

TIPS VENDOR AGREEMENT

TIPS RFP 230701 Indoor Air Quality Equipment and Services

The following Vendor Agreement (“Agreement”) creates a legal agreement between The Interlocal Purchasing System (“TIPS”), a government purchasing cooperative and Department of Texas Region 8 Education Service Center and (INSERT ENTITY NAME):

Medical Illumination International, Inc.

(ENTER ENTITY NAME]

its owners, agents, subsidiaries, and affiliates (together, “Vendor”) (individually, “Party”, and collectively the “Parties”) and this agreement shall exclusively govern the contractual relationship (“Agreement”) between the Parties.

TIPS, a governmental entity and a national purchasing cooperative seeks to provide a valuable and necessary solution to public entities and qualifying non-profits by performing the public procurement solicitation process and awarding compliant contracts to qualified vendors. Then, where the law of a customer’s jurisdiction allows, instead of public entities and qualifying non-profits expending time, money, and resources on the extensive public procurement process, the use of TIPS allows public entities to quickly select and purchase their preferred products or services from qualified, competitively evaluated vendors through cooperative purchasing.

1. **Purpose.** The purpose of this Agreement is to identify the terms and conditions of the relationship between TIPS and Vendor. Public entities and qualifying non-profits that properly join or utilize TIPS (“TIPS Members”) may elect to “piggyback” off of TIPS’ procurements and agreements where the laws of their jurisdiction allow. TIPS Members are not contractual parties to this Agreement although terms and conditions of this Agreement may ensure benefits to TIPS Members.
2. **Authority.** The Parties agree that the signatories below are individual authorized to enter into this Agreement on behalf of their entity and that they are acting under due and proper authority under applicable law.
3. **Definitions.**
 - a. **TIPS Pricing:** The specific pricing, discounts, and other pricing terms and incentives which Vendor submitted and TIPS approved for each respective TIPS Contract awarded to Vendor and all permissible, subsequent pricing updates submitted by Vendor and accepted by TIPS, if any.
 - b. **Authorized Reseller:** A reseller or dealer authorized and added by a Vendor through their online TIPS Vendor Portal to make TIPS sales according to the terms and conditions herein.
4. **Entire Agreement.** This Agreement resulted from TIPS posting a “TIPS Solicitation” (RFP, RCSP, RFQ, or other) and Vendor submitting a proposal in response to that posted TIPS Solicitation for evaluation and award. The Parties agree that this Agreement consists of the provisions set forth herein and: (1) The TIPS solicitation document resulting in this Agreement; (2) Any addenda or clarifications issued in relation to the TIPS solicitation; (3) All solicitation information provided to Vendor by TIPS through the TIPS eBid System; (3) Vendor’s entire proposal response to the TIPS solicitation including all accepted required attachments, acknowledged notices and certifications, accepted negotiated terms, pricing, accepted responses to questions, and accepted written clarifications of Vendor’s proposal, and; any properly included attachments to this Agreement. All documentation and information listed is hereby incorporated by reference as if set forth herein verbatim. In the event of conflict between the terms herein and one of the incorporated documents the terms and conditions herein shall control.
5. **Vendor’s Specific Warranties, Terms, and License Agreements.** Because TIPS serves public entities and non-profits throughout the nation all of which are subject to specific laws and policies of their jurisdiction, as a matter of standard practice, TIPS does not typically accept a Vendor’s specific “Sale Terms” (warranties, license agreements, master agreements, terms and conditions, etc.) on behalf of all TIPS Members. TIPS may permit Vendor to attach those to this Agreement to display to interested customers what terms may apply to their Supplemental Agreement with Vendor (if submitted by Vendor for that purpose). However, unless this term of the Agreement is negotiated and modified to state otherwise, those specific Sale Terms are not accepted by TIPS on behalf of all TIPS Members and each Member may choose whether to accept, negotiate, or reject those specific Sale Terms, which must be reflected in a separate agreement between Vendor and the Member in order to be effective.

- 6. Vendor Identity and Contact Information.** It is Vendor's sole responsibility to ensure that all identifying vendor information (name, EIN, d/b/a's, etc.) and contact information is updated and current at all times within the TIPS eBid System and the TIPS Vendor Portal. It is Vendor's sole responsibility to confirm that all e-correspondence issued from tips-usa.com, ionwave.net, and tipsconstruction.com to Vendor's contacts are received and are not blocked by firewall or other technology security. Failure to permit receipt of correspondence from these domains and failure to keep vendor identity and contact information current at all times during the life of the contract may cause loss of TIPS Sales, accumulating TIPS fees, missed rebid opportunities, lapse of TIPS Contract(s), and unnecessary collection or legal actions against Vendor. It is no defense to any of the foregoing or any breach of this Agreement that Vendor was not receiving TIPS' electronic communications issued by TIPS to Vendor's listed contacts.
- 7. Initiation of TIPS Sales.** When a public entity initiates a purchase with Vendor, if the Member inquires verbally or in writing whether Vendor holds a TIPS Contract, it is the duty of the Vendor to verify whether the Member is seeking a TIPS purchase. Once verified, Vendor must include the TIPS Contract Number on all purchase communications and sales documents exchanged with the TIPS Member.
- 8. TIPS Sales and Supplemental Agreements.** The terms of the specific TIPS order, including but not limited to: shipping, freight, insurance, delivery, fees, bonding, cost, delivery expectations and location, returns, refunds, terms, conditions, cancellations, order assistance, etc., shall be controlled by the purchase agreement (Purchase Order, Contract, Invoice, etc.) (hereinafter "Supplemental Agreement") entered into between the TIPS Member Customer and Vendor only. TIPS is not a party to any Supplemental Agreement. All Supplemental Agreements shall include Vendor's Name, as known to TIPS, and TIPS Contract Name and Number. Vendor accepts and understands that TIPS is not a legal party to TIPS Sales and Vendor is solely responsible for identifying fraud, mistakes, unacceptable terms, or misrepresentations for the specific order prior to accepting. Vendor agrees that any order issued from a customer to Vendor, even when processed through TIPS, constitutes a legal contract between the customer and Vendor only. When Vendor accepts or fulfills an order, even when processed through TIPS, Vendor is representing that Vendor has carefully reviewed the order for legality, authenticity, and accuracy and TIPS shall not be liable or responsible for the same. In the event of a conflict between the terms of this TIPS Vendor Agreement and those contained in any Supplemental Agreement, the provisions set forth herein shall control unless otherwise agreed to and authorized by the Parties in writing within the Supplemental Agreement.
- 9. Right of Refusal.** Vendor has the right not to sell to a TIPS Member under the awarded agreement at Vendor's discretion unless otherwise required by law.
- 10. Reporting TIPS Sales.** Vendor must report all TIPS Sales to TIPS. If a TIPS sale is initiated by Vendor receiving a TIPS Member's purchase order from TIPS directly, Vendor may consider that specific TIPS Sale reported. Otherwise, with the exception of TIPS Automated Vendors, who have signed an exclusive agreement with TIPS regarding reporting, all TIPS Sales must be reported to TIPS by either: (1) Emailing the purchase order or similar purchase document (with Vendor's Name, as known to TIPS, and the TIPS Contract Name and Number included) to TIPS at tipspo@tips-usa.com with "Confirmation Only" in the subject line of the email within three business days of Vendor's acceptance of the order, or; (2) Within 3 business days of the order being accepted by Vendor, Vendor must login to the TIPS Vendor Portal and successfully self-report all necessary sale information within the Vendor Portal and confirm that it shows up accurately on your current Vendor Portal statement. No other method of reporting is acceptable unless agreed to by the Parties in writing. Failure to report all sales pursuant to this provision may result in immediate cancellation of Vendor's TIPS Contract(s) for cause at TIPS' sole discretion. Please refer to the TIPS [Accounting FAQ's](#) for more information about reporting sales and if you have further questions, contact the Accounting Team at accounting@tips-usa.com.
- 11. TIPS Administration Fees.** The collection of administrative fees by TIPS, a government entity, for performance of these procurement services is required pursuant to Texas Government Code Section 791.011 et. seq. The administration fee ("TIPS Administration Fee") is the amount legally owed by Vendor to TIPS for TIPS Sales made by Vendor. The TIPS Administration Fee amount is typically a set percentage of the amount paid by the TIPS Member for each TIPS Sale, less shipping cost, bond cost, and taxes if applicable and identifiable, which is legally due to TIPS, but the exact TIPS Administration Fee for this Contract is published in the corresponding solicitation and is incorporated herein by reference. TIPS Administration Fees are due to TIPS immediately upon Vendor's receipt of payment, including partial payment, for a TIPS Sale. The TIPS Administration Fee is assessed on the amount paid by the TIPS Member, not on the Vendor's cost or on the amount for which the Vendor sold the item to a dealer or Authorized Reseller. Upon receipt of payment for a TIPS Sale, including partial payment (which renders TIPS Administration Fees immediately due), Vendor shall issue to TIPS the corresponding TIPS Administration Fee payment as soon as possible but not later than thirty-one calendar days following Vendor's receipt of payment. Vendor shall pay TIPS via check unless otherwise agreed to by the Parties in writing. Vendor shall include clear documentation with the issued payment dictating to which sale(s) the amount should be applied. Vendor may create a payment report within their TIPS Vendor Portal which is the preferred documentation dictating to which TIPS Sale(s) the amount should be applied. Failure to pay all TIPS Administration Fees pursuant to this provision may result in immediate cancellation of Vendor's TIPS Contract(s) for cause at TIPS' sole discretion as well as the initiation of collection and legal actions by TIPS against Vendor to the extent permitted by law. Any overpayment of participation fees to TIPS by Vendor will be refunded to the Vendor

within ninety (90) days of receipt of notification if TIPS receives written notification of the overpayment not later than the expiration of six (6) months from the date of overpayment and TIPS determines that the amount was not legally due to TIPS pursuant to this agreement and applicable law. Any notification of overpayment received by TIPS after the expiration of six (6) months from the date that TIPS received the payment will render the overpayment non-refundable. Region 8 ESC and TIPS reserve the right to extend the six (6) month deadline if approved by the Region 8 ESC Board of Directors. TIPS reserves all rights under the law to collect TIPS Administration Fees due to TIPS pursuant to this Agreement.

- 12. Term of the Agreement.** This Agreement with TIPS is for approximately three years with a one-year, consecutive option for renewal as described herein. Renewal options are not automatic and shall only be effective if offered by TIPS at its sole discretion. If TIPS offers a renewal option, the Vendor will be notified via email issued to Vendor's then-listed Primary Contact. The renewal option shall be deemed accepted by Vendor unless Vendor notifies TIPS of its objection to the renewal option in writing and confirms receipt by TIPS.

Actual Effective Date: Agreement is effective upon signature by authorized representatives of both Parties. The Effective Date does not affect the "Term Calculation Start Date."

Term Calculation Start Date: To keep the contract term consistent for all vendors awarded under a single TIPS contract, Vendor shall calculate the foregoing term as starting on the last day of the month that "Award Notifications" are anticipated as published in the Solicitation, regardless of the actual Effective Date.

Example of Term Calculation Start Date: If the anticipated "Award Date" published in the Solicitation is May 22, 2023, but extended negotiations delay award until June 27, 2023 (Actual Effective Date), the Term Calculation Start Date shall be May 31, 2023 in this example.

Contract Expiration Date: To keep the contract term consistent for all vendors awarded under a single TIPS contract, the term expiration date shall be three-years from the Term Calculation Start Date.

Example of Contract Expiration Date: If the anticipated "Award Date" published in the Solicitation is May 22, 2023, but extended negotiations delay award until June 27, 2023 (Actual Effective Date), the Term Calculation Start Date shall be May 31, 2023, and the Contract Expiration Date of the resulting initial "three-year" term, (which is subject to an extension(s)) will be May 31, 2026 in this example.

Option(s) for Renewal: Any option(s) for renewal shall begin on the Contract Expiration Date, or the date of the expiration of the prior renewal term where applicable, and continue for the duration specified for the renewal option herein.

Example of Option(s) for Renewal: In this example, if TIPS offers a one-year renewal and the Contract Expiration Date is May 31, 2026, then the one-year renewal is effective from May 31, 2026, to May 31, 2027.

TIPS may offer to extend Vendor Agreements to the fullest extent the TIPS Solicitation resulting in this Agreement permits.

- 13. TIPS Pricing.** Vendor agrees and understands that for each TIPS Contract that it holds, Vendor submitted, agreed to, and received TIPS' approval for specific pricing, discounts, and other pricing terms and incentives which make up Vendor's TIPS Pricing for that TIPS Contract ("TIPS Pricing"). Vendor confirms that Vendor will not add the TIPS Administration Fee as a charge or line-item in a TIPS Sale. Vendor hereby certifies that Vendor shall only offer goods and services through this TIPS Contract if those goods and services are included in or added to Vendor's TIPS Pricing and approved by TIPS. TIPS reserves the right to review Vendor's pricing update requests as specifically as line-item by line-item to determine compliance. However, Vendor contractually agrees that all submitted pricing updates shall be within the original terms of the Vendor's TIPS Pricing (scope, proposed discounts, price increase limitations, and other pricing terms and incentives originally proposed by Vendor) such that TIPS may accept Vendors price increase requests as submitted without additional vetting at TIPS discretion. Any pricing quoted by Vendor to a TIPS Member or on a TIPS Quote shall never exceed Vendor's TIPS Pricing for any good or service offered through TIPS. TIPS Pricing price increases and modifications, if permitted, will be honored according to the terms of the solicitation and Vendor's proposal, incorporated herein by reference.

- 14. Indemnification of TIPS.** VENDOR AGREES TO INDEMNIFY, HOLD HARMLESS, AND DEFEND TIPS, TIPS MEMBERS, TIPS OFFICERS, TIPS EMPLOYEES, TIPS DIRECTORS, AND TIPS TRUSTEES (THE "TIPS INDEMNITEES") FROM AND AGAINST ALL CLAIMS AND SUITS BY THIRD-PARTIES FOR DAMAGES, INJURIES TO PERSONS (INCLUDING DEATH), PROPERTY DAMAGES, LOSSES, EXPENSES, FEES, INCLUDING COURT COSTS, ATTORNEY'S FEES, AND EXPERT FEES, ARISING OUT OF OR RELATING TO VENDOR'S PERFORMANCE UNDER THIS AGREEMENT (INCLUDING THE PERFORMANCE OF VENDOR'S OFFICERS, EMPLOYEES, AGENTS, AUTHORIZED RESELLERS, SUBCONTRACTORS, LICENSEES, OR INVITEES), REGARDLESS OF THE NATURE OF THE CAUSE OF ACTION, INCLUDING WITHOUT LIMITATION CAUSES OF ACTION BASED UPON COMMON, CONSTITUTIONAL, OR STATUTORY LAW OR BASED IN

WHOLE OR IN PART UPON ALLEGATIONS OF NEGLIGENT OR INTENTIONAL ACTS OR OMISSIONS ON THE PART OF VENDOR, ITS OFFICERS, EMPLOYEES, AGENTS, AUTHORIZED RESELLERS, SUBCONTRACTORS, LICENSEES, OR INVITEES. NO LIMITATION OF LIABILITY FOR DAMAGES FOR PERSONAL INJURY OR PROPERTY DAMAGE ARE PERMITTED OR AGREED TO BY TIPS. APART FROM THIS INDEMNIFICATION PROVISION REQUIRING INDEMNIFICATION OF THE TIPS INDEMNITEES' ATTORNEY'S FEES AS SET FORTH ABOVE, RECOVERY OF ATTORNEYS' FEES BY THE PREVAILING PARTY IS AUTHORIZED ONLY IF AUTHORIZED BY TEX. EDUC. CODE § 44.032(F).

- 15. Indemnification and Assumption of Risk – Vendor Data.** VENDOR AGREES THAT IT IS VOLUNTARILY PROVIDING DATA (INCLUDING BUT NOT LIMITED TO: VENDOR INFORMATION, VENDOR DOCUMENTATION, VENDOR'S PROPOSALS, VENDOR PRICING SUBMITTED OR PROVIDED TO TIPS, TIPS CONTRACT DOCUMENTS, TIPS CORRESPONDENCE, VENDOR LOGOS AND IMAGES, VENDOR'S CONTACT INFORMATION, VENDOR'S BROCHURES AND COMMERCIAL INFORMATION, VENDOR'S FINANCIAL INFORMATION, VENDOR'S CERTIFICATIONS, AND ANY OTHER VENDOR INFORMATION OR DOCUMENTATION, INCLUDING WITHOUT LIMITATION SOFTWARE AND SOURCE CODE UTILIZED BY VENDOR, SUBMITTED TO TIPS BY VENDOR AND ITS AGENTS) ("VENDOR DATA") TO TIPS. FOR THE SAKE OF CLARITY, AND WITHOUT LIMITING THE BREADTH OF THE INDEMNITY OBLIGATIONS IN SECTION 14 ABOVE, VENDOR AGREES TO PROTECT, INDEMNIFY, AND HOLD THE TIPS INDEMNITEES HARMLESS FROM AND AGAINST ANY AND ALL LOSSES, CLAIMS, ACTIONS, DEMANDS, ALLEGATIONS, SUITS, JUDGMENTS, COSTS, EXPENSES, FEES, INCLUDING COURT COSTS, ATTORNEY'S FEES, AND EXPERT FEES AND ALL OTHER LIABILITY OF ANY NATURE WHATSOEVER ARISING OUT OF OR RELATING TO: (I) ANY UNAUTHORIZED, NEGLIGENT OR WRONGFUL USE OF, OR CYBER DATA BREACH INCIDENT AND VIRUSES OR OTHER CORRUPTING AGENTS INVOLVING, VENDOR'S DATA, PRICING, AND INFORMATION, COMPUTERS, OR OTHER HARDWARE OR SOFTWARE SYSTEMS, AND; (II) ALLEGATIONS OR CLAIMS THAT ANY VENDOR DATA INFRINGES ON THE INTELLECTUAL PROPERTY RIGHTS OF A THIRD-PARTY OR VENDOR.
- 16. Procedures Related to Indemnification.** In the event that an indemnity obligation arises, Vendor shall pay all amounts set forth in Section 14 and 15 above (including any settlements) and – if it has accepted its indemnity obligation without qualification – control the legal defense to such claim or cause of action, including without limitation attorney selection, strategy, discovery, trial, appeal, and settlement, and TIPS shall, at Vendor's cost and expense (with respect to reasonable out of pocket costs and expenses incurred by TIPS which shall be reimbursed to TIPS by Vendor), provide all commercially reasonable assistance requested by Vendor. In controlling any defense, Vendor shall ensure that all assertions of governmental immunity and all applicable pleas and defenses shall be promptly asserted.
- 17. Indemnity for Underlying Sales and Supplemental Agreements.** Vendor shall be solely responsible for any customer claims or any disputes arising out of TIPS Sales or any Supplemental Agreement as if sold in the open-market. The Parties agree that TIPS shall not be liable for any claims arising out of Vendor's TIPS Sales or Supplemental Agreements, including but not limited to: allegations of product defect or insufficiency, allegations of service defect or insufficiency, allegations regarding delivery defect or insufficiency, allegations of fraud or misrepresentation, allegations regarding pricing or amounts owed for TIPS sales, and/or allegations regarding payment, over-payment, under-payment, or non-payment for TIPS Sales. Payment/Drafting, overpayment/over-drafting, under-payment/under-drafting, or non-payment for TIPS Sales between customer and Vendor and inspections, rejections, or acceptance of such purchases shall be the exclusive respective obligations of Vendor/Customer, and disputes shall be handled in accordance with the terms of the underlying Supplemental Agreement(s) entered into between Vendor and Customer. Vendor acknowledges that TIPS is not a dealer, subcontractor, agent, or reseller of Vendor's goods and services and shall not be responsible for any claims arising out of alleged insufficiencies or defects in Vendor's goods and services, should any arise.
- 18. Confidentiality of Vendor Data.** Vendor understands and agrees that by signing this Agreement, all Vendor Data is hereby released to TIPS, TIPS Members, and TIPS third-party administrators to effectuate Vendor's TIPS Contract except as provided for herein. The Parties agree that Vendor Data is accessible by all TIPS Members as if submitted directly to that TIPS Member Customer for purchase consideration. If Vendor otherwise considers any portion of Vendor's Data to be confidential and not subject to public disclosure pursuant to Chapter 552 Texas Gov't Code (the "Public Information Act") or other law(s) and orders, Vendor must have identified the claimed confidential materials through proper execution of the Confidentiality Claim Form which is required to be submitted as part of Vendor's proposal resulting in this Agreement and incorporated by reference. The Confidentiality Claim Form included in Vendor's proposal and incorporated herein by reference is the sole indicator of whether Vendor considers any Vendor Data confidential in the event TIPS receives a Public Information Request. If TIPS receives a request, any responsive documentation not deemed confidential by you in this manner will be automatically released. For Vendor Data deemed confidential by you in this manner, TIPS will follow procedures of controlling statute(s) regarding any claim of confidentiality and shall not be liable for any release of information required by law, including Attorney General determination and opinion. In the event that TIPS receives a written request for information pursuant to the Public Information Act that affects Vendor's interest in any information or data furnished to TIPS by Vendor, and TIPS requests an opinion from the Attorney General, Vendor may, at its own option and expense, prepare comments and submit information directly to the Attorney General stating why the requested information is exempt from disclosure pursuant to the requirements of the Public Information Act. Vendor is solely responsible for submitting the memorandum brief and information to the Attorney General

