may be executed by Client and ARL in addition to the Quote. In such instance, ARL will perform the Services in accordance with the Quote, cGMP, and the Quality Agreement. ARL will not be required to perform any Services in accordance with cGMP unless a Quality Agreement exists.

ARL makes no representations or warranties regarding the release of any Client product. The test results and underlying data of the test results are insufficient to determine whether to release any pharmaceutical products for distribution. The test results and underlying data of the test results only relate to the sample that was tested.

3. Test Material. Client is responsible for selecting the samples or other materials ("Test Material") that Client sends to ARL for Services in compliance with all applicable laws, regulations, and rules of the relevant governmental regulatory authorities. Client will provide ARL (at no cost to ARL) sufficient amounts of Test Material necessary to perform each test, as well as such data and other information as may be necessary or useful for ARL to perform the Services and to apprise ARL of the stability, proper storage, and safe handling requirements with respect to the Test Material, including a Safety Data Sheet (SDS) or equivalent documentation. Client will promptly send to ARL any additional Test Material requested by ARL for completion of the Services. Client will be responsible for the shipping and handling of all Test Material sent to ARL. Thirty (30) days following the completion, termination, or suspension of any Services, ARL will discard any remaining Test Material unless Client advises ARL in writing prior to the expiration of the thirty (30) day period that Client wants the remaining Test Material returned and provides ARL with instructions in writing and payment for the return of the remaining Test Material. Client will not use, nor cause another person or entity to use, any Test Material for human or animal consumption or use.

4. Change in Scope. Client may request a change in scope of any Services, but ARL must agree to such change prior to implementing the change, and ARL may revise the fee for the Services affected by the change in scope.

5. Termination of Routine Testing.
5.1 Client may terminate a routine test at any time prior to ARL's commencement of the routine test. In such event, ARL, in its sole discretion, may charge a termination fee of $20 per canceled test for any testing terminated by the Client after ARL's receipt of the relevant Test Material.

5.2 ARL may terminate a routine test at any time, including in process testing.

6. Termination of On-Going Studies. Client may terminate any on-going studies performed by ARL at any time without cause upon fifteen (15) business days prior written notice to ARL. In such event, Client shall pay ARL for all Services rendered through the effective date of termination, together with any additional expenses incurred by ARL in connection with the termination of the study, including those which were previously committed to by ARL for completion of the study. ARL may terminate any on-going studies performed at any time without cause, however if ARL terminates any routine test without cause ARL shall refund to Client any Fees paid for Terminated Services and return any remaining Test Materials.

7. Personnel. To the best of ARL's knowledge, none of its employees who will participate in testing have been debarred, or are under consideration to be debarred, by the Food and Drug Administration from working in or providing Services to any pharmaceutical or biotechnology company under the Generic Drug Enforcement Act of 1992, as amended.

8. Inspections. Once per year, upon thirty (30) days advance notice to ARL, Client or its designated representative, if such representative is reasonably acceptable to ARL, may visit ARL's facilities to observe the testing. The visit must be during normal business hours and occur at a mutually agreeable time. Client is responsible for any and all of its costs incurred to perform the inspection.

9. Test Records and Reports. ARL will keep complete and accurate records of each test for five (5) years after completion of the test.

10. Fees.
10.1 Client shall promptly pay all fees ("Fees") for Services when due and payable. All payments must be in US Dollars. If Client requests a rush for the performance of any Service, ARL may, in its sole discretion, add a surcharge to the rushed Services.

10.2 Each new Client must request a credit review. Once ARL establishes a credit limit for Client, ARL will invoice Client for Services and Client must pay each invoice within thirty (30) days of the date of the invoice.

10.3 For Services performed pursuant to a Quote, Client must pay the amounts specified in the Quote. The pricing of each Quote is valid for ninety (90) days from the date of the Quote. Client shall pay all invoices and other amounts due under the Quote within thirty (30) days of receipt of the relevant invoice unless otherwise specified in the Quote. Any changes in the Fees must be mutually agreed to by the parties in a written amendment to the Quote.

10.4 All Fees for all Services, whether or not performed pursuant to a Quote, must be paid by the applicable due date. All Fees not paid will bear interest at a rate of one and one-half percent (1.5%) per month from the applicable due date until paid. If Client does not pay each invoice when due, ARL may elect to suspend any Services, including, but not limited to, any testing that may be in progress, delaying the

start of new testing, and withholding reports or other deliverables. Additionally, Client shall reimburse ARL for all costs related to collection of unpaid Fees, including reasonable attorneys' Fees and costs, and costs for storage or disposal of Test Material under Section 3.

10.5 Any costs incurred by ARL for any work permits, licenses, fees, disposal costs, or other government approvals, registrations, permits, or licenses which may be required to fulfill its obligations and which are specific to a Quote or to the samples being tested shall be attributable to Client. This Section 10.5 however, excludes all general fees associated with standard licenses, permits and registrations required to operate a business in the industry in which ARL is engaged.

10.6 Payments can be made via check, ACH, credit card or wire transfer. Credit card payments will be subject to a surcharge of 2.9% (subject to change). Wire transfers will be subject to a $25 fee (subject to change).

10.7 ARL is entitled to all Fees irrespective of the results or conclusions reached in any report.

11. Subcontractors. ARL may outsource or use contractors for any or all Services.

12. Confidentiality. If the parties have executed a confidentiality agreement prior to the commencement of Services, that confidentiality agreement will control the disclosure of confidential information between the parties through the performance of Services. If the parties have not executed such an agreement, these Terms and Conditions control the exchange of Confidential Information between the Parties.

In the event there is no confidentiality agreement between the parties, the parties anticipate that they may exchange proprietary and confidential information (the "Confidential Information") related to the performance of Services. All Confidential Information must be identified in writing as confidential. Each party will use commercially reasonable efforts to maintain the other party's Confidential Information in confidence and will employ reasonable procedures to prevent its unauthorized publication or disclosure to third parties. No party may use the other party's Confidential Information for any purpose other than performance of the Services.

Following the completion, termination, or suspension of any Services, if requested by the client, ARL will promptly return or destroy the Confidential Information in ARL's possession. Client will be responsible for the costs of return the Confidential Information or any costs incurred by ARL for the destruction of the confidential material. However, ARL may retain one copy of the Client's Confidential Information for legal or regulatory compliance reasons and will not be required to access or delete electronic backup, active archive, or achieved copies of the Client's Confidential Information that were generated in accordance with the Client's bona fide backup or archiving practices.

13. Warranties. Client warrants that it owns all rights, title, and interest in and to all Test Material and intellectual property related thereto, and that ARL's use of any and all such Test Material in connection with the Services does not infringe any copyrights, patent rights, trade secrets, or other intellectual property rights of any third party. Client also warrants that it will comply with all applicable laws, regulations, and rules of the relevant governmental regulatory authorities related to the sale, distribution, final product release, or other use of any Test Material.

ARL warrants to Client that all Services provided to Client will be in accordance with generally prevailing industry standards of professional conduct and comply with all applicable laws, regulations, and rules of the relevant governmental regulatory authorities. If Services are performed pursuant to a Quote, ARL also warrants that the Services will conform to the specifications in the Quote. These warranties of ARL are made only to Client, are not transferable, and do not extend to the benefit of any other person or entity. OTHER THAN THE FOREGOING WARRANTIES, THE SERVICES ARE SOLD AND PROVIDED "AS IS," WITHOUT WARRANTY OF ANY KIND, WHETHER STATUTORY, EXPRESS, OR IMPLIED. THE WARRANTIES PROVIDED IN THIS PARAGRAPH ARE ARL'S SOLE AND EXCLUSIVE WARRANTIES WITH RESPECT TO THE SERVICES AND IN LIEU OF ALL OTHER WARRANTIES, WHETHER STATUTORY, EXPRESS, OR IMPLIED. ALL OTHER WARRANTIES ARE EXPRESSLY DISCLAIMED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, AND RESULTS OBTAINED (INCLUDING, WITHOUT LIMITATION, ANY CLAIM OF INACCURATE, INVALID, OR INCOMPLETE RESULTS), WHETHER ARISING BY STATUTE, OTHER SOURCES OF LAW, OR FROM COURSE OF PERFORMANCE OR DEALING, OR USAGE OF TRADE.