within the time period prescribed by the Public Information Act. Notwithstanding any other information provided in this solicitation or Vendor designation of certain Vendor Data as confidential or proprietary, Vendor's acceptance of this TIPS Vendor Agreement constitutes Vendor's consent to the disclosure of Vendor's Data, including any information deemed confidential or proprietary, to TIPS Members or as ordered by a Court or government agency, including without limitation the Texas Attorney General. Vendor agrees that TIPS shall not be responsible or liable for any use or distribution of information or documentation by TIPS Members or as required by law.

- 19. Vendor's Authorized Resellers.** TIPS recognizes that many vendors operate in the open market through the use of resellers or dealers. For that reason, TIPS permits Vendor to authorize Authorized Resellers within its Vendor Portal and make TIPS Sales through the Authorized Reseller(s). Once authorized by Vendor in the Vendor Portal, the Authorized Reseller(s) may make TIPS sales to TIPS Members. However, all purchase documents must include: (1) Authorized Reseller's Name; (2) Vendor's Name, as known to TIPS, and; (3) Vendor's TIPS Contract Name and Number under which it is making the TIPS Sale. Either Vendor or Reseller may report the sale pursuant to the terms herein. However, Vendor agrees that it is legally responsible for all reporting and fee payment as described herein for TIPS Sales made by Authorized Resellers. The TIPS Administration Fee is assessed on the amount paid by the TIPS Member, not on the Vendor's cost or on the amount for which the Vendor sold the item to a dealer or Authorized Reseller. The Parties intend that Vendor shall be responsible and liable for TIPS Sales made by Vendor's Authorized Resellers. Vendor agrees that it is voluntarily authorizing this Authorized Reseller and in doing so, Vendor agrees that it is doing so at its own risk and agrees to protect, indemnify, and hold TIPS harmless in accordance with Sections 14-17 above related to Authorized Reseller TIPS Sales made pursuant to this Agreement or purporting to be made pursuant to this Agreement that may be asserted against Vendor whether rightfully brought or otherwise. The Parties further agree that it is no defense to Vendor's breach of this Agreement that an Authorized Reseller caused Vendor of breach this Agreement.
- 20. Circumvention of TIPS Sales.** When a public entity initiates a purchase with Vendor, if the Member inquires verbally or in writing whether Vendor holds a TIPS Contract, it is the duty of the Vendor to verify whether the Member is seeking a TIPS purchase. Any request for quote, customer communication, or customer purchase initiated through or referencing a TIPS Contract shall be completed through TIPS pursuant to this Agreement. Any encouragement or participation by Vendor in circumventing a TIPS sale being completed may result in immediate termination of Vendor's TIPS Contract(s) for cause as well as preclusion from future TIPS opportunities at TIPS sole discretion.
- 21. State of Texas Franchise Tax.** By signature hereon, Vendor hereby certifies that Vendor is not currently delinquent in the payment of any franchise taxes owed to the State of Texas under Chapter 171 of the Texas Tax Code.
- 22. Termination.**
- A) Termination for Convenience. TIPS may, by written notice to Vendor, terminate this Agreement for convenience, in whole or in part, at any time by giving thirty (30) days' written notice to Vendor of such termination, and specifying the effective date thereof.
 - B) Termination for Cause. If Vendor fails to materially perform pursuant to the terms of this Agreement, TIPS shall provide written notice to Vendor specifying the default. If Vendor does not cure such default within thirty (30) days, TIPS may terminate this Agreement, in whole or in part, for cause. If TIPS terminates this Agreement for cause, and it is later determined that the termination for cause was wrongful, the termination shall automatically be converted to and treated as a termination for convenience.
 - C) Vendor's Termination. If TIPS fails to materially perform pursuant to the terms of this Agreement, Vendor shall provide written notice to TIPS specifying the default ("Notice of Default"). If TIPS does not cure such default within thirty (30) days, Vendor may terminate this Agreement, in whole or in part, for cause. If Vendor terminates this Agreement for cause, and it is later determined that the termination for cause was wrongful, the termination shall automatically be converted to and treated as a termination for convenience.
 - D) Upon termination, all TIPS Sale orders previously accepted by Vendor shall be fulfilled and Vendor shall be paid for all TIPS Sales executed pursuant to the applicable terms. All TIPS Sale orders presented to Vendor but not fulfilled by Vendor, prior to the actual termination of this agreement shall be honored at the option of the TIPS Member. TIPS shall submit to Vendor an invoice for any outstanding TIPS Administration Fees and approved expenses and Vendor shall pay such fees and expenses within 30 calendar days of receipt of such valid TIPS invoice. Vendor acknowledges and agrees that continued participation in TIPS is subject to TIPS' sole discretion and that any Vendor may be removed from the TIPS program at any time with or without cause. This

termination clause does not affect TIPS Sales Supplemental Agreements pursuant to this term regarding termination and the Survival Clause term.

- E) Vendor hereby waives any and all claims for damages, including, but not limited, to consequential damages or lost profits, that might arise from TIPS' act of terminating this Agreement.

- 23. Survival Clause.** It is the intent of the Parties that this Agreement and procurement method applies to any TIPS Sale made during the life of this Agreement even if made on or near the Contract Expiration Date as defined herein. Thus, all TIPS Sales, including but not limited to: leases, service agreements, license agreements, open purchase orders, warranties, and contracts, even if they extend months or years past the TIPS Contract Expiration Date, shall survive the expiration or termination of this Agreement subject to the terms and conditions of the Supplemental Agreement between Customer and Vendor or unless otherwise specified herein.
- 24. Audit Rights.** Due to transparency statutes and public accountability requirements of TIPS and TIPS Members, Vendor shall at their sole expense, maintain documentation of all TIPS Sales for a period of three years from the time of the TIPS Sale. In order to ensure and confirm compliance with this agreement, TIPS shall have authority to conduct audits of Vendor's TIPS Pricing or TIPS Sales with thirty-days' notice unless the audit is ordered by a Court Order or by a Government Agency with authority to do so without said notice. Notwithstanding the foregoing, in the event that TIPS is made aware of any pricing being offered to eligible entities that is materially inconsistent with Vendor's TIPS Pricing, TIPS shall have the ability to conduct the audit internally or may engage a third- party auditing firm to investigate any possible non-compliant conduct or may terminate the Agreement according to the terms of this Agreement. In the event of an audit, the requested materials shall be reasonably provided in the time, format, and at the location acceptable to TIPS. TIPS agrees not to perform a random audit the TIPS transaction documentation more than once per calendar year, but reserves the right to audit for just cause or as required by any governmental agency or court with regulatory authority over TIPS or the TIPS Member. These audit rights shall survive termination of this Agreement for a period of one (1) year from the effective date of termination.
- 25. Conflicts of Interest.** The Parties confirm that they have not offered, given, or accepted, nor intend to give at any time hereafter any economic opportunity, future employment, gift, loan, gratuity, special discount, trip, favor, service to the other in connection with this Agreement. Vendor affirms that, to the best of Vendor's knowledge, this Agreement has been arrived at independently, and is awarded without collusion with anyone to obtain information or gain any favoritism that would in any way limit competition or give an unfair advantage over other vendors in the award of this Agreement. Vendor agrees that it has disclosed any necessary affiliations with Region 8 Education Service Center and the TIPS Department, if any, through the Conflict of Interest attachment provided in the solicitation resulting in this Agreement.
- 26. Volume of TIPS Sales.** Nothing in this Agreement or any TIPS communication may be construed as a guarantee that TIPS or TIPS Members will submit any TIPS orders to Vendor at any time.
- 27. Compliance with the Law.** The Parties agree to comply fully with all applicable federal, state, and local statutes, ordinances, rules, and regulations applicable to their entity in connection with the programs contemplated under this Agreement.
- 28. Severability.** If any term(s) or provision(s) of this Agreement are held by a court of competent jurisdiction to be invalid, void, or unenforceable, then such term(s) or provision(s) shall be deemed restated to reflect the original intention of the Parties as nearly as possible in accordance with applicable law and the remainder of this Agreement, and the remainder of the provisions of this Agreement shall remain in full force and effect and shall in no way be affected, impaired or invalidated, unless such holding causes the obligations of the Parties hereto to be impossible to perform or shall render the terms of this Agreement to be inconsistent with the intent of the Parties hereto.
- 29. Force Majeure.** If by reason of Force Majeure, either party hereto shall be rendered unable wholly or in part to carry out its obligations under this Agreement through no fault of its own then such party shall give notice and full particulars of Force Majeure in writing to the other party within a reasonable time after occurrence of the event or cause relied upon. Upon delivering such notice, the obligation of the affected party, so far as it is affected by such Force Majeure as described, shall be suspended during the continuance of the inability then claimed but for no longer period, and such party shall endeavor to remove or overcome such inability with all reasonable dispatch. In the event that Vendor's obligations are suspended by reason of Force Majeure, all TIPS Sales accepted prior to the Force Majeure event shall be the legal responsibility of Vendor and the terms of the TIPS Sale Supplemental Agreement shall control Vendor's failure to fulfill for a Force Majeure event.
- 30. Immunity.** Vendor agrees that nothing in this Agreement shall be construed as a waiver of sovereign or government immunity; nor constitute or be construed as a waiver of any of the privileges, rights, defenses, remedies, or immunities available to Region 8 Education Service Center or its TIPS Department. The failure to enforce, or any delay in the enforcement of, any privileges, rights, defenses,

remedies, or immunities available to Region 8 Education Service Center or its TIPS Department under this Agreement or under applicable law shall not constitute a waiver of such privileges, rights, defenses, remedies, or immunities or be considered as a basis for estoppel.

- 31. Insurance Requirements.** Vendor agrees to maintain the following minimum insurance requirements for the duration of this Agreement. All policies held by Vendor to adhere to this term shall be written by a carrier with a financial size category of VII and at least a rating of "A-" by A.M. Best Key Rating Guide. The coverages and limits are to be considered minimum requirements and in no way limit the liability of the Vendor(s). Any immunity available to TIPS or TIPS Members shall not be used as a defense by the contractor's insurance policy. Only deductibles applicable to property damage are acceptable, unless proof of retention funds to cover said deductibles is provided. "Claims made" policies will not be accepted. Vendor's required minimum coverage shall not be suspended, voided, cancelled, non-renewed or reduced in coverage or in limits unless replaced by a policy that provides the minimum required coverage except after thirty (30) days prior written notice by certified mail, return receipt requested has been given to TIPS or the TIPS Member if a project or pending delivery of an order is ongoing. Upon request, certified copies of all insurance policies shall be furnished to the TIPS or the TIPS Member. Vendor agrees that when Vendor or its subcontractors are liable for any damages or claims, Vendor's policy, shall be primary over any other valid and collectible insurance carried by the Member or TIPS.

General Liability: \$1,000,000 each Occurrence/Aggregate
Automobile Liability: \$300,000 Includes owned, hired & non-owned
Workers' Compensation: Statutory limits for the jurisdiction in which the Vendor performs under this Agreement. If Vendor performs in multiple jurisdictions, Vendor shall maintain the statutory limits for the jurisdiction with the greatest dollar policy limit requirement.
Umbrella Liability: \$1,000,000 each Occurrence/Aggregate

- 32. Waiver.** No waiver of any single breach or multiple breaches of any provision of this Agreement shall be construed to be a waiver of any breach of any other provision. No delay in acting regarding any breach of any provision shall be construed to be a waiver of such breach.
- 33. Binding Agreement.** This Agreement shall be binding and inure to the benefit of the Parties hereto and their respective heirs, legal successors, and assigns.
- 34. Headings.** The paragraph headings contained in this Agreement are included solely for convenience of reference and shall not in any way affect the meaning or interpretation of any of the provisions of this Agreement.
- 35. Choice of Law and Venue.** This Agreement shall be governed by, construed, and enforced in accordance with the laws of the State of Texas. Any proceeding, claim, action, or alternative dispute resolution arising out of or relating to this Agreement or involving TIPS shall be brought in a State Court of competent jurisdiction in Camp County, Texas, or if Federal Court is legally required, a Federal Court of competent jurisdiction in the Eastern District of Texas, and each of the Parties irrevocably submits to the exclusive jurisdiction of said court in any such proceeding, waives any objection it may now or hereafter have to venue or to convenience of forum, agrees that all claims in respect of the proceeding shall be heard and determined only in any such court, and agrees not to bring any proceeding arising out of or relating to this procurement process or any contract resulting from or and contemplated transaction in any other court. The Parties agree that either or both of them may file a copy of this paragraph with any court as written evidence of the knowing, voluntary and freely bargained for agreement between the Parties irrevocably to waive any objections to venue or to convenience of forum.
- 36. Relationship of the Parties.** Nothing contained in this Agreement shall be construed to make one Party an agent of the other Party nor shall either party have any authority to bind the other in any respect, unless expressly authorized by the other party in writing. The Parties are independent contractors and nothing in this Agreement creates a relationship of employment, trust, agency or partnership between them.
- 37. Assignment.** No assignment of this Agreement or of any duty or obligation of performance hereunder, shall be made in whole or in part by a Party hereto without the prior written consent of the other Party. Written consent of TIPS shall not be unreasonably withheld.
- 38. Minimum Condition and Warranty Requirements for TIPS Sales.** All goods quoted or sold through a TIPS Sale shall be new unless clearly stated otherwise in writing. All new goods and services shall include the applicable manufacturers minimum standard warranty unless otherwise agreed to in the Supplemental Agreement.

- 39. Minimum Customer Support Requirements for TIPS Sales.** Vendor shall provide timely and commercially reasonable support for TIPS Sales or as agreed to in the applicable Supplemental Agreement.
- 40. Minimum Shipping Requirements for TIPS Sales.** Vendor shall ship, deliver, or provide ordered goods and services within a commercially reasonable time after acceptance of the order. If a delay in delivery is anticipated, Vendor shall notify the TIPS Member as to why delivery is delayed and provide an updated estimated time for completion. The TIPS Member may cancel the order if the delay is not commercially acceptable or not consistent with the Supplemental Agreement applicable to the order.
- 41. Minimum Vendor License Requirements.** Vendor shall maintain, in current status, all federal, state, and local licenses, bonds and permits required for the operation of the business conducted by Vendor. Vendor shall remain fully informed of and in compliance with all ordinances and regulations pertaining to the lawful provision of goods or services under the TIPS Agreement. TIPS and TIPS Members reserve the right to stop work and/or cancel a TIPS Sale or terminate this or any TIPS Sale Supplemental Agreement involving Vendor if Vendor's license(s) required to perform under this Agreement or under the specific TIPS Sale have expired, lapsed, are suspended or terminated subject to a 30-day cure period unless prohibited by applicable statute or regulation.
- 42. Minimum Vendor Legal Requirements.** Vendor shall remain aware of and comply with this Agreement and all local, state, and federal laws governing the sale of products/services offered by Vendor under this contract. Such applicable laws, ordinances, and policies must be complied with even if not specified herein.
- 43. Minimum Site Requirements for TIPS Sales (when applicable to TIPS Sale).**

Cleanup: When performing work on site at a TIPS Member's property, Vendor shall clean up and remove all debris and rubbish resulting from their work as required or directed by the TIPS Member or as agreed by the parties. Upon completion of work, the premises shall be left in good repair and an orderly, neat, clean and unobstructed condition.

Preparation: Vendor shall not begin a project for which a TIPS Member has not prepared the site, unless Vendor does the preparation work at no cost, or until TIPS Member includes the cost of site preparation in the TIPS Sale Site preparation includes, but is not limited to: moving furniture, installing wiring for networks or power, and similar pre-installation requirements.

Registered Sex Offender Restrictions: For work to be performed at schools, Vendor agrees that no employee of Vendor or a subcontractor who has been adjudicated to be a registered sex offender will perform work at any time when students are, or reasonably expected to be, present unless otherwise agreed by the TIPS Member. Vendor agrees that a violation of this condition shall be considered a material breach and may result in the cancellation of the TIPS Sale at the TIPS Member's discretion. Vendor must identify any additional costs associated with compliance of this term. If no costs are specified, compliance with this term will be provided at no additional charge.

Safety Measures: Vendor shall take all reasonable precautions for the safety of employees on the worksite, and shall erect and properly maintain all necessary safeguards for protection of workers and the public. Vendor shall post warning signs against all hazards created by the operation and work in progress. Proper precautions shall be taken pursuant to state law and standard practices to protect workers, general public and existing structures from injury or damage.

Smoking: Persons working under Agreement shall adhere to the TIPS Member's or local smoking statutes, codes, ordinances, and policies.

- 44. Payment for TIPS Sales.** TIPS Members may make payments for TIPS Sales directly to Vendor, Vendor's Authorized Reseller, or as otherwise agreed to in the applicable Supplemental Agreement after receipt of the invoice and in compliance with applicable payment statutes. Regardless of how payment is issued or received for a TIPS Sale, Vendor is responsible for all reporting and TIPS Administration Fee payment requirements as stated herein.
- 45. Marketing.** Vendor agrees to allow TIPS to use their name and logo within the TIPS website, database, marketing materials, and advertisements unless Vendor negotiates this term to include a specific acceptable-use directive. Any use of TIPS' name and logo or any form of publicity, inclusive of press release, regarding this Agreement by Vendor must have prior approval from TIPS which will not be unreasonably withheld. Request may be made by email to tips@tips-usa.com. For marketing efforts directed to TIPS Members, Vendor must request and execute a separate Joint Marketing Disclaimer, at marketing@tips-usa.com, before TIPS can release contact information for TIPS Member entities for the purpose of marketing your TIPS contract(s). Vendor must adhere to strict Marketing Requirements once a disclaimer is executed. The Joint Marketing Disclaimer is a supplemental agreement specific to joint marketing efforts and has no effect on the terms of the TIPS Vendor Agreement. Vendor agrees that any images, photos, writing, audio, clip art,

music, or any other intellectual property ("Property") or Vendor Data utilized, provided, or approved by Vendor during the course of the joint marketing efforts are either the exclusive property of Vendor, or Vendor has all necessary rights, license, and permissions to utilize said Property in the joint marketing efforts. Vendor agrees that they shall indemnify and hold harmless TIPS and its employees, officers, agents, representatives, contractors, assignees, designees, and TIPS Members from any and all claims, damages, and judgments involving infringement of patent, copyright, trade secrets, trade or services marks, and any other intellectual or intangible property rights and/or claims arising from the Vendor's (including Vendor's officers', employees', agents', Authorized Resellers', subcontractors', licensees', or invitees') unauthorized use or distribution of Vendor Data and Property.

- 46. Tax Exempt Status of TIPS Members.** Most TIPS Members are tax exempt entities and the laws and regulations applicable to the specific TIPS Member customer shall control.
- 47. Automatic Renewal Limitation for TIPS Sales.** No TIPS Sale may incorporate an automatic renewal clause that exceeds month to month terms with which the TIPS Member must comply. All renewal terms incorporated into a TIPS Sale Supplemental Agreement shall only be valid and enforceable when Vendor received written confirmation of acceptance of the renewal term from the TIPS Member for the specific renewal term. The purpose of this clause is to avoid a TIPS Member inadvertently renewing an Agreement during a period in which the governing body of the TIPS Member has not properly appropriated and budgeted the funds to satisfy the Agreement renewal. Any TIPS Sale Supplemental Agreement containing an "Automatic Renewal" clause that conflicts with these terms is rendered void and unenforceable.
- 48. Choice of Law Limitation for TIPS Sales.** Vendor agrees that if any "Choice of Law" provision is included in any TIPS Sale agreement/contract between Vendor and a TIPS Member, that clause must provide that the "Choice of Law" applicable to the TIPS Sale agreement/contract between Vendor and TIPS Member shall be the state where the TIPS Member operates unless the TIPS Member expressly agrees otherwise. Any TIPS Sale Supplemental Agreement containing a "Choice of Law" clause that conflicts with these terms is rendered void and unenforceable.
- 49. Venue Limitation for TIPS Sales.** Vendor agrees that if any "Venue" provision is included in any TIPS Sale Agreement/contract between Vendor and a TIPS Member, that clause must provide that the "Venue" for any litigation or alternative dispute resolution shall be in the state and county where the TIPS Member operates unless the TIPS Member expressly agrees otherwise. Any TIPS Sale Supplemental Agreement containing a "Venue" clause that conflicts with these terms is rendered void and unenforceable.
- 50. Indemnity Limitation for TIPS Sales.** Texas and other jurisdictions restrict the ability of governmental entities to indemnify others. Vendor agrees that if any "Indemnity" provision which requires the TIPS Member to indemnify Vendor is included in any TIPS sales agreement/contract between Vendor and a TIPS Member, that clause must either be stricken or qualified by including that such indemnity is only permitted, "to the extent permitted by the laws and constitution of [TIPS Member's State]" unless the TIPS Member expressly agrees otherwise. Any TIPS Sale Supplemental Agreement containing an "Indemnity" clause that conflicts with these terms is rendered void and unenforceable.
- 51. Arbitration Limitation for TIPS Sales.** Vendor agrees that if any "Arbitration" provision is included in any TIPS Sale agreement/contract between Vendor and a TIPS Member, that clause may not require that the arbitration is mandatory or binding. Vendor agrees that if any "Arbitration" provision is included in any TIPS Sale agreement/contract between Vendor and a TIPS Member, that clause provides for only voluntary and non-binding arbitration unless the TIPS Member expressly agrees otherwise. Any TIPS Sale Supplemental Agreement containing a "Arbitration" clause that conflicts with these terms is rendered void and unenforceable.

In Witness Whereof, the parties hereto, each acting under due and proper authority, have signed this Agreement.

TIPS VENDOR AGREEMENT SIGNATURE FORM TIPS RFP

230701 Indoor Air Quality Equipment and Services

Vendor Name: Medical Illumination International, Inc.

Vendor Address: 19749 Dearborn Street

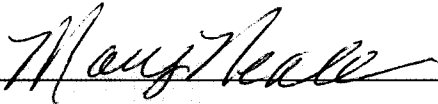
City: Chatsworth State: CA Zip Code: 91311

Vendor Authorized Signatory Name: Mary Neale

Vendor Authorized Signatory Title: General Counsel

Vendor Authorized Signatory Phone: (818) 838-3025, ext. 130

Vendor Authorized Signatory Email: mneale@medillum.com

Vendor Authorized Signature:  Date: 8-17-23

(The following is for TIPS completion only)

TIPS Authorized Signatory Name: Dr. Fitts

TIPS Authorized Signatory Title: Executive Director

TIPS Authorized Signature:  Date: 9/28/2023



230701

**Medical Illumination International, Inc.
Supplier Response**

Event Information

Number: 230701

Title: Indoor Air Quality Equipment and Services

Type: Request for Proposal

Issue Date: 7/6/2023

Deadline: 8/18/2023 03:00 PM (CT)

Notes: This is a solicitation issued by The Interlocal Purchasing System (TIPS), a department of Texas Region 8 Education Service Center. It is an Indefinite Delivery, Indefinite Quantity ("IDIQ") solicitation. It will result in contracts that provide, through adoption/"piggyback" an indefinite quantity of supplies/services, during a fixed period of time, to TIPS public entity and qualifying non-profit "TIPS Members" throughout the nation. Thus, there is no specific project or scope of work to review. Rather this solicitation is issued as a prospective award for utilization when any TIPS Member needs the goods or services offered during the life of the agreement.

IF YOU CURRENTLY HOLDS TIPS CONTRACT 200701 INDOOR AIR QUALITY EQUIPMENT AND SERVICES ("200701"), YOU MUST RESPOND TO THIS SOLICITATION TO PREVENT LAPSE OF CONTRACT UNLESS YOU HOLD ANOTHER CURRENT TIPS CONTRACT THAT COVERS ALL OF YOUR AIR QUALITY OFFERINGS. THIS AWARDED CONTRACT WILL REPLACE YOUR EXPIRING TIPS CONTRACT 200701.

IF YOU HOLD ANOTHER TIPS CONTRACT OTHER THAN 200701 WHICH COVERS ALL OF YOUR AIR QUALITY OFFERINGS AND YOU ARE SATISFIED WITH IT, THERE IS NO NEED TO RESPOND TO THIS SOLICITATION UNLESS YOU PREFER TO HOLD BOTH

Contact Information

Address: Region 8 Education Service Center
4845 US Highway 271 North
Pittsburg, TX 75686

Phone: +1 (866) 839-8477

Email: bids@tips-usa.com

Medical Illumination International, Inc. Information

Contact: Gloria Sorensen
Address: 19749 Dearborn Street
Chatsworth, CA 91340
Phone: (818) 838-3025
Fax: (818) 838-3725
Toll Free: (800) 831-1222
Email: gloria@medillum.com
Web Address: www.vidashield.com

By submitting your response, you certify that you are authorized to represent and bind your company.

Mary Neale

Signature

Submitted at 8/18/2023 12:30:47 PM (CT)

mneale@medillum.com

Email

Requested Attachments

Vendor Agreement

230701 Vendor Agreement Name
Included.pdf

The Vendor Agreement must be downloaded from the “Attachments” section of the IonWave eBid System, reviewed, Vendor Name placed in the line provided at the top, and uploaded to this location. If Vendor has proposed deviations to the Vendor Agreement, Vendor may assert so in the Attribute Questions and those shall be addressed during evaluation.

Pricing Form 1

230701 Pricing Form 1
Completed.xlsx

Pricing Form 1 must be downloaded from the “Attachments” section of the IonWave eBid System, reviewed, properly completed as instructed, and uploaded to this location.

Alternate or Supplemental Pricing Documents

No response

Optional. If when completing Pricing Form 1 & Pricing Form 2 you direct TIPS to view additional, alternate, or supplemental pricing documentation, you may upload that documentation.

Reference Form

230701 Reference Form
Completed.xls

The Reference Form must be downloaded from the “Attachments” section of the IonWave eBid System, reviewed, properly completed, and uploaded to this location. The Reference Form must be uploaded in Excel format.

Required Confidentiality Claim Form

Contract 230701 Confidentiality
Claim Form.pdf

The Required Confidentiality Claim Form must be downloaded from the “Attachments” section of the IonWave eBid System, reviewed, properly completed, and uploaded to this location. This is the only way for Vendor to assert confidentiality of any information submitted.

Conflict of Interest Questionnaire - Form CIQ

No response

Do not upload this form unless you have a reportable conflict with TIPS. There is an Attribute entitled “Conflict of Interest Questionnaire Requirement” immediately followed by an Attribute entitled “Conflict of Interest Questionnaire Requirement – Form CIQ – Continued.” Properly respond to those Attributes and only upload this form if applicable/instructed. If upload is required based on your response to those Attributes, the Conflict of Interest Questionnaire – Form CIQ must be downloaded from the “Attachments” section of the IonWave eBid System, reviewed, properly completed, and uploaded at this location.

Vendor’s Warranties, Terms, and Conditions (Supplemental Vendor Information Only)

MI Warranty 8-23.pdf

Optional. If Vendor would like to display any standard warranties, terms, or conditions which are often applicable to their offerings for TIPS and TIPS Member Customer consideration, Vendor may upload those at this location. These supplemental documents shall not be considered part of the TIPS Contract. Rather, they are Vendor Supplemental Information for marketing and informational purposes only.

Supplemental Vendor Information (Supplemental Vendor Information Only)

VidaShield Brochure and White Paper.pdf

Optional. If Vendor would like to display or include any brochures, promotional documents, marketing materials, or other Vendor Information for TIPS and TIPS Member Customer consideration, Vendor may upload those at this location. These supplemental documents shall not be considered part of the TIPS Contract. Rather, they are Vendor Supplemental Information for marketing and informational purposes only.

Disclosure of Lobbying Activities - Standard Form - LLL

No response

Do not upload this form unless Vendor has reportable lobbying activities. There are Attributes entitled, “2 CFR Part 200 or Federal Provision - Byrd Anti-Lobbying Amendment – Continued.” Properly respond to those Attributes and only upload this form if applicable/instructed. If upload is required based on your response to those Attributes, the Disclosure of Lobbying Activities – Standard Form - LLL must be downloaded from the “Attachments” section of the IonWave eBid System, reviewed, properly completed, and uploaded to this location.

Current Form W-9

W9 MI 2023 SIG(1).pdf

Vendor must upload their current IRS Tax Form W-9. The legal name, EIN, and d/b/a's listed should match the information provided herein exactly. This form will be utilized by TIPS to properly identify your entity.

Certificates & Licenses (Supplemental Vendor Information Only)

No response

Optional. If Vendor would like to display any applicable certificates or licenses (including HUB certificates) for TIPS and TIPS Member Customer consideration, Vendor may upload those at this location. These supplemental documents shall not be considered part of the TIPS Contract. Rather, they are Vendor Supplemental Information for marketing and informational purposes only.

Pricing Form 2

230701 Pricing Form 2 Completed - NA.xlsx

Pricing Form 2 must be downloaded from the “Attachments” section of the IonWave eBid System, reviewed, properly completed as instructed, and uploaded to this location.

Vendor Logo (Supplemental Vendor Information Only)

No response

Optional. If Vendor desires that their logo be displayed on their public TIPS profile for TIPS and TIPS Member viewing, Vendor may upload that logo at this location. These supplemental documents shall not be considered part of the TIPS Contract. Rather, they are Vendor Supplemental Information for marketing and informational purposes only.

Vendor Agreement Signature Form

Contract 230701 Vendor Agreement Signature Form.pdf

The Vendor Agreement Signature Form must be downloaded from the “Attachments” section of the IonWave eBid System, reviewed, properly completed, and uploaded to this location. If Vendor has proposed deviations to the Vendor Agreement, Vendor may leave the signature line of this page blank and assert so in the Attribute Questions and those shall be addressed during evaluation.

Bid Attributes

1	<p>Disadvantaged/Minority/Women Business & Federal HUBZone</p> <p>Some participating public entities are required to seek Disadvantaged/Minority/Women Business & Federal HUBZone ("D/M/WBE/Federal HUBZone") vendors. Does Vendor certify that their entity is a D/M/WBE/Federal HUBZone vendor?</p> <p>If you respond "Yes," you must upload current certification proof in the appropriate "Response Attachments" location.</p> <p><input type="text" value="NO"/></p>
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2 Historically Underutilized Business (HUB)

Some participating public entities are required to seek Historically Underutilized Business (HUB) vendors as defined by the Texas Comptroller of Public Accounts Statewide HUB Program. Does Vendor certify that their entity is a HUB vendor?

If you respond "Yes," you must upload current certification proof in the appropriate "Response Attachments" location.

No

3 National Coverage

Can the Vendor provide its proposed goods and services to all 50 US States?

Yes - All 50 States

4 States Served

If Vendor answered "No" to the question entitled "National Coverage," please list all states where vendor can provide the goods and services proposed directly below. Your response may dictate which potential TIPS Member customers consider purchasing your offerings.

No response

5 Description of Vendor Entity and Vendor's Goods & Services

If awarded, this description of Vendor and Vendor's goods and services will appear on the TIPS website for customer/public viewing.

Medical Illumination International, Inc. is an employee-owned business founded 45 years ago with the sole focus of providing to the medical field the best-engineered, highest quality and most cost-effective surgery and examination lighting systems. For that reason, our expertise is recognized and respected globally by physicians, surgeons, and others within the medical field. Over the years, building on our strong reputation within the medical field, we added complementary products to our product mix, and in 2017, seeing a great need for a robust, yet user-friendly, disinfection system, we began offering our patented VidaShield UV24 Air Purification System. VidaShield UV24 is a fast, continuous UV-C air purification system designed as a light fixture. Ultraviolet light is used throughout healthcare, schools and other settings to neutralize microorganisms on surfaces, in water, and in air. UV-C is very effective in neutralizing pathogens, however, it is also harmful to humans when they are exposed to its direct rays. Unlike other devices, the VidaShield UV24 system may be operated in occupied rooms allowing for 24 hour per day shielded ultraviolet germicidal irradiation. This revolutionary device draws room air in through an array of fans and filters to an unseen UV-C radiation chamber mounted above a traditional two by four light fixture and then returns treated air back to the room. Medical Illumination takes pride in working closely with customers to find out exactly what they need, whether it be in medical lighting or in UV-C lighting technology for disinfection. Our products are all made in the United States and are installed in hospitals, clinics, pharmacies, schools, day cares, gyms, entertainment venues, and offices the world over.

6 Primary Contact Name

Please identify the individual who will be primarily responsible for all TIPS matters and inquiries for the duration of the contract.