14. Limitation of Liability. ARL WILL NOT BE LIABLE FOR PENALTIES OR LIQUIDATED DAMAGES, OR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, COLLATERAL, PUNITIVE, EXEMPLARY, OR OTHER DAMAGES OR LOSSES OF ANY TYPE OR KIND (INCLUDING, WITHOUT LIMITATION, LOSS OF USE AND LOST PROFITS) REGARDLESS OF WHETHER ANY SUCH LOSSES OR DAMAGES ARE CHARACTERIZED AS ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, TORT, STRICT LIABILITY, OR OTHERWISE, EVEN IF ARL IS ADVISED OF THE POSSIBILITY OF SUCH LOSSES OR DAMAGES, OR SUCH LOSSES OR DAMAGES ARE FORESEEABLE.

NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THESE TERMS AND CONDITIONS, CLIENT'S SOLE AND EXCLUSIVE REMEDY FOR ARL'S BREACH OF WARRANTIES SET FORTH IN THESE TERMS AND CONDITIONS WILL BE, AT ARL'S SOLE AND ABSOLUTE DISCRETION: (i) RE-PERFORMANCE OF THE SERVICES AFFECTED BY THE BREACH OF WARRANTY AT ARL'S SOLE COST AND EXPENSE, OR (ii) REFUND OF THE SERVICE FEES PAID TO ARL BY CLIENT FOR THE SERVICES AFFECTED BY THE BREACH OF WARRANTY. FOR ALL OTHER CLAIMS ASSERTED BY CLIENT AGAINST ARL RELATED TO THE SERVICES, THE APPLICABLE QUOTE (IF ANY), OR THESE TERMS AND CONDITIONS (INCLUDING CLAIMS FOR INDEMNIFICATION), ARL'S MAXIMUM LIABILITY FOR ANY DAMAGES OR LOSSES, REGARDLESS OF THE FORM OF ACTION OR PROCEEDING, WILL NOT EXCEED THE TOTAL SERVICE FEES PAID BY CLIENT FOR THE SERVICES GIVING RISE TO THE DAMAGES OR LOSSES.

UNLESS OTHERWISE STATED IN A QUOTE, SAMPLES ARE AND REMAIN AT ALL TIMES (INCLUDING, WITHOUT LIMITATION, WHILST AT ARL'S

FACILITIES AND DURING TRANSPORTATION TO AND FROM ARL'S FACILITIES) AT THE ENTIRE RISK OF THE CLIENT WHO SHALL BE RESPONSIBLE FOR EFFECTING AND MAINTAINING ITS OWN INSURANCE COVER IN RELATION THERETO, IT BEING HEREBY ACKNOWLEDGED BY THE CLIENT THAT THE FEES OF ARL DO NOT INCLUDE INSURANCE.

15. Indemnification. Subject to the Limitation of Liability contained herein, ARL shall indemnify Client and its respective directors, officers, employees, and agents (collectively, the "Client Indemnitees") from and against any losses, damages, fines, and liabilities, including attorney fees and litigation expenses (collectively, "Damages"), incurred by the Client Indemnitees as a result of any third-party claims, demands, suits, actions, or causes of action (collectively, "Claim") arising from: (i) ARL's breach, violation, non-compliance, or non-performance of these Terms and Conditions or Quote (if applicable); and (ii) ARL's gross negligence or willful misconduct in the performance of Services.
. ARL will pay any Damages which are assessed against the Client Indemnitees by final judgment after exhaustion of all reasonable appeals. ARL will pay any Damages subject to the Limitations of Liability set forth herein.

Client shall indemnify and defend ARL and its respective directors, officers, employees, and agents (together, the "ARL Indemnitees") from and against any third-party Claim, and any Damages resulting from such Claim, against an ARL Indemnitees arising from: (i) Client's breach, violation, non-compliance, or non-performance of these Terms and Conditions or Quote (if applicable); (ii) Client's gross negligence or willful misconduct; (iii) the marketing, labeling, recall, manufacture, distribution, use, sale, or other disposition by Client or any distributor, customer, sublicensee, or representative of Client, of any Test Material, product, process, technology, or other material or information that Client provides to ARL (collectively, the "Client Supplied Materials and Technology"); (iv) any assertion that the Client Supplied Materials and Technology or an ARL Indemnitee's use of the Client Supplied Materials and Technology infringes the know-how, trade secrets, patent rights, copyrights, or other intellectual property rights or confidential information rights of a third party. If Client breaches its duty to defend an ARL Indemnitee against such a third-party Claim, Client shall reimburse that ARL Indemnitee for the reasonable attorney fees and litigation expenses incurred by that ARL Indemnitee in defending the Claim, and the reasonable attorney fees and litigation expenses incurred in recouping the defense attorney fees and litigation expenses from Client.