Brett Messina

7 Primary Contact Title

Primary Contact Title

Vice President of Sales & Marketing

8	<p>Primary Contact Email</p> <p>Please enter a valid email address that will definitely reach the Primary Contact.</p> <input type="text" value="brett.messina@nuvosurgical.com"/>
9	<p>Primary Contact Phone</p> <p>Numbers only, no symbols or spaces (Ex. 8668398477). The system will auto-populate your entry with commas once submitted which is appropriate and expected (Ex. 8,668,398,477).</p> <p>Please provide the accurate and current phone number where the individual who will be primarily responsible for all TIPS matters and inquiries for the duration of the contract can be reached directly.</p> <input type="text" value="8148994220"/>
10	<p>Primary Contact Fax</p> <p>Numbers only, no symbols or spaces (Ex. 8668398477). The system will auto-populate your entry with commas once submitted which is appropriate and expected (Ex. 8,668,398,477).</p> <input type="text" value="8148991410"/>
11	<p>Primary Contact Mobile</p> <p>Numbers only, no symbols or spaces (Ex. 8668398477). The system will auto-populate your entry with commas once submitted which is appropriate and expected (Ex. 8,668,398,477).</p> <input type="text" value="8145042998"/>
12	<p>Secondary Contact Name</p> <p>Please identify the individual who will be secondarily responsible for all TIPS matters and inquiries for the duration of the contract.</p> <input type="text" value="Gloria Sorensen"/>
13	<p>Secondary Contact Title</p> <p>Secondary Contact Title</p> <input type="text" value="Customer Service Manager"/>
14	<p>Secondary Contact Email</p> <p>Please enter a valid email address that will definitely reach the Secondary Contact.</p> <input type="text" value="gloria@medillum.com"/>
15	<p>Secondary Contact Phone</p> <p>Numbers only, no symbols or spaces (Ex. 8668398477). The system will auto-populate your entry with commas once submitted which is appropriate and expected (Ex. 8,668,398,477).</p> <p>Please provide the accurate and current phone number where the individual who will be secondarily responsible for all TIPS matters and inquiries for the duration of the contract can be reached directly.</p> <input type="text" value="8188383025"/>
16	<p>Secondary Contact Fax</p> <p>Numbers only, no symbols or spaces (Ex. 8668398477). The system will auto-populate your entry with commas once submitted which is appropriate and expected (Ex. 8,668,398,477).</p> <input type="text" value="8188383725"/>

17	Secondary Contact Mobile Numbers only, no symbols or spaces (Ex. 8668398477). The system will auto-populate your entry with commas once submitted which is appropriate and expected (Ex. 8,668,398,477). <input type="text" value="No response"/>
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18	Administration Fee Contact Name Please identify the individual who will be responsible for all payment, accounting, and other matters related to Vendor's TIPS Administration Fee due to TIPS for the duration of the contract. <input type="text" value="Mila Kasman"/>
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19	Administration Fee Contact Email Please enter a valid email address that will definitely reach the Administration Fee Contact. <input type="text" value="mila@medillum.com"/>
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20	Administration Fee Contact Phone Numbers only, no symbols or spaces (Ex. 8668398477). The system will auto-populate your entry with commas once submitted which is appropriate and expected (Ex. 8,668,398,477). <input type="text" value="8188383025"/>
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21	Purchase Order and Sales Contact Name Please identify the individual who will be responsible for receiving and processing purchase orders and sales under the TIPS Contract. <input type="text" value="Gloria Sorensen"/>
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22	Purchase Order and Sales Contact Email Please enter a valid email address that will definitely reach the Purchase Order and Sales Contact. <input type="text" value="gloria@medillum.com"/>
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23	Purchase Order and Sales Contact Phone Numbers only, no symbols or spaces (Ex. 8668398477). The system will auto-populate your entry with commas once submitted which is appropriate and expected (Ex. 8,668,398,477). <input type="text" value="8188383025"/>
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24	Company Website Company Website (Format - www.company.com) <input type="text" value="http://www.vidashield.com"/>
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25	Entity D/B/A's and Assumed Names You must confirm that you are responding to this solicitation under your legal entity name. Go now to your Supplier Profile in this eBid System and confirm that your profile reflects your "Legal Name" as it is listed on your W9. In this question, please identify all of your entity's assumed names and D/B/A's. Please note that you will be identified publicly by the Legal Name under which you respond to this solicitation unless you organize otherwise with TIPS after award. <input type="text" value="Nuvo Surgical"/>
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26	Primary Address Primary Address <input type="text" value="19749 Dearborn Street"/>
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27	Primary Address City
	Primary Address City <input type="text" value="Chatsworth"/>

28	Primary Address State
	Primary Address State (2 Digit Abbreviation) <input type="text" value="California"/>

29	Primary Address Zip
	Primary Address Zip <input type="text" value="91311"/>

30	Search Words Identifying Vendor
	Please list all search words and phrases to be included in the TIPS database related to your entity. Do not list words which are not associated with the bid category/scope (See bid title for general scope). This will help users find you through the TIPS website search function. You may include product names, manufacturers, specialized services, and other words associated with the scope of this solicitation. <input type="text" value="Air Purification VidaShield Disinfection Pathogen Clean Air Ultraviolet UV Air UV Disinfection Pathogen Bacteria Mold Virus COVID"/>

31	Certification of Vendor Residency (Required by the State of Texas)
	Does Vendor's parent company or majority owner: (A) have its principal place of business in Texas; or (B) employ at least 500 persons in Texas? Texas Education Code Section 44.031 requires that this information be considered in evaluation for certain contracts. However, Vendor response does not affect points, scoring, or potential award. <input type="text" value="No"/>

32	Vendor's Principal Place of Business (City)
	In what city is Vendor's principal place of business located? <input type="text" value="Chatsworth"/>

33	Vendor's Principal Place of Business (State)
	In what state is Vendor's principal place of business located? <input type="text" value="California"/>

34	Vendor's Years in Business
	How many years has the business submitting this proposal been operating in its current capacity and field of work? <input type="text" value="45"/>

35 Certification Regarding Entire TIPS Agreement

Vendor agrees that, if awarded, Vendor's final TIPS Contract will consist of the provisions set forth in the finalized TIPS Vendor Agreement, Vendor's responses to these attribute questions, and: (1) The TIPS solicitation document resulting in this Agreement; (2) Any addenda or clarifications issued in relation to the TIPS solicitation; (3) All solicitation information provided to Vendor by TIPS through the TIPS eBid System; (3) Vendor's entire proposal response to the TIPS solicitation including all accepted required attachments, acknowledged notices and certifications, accepted negotiated terms, accepted pricing, accepted responses to questions, and accepted written clarifications of Vendor's proposal, and; any properly included attachments to the TIPS Contract.

Does Vendor agree?

Yes, Vendor agrees

36 Minimum Percentage Discount Offered to TIPS Members on all Goods and Services (READ CAREFULLY)

Please read thoroughly and carefully as an error on your response can render your contract award unusable.

TIPS Members often turn to TIPS Contracts for ease of use and to receive discounted pricing.

What is the minimum percentage discount that you can offer TIPS Members off of all goods and service pricing (whether offered through Pricing Form 1, Pricing Form 2, or in another accepted format) that you offer? Only limited goods/services specifically identified and excluded from this discount in Vendor's original proposal may be excluded from this discount.

Vendor must respond with a percentage from 0%-100%. The percentage discount that you input below will be applied to your "Catalog Pricing", as defined in the solicitation, for all TIPS Sales made during the life of the contract. You cannot alter this percentage discount once the solicitation legally closes. You will always be required to discount every TIPS Sale by the percentage included below with the exception of limited goods/services specifically identified and excluded from this discount in Vendor's original proposal. If you add goods or services to your "Catalog Pricing" during the life of the contract, you will be required to sell those new items with this discount applied.

Example: In this example, you enter a 10% minimum percentage discount below. In year-one of your TIPS Contract, your published "Catalog Pricing" (website/store/published pricing) for "Tablet A" is \$100 and for "Tablet Set-Up Service" is \$100. In this example, you must sell those items under the TIPS Contract at the proposed 10% discounted price of: "Tablet A" - \$90, "Tablet Set-Up Service" - \$90. In year two of your TIPS Contract, you update your "Catalog Pricing" with the market. You add "Tablet B" to your "Catalog Pricing" for \$200 and have increased the price of "Tablet A" to \$110 and the price of "Tablet Set-Up Service" to \$110. In this example, after the "Catalog Pricing" update, you must still sell those items under the TIPS Contract at the proposed 10% discounted price of: "Tablet A" - \$99, "Tablet Set-Up Service" - \$99, and "Tablet B" - \$180.00.

With the exception of limited goods/services specifically identified and excluded from this discount in Vendor's original proposal, if you cannot honor the discount on all goods and items now included or which may be added in the future with certainty, then you should offer a lesser discount percentage below.

What is the minimum percentage discount that you can offer TIPS Members off of all goods and service pricing (whether offered through Pricing Form 1, Pricing Form 2, or in another accepted format) that you offer?

10%

37 Honoring Vendor's Minimum Percentage Discount

Vendor is asked in these Attribute Questions to provide a Minimum Percentage Discount offered to TIPS Members on all goods and services sold under the TIPS Contract. Points will be assigned for your response and scoring of your proposal will be affected. A "YES" answer will be awarded the maximum 10 points and a "NO" answer will be awarded 0 points.

Does Vendor agree to honor the Minimum Percentage Discount off of their TIPS "Catalog Pricing" that Vendor proposed for all TIPS Sales made for the duration of the TIPS Contract?

38 Volume and Additional Discounts

In addition to the Minimum Percentage Discount proposed herein, does Vendor ever expect and intend to offer additional, greater, or volume discounts to TIPS Members?

Point(s) may be assigned for your response in the category of "Pricing" during scoring and evaluation.

39 "Catalog Pricing" and Pricing Requirements

This is a requirement of the TIPS Contract and is non-negotiable.

In this solicitation and resulting contract, "Catalog Pricing" shall be defined as:

"The then available list of goods or services, in the most current listing regardless of date, that takes the form of a catalog, price list, price schedule, shelf-price or other viewable format that:

- A. is regularly maintained by the manufacturer or Vendor of an item; and
- B. is either published or otherwise available for review by TIPS or a customer during the purchase process;
- C. to which the Minimum Percentage Discount proposed by the proposing Vendor may be applied.

If awarded on this TIPS Contract, for the duration of the contract, Vendor agrees to provide, upon request, their then current "Catalog Pricing." Or, in limited circumstances where Vendor has proposed the Percentage Mark-Up method of pricing in this proposal, proof of Vendor's "cost" may be accepted by TIPS in place of catalog pricing.

4 0 EXCEPTIONS & DEVIATIONS TO TIPS STANDARD TERMS AND CONDITIONS

Vendor agrees that, if awarded, Vendor's final TIPS Contract will consist of the provisions set forth in the finalized TIPS Vendor Agreement, Vendor's responses to these attribute questions, and: (1) The TIPS solicitation document resulting in this Agreement; (2) Any addenda or clarifications issued in relation to the TIPS solicitation; (3) All solicitation information provided to Vendor by TIPS through the TIPS eBid System; (3) Vendor's entire proposal response to the TIPS solicitation including all accepted required attachments, acknowledged notices and certifications, accepted negotiated terms, accepted pricing, accepted responses to questions, and accepted written clarifications of Vendor's proposal, and; any properly included attachments to the TIPS Contract. In the event of conflict between the terms of the finalized Vendor Agreement and one of the incorporated documents the terms and conditions which are in the best interest of governmental/qualifying non-profit TIPS Members shall control at TIPS sole discretion.

If Vendor responds, "No, Vendor does not agree" to this Attribute, after this solicitation legally closes and TIPS begins evaluating Vendor's file, TIPS will provide Vendor with a draft Word Document version of the Vendor Agreement and will be instructed to include all requested negotiations as redline edits for TIPS consideration. This is the only proper way to submit proposed deviations for TIPS consideration. TIPS reserves the right to accept, decline, or modify Vendor's requested negotiated terms. For this reason, answering "No, Vendor does not agree" may ultimately delay or prevent award.

Does Vendor agree with TIPS standard terms and conditions as presented in the TIPS solicitation document (RFP, RCSP, RFQ, or other) and the TIPS Vendor Agreement document?

Yes, Vendor agrees

4 1 TIPS Sales Reporting Requirements

This is a requirement of the TIPS Contract and is non-negotiable.

By submitting this proposal, Vendor certifies that Vendor will properly report all TIPS sales. With the exception of TIPS Automated Vendors, who have signed an exclusive agreement with TIPS regarding reporting, all TIPS Sales must be reported to TIPS by either:

(1) Emailing the purchase order or similar purchase document (with Vendor's Name, as known to TIPS, and the TIPS Contract Name and Number included) to TIPS at tipspo@tips-usa.com with "Confirmation Only" in the subject line of the email within three business days of Vendor's acceptance of the order, or;

(2) Within 3 business days of the order being accepted by Vendor, Vendor must login to the TIPS Vendor Portal and successfully self-report all necessary sale information within the Vendor Portal and confirm that it shows up accurately on your current Vendor Portal statement.

No other method of reporting is acceptable unless agreed to by the Parties in writing. Failure to report all sales pursuant to this provision may result in immediate cancellation of Vendor's TIPS Contract(s) for cause at TIPS' sole discretion.

4 2 TIPS Administration Fee Requirement and Acknowledgment

This is a requirement of the TIPS Contract and is non-negotiable.

The collection of fees by TIPS, a government entity, for performance of these procurement services is required pursuant to Texas Government Code Section 791.011 et. seq. The TIPS Administration Fee is the amount legally owed by Vendor to TIPS for TIPS Sales made by Vendor. The TIPS Administration Fee amount is typically a set percentage of each TIPS Sale legally due to TIPS, but the exact TIPS Administration Fee for this Contract is published in the corresponding RFP or RCSP document. TIPS Administration Fees are due to TIPS immediately upon Vendor's receipt of payment, including partial payment, for a TIPS Sale.

By submitting a proposal, Vendor agrees that it has read, understands, and agrees to the published TIPS Administration Fee amount, calculation, and payment requirements. By submitting a proposal Vendor further confirms that all TIPS Pricing includes the TIPS Administration Fee and Vendor will not show adding the TIPS Administration Fee as a charge or line-item in any TIPS Sale.

4 **TIPS Member Access to Vendor Proposal & Documentation**

3 **This is a requirement of the TIPS Contract and is non-negotiable.**

Notwithstanding any other information provided in this solicitation or Vendor designation of certain documentation as confidential or proprietary, Vendor's submission of this proposal constitutes Vendor's express consent to the disclosure of Vendor's comprehensive proposal, including any information deemed confidential or proprietary, **to TIPS Members**. The proposing Vendor agrees that TIPS shall not be responsible or liable for any use or distribution of information or documentation to TIPS Members or by TIPS Members. By submitting this proposal, Vendor certifies the foregoing.

4 **Non-Collusive Bidding Certificate**

4 **This is a requirement of the TIPS Contract and is non-negotiable.**

By submission of this proposal, the Vendor certifies that:

- 1) This proposal has been independently arrived at without collusion with any other entity, bidder, or with any competitor;
- 2) This proposal has not been knowingly disclosed and will not be knowingly disclosed, prior to the opening of bids, or proposals for this project, to any other bidder, competitor or potential competitor;
- 3) No attempt has been or will be made to induce any other person, partnership or corporation to modify, submit, or not to submit a bid or proposal; and
- 4) The person signing this bid or proposal certifies that they are duly authorized to execute this proposal/contract on behalf of Vendor and they have fully informed themselves regarding the accuracy of the statements contained in this certification, and under the penalties being applicable to the bidder as well as to the person signing in its behalf;

4 **Antitrust Certification Statements (Tex. Government Code § 2155.005)**

5 **This is a requirement of the TIPS Contract and is non-negotiable.**

By submission of this bid or proposal, Vendor certifies under penalty of perjury of the laws of the State of Texas that:

- (1) I am duly authorized to execute this proposal/contract on my own behalf or on behalf of the company, corporation, firm, partnership or individual (Vendor) identified herein;
- (2) In connection with this proposal, neither I nor any representative of Vendor has violated any provision of the Texas Free Enterprise and Antitrust Act, Tex. Bus. & Comm. Code Chapter 15;
- (3) In connection with this proposal, neither I nor any representative of the Vendor has violated any federal antitrust law;
- (4) Neither I nor any representative of Vendor has directly or indirectly communicated any of the contents of this bid to a competitor of the Company or any other company, corporation, firm, partnership or individual engaged in the same line of business as the Company.

4 **Limitation on Out-of-State Litigation - Texas Business and Commerce Code § 272**

6 **This is a requirement of the TIPS Contract and is non-negotiable.**

Texas Business and Commerce Code § 272 prohibits a construction contract, or an agreement collateral to or affecting the construction contract, from containing a provision making the contract or agreement, or any conflict arising under the contract or agreement, subject to another state's law, litigation in the courts of another state, or arbitration in another state. If included in Texas construction contracts, such provisions are voidable by a party obligated by the contract or agreement to perform the work.

By submission of this proposal, Vendor acknowledges this law and ***if Vendor enters into a construction contract with a Texas TIPS Member*** under this procurement, Vendor certifies compliance.

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Required Confidentiality Claim Form

This is a requirement of the TIPS Contract and is non-negotiable.

TIPS provides the required TIPS Confidentiality Claim Form in the "Attachments" section of this solicitation. Vendor must execute this form by either signing and waiving any confidentiality claim, or designating portions of Vendor's proposal confidential. If Vendor considers any portion of Vendor's proposal to be confidential and not subject to public disclosure pursuant to Chapter 552 Texas Gov't Code or other law(s) and orders, Vendor must have identified the claimed confidential materials through proper execution of the Confidentiality Claim Form.

If TIPS receives a public information act or similar request, any responsive documentation not deemed confidential by you in this manner will be automatically released. For Vendor documents deemed confidential by you in this manner, TIPS will follow procedures of controlling statute(s) regarding any claim of confidentiality and shall not be liable for any release of information required by law, including Attorney General determination and opinion.

Notwithstanding any other Vendor designation of Vendor's proposal as confidential or proprietary, Vendor's submission of this proposal constitutes Vendor's agreement that proper execution of the required TIPS Confidentiality Claim Form is the only way to assert any portion of Vendor's proposal as confidential.

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Non-Discrimination Statement and Certification

This is a requirement of the TIPS Contract and is non-negotiable.

In accordance with Federal civil rights law, all U.S. Departments, including but not limited to the USDA, USDE, FEMA, are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by federal funds (not all bases apply to all programs).

Vendor certifies that Vendor will comply with applicable Non-Discrimination and Equal Opportunity provisions set forth in TIPS Member Customers' policies and other regulations at the local, state, and federal levels of governments.

Yes, I certify

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Limitation of Vendor Indemnification and Similar Clauses

This is a requirement of the TIPS Contract and is non-negotiable.

TIPS, a department of Region 8 Education Service Center, a political subdivision, and local government entity of the State of Texas, is prohibited from indemnifying third-parties (pursuant to the Article 3, Section 52 of the Texas Constitution) except as otherwise specifically provided for by law or as ordered by a court of competent jurisdiction. Article 3, Section 52 of the Texas Constitution states that "no debt shall be created by or on behalf of the State ... " and the Texas Attorney General has opined that a contractually imposed obligation of indemnity creates a "debt" in the constitutional sense. Tex. Att'y Gen. Op. No. MW-475 (1982). Thus, contract clauses which require TIPS to indemnify Vendor, pay liquidated damages, pay attorney's fees, waive Vendor's liability, or waive any applicable statute of limitations must be deleted or qualified with "to the extent permitted by the Constitution and Laws of the State of Texas."

Does Vendor agree?

Yes, I Agree

50

Alternative Dispute Resolution Limitations

This is a requirement of the TIPS Contract and is non-negotiable.

TIPS, a department of Region 8 Education Service Center, a political subdivision, and local government entity of the State of Texas, does not agree to binding arbitration as a remedy to dispute and no such provision shall be permitted in this Agreement with TIPS. Vendor agrees that any claim arising out of or related to this Agreement, except those specifically and expressly waived or negotiated within this Agreement, may be subject to non-binding mediation at the request of either party to be conducted by a mutually agreed upon mediator as prerequisite to the filing of any lawsuit arising out of or related to this Agreement. Mediation shall be held in either Camp or Titus County, Texas. Agreements reached in mediation will be subject to the approval by the Region 8 ESC's Board of Directors, authorized signature of the Parties if approved by the Board of Directors, and, once approved by the Board of Directors and properly signed, shall thereafter be enforceable as provided by the laws of the State of Texas.

Does Vendor agree?

51

No Waiver of TIPS Immunity

This is a requirement of the TIPS Contract and is non-negotiable.

Vendor agrees that nothing in this Agreement shall be construed as a waiver of sovereign or government immunity; nor constitute or be construed as a waiver of any of the privileges, rights, defenses, remedies, or immunities available to Region 8 Education Service Center or its TIPS Department. The failure to enforce, or any delay in the enforcement, of any privileges, rights, defenses, remedies, or immunities available to Region 8 Education Service Center or its TIPS Department under this Agreement or under applicable law shall not constitute a waiver of such privileges, rights, defenses, remedies, or immunities or be considered as a basis for estoppel.

Does Vendor agree?

Yes, Vendor agrees

52

Payment Terms and Funding Out Clause

This is a requirement of the TIPS Contract and is non-negotiable.

Vendor agrees that TIPS and TIPS Members shall not be liable for interest or late-payment fees on past-due balances at a rate higher than permitted by the laws or regulations of the jurisdiction of the TIPS Member.