16. Ownership. ARL will exclusively own all techniques, methods, processes, models, tools, assays, test results, and the underlying data of the test results that are developed, generated, conceived, or utilized in the performance of the Services.

17. Licenses. Client grants to ARL a non-exclusive, irrevocable, fully paid-up, worldwide license (including the right to sublicense to any subcontractor for that subcontractor's performance of any Services) to use and duplicate any proprietary technology and Test Material disclosed to ARL solely to the extent necessary to perform the Services.

Upon the Client discharging all obligations contained in these Terms and Conditions (and all obligations found in any applicable Quote)and payment of all Fees relating to the specific test results of specific Test Material, ARL grants to Client a non-exclusive, irrevocable, fully paid-up, worldwide license (including the right to sublicense) to use, duplicate, and disseminate the test results and underlying data of the test results that are disclosed by ARL to Client in connection with the Services.

18. Controlling Terms. In the event that there is any conflict between these Terms and Conditions and the Quote, the terms in the Quote will apply.

19. Independent Contractor. The business relationship of the parties is that of independent contractors and not of partners, joint venturers, employers, employees, or any similar kind of relationship.

20. Force Majeure. ARL will not be liable for any delay or failure of performance, including, without limitation, failure to perform a Service, where such delay or failure arises or results from any cause beyond ARL's reasonable control, including, but not limited to, flood, fire, explosion, natural catastrophe, military operations, war, computer or other equipment failure, severe weather, earthquake, tornado, or other act of God, power loss or reduction, labor disputes of any kind (whether relating to its own employees or others), embargos, governmental regulation, or an inability or delay in obtaining materials. In the event of any such delay or failure of performance, ARL will have additional time to perform the Services as reasonably necessary under the circumstances.

21. Applicable Law, Jurisdiction, and Venue. The Services, these Terms and Conditions, and any applicable Quote are governed by, and construed in accordance with, the laws of the State of Oklahoma, USA, without regard to any choice of law principle that would dictate the application of the law of another jurisdiction. Venue of all disputes regarding the Services, these Terms and Conditions, or an applicable Quote must be brought in the District Court for the State of Oklahoma, Oklahoma County. Each party waives any right to or option for a trial by jury.

22. Shortened Statute of Limitations. Any claim against ARL for breach of warranty, or any other claim related to the Services, a Quote, or these Terms and Conditions (including a claim for indemnification), must be brought within one (1) year from the date the cause of action arose

23. Entire Agreement. These Terms and Conditions and the Quote (if any) constitute the complete, final, and exclusive expression of the agreement between the parties, superseding any and all previous agreements and understandings, whether oral or written.

24. Modification and Waiver.
24.1 No modification or waiver of the provisions of these Terms and Conditions or a Quote will be valid or binding on either party unless set forth in a writing signed by both parties. No waiver of any term, right, or condition of these Terms and Conditions or a Quote may be construed or deemed to be a waiver or continuing waiver of any such term, right, or condition on any subsequent occasion, or a waiver of any other term, right, or condition.

24.2 No failure or delay by ARL to exercise any right, power, or remedy will operate as a waiver of it nor will any partial exercise preclude any further exercise of the same or of some other right, power, or remedy.

25. Severability. If any of the provisions of these Terms and Conditions or an applicable Quote are deemed to be invalid or prohibited under applicable law, such provisions will be ineffective to the extent of such invalidity or prohibition, without invalidating the remainder of such provision or the remaining provisions of these Terms and Conditions or the Quote.

26. Voluntary Agreement. Each party represents that they have carefully read and understand all provisions, terms, and aspects of these Terms and Conditions and the applicable Quote (if any), and have knowingly and voluntarily agreed to be bound by them. Each party also represents that they have had the opportunity to review these Terms and Conditions and the applicable Quote (if any) with legal counsel of such party's choice.

Revised 10/2024