Funding-Out Clause: Vendor agrees to abide by the applicable laws and regulations, including but not limited to Texas Local Government Code § 271.903, or any other statutory or regulatory limitation of the jurisdiction of any TIPS Member, which requires that contracts approved by TIPS or a TIPS Member are subject to the budgeting and appropriation of currently available funds by the entity or its governing body.

Does Vendor agree?

Yes, Vendor agrees

53

Certification Regarding Prohibition of Certain Terrorist Organizations (Tex. Gov. Code 2270)

Vendor certifies that Vendor is not a company identified on the Texas Comptroller's list of companies known to have contracts with, or provide supplies or services to, a foreign organization designated as a Foreign Terrorist Organization by the U.S. Secretary of State.

Does Vendor certify?

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Certification Regarding Prohibition of Boycotting Israel (Tex. Gov. Code 2271)

If (a) Vendor is not a sole proprietorship; (b) Vendor has ten (10) or more full-time employees; and (c) this Agreement or any agreement with a TIPS Member under this procurement has value of \$100,000 or more, the following certification shall apply; otherwise, this certification is not required. Vendor certifies, where applicable, that neither the Vendor, nor any affiliate, subsidiary, or parent company of Vendor, if any, boycotts Israel, and Vendor agrees that Vendor and Vendor Companies will not boycott Israel during the term of this Agreement. For purposes of this Agreement, the term "boycott" shall mean and include refusing to deal with, terminating business activities with, or otherwise taking any action that is intended to penalize, inflict economic harm on, or limit commercial relations with Israel, or with a person or entity doing business in Israel or in an Israeli-controlled territory but does not include an action made for ordinary business purposes.

When applicable, does Vendor certify?

Yes, Vendor certifies

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Certification Regarding Prohibition of Contracts with Certain Foreign-Owned Companies (Tex. Gov. Code 2274)

Certain public entities are prohibited from entering into a contract or other agreement relating to critical infrastructure that would grant Vendor direct or remote access to or control of critical infrastructure in this state, excluding access specifically allowed by a customer for product warranty and support purposes.

Vendor certifies that neither it nor its parent company nor any affiliate of Vendor or its parent company, is (1) owned by or the majority of stock or other ownership interest of the company is held or controlled by individuals who are citizens of China, Iran, North Korea, Russia, or a designated country; (2) a company or other entity, including governmental entity, that is owned or controlled by citizens of or is directly controlled by the government of China, Iran, North Korea, Russia, or a designated country; or (3) headquartered in China, Iran, North Korea, Russia, or a designated country.

For purposes of this certification, "critical infrastructure" means "a communication infrastructure system, cybersecurity system, electric grid, hazardous waste treatment system, or water treatment facility." Vendor certifies that Vendor will not grant direct or remote access to or control of critical infrastructure, except for product warranty and support purposes, to prohibited individuals, companies, or entities, including governmental entities, owned, controlled, or headquartered in China, Iran, North Korea, Russia, or a designated country, as determined by the Governor.

When applicable, does Vendor certify?

Yes, Vendor certifies

5 Certification Regarding Prohibition of Discrimination Against Firearm and Ammunition Industries (Tex. Gov. Code 2274)

If (a) Vendor is not a sole proprietorship; (b) Vendor has at least ten (10) full-time employees; and (c) this Agreement or any Supplemental Agreement with certain public entities have a value of at least \$100,000 that is paid wholly or partly from public funds; (d) the Agreement is not excepted under Tex. Gov. Code 2274 and (e) the purchasing public entity has determined that Vendor is not a sole-source provider or the purchasing public entity has not received any bids from a company that is able to provide this written verification, the following certification shall apply; otherwise, this certification is not required.

Vendor certifies that Vendor, or association, corporation, partnership, joint venture, limited partnership, limited liability partnership, or limited liability company, including a wholly owned subsidiary, majority-owned subsidiary parent company, or affiliate of these entities or associations, that exists to make a profit, does not have a practice, policy, guidance, or directive that discriminates against a firearm entity or firearm trade association and will not discriminate during the term of this contract against a firearm entity or firearm trade association.

For purposes of this Agreement, “discriminate against a firearm entity or firearm trade association” shall mean, with respect to the entity or association, to: “(1) refuse to engage in the trade of any goods or services with the entity or association based solely on its status as a firearm entity or firearm trade association; (2) refrain from continuing an existing business relationship with the entity or association based solely on its status as a firearm entity or firearm trade association; or (3) terminate an existing business relationship with the entity or association based solely on its status as a firearm entity or firearm trade association.”

“Discrimination against a firearm entity or firearm trade association” does not include: “(1) the established policies of a merchant, retail seller, or platform that restrict or prohibit the listing or selling of ammunition, firearms, or firearm accessories; and (2) a company’s refusal to engage in the trade of any goods or services, decision to refrain from continuing an existing business relationship, or decision to terminate an existing business relationship to comply with federal, state, or local law, policy, or regulations or a directive by a regulatory agency, or for any traditional business reason that is specific to the customer or potential customer and not based solely on an entity’s or association’s status as a firearm entity or firearm trade association.”

When applicable, does Vendor certify?

Yes, Vendor certifies

5 Certification Regarding Termination of Contract for Non-Compliance (Tex. Gov. Code 552.374)

If Vendor is not a governmental body and (a) this Agreement or any Supplemental Agreement with a public entity has a stated expenditure of at least \$1 million in public funds for the purchase of goods or services by certain public entities; or (b) this Agreement or any Supplemental Agreement results in the expenditure of at least \$1 million in public funds for the purchase of goods or services by certain public entities in their fiscal year, the following certification shall apply; otherwise, this certification is not required.

As required by Tex. Gov. Code 552.374, the following statement is included in the RFP and the Agreement (unless the Agreement is (1) related to the purchase or underwriting of a public security; (2) is or may be used as collateral on a loan; or (3) proceeds from which are used to pay debt service of a public security of loan): “The requirements of Subchapter J, Chapter 552, Government Code, may apply to this solicitation and Agreement and the Vendor agrees that this Agreement and any applicable Supplemental Agreement can be terminated if Vendor knowingly or intentionally fails to comply with a requirement of that subchapter.”

Pursuant to Chapter 552 of the Texas Government Code, Vendor certifies that Vendor shall: (1) preserve all contracting information related to this Agreement as provided by the records retention requirements applicable to TIPS or the purchasing TIPS Member for the duration of the Agreement; (2) promptly provide to TIPS or the purchasing TIPS Member any contracting information related to the Agreement that is in the custody or possession of Vendor on request of TIPS or the purchasing TIPS Member; and (3) on completion of the Agreement, either (a) provide at no cost to TIPS or the purchasing TIPS Member all contracting information related to the Agreement that is in the custody or possession of Vendor, or (b) preserve the contracting information related to the Agreement as provided by the records retention requirements applicable to TIPS or the purchasing TIPS Member.

When applicable, does Vendor certify?

Yes, Vendor certifies

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Certification Regarding Prohibition of Boycotting Certain Energy Companies (Tex. Gov. Code 2274)

If (a) Vendor is not a sole proprietorship; (b) Vendor has ten (10) or more full-time employees; and (c) this Agreement or any Supplemental Agreement with certain public entities has a value of \$100,000 or more that is to be paid wholly or partly from public funds, the following certification shall apply; otherwise, this certification is not required.

Vendor certifies that Vendor, or any wholly owned subsidiary, majority-owned subsidiary, parent company, or affiliate of these entities or business associations, if any, do not boycott energy companies and will not boycott energy companies during the term of the Agreement or any applicable Supplemental Agreement.

For purposes of this certification the term "company" shall mean an organization, association, corporation, partnership, joint venture, limited partnership, limited liability partnership, or limited liability company, that exists to make a profit.

The term "boycott energy company" shall mean "without an ordinary business purpose, refusing to deal with, terminating business activities with, or otherwise taking any action intended to penalize, inflict economic harm on, or limit commercial relations with a company because the company (a) engages in the exploration, production, utilization, transportation, sale, or manufacturing of fossil fuel-based energy and does not commit or pledge to meet environmental standards beyond applicable federal and state law, or (b) does business with a company described by paragraph (a)." (See Tex. Gov. Code 809.001).

When applicable, does Vendor certify?

Yes, Vendor certifies

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Felony Conviction Notice - Texas Education Code 44.034

Texas Education Code, Section 44.034, Notification of Criminal History, Subsection (a), states, "a person or business entity that enters into a contract with a school district must give advance notice to the district if the person or an owner or operator of the business entity has been convicted of a felony. The notice must include a general description of the conduct resulting in the conviction of a felony."

Subsection (b) states, "a school district may terminate a contract with a person or business entity if the district determines that the person or business entity failed to give notice as required by Subsection (a) or misrepresented the conduct resulting in the conviction. The district must compensate the person or business entity for services performed before the termination of the contract."

Subsection (c) states, "This section does not apply to a publicly held corporation.

Vendor certifies one of the following:

- A. My firm is a publicly held corporation; therefore, this reporting requirement is not applicable, or;
- B. My firm is not owned nor operated by anyone who has been convicted of a felony, or;
- C. My firm is owned or operated by the following individual(s) who has/have been convicted of a felony.

If Vendor responds with Option (C), Vendor is required to provide information in the next attribute.

B. My firm is not owned nor operated by felon.

60 Felony Conviction Notice - Texas Education Code 44.034 - Continued

If Vendor selected Option (C) in the previous attribute, Vendor must provide the following information herein:

1. Name of Felon(s)
2. The Felon(s) title/role in Vendor's entity, and
3. Details of Felon(s) Conviction(s).

No response

61 Conflict of Interest Questionnaire Requirement

Vendor agrees that it has looked up, read, and understood the current version of Texas Local Government Code Chapter 176 which generally requires disclosures of conflicts of interests by Vendor hereunder if Vendor:

- (1) has an employment or other business relationship with a local government officer of our local governmental entity, or a family member of the officer, described by Section 176.003(a)(2)(A);
- (2) has given a local government officer of our local governmental entity, or a family member of the officer, one or more gifts with the aggregate value specified by Section 176.003(a)(2)(B), excluding any gift described by Section 176.003(a-1); or
- (3) has a family relationship with a local government officer of our local governmental entity.
- (4) Any other financial, commercial, or familial relationship with our local government that may warrant reporting under this statute.

Does Vendor certify that it has NO reportable conflict of interest?

Yes, Vendor certifies - VENDOR HAS NO CONFLICT

62 Conflict of Interest Questionnaire Requirement - Form CIQ - Continued

If you responded "No, Vendor does not certify - VENDOR HAS CONFLICT" to the Conflict of Interest Questionnaire question above, you are required by law to fully execute and upload the form attachment entitled "Conflict of Interest Questionnaire - Form CIQ." If you accurately claimed no conflict above, you may disregard the form attachment entitled "Conflict of Interest Questionnaire - Form CIQ."

Have you uploaded this form if applicable?

Not Applicable

63 Upload of Current W-9 Required

Vendors are required by TIPS to upload a current, accurate W-9 Internal Revenue Service (IRS) Tax Form for your entity. This form will be utilized by TIPS to properly identify your entity.

You must confirm that you are responding to this solicitation under your legal entity name. Go now to your Supplier Profile in this eBid System and confirm that your profile reflects your "Legal Name" as it is listed on your W9.

64 Regulatory Good Standing Certification

Does Vendor certify that its entity is in good standing will all government entities and agencies, whether local, state, or federal, that regulate any aspect of Vendor's field of work or business operations?

If Vendor selects "No", Vendor must provide explanation on the following attribute question.

Yes, Vendor certifies

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5 **Regulatory Good Standing Certification - Explanation - Continued**

If Vendor responded to the prior attribute that "No", Vendor is not in good standing, Vendor must provide an explanation of that lack of good standing here for TIPS consideration.

No response

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6 **Instructions Only - Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion**
Instructions for Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion

1. By answering yes to the next Attribute question below, the vendor and prospective lower tier participant is providing the certification set out herein in accordance with these instructions.
2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification in addition to other remedies available to the federal government, the department or agency with which this transaction originated may pursue available remedies, including suspension and / or debarment.
3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participants," "person," "primary covered transaction," "principal," "proposal" and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.
5. The prospective lower tier participant agrees by submitting this form that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.
6. The prospective lower tier participant further agrees by submitting this form that it will include this clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transaction" without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.
8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible or voluntarily excluded from participation in this transaction, in addition to other remedies available to the federal government, the department or agency with which this transaction originated may pursue available remedies, including suspension and / or debarment.

6 **Suspension or Debarment Certification**

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Read the instructions in the attribute above and then answer the following accurately.

Vendor certifies that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

Does Vendor certify?

Yes, Vendor certifies

6 **Vendor Certification of Criminal History - Texas Education Code Chapter 22**

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Texas Education Code Chapter 22 requires entities that contract with school districts to provide services to obtain criminal history record information regarding covered employees. Contractors must certify to the district that they have complied. Covered employees with disqualifying criminal histories are prohibited from serving at a school district pursuant to this law.

DEFINITIONS

Covered employees: Employees of a contractor or subcontractor who have or will have continuing duties related to the service to be performed at the District and have or will have direct contact with students. The District will be the final arbiter of what constitutes direct contact with students.

Disqualifying criminal history: Any conviction or other criminal history information designated by the District, or one of the following offenses, if at the time of the offense, the victim was under 18 or enrolled in a public school: (a) a felony offense under Title 5, Texas Penal Code; (b) an offense for which a defendant is required to register as a sex offender under Chapter 62, Texas Code of Criminal Procedure; or (c) an equivalent offense under federal law or the laws of another state.

Vendor certifies:

NONE (Section A): None of the employees of Vendor and any subcontractors are covered employees, as defined above. If this box is checked, I further certify that Contractor has taken precautions or imposed conditions to ensure that the employees of Vendor and any subcontractor will not become covered employees. Contractor will maintain these precautions or conditions throughout the time the contracted services are provided under this procurement.

OR

SOME (Section B): Some or all of the employees of Vendor and any subcontractor are covered employees. If this box is checked, I further certify that: (1) Vendor has obtained all required criminal history record information regarding its covered employees. None of the covered employees has a disqualifying criminal history; (2) If Vendor receives information that a covered employee subsequently has a reported criminal history, Vendor will immediately remove the covered employee from contract duties and notify the purchasing entity in writing within 3 business days; (3) Upon request, Vendor will provide the purchasing entity with the name and any other requested information of covered employees so that the purchasing entity may obtain criminal history record information on the covered employees; (4) If the purchasing entity objects to the assignment of a covered employee on the basis of the covered employee's criminal history record information, Vendor agrees to discontinue using that covered employee to provide services at the purchasing entity.

Which option does Vendor certify?

Yes, I certify - NONE (Section A)

6 **Certification Regarding "Choice of Law" Terms with TIPS Members**

9 Vendor agrees that if any "Choice of Law" provision is included in any sales agreement/contract between Vendor and a TIPS Member, that clause must provide that the "Choice of Law" applicable to the sales agreement/contract between Vendor and TIPS Member shall be the state where the TIPS Member operates unless the TIPS Member expressly agrees otherwise. Any TIPS Sale Supplemental Agreement containing a "Choice of Law" clause that conflicts with these terms is rendered void and unenforceable.

If Vendor disagrees, after this solicitation legally closes and TIPS begins evaluating Vendor's file, TIPS will provide Vendor with a draft Word Document version of the Vendor Agreement and will be instructed to include all requested negotiations as redline edits for TIPS consideration.

Does Vendor agree?

7 **Certification Regarding "Venue" Terms with TIPS Members**

0 Vendor agrees that if any "Venue" provision is included in any sales agreement/contract between Vendor and a TIPS Member, that clause must provide that the "Venue" for any litigation or alternative dispute resolution is shall be in the state and county where the TIPS Member operates unless the TIPS Member expressly agrees otherwise. Any TIPS Sale Supplemental Agreement containing a "Venue" clause that conflicts with these terms is rendered void and unenforceable.

If Vendor disagrees, after this solicitation legally closes and TIPS begins evaluating Vendor's file, TIPS will provide Vendor with a draft Word Document version of the Vendor Agreement and will be instructed to include all requested negotiations as redline edits for TIPS consideration.

Does Vendor agree?

7 **Certification Regarding "Automatic Renewal" Terms with TIPS Members**

1 Vendor agrees that no TIPS Sale may incorporate an "Automatic Renewal" clause that exceeds month to month terms with which the TIPS Member must comply. All renewal terms incorporated into a TIPS Sale Supplemental Agreement shall only be valid and enforceable when Vendor received written confirmation of acceptance of the renewal term from the TIPS Member for the specific renewal term. The purpose of this clause is to avoid a TIPS Member inadvertently renewing a Supplemental Agreement during a period in which the governing body of the TIPS Member has not properly appropriated and budgeted the funds to satisfy the Agreement renewal. Any TIPS Sale Supplemental Agreement containing an "Automatic Renewal" clause that conflicts with these terms is rendered void and unenforceable.

If Vendor disagrees, after this solicitation legally closes and TIPS begins evaluating Vendor's file, TIPS will provide Vendor with a draft Word Document version of the Vendor Agreement and will be instructed to include all requested negotiations as redline edits for TIPS consideration.

Does Vendor agree?

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2** Certification Regarding "Indemnity" Terms with TIPS Members

Texas and other jurisdictions restrict the ability of governmental entities to indemnify others. Vendor agrees that if any "Indemnity" provision which requires the TIPS Member to indemnify Vendor is included in any sales agreement/contract between Vendor and a TIPS Member, that clause must either be stricken or qualified by including that such indemnity is only permitted, "to the extent permitted by the laws and constitution of [TIPS Member's State]" unless the TIPS Member expressly agrees otherwise. Any TIPS Sale Supplemental Agreement containing an "Indemnity" clause that conflicts with these terms is rendered void and unenforceable.

If Vendor disagrees, after this solicitation legally closes and TIPS begins evaluating Vendor's file, TIPS will provide Vendor with a draft Word Document version of the Vendor Agreement and will be instructed to include all requested negotiations as redline edits for TIPS consideration.

Does Vendor agree?

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3** Certification Regarding "Arbitration" Terms with TIPS Members

Vendor agrees that if any "Arbitration" provision is included in any TIPS Sale agreement/contract between Vendor and a TIPS Member, that clause may **not** require that the arbitration is mandatory or binding. Vendor agrees that if any "Arbitration" provision is included in any TIPS Sale agreement/contract between Vendor and a TIPS Member, that clause provides for only voluntary and non-binding arbitration unless the TIPS Member expressly agrees otherwise. Any TIPS Sale Supplemental Agreement containing a "Arbitration" clause that conflicts with these terms is rendered void and unenforceable.

If Vendor disagrees, after this solicitation legally closes and TIPS begins evaluating Vendor's file, TIPS will provide Vendor with a draft Word Document version of the Vendor Agreement and will be instructed to include all requested negotiations as redline edits for TIPS consideration.

Does Vendor agree?

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4** 2 CFR PART 200 AND FEDERAL CONTRACT PROVISIONS EXPLANATION

TIPS and TIPS Members will sometimes seek to make purchases with federal funds. In accordance with 2 C.F.R. Part 200 of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (sometimes referred to as "EDGAR"), Vendor's response to the following questions labeled "2 CFR Part 200 or Federal Provision" will indicate Vendor's willingness and ability to comply with certain requirements which may be applicable to TIPS purchases paid for with federal funds, if accepted by Vendor.

Your responses to the following questions labeled "2 CFR Part 200 or Federal Provision" will dictate whether TIPS can list this awarded contract as viable to be considered for a federal fund purchase. **Failure to certify all requirements labeled "2 CFR Part 200 or Federal Provision" will mean that your contract is listed as not viable for the receipt of federal funds. However, it will not prevent award.**

If you do enter into a TIPS Sale when you are accepting federal funds, the contract between you and the TIPS Member will likely require these same certifications.

7 5 2 CFR Part 200 or Federal Provision - Vendor Willingness to Accept Federal Funds

This certification is not required by federal law. However, TIPS Members are public entities and qualifying non-profits which often receive federal funding and grants (ESSER, CARES Act, EDGAR, etc.) **Accepting such funds often requires additional required certifications and responsibilities for Vendor.** The following attribute questions include these required certifications. Your response to this questions, the following certifications, and other factors will determine whether your contract award will be deemed as eligible for federal fund expenditures by TIPS Members.

If awarded, is Vendor willing to accept payment for goods and services offered under this contract paid for by a TIPS Member with federal funds?

7 6 2 CFR Part 200 or Federal Provision - Contracts

Contracts for more than the simplified acquisition threshold currently set at \$250,000 (2 CFR § 200.320), which is the inflation adjusted amount determined by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) as authorized by 41 U.S.C. 1908, must address administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, and provide for such sanctions and penalties as appropriate.

Notice: Pursuant to the above, when federal funds are expended by ESC Region 8 and TIPS Members, ESC Region 8 and TIPS Members reserve all rights and privileges under the applicable laws and regulations with respect to this procurement in the event of breach of contract by either party.

Does vendor agree?

7 7 2 CFR Part 200 or Federal Provision - Termination

Termination for cause and for convenience by the grantee or subgrantee including the manner by which it will be effected and the basis for settlement. (All contracts in excess of \$10,000)

Pursuant to the above, when federal funds are expended by ESC Region 8 and TIPS Members, ESC Region 8 and TIPS Members reserve the right to terminate any agreement in excess of \$10,000 resulting from this procurement process for cause after giving the vendor an appropriate opportunity and up to 30 days, to cure the causal breach of terms and conditions. ESC Region 8 and TIPS Members reserve the right to terminate any agreement in excess of \$10,000 resulting from this procurement process for convenience with 30 days notice in writing to the awarded vendor. The Vendor would be compensated for work performed and goods procured as of the termination date if for convenience of the ESC Region 8 and TIPS Members. Any award under this procurement process is not exclusive and the ESC Region 8 and TIPS reserves the right to purchase goods and services from other vendors when it is in the best interest of the ESC Region 8 and TIPS.

Does vendor agree?

7 **2 CFR Part 200 or Federal Provision - Clean Air Act**

8 Clean Air Act (42 U.S.C. 7401-7671q.) and the Federal Water Pollution Control Act (33 U.S.C. 1251-1387), as amended—Contracts and subgrants of amounts in excess of \$150,000 must contain a provision that requires the non-Federal award to agree to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. 7401-7671q) and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251-1387). Violations must be reported to the Federal awarding agency and the Regional Office of the Environmental Protection Agency (EPA).

Pursuant to the Clean Air Act, et al above, when federal funds are expended by ESC Region 8 and TIPS Members, ESC Region 8 and TIPS Members require that the proposer certify that during the term of an award by the ESC Region 8 and TIPS Members resulting from this procurement process the vendor agrees to comply with all of the above regulations, including all of the terms listed and referenced therein.

Does vendor agree?

Yes, Vendor agrees

7 **2 CFR Part 200 or Federal Provision - Byrd Anti-Lobbying Amendment**

9 Byrd Anti-Lobbying Amendment (31 U.S.C. 1352)—Contractors that apply or bid for an award exceeding \$100,000 must file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. 1352. Each tier must also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the non-Federal award.

Pursuant to the above, when federal funds are expended by ESC Region 8 and TIPS Members, ESC Region 8 and TIPS Members require the proposer certify that during the term and during the life of any contract with ESC Region 8 and TIPS Members resulting from this procurement process the vendor certifies that it is in compliance with all applicable provisions of the Byrd Anti-Lobbying Amendment (31 U.S.C. 1352).

Does Vendor agree?

Yes, Vendor agrees

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2 CFR Part 200 or Federal Provision - Byrd Anti-Lobbying Amendment - Continued

Applicable to Grants, Subgrants, Cooperative Agreements, and Contracts Exceeding \$100,000 in Federal Funds

Submission of this certification is a prerequisite for making or entering into this transaction and is imposed by the Byrd Anti-Lobbying Amendment (31 U.S.C. 1352). This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of congress, or an employee of a Member of Congress in connection with the awarding of a Federal contract, the making of a Federal grant, the making of a Federal loan, the entering into a cooperative agreement, and the extension, continuation, renewal, amendment, or modification of a Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all covered subawards exceeding \$100,000 in Federal funds at all appropriate tiers and that all subrecipients shall certify and disclose accordingly.

Does Vendor certify that it has NOT lobbied as described herein?

Yes, Vendor certifies - NO Reportable Lobbying

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2 CFR Part 200 or Federal Provision - Byrd Anti-Lobbying Amendment - Continued

If you answered "No, Vendor does not certify - Lobbying to Report" to the above attribute question, you must download, read, execute, and upload the attachment entitled "Disclosure of Lobbying Activities - Standard Form - LLL", as instructed, to report the lobbying activities you performed or paid others to perform.

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2 CFR Part 200 or Federal Provision - Federal Rule

Compliance with all applicable standards, orders, or requirements issued under section 306 of the Clean Air Act (42 U.S.C. 1857(h)), section 508 of the Clean Water Act (33 U.S.C. 1368), Executive Order 11738, and Environmental Protection Agency regulations (40 CFR part 15). (Contracts, subcontracts, and subgrants of amounts in excess of \$100,000)

Pursuant to the above, when federal funds are expended by ESC Region 8 and TIPS Members, ESC Region 8 and TIPS Members requires the proposer certify that in performance of the contracts, subcontracts, and subgrants of amounts in excess of \$250,000, the vendor will be in compliance with all applicable standards, orders, or requirements issued under section 306 of the Clean Air Act (42 U.S.C. 1857(h)), section 508 of the Clean Water Act (33 U.S.C. 1368), Executive Order 11738, and Environmental Protection Agency regulations (40 CFR part 15).

Does vendor certify compliance?

Yes, Vendor certifies

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2 CFR Part 200 or Federal Provision - Procurement of Recovered Materials

A non-Federal entity that is a state agency or agency of a political subdivision of a state and its contractors must comply with section 6002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act. The requirements of Section 6002 include: (1) procuring only items designated in guidelines of the Environmental Protection Agency (EPA) at 40 CFR part 247 that contain the highest percentage of recovered materials practicable, consistent with maintaining a satisfactory level of competition, where the purchase price of the item exceeds \$10,000 or the value of the quantity acquired during the preceding fiscal year exceeded \$10,000; (2) procuring solid waste management services in a manner that maximizes energy and resource recovery; and establishing an affirmative procurement program for procurement of recovered materials identified in the EPA guidelines.

Does vendor certify that it is in compliance with these provisions?

Yes, Vendor certifies

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2 CFR Part 200 or Federal Provision - Rights to Inventions

If the Federal award meets the definition of "funding agreement" under 37 CFR §401.2 (a) and the recipient or subrecipient wishes to enter into a contract with a small business firm or nonprofit organization regarding the substitution of parties, assignment or performance of experimental, developmental, or research work under that "funding agreement," the recipient or subrecipient must comply with the requirements of 37 CFR Part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," and any implementing regulations issued by the awarding agency.

Pursuant to the above, when the foregoing applies to ESC Region 8 and TIPS Members, Vendor certifies that during the term of an award resulting from this procurement process, Vendor agrees to comply with all applicable requirements as referenced in the Federal rule above.

Does vendor certify?

Yes, Vendor certifies

8 5 2 CFR Part 200 or Federal Provision - Domestic Preferences for Procurements and Compliance with Buy America Provisions

As appropriate and to the extent consistent with law, TIPS Member Customers, to the greatest extent practicable under a Federal award, may provide a preference for the purchase, acquisition, or use of goods, products, or materials produced in the United States (including but not limited to iron, aluminum, steel, cement, and other manufactured products). Vendor agrees that the requirements of this section will be included in all subawards including all contracts and purchase orders for work or products under this award, to the greatest extent practicable under a Federal award. For purposes of 2 CFR Part 200.322, "Produced in the United States" means, for iron and steel products, that all manufacturing processes, from the initial melting stage through the application of coatings, occurred in the United States. Moreover, for purposes of 2 CFR Part 200.322, "Manufactured products" means items and construction materials composed in whole or in part of non-ferrous metals such as aluminum, plastics and polymer-based products such as polyvinyl chloride pipe, aggregates such as concrete, glass, including optical fiber, and lumber.

Vendor certifies that it is in compliance with all applicable provisions of the Buy America Act. Purchases made in accordance with the Buy America Act must still follow the applicable procurement rules calling for free and open competition. For purposes of 2 CFR Part 200.322,

"Produced in the United States" means, for iron and steel products, that all manufacturing processes, from the initial melting stage through the application of coatings, occurred in the United States.

"Manufactured products" means items and construction materials composed in whole or in part of non-ferrous metals such as aluminum; plastics and polymer-based products such as polyvinyl chloride pipe; aggregates such as concrete; glass, including optical fiber; and lumber.

Pursuant to the above, when federal funds are expended by ESC Region 8 and TIPS Members, Vendor certifies that to the greatest extent practicable Vendor will provide a preference for the purchase, acquisition, or use of goods, products, or materials produced in the United States (including but not limited to iron, aluminum, steel, cement, and other manufactured products).

Does Vendor Certify?

Yes, Vendor certifies

8 6 2 CFR Part 200 or Federal Provision - Ban on Foreign Telecommunications

ESC 8 and TIPS Members are prohibited from obligating or expending Federal financial assistance, to include loan or grant funds, to: (1) procure or obtain, (2) extend or renew a contract to procure or obtain, or (3) enter into a contract (or extend or renew a contract) to procure or obtain, equipment, services, or systems that use "covered telecommunications" equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. "Covered telecommunications" equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities), and physical security surveillance of critical infrastructure and other national security purposes, and video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities) for the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes detailed in 2 CFR § 200.216.

Pursuant to the above, when federal funds are expended by ESC Region 8 and TIPS Members, Vendor certifies that Vendor will not purchase equipment, services, or systems that use "covered telecommunications", as defined by 2 CFR §200.216 equipment or services as a substantial or essential component of any system, or as critical technology as part of any system.

Does vendor certify?

Yes, Vendor certifies

8 **2 CFR Part 200 or Federal Provision - Contract Cost & Price**

For contracts more than the simplified acquisition threshold currently set at \$250,000, a TIPS Member may, in very rare circumstances, be required to negotiate profit as a separate element of the price pursuant to 2 C.F.R. 200.324(b). Under those circumstances, Vendor agrees to provide information and negotiate with the TIPS Member regarding profit as a separate element of the price. However, Vendor certifies that the total price charged by the Vendor shall not exceed the Vendor's TIPS pricing and pricing terms proposed.

Does Vendor certify?

Yes, Vendor certifies

8 **2 CFR Part 200 or Federal Provision - Equal Employment Opportunity**

Except as otherwise provided under 41 CFR Part 60, all contracts that meet the definition of "federally assisted construction contract" in 41 CFR Part 60-1.3 must include the equal opportunity clause provided under 41 CFR 60-1.4(b), in accordance with Executive Order 11246, "Equal Employment Opportunity" (30 FR 12319, 12935, 3 CFR Part, 1964-1965 Comp., p. 339), as amended by Executive Order 11375, "Amending Executive Order 11246 Relating to Equal Employment Opportunity," and implementing regulations at 41 CFR part 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor."

Pursuant to the above, when federal funds are expended by ESC Region 8 and TIPS Members on any federally assisted construction contract, the equal

opportunity clause is incorporated by reference here.

Does Vendor Certify?

Yes, Vendor certifies

8 **2 CFR Part 200 or Federal Provision - Davis Bacon Act Compliance**

Texas Statute requires compliance with Davis-Bacon Act, as amended (40 U.S.C. 3141-3148). When required by Federal program legislation, all prime construction contracts in excess of \$2,000 awarded by non-Federal entities must include a provision for compliance with the Davis-Bacon Act (40 U.S.C. 3141-3144, and 3146- 3148) as supplemented by Department of Labor regulations (29 CFR Part 5, "Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction"). In accordance with the statute, contractors must be required to pay wages to laborers and mechanics at a rate not less than the prevailing wages specified in a wage determination made by the Secretary of Labor. In addition, contractors must be required to pay wages not less than once a week. The non-Federal entity must place a copy of the current prevailing wage determination issued by the Department of Labor in each solicitation. The decision to award a contract or subcontract must be conditioned upon the acceptance of the wage determination. The non-Federal entity must report all suspected or reported violations to the Federal awarding agency. The contracts must also include a provision for compliance with the Copeland "Anti-Kickback" Act (40 U.S.C. 3145), as supplemented by Department of Labor regulations (29 CFR Part 3, "Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States"). The Act provides that each contractor or subrecipient must be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he or she is otherwise entitled. The non-Federal entity must report all suspected or reported violations to the Federal awarding agency.

Pursuant to state and federal requirements, Vendor certifies that it will be in compliance with all applicable Davis-Bacon Act provisions if/when applicable.

Does Vendor certify?

Yes, Vendor certifies

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2 CFR Part 200 or Federal Provision - Contract Work Hours and Safety Standards

Where applicable, all contracts awarded by ESC 8 and TIPS Members in excess of \$100,000 that involve the employment of mechanics or laborers must include a provision for compliance with 40 U.S.C. 3702 and 3704, as supplemented by Department of Labor regulations (29 CFR Part 5). Under 40 U.S.C. 3702 of the Act, each contractor must be required to compute the wages of every mechanic and laborer on the basis of a standard work week of 40 hours. Work in excess of the standard work week is permissible provided that the worker is compensated at a rate of not less than one and a half times the basic rate of pay for all hours worked in excess of 40 hours in the work week. The requirements of 40 U.S.C. 3704 are applicable to construction work and provide that no laborer or mechanic must be required to work in surroundings or under working conditions which are unsanitary, hazardous or dangerous. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence. Pursuant to the above, when federal funds are expended by ESC Region 8 and TIPS Members, Vendor certifies that during the term of an award for all contracts resulting from this procurement process, Vendor will be in compliance with all applicable provisions of the Contract Work Hours and Safety Standards Act.

Does Vendor certify?

Yes, Vendor certifies

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2 CFR Part 200 or Federal Provision - FEMA Fund Certification & Certification of Access to Records

If and when Vendor accepts a TIPS purchase paid for in full or part with FEMA funds, Vendor certifies that:

(1) Vendor agrees to provide the TIPS Member, the FEMA Administrator, the Comptroller General of the United States, or any of their authorized representatives access to and rights to reproduce any books, documents, papers, and records of the Contractor which are directly pertinent to this contract, or any contract resulting from this procurement, for the purposes of making audits, examinations, excerpts, and transcriptions. This right also includes timely and reasonable access to Vendor's personnel for the purpose of interview and discussion relating to such documents. Vendor agrees to provide the FEMA Administrator or an authorized representatives access to construction or other work sites pertaining to the work being completed under the contract. Vendor acknowledges and agrees that no language in this contract or the contract with the TIPS Member is intended to prohibit audits or internal reviews by the FEMA Administrator or the Comptroller General of the United States.

(2) The Vendor shall not use the Department of Homeland Security's seal(s), logos, crests, or reproductions of flags or likenesses of DHS agency officials without specific FEMA pre-approval.

(3) The Vendor will comply with all applicable Federal law, regulations, executive orders, FEMA policies, procedures, and directives.

(4) The Federal Government is not a party to this contract and is not subject to any obligations or liabilities to the non-Federal entity, contractor, or any other party pertaining to any matter resulting from the contract.

(5) The Vendor acknowledges that 31 U.S.C. Chap. 38 (Administrative Remedies for False Claims and Statements) applies to the Vendor's actions pertaining to this contract.

Does Vendor certify?

Yes, Vendor certifies

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2 CFR Part 200 or Federal Provision - Certification of Compliance with the Energy Policy and Conservation Act

When appropriate and to the extent consistent with the law, Vendor certifies that it will comply with the Energy Policy and Conservation Act (42 U.S.C. 6321 et seq; 49 C.F.R. Part 18) and any state mandatory standards and policies relating to energy efficiency which are contained in applicable state energy conservation plans issued in compliance with the Act.

Does Vendor certify?

Yes, Vendor certifies

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2 CFR Part 200 or Federal Provision - Certification of Compliance with Never Contract with the Enemy

Where applicable, all contracts awarded by ESC 8 and TIPS Members in excess of \$50,000.00, within the period of performance, and which are performed outside of the United States, including U.S. territories, are subject to the regulations implementing Never Contract with the Enemy in 2 CFR part 183. Per 2 CFR part 183, in the situation specified, ESC 8 and TIPS Members shall terminate any contract or agreement resulting from this procurement which violates the Never Contract with the Enemy regulation in 2 CFR part 183, including if Vendor is actively opposing the United States or coalition forces involved in a contingency operation in which members of the the Armed Forces are actively engaged in hostilities. Vendor certifies that it is neither an excluded entity under the System for Award Management (SAM) nor Federal Awardee Performance and Integrity Information System (FAPIS) for any contract terminated due to Never Contract with the Enemy as a Termination for Material Failure to Comply.

Does Vendor certify?

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2 CFR Part 200 or Federal Provision - Certification of Compliance with EPA Regulations

For contracts resulting from this procurement, in excess of \$100,000.00 and paid for with federal funds, Vendor certifies that Vendor will comply with all applicable standards, orders, regulations, and/or requirements issued pursuant to the Clean Air Act of 1970, as amended (42 U.S.C. 1857(h)), Section 508 of the Clean Water Act, as amended (33 U.S.C. 1368), Executive Order 117389 and Environmental Protection Agency Regulation, 40 CFR Part 15.

Does Vendor certify?

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2 CFR Part 200 or Federal Provision - Record Retention Requirements

For contracts resulting from this procurement, paid for by ESC 8 or TIPS Members with federal funds, Vendor certifies that Vendor will comply with the record retention requirements detailed in 2 CFR § 200.334. Vendor certifies that Vendor will retain all records as required by 2 CFR § 200.334 for a period of three years after final expenditure or financial reports, as applicable, and all other pending matters are closed.

Does Vendor certify?

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2 CFR Part 200 or Federal Provision - Subcontracting and Affirmative Steps for Small and Minority Businesses, Women's Business Enterprises, and Labor Surplus Area Firms.

Do you ever anticipate the possibility of subcontracting any of your work under this award if you are successful?

If you respond "Yes", you must respond to the following attribute question accurately. If you respond "No", you may skip the following attribute question.

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2 CFR Part 200 or Federal Provision - If "Yes" Response to Above Attribute - Continued - Subcontracting and Affirmative Steps for Small and Minority Businesses, Women's Business Enterprises, and Labor Surplus Area Firms.

Only respond to this question if you responded "Yes" to the attribute question directly above. Skip this question if you responded "No" to the attribute question directly above.

Does Vendor certify that it will follow the following affirmative steps? Federal Regulation 2 CFR §200.321 Contracting with small and minority businesses, women's business enterprises, and labor surplus area firms. (a)The non-Federal entity must take all necessary affirmative steps to assure that minority businesses, women's business enterprises, and labor surplus area firms are used when possible.

(b) Affirmative steps must include:

- (1) Placing qualified small and minority businesses and women's business enterprises on solicitation lists;
- (2) Assuring that small and minority businesses, and women's business enterprises are solicited whenever they are potential sources;
- (3) Dividing total requirements, when economically feasible, into smaller tasks or quantities to permit maximum participation by small and minority businesses, and women's business enterprises;
- (4) Establishing delivery schedules, where the requirement permits, which encourage participation by small and minority businesses, and women's business enterprises;
- (5) Using the services and assistance, as appropriate, of such organizations as the Small Business Administration and the Minority Business Development Agency of the Department of Commerce ; and
- (6) Requiring the prime contractor, if subcontracts are to be let, to take the affirmative steps listed in paragraphs(1) through (5) of this section.

Does Vendor certify?

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ACKNOWLEDGMENT & BINDING CORPORATE AUTHORITY

By submitting this proposal, the individual(s) submitting on behalf of the Vendor certify that they are authorized by Vendor to complete and submit this proposal on behalf of Vendor and that this proposal was duly submitted on behalf of Vendor by authority of its governing body, if any, and within the scope of its corporate powers.

Vendor further certifies that it has read, examined, and understands all portions of this solicitation including but not limited to all attribute questions, attachments, solicitation documents, bid notes, and the Vendor Agreement(s). Vendor certifies that, if necessary, Vendor has consulted with counsel in understanding all portions of this solicitation.

TIPS 230701 Indoor Air Quality Equipment and Services	Medical Illumination International, Inc.
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TIPS REFERENCE FORM

All requested information must be typed and uploaded in Excel format. Do not handwrite or upload in any format other than Excel. Emails provided must be current and active. Do not include TIPS/Region 8 employees as a reference. The entities that you provide must be paying customers, not affiliates/partners/manufacturers/resellers, etc.

You must provide below at least three (3) references from three different entity customers, preferably government or non-profit entities, who have purchased goods or services from your vendor entity within the last three years.

Customer Entity Name	Customer Contact Name	Valid Contact Email	Valid Contact Phone
KIPP DC Public Schools	Kevin Mehm	kevin.mehm@kipfdc.org	202-425-9583
Phoenix Endodontics	Jacqueline Allen, D.D.S.	www.phoenixendodontist.com	602-242-4745
PMM Companies	Jason Salisbury	jsalsbury@pmmcompanies.com	202.347.5118

REQUIRED CONFIDENTIALITY CLAIM FORM

(VENDOR MUST COMPLETE THE FOLLOWING VENDOR INFORMATION)

Vendor Entity Name: Medical Illumination International, Inc.

Vendor Authorized Signatory Name: Mary Neale

Vendor Authorized Signatory Title: General Counsel

Vendor Authorized Signatory Email: mneale@medillum.com

Vendor Address: 19749 Dearborn Street

City: Chatsworth State: CA Zip Code: 91311

Vendor agrees that it is voluntarily providing its data (including but not limited to: Vendor information, Vendor documentation, Vendor's proposal, Vendor pricing submitted or provided to TIPS, TIPS contract documents, TIPS correspondence, Vendor logos and images, Vendor's contact information, Vendor's brochures and commercial information, Vendor's financial information, Vendor's certifications, and any other Vendor information or documentation submitted to TIPS by Vendor and its agents) (Hereinafter, "Vendor Data") to TIPS. Vendor understands and agrees that TIPS is a government entity subject to public information laws including but not limited to Texas Government Code (TGC) Chapter 552. Vendor agrees that regardless of confidentiality designations herein, Vendor's submission of a proposal constitutes Vendor's consent to the disclosure and release of Vendor's Data and comprehensive proposal, including any information deemed confidential or proprietary herein, to and by TIPS Members.

Notwithstanding the foregoing permissible release to TIPS Members, if Vendor considers any portion of Vendor's proposal to be otherwise confidential and not subject to public disclosure pursuant to public information laws, including but not limited to TGC Chapter 552, Vendor must properly execute Option 1 only below, attach to this PDF all documents and information that Vendor deems confidential, and upload the consolidated documentation. Regardless of the Option selected below, this form must be completed and uploaded to the "Response Attachments" section of the eBid System entitled "Required Confidentiality Claim Form." Execution and submission of this form is the sole indicator of whether Vendor considers any Vendor Data confidential in the event TIPS receives a request, a Public Information Request, or subpoena. If TIPS receives a request, any responsive documentation not deemed confidential by you through proper execution of Option 1 of this form will be automatically released. For information deemed confidential by you through proper execution of Option 1 of this form, TIPS will follow procedures of controlling statute(s) regarding withholding that documentation and shall not be liable for any release of information required by law, including Attorney General opinion or court order.

(VENDOR MUST COMPLETE ONE OF THE TWO OPTIONS AND UPLOAD IN THE EBID SYSTEM)

OPTION 1 – DESIGNATING CONFIDENTIAL MATERIALS – YES, VENDOR HAS ATTACHED CONFIDENTIAL MATERIALS

(Confirm each bullet point and sign below)

- Vendor claims some Vendor Data confidential to the extent permitted by TGC Chapter 552 and other applicable law.
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Medical Illumination International, Inc.
Limited Warranty

This document comprises the general terms of your product's Limited Warranty. This Limited Warranty is applicable to products sold by Medical Illumination International, Inc. or one of its subsidiaries or divisions (collectively, "MI") through one of MI's authorized dealers, distributors or sales representatives (an "Authorized Dealer"). This Limited Warranty is not applicable to any MI product not purchased from an Authorized Dealer. This Limited Warranty extends only to the first retail purchaser of a product and is not transferable or assignable.

Your product is warranted against defective material and/or workmanship, excluding normal replacement parts, for a period of three (3) years from the date of shipment. Normal replacement parts include, but are not limited to, bulbs, sterilizable handles, filters and glass items. This Limited Warranty applies exclusively to the repair or replacement of parts recognized as defective by MI that are in normal use and have not been modified or repaired by unauthorized personnel.

This Limited Warranty is in lieu of all other warranties, expressed or implied, including any implied warranty of fitness for a particular purpose and all other obligations or liabilities, including liability for incidental, special or consequential damages or labor.

In the event of a defect or failure covered under this Limited Warranty, please contact MI immediately by phone (818/838-3025), fax (818/838-3725), email (info@medillum.com) or through our website (<http://www.medillum.com>). Be prepared to give the model number, serial number and full description of the issue. This Limited Warranty will not apply if the MI serial number affixed to the product has been removed, obliterated or defaced.

Our Customer Service department will attempt to solve the problem over the phone. If it becomes necessary, we will determine, in our sole discretion, the best way to address the issue. We may require that the product be sent to our factory for repair. In limited instances, we may dispatch an authorized service technician. No product serviced by other than our authorized service technician will be covered by this Limited Warranty.

In the event we determine that your product needs to be repaired, either onsite or by return to our factory, please do not continue to use your product. MI is not responsible for any costs, expenses, losses or damage resulting from your continued use of the product prior to its authorized repair. MI is not responsible for costs or expenses incurred for loss of use of the product.

If we require the return of the product to our factory, you will be provided with a Return Authorization number. Products sent to the factory without a Return Authorization number will not be accepted. It is your obligation to arrange for return shipment of your product to the factory for warranty service, which shall be at your expense. Your Product must be returned to our factory within thirty (30) days of the date of the Return Authorization. Carefully package the product and return it, freight prepaid and insured, with the Return Authorization number clearly marked on the outside of the box, to Medical Illumination International, Inc., 19749 Dearborn Street, Chatsworth, CA 91311, RA# _____.

Damage resulting from inadequate packing is not covered by this warranty, and shipping insurance does not cover damage due to inadequate packing. MI cannot be held responsible for in-transit loss or damage. In the event that freight-related damage should occur, we will notify you immediately so that you can file a damage claim with the freight carrier.

Within the warranty period, MI will evaluate your returned product, repair as appropriate, and ship the product back to you with freight costs prepaid by MI. In the event that damage or failure is discovered that is not covered by this Limited Warranty, we will contact you for your approval of all costs that may be incurred prior to commencing any repairs.

This Limited Warranty does not cover the following:

- Any field labor or outside services, including, but not limited to, electricians, contractors, installation services, routine maintenance or other repair services.
- Damage to the product resulting from tampering, accident, abuse, negligence, alteration or other causes unrelated to problems with material and/or workmanship.
- Damage due to improper installation, use, cleaning or maintenance, as outlined in the Installation and Service Manual.
- Labor costs associated with removing, re-packaging for shipment or reinstalling product.



VidaShield is a fast, continuous air purification system ideal for schools, universities and daycare centers. This patented device is uniquely designed by combining an ultraviolet germicidal irradiation (UVGI) chamber and air circulating fans with an overhead ceiling light. The innovative design allows for 24/7 operation in occupied spaces.

Conveniently installed in ceilings, VidaShield is an unobtrusive space saver and serves a dual purpose by providing excellent light output and improving indoor air quality (IAQ).

Why is **IAQ** Important?

Poor IAQ is caused by numerous pollutants like bacteria, viruses, mold, dust and dander. These directly affect the health of children and adults and can lead to allergy symptoms or even exacerbate illnesses like asthma.

The **Problem**

- + 7 million children w/ asthma
- + 1 out of 10 children suffers from asthma
- + Adults miss 14.5 million work days to asthma
- + Productivity linked to absenteeism costs \$225.8 billion annually

The **Solution**

- + Shielded UV-C
- + 24 Hour Continuous Operation
- + Reduces Odor
- + Improves Indoor Air Quality
- + Energy Efficient

BENEFITS OF VIDASHIELD



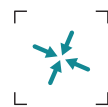
**REDUCES
BACTERIA**



**REDUCES
SETTLING**



**CLEANS
24/7 by 365**



**SAVES
SPACE**

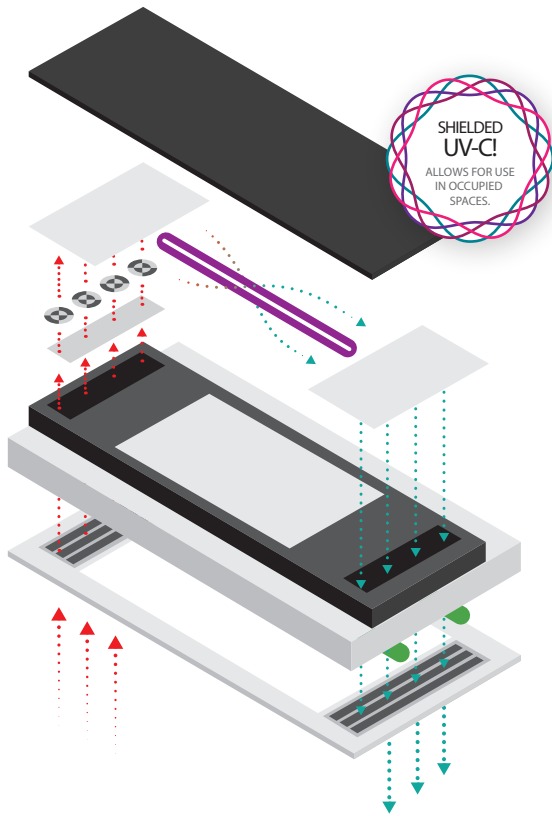


**MINIMAL
MAINTENANCE**



**IMPROVES
IAQ**

HOW VIDASHIELD WORKS



UV-C technology has been used as a disinfection method for decades. The UV-C wavelength of 253.7 nanometers has been proven to be effective at neutralizing dangerous microorganisms. The challenge with UV-C technology has always been the method of delivery. It can't be used in occupied spaces and is only effective on direct line of sight areas. Until now!

The patented VidaShield system uses UV-C and filtration to draw in and treat environmental air. VidaShield can treat a volume of air equivalent to an 10' x 10' x 8' room, four times per hour.

OVERVIEW

- Installation of VidaShield systems improves odors and freshens the overall quality of the air.
- The VidaShield system unobtrusively improves indoor air quality by reducing viruses, bacteria, and fungi in treated air as well as the settling of airborne pathogens from the treated air onto surrounding surfaces.
- VidaShield doesn't require a person to operate the unit and maintenance requirements are minimal on the system. The lumen output on the UV lamp will start to diminish after approximately 9000 hours (375 days) so it is recommended you change the UV lamp annually to maintain maximum efficacy of the unit.



The kids seem to be a little healthier and feeling better and a few teachers who have upper respiratory issues say they aren't as pronounced as they were experiencing before.

Dr. John Ruis, Superintendent.



For more information contact your VidaShield Sales Representative.

(800) 831-1222 | info@vidashield.com | www.vidashield.com



**FAST, CONTINUOUS
UV-C AIR PURIFICATION**

Improving the Hospital Environment by Reducing the Bioburden





Hospitals are making the right decisions when it comes to preventing infections, but there is one area that is often overlooked. There is an **Invisible Threat** that travels throughout facilities, impacts patient care, employee retention and even creates financial risk.

The American Journal of Infection Control recently cited a study that detailed how airborne dispersion of pathogens can be rapid, widespread and difficult to prevent.⁷ Hospital air can also be a potential route for transmission of pathogenic aerosols like Methicillin resistant Staphylococcus aureus and C. difficile.^{2,3}

Options to combat this threat were limited; before **VIDASHIELD UV24™**.

JOIN LEADING HOSPITALS IN BATTLING THE INVISIBLE THREAT

Leading hospitals are combatting contaminated air with a proven, patented UV-C air purification system uniquely designed inside a lighting fixture called **VIDASHIELD UV24**.

Housed in a shielded UV chamber in the ceiling and ideally located for maximum effectiveness, **VIDASHIELD UV24** continuously reduces harmful bacteria and fungi from treated air while improving air quality and minimizing odors.



24/7/365



CONTINUALLY



UNOBTRUSIVELY



AUTOMATICALLY

Fill The Gap With Continuous Cleaning

Accepted protocols to address surface contamination are based on episodic cleaning and while hospitals are very diligent in their disinfection procedures, the **time between** and the **quality of cleaning** affects the risk. Eliminates 100% of human error.

Infection Control Bundle:

- ✓ Surface Cleaning
- ✓ Hand Hygiene
- ✓ Treatment
- ✓ PPE
- ✓ UV-C Air Purification

Surface Cleaning

Hand Hygiene

PPE

Treatment

VIDASHIELD

UV24

Hand Hygiene

Surface Cleaning



VIDASHIELD UV24 effectively fills the gap created when terminal cleaning isn't an option. Protect patients and staff from **The Invisible Threat** of contaminated air posed by episodic cleaning.



Critical Care Meets Constant Cleaning

VIDASHIELD UV24 is ideal for use in critical care areas with the highest risk of HAIs – where proper cleaning can be difficult and crowds may limit access for terminal cleaning devices.



ICU



NICU



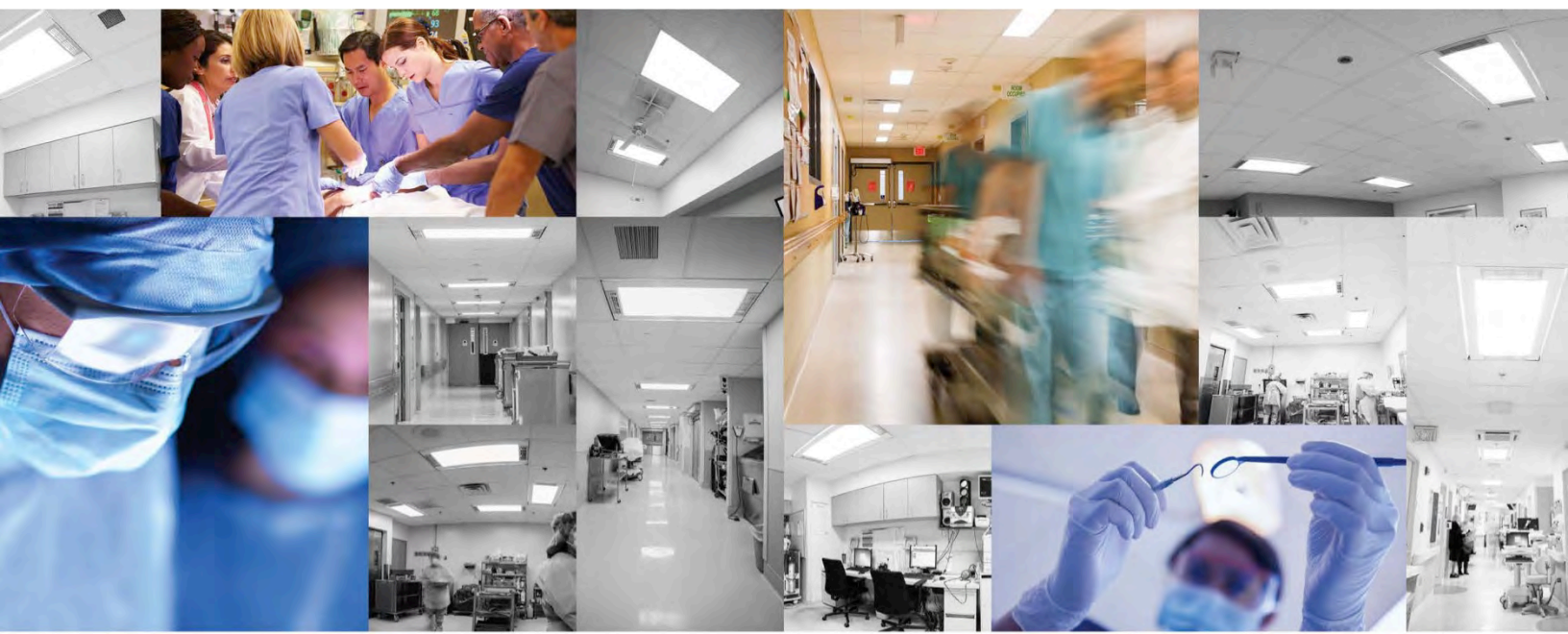
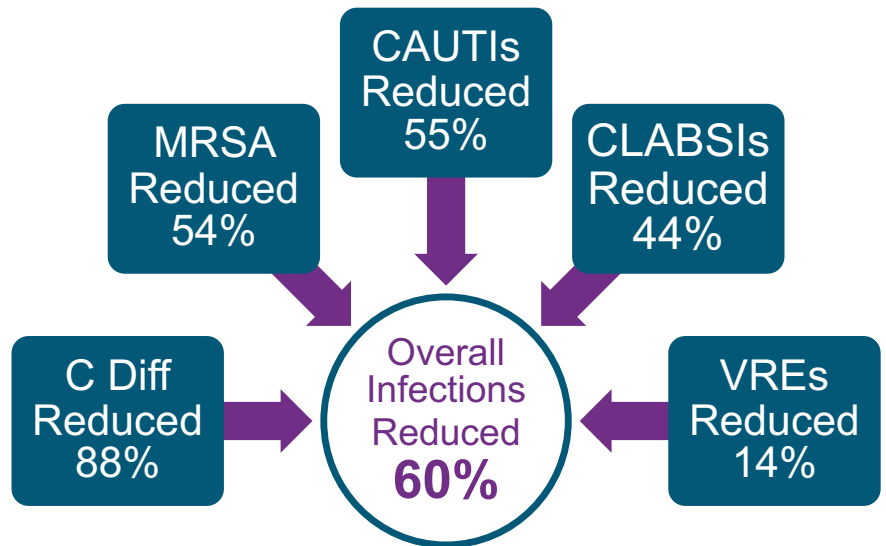
ED



RECOVERY

VIDASHIELD UV24 reduces the levels of bacteria and fungi in treated air and reduces the settling of viable bacteria and fungi from treated air onto surfaces.

In a recent patient outcome study, a long term acute care hospital in Kentucky reported a **60% reduction** in their overall infection rates.⁵



Available in Three Models



VS01

Fluorescent or LED Tubes



VS02

LED Panel



VS03

No Downlight



A highly reflective, sealed UV-C chamber houses the UV lamp above the ceiling out of harm's way. No UV light leaks out of the VidaShield system, allowing for use in occupied spaces.



Back of system mounted in ceiling;
with cover off and on



VIDASHIELD UV24 SYSTEM DETAILS

System: Energy efficient

Installation: Easy; does not upset HVAC system

Dimensions: 24" wide x 48" long x 6" high (UV chamber included)

Weight: 44 lbs.

Voltage: Universal 110-277v

UV Lamp: Ultraviolet germicidal lamp operates at peak wavelength of 254nm, doesn't produce ozone

Annual Maintenance: UV lamp

Other Maintenance: MERV 6 filter replacement every 3 months



3 Year Limited Warranty
ETL Listed





For more information, contact your VidaShield UV24 sales representative.

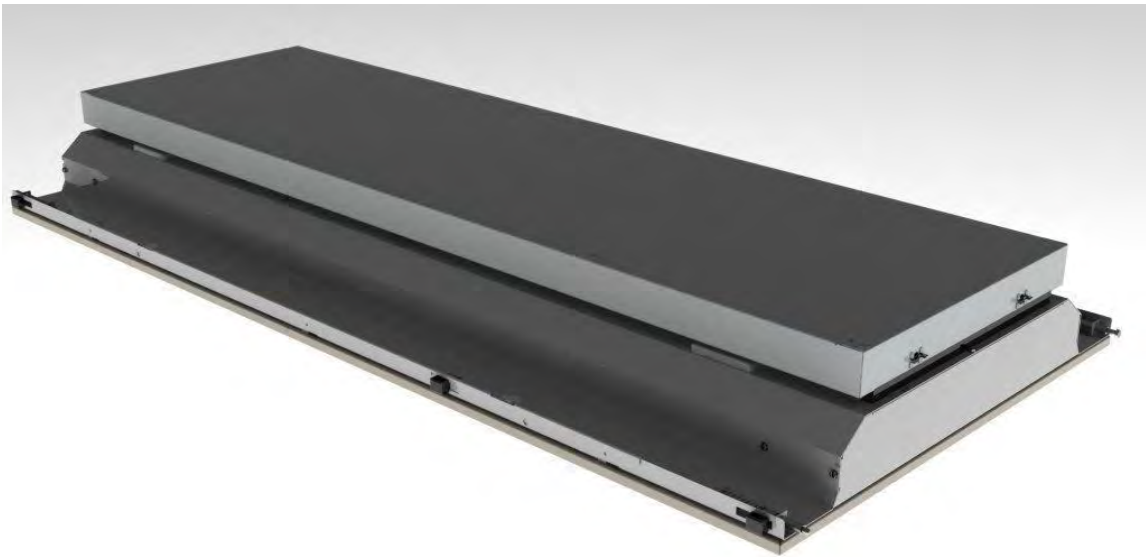
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Medical Illumination
547 Library Street
San Fernando, CA 91340



The VidaShield UV24 brand is owned, sold, distributed, marketed and manufactured by Medical Illumination in San Fernando, California. It is also known as the UV24 overhead air purification system. For more information, log onto medillum.com.

Report on the Performance of the UV24 System



By Dr. Wladyslaw J. Kowalski

December 7, 2011

Medical Illumination - 547 Library Street, San Fernando, CA 91340
Nuvo - 5368 Kuhl Road, Pennsylvania, 16510 (div of Medical Illumination)

Executive Summary

The superior performance of the UV24 System will enable high levels of air disinfection to be achieved as well as a consequent reduction in the risk of airborne nosocomial infection in any health care environment. This report evaluates the performance of the UV24 System in terms of the removal rates of known airborne nosocomial or hospital-acquired pathogens, including bacteria, viruses, and fungi. Removal rates due to filtration and UV irradiation are evaluated using computer models and tabulated for various operating conditions. These removal rates, which will reduce concentrations of airborne pathogens, are used to estimate the risk of infection to occupants and this risk is presented in terms of the Zonal Protection Factor (ZPF). The ZPF is a measure of the percentage of occupants protected from infection. Removal rates for most pathogens are in excess of 90% in the primary configurations. At the nominal design airflow of **50 cfm**, and with a **MERV 6** filter and a UV lamp with **15 W** of UV output, the UV24 System provides overall **single pass removal rates of approximately 97%** on the average for the 44 airborne nosocomial pathogens in the database. For the nominal design floor area of 100 ft², the unit will provide Zonal Protection Factors that exceed 91% for most of the pathogens in the database, with an **average ZPF of 90%**. ZPF data is provided for alternate airflows ranging from 50 ft² to 300 ft² as shown in Table 6. Both the single pass removal rates and the ZPFs are close to the limits of what can be achieved with a combined UV and filtration system, and this unit should outperform other similar units while consuming the least amount of energy as it has been optimized for both high performance and low power consumption. Quiet operation also makes this unit suitable for any hospital environment and it can be used in general wards, procedure rooms, hallways, laboratories, and other facilities.

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Introduction

The UV24 System is a UV air disinfection system incorporated into a ceiling light fixture such that it has no visible profile. It is intended to disinfect the air of bacteria, viruses, and fungi in hospital environments. The system includes an ultraviolet (UV) lamp, a filter, and a fan that will recirculate air locally, such as in a hallway or procedure room. Light baffles ensure that no hazardous levels of UV will escape into the local area. The system is designed to operate quietly while delivering air of the highest purity, with disinfection rates approaching 100%. Targeted microorganisms include MRSA, VRE, *Acinetobacter*, *Streptococcus* species, Influenza, VZV, *Pseudomonas*, *Clostridium difficile*, and other causative agents of hospital-acquired infections (HAIs). This report summarizes the predicted performance of the unit in terms of UV dose, filter removal rates, and overall disinfection or kill rates of pathogenic nosocomial microbes. Comparative predictions are provided for reductions of airborne concentrations of microbes for particular floor areas and room volumes. These airborne reductions are related to the risk of reduced infections. This unit will also remove fungal and bacterial spores at rates that are specified in this report.

System Description

The UV24 System consists of a ceiling light fixture that includes a UV lamp, a filter, light baffles, and a UV irradiation chamber. Air is drawn into the unit, filtered and disinfected, and then exhausted back into the local airspace. A MERV 6 filter is included to keep dust off the UV lamp, but this filter also serves to remove a percentage of airborne pathogens. Figure 1 shows a partially exploded view of the major components of the system. From top to bottom are shown the UV irradiation chamber, the lighting components, and the bottom grille.

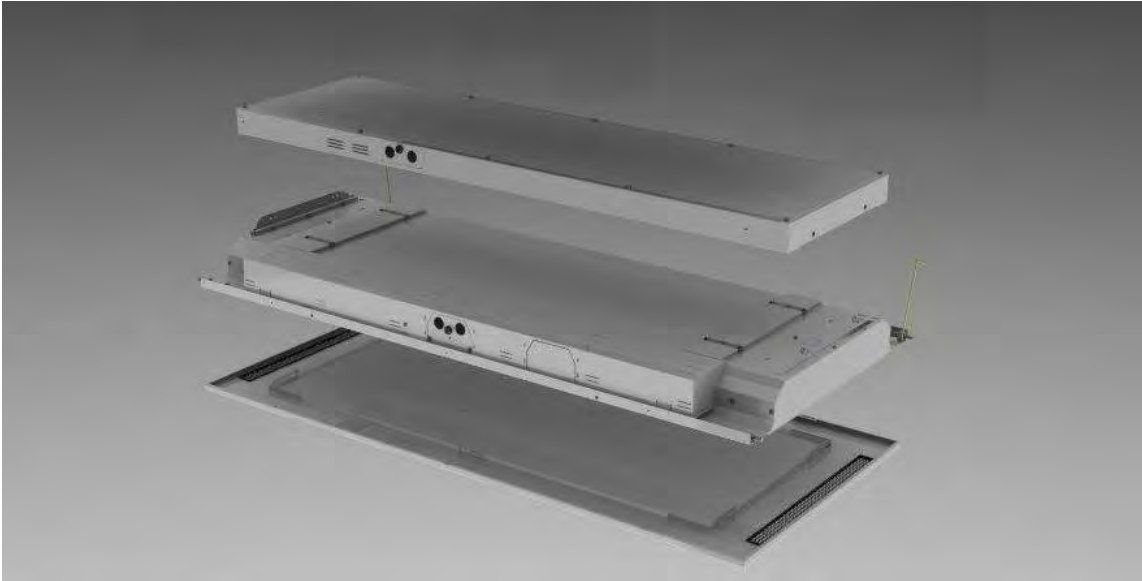


Figure 1: Partially exploded view of the UV24 System showing major components.

Figure 2 shows the internal arrangement of the UV irradiation chamber, including the UV lamps and the fans at the outlet. The irradiation chamber is lined or coated with reflective materials to increase the total irradiance.



Figure 2: Schematic image of UV24 System showing internal UV lamps and irradiation chamber.

The properties of the reflective material were provided in the manufacturer's documents. The reflectivity of the aluminum surface is approximately 75-85% in the UV spectrum. Dimensions and design specifications are summarized in Table 1. These dimensions have been adjusted from those shown in the previous figure. The two configurations represent two different UV lamp sizes. The nominal airflow is 50 cfm. The airflow affects the air velocity and the exposure time (Et). Lamp dimensions and coordinates are unchanged from Table 1. At the nominal airflow of 50 scfm the air velocity is approximately 252 fpm. This is an acceptable airflow and will not decrease filter performance – in fact, filter performance will be slightly improved over the results given in the tables. The normal operating design airflow for a UV lamp is about 400-600 fpm.

Table 1: Specifications for UV24 System

Lamp Type	T5
# Lamps	1
Lamp UV Output, W	15
Width, in	14.5
Length, in	30.979
Height, in	1.97
Width, ft	1.21
Length, ft	2.58
Height, ft	0.16
Width, cm	36.83
Length, cm	78.69
Height, cm	5.0038
Nominal Airflow, Q, cfm	50
Nominal Airflow, Q, m ³ /min	1.42
Velocity, fpm	252
Velocity, fps	4.20
Velocity, cm/s	128.04
Velocity, m/s	1.28
Face Area, in ²	28.57
Face Area, ft ²	0.1984
Face Area, cm ²	184.29
Face Area, m ²	0.0184
Exposure Time, Et, s	0.6145
lamp end coordinate, x1, cm	18.42
lamp end coordinate, x2, cm	18.42
lamp end coordinate, y1, cm	2.50
lamp end coordinate, y2, cm	2.50
lamp end coordinate, z1, cm	10.77
lamp end coordinate, z2, cm	67.92
lamp arc length, arcl, cm	57.15
lamp radius, r, cm	0.79

A MERV 6 filter is included in the unit and a representative filter performance curve is adapted from Kowalski and Bahnfleth (2002). Figure 3 shows the filter performance curve. The removal efficiency at any microbial particle size can be estimated from this curve.

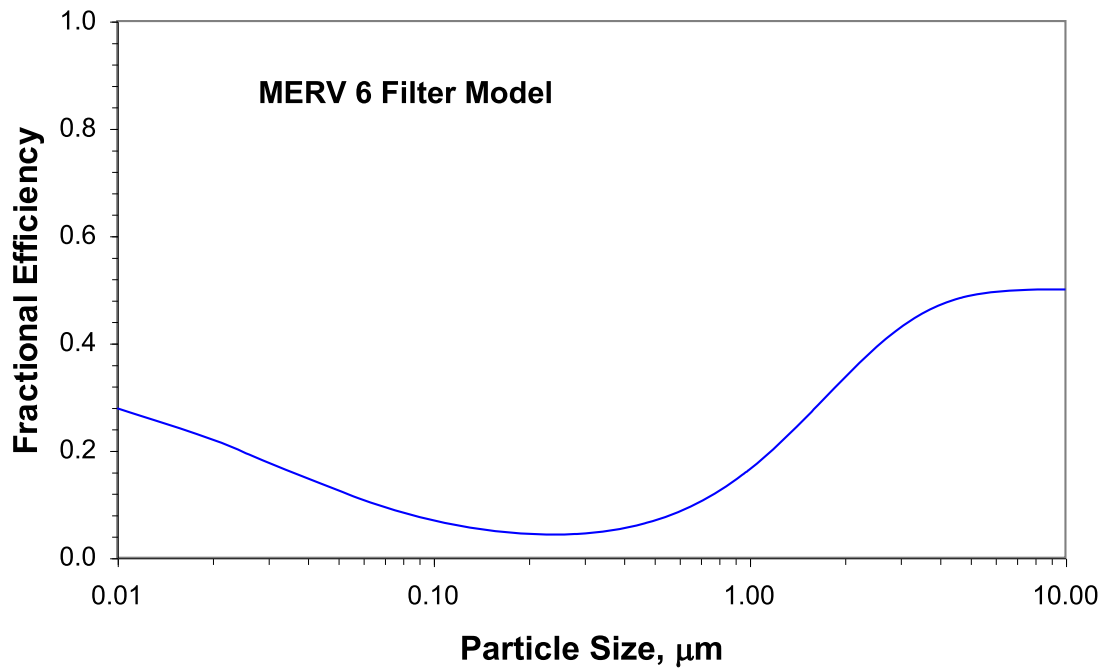


Figure 3: Performance of a generic MERV 6 filter. Based on modeling per Kowalski & Bahnfleth (2002).

Fan Pressure Loss and Noise

One of the design criteria for the UV24 System is that it must have quiet operation and produce the lowest possible level of noise. Noise is produced by the airflow as it moves through the fan and from turbulence inside the unit. The higher the pressure drop through the system the higher the fan static pressure and noise level. The unit includes smooth baffles to reduce turbulence inside the unit and fans have been selected for quiet operation. In order to minimize pressure losses a low pressure drop MERV 6 filter has been selected.

Analysis Results

Table 2 lists all nosocomial or HAI microbes that are known or suspected of having an airborne opponent in their transmission cycle. These include bacteria, viruses, fungal spores, and bacterial spores. Table 2 identifies the predicted filter removal rate for all these microbes based on the Figure 3 filter model. These filter removal rates will be combined with the UV disinfection rates to develop the overall removal rates of the pathogens. The filter removal rates are computed based on the log mean diameter of each pathogen. The size range of any microbe in nature will have a lognormal distribution, or a normal distribution (bell curve) on a logarithmic scale. The log mean diameter is an adequate representation of the mean size of any microbial population (Kowalski et al 1999). The log mean diameter will therefore be an adequate predictor of removal rates through any filter with a known performance curve.

Table 2: MERV 6 Filter Removal Rates of Airborne Nosocomial Pathogens

Microbe	Type	Size µm	MERV 6 Removal Rate	
			fraction	%
Acinetobacter	Bacteria	1.225	0.2089	20.9
Adenovirus	Virus	0.079	0.0853	8.5
Aspergillus spores	Fungi	3.354	0.4476	44.8
Blastomyces dermatitidis spores	Fungi	12.649	0.5000	50.0
Bordetella pertussis	Bacteria	0.245	0.0431	4.3
Clostridium difficile spores	Bacteria	2	0.3353	33.5
Clostridium perfringens spores	Bacteria	1	0.1643	16.4
Coronavirus (SARS)	Virus	0.11	0.0643	6.4
Corynebacterium diphtheriae	Bacteria	0.698	0.1040	10.4
Coxsackievirus	Virus	0.027	0.1886	18.9
Cryptococcus neoformans spores	Fungi	4.899	0.4872	48.7
Enterobacter cloacae	Bacteria	1.414	0.2442	24.4
Enterococcus	Bacteria	1.414	0.2442	24.4
Fusarium spores	Fungi	11.225	0.5000	50.0
Haemophilus influenzae	Bacteria	0.285	0.0443	4.4
Haemophilus parainfluenzae	Bacteria	1.732	0.2973	29.7
Influenza A virus	Virus	0.098	0.0709	7.1
Klebsiella pneumoniae	Bacteria	0.671	0.0988	9.9
Legionella pneumophila	Bacteria	0.52	0.0721	7.2
Measles virus	Virus	0.158	0.0493	4.9
Mucor spores	Fungi	7.071	0.4983	49.8
Mumps virus	Virus	0.164	0.0483	4.8
Mycobacterium avium	Bacteria	1.118	0.1879	18.8
Mycobacterium tuberculosis	Bacteria	0.637	0.0925	9.3
Mycoplasma pneumoniae	Bacteria	0.177	0.0464	4.6
Neisseria meningitidis	Bacteria	0.775	0.1190	11.9
Nocardia asteroides	Bacteria	1.118	0.1879	18.8
Norwalk virus	Virus	0.029	0.1809	18.1
Parainfluenza virus	Virus	0.194	0.0447	4.5
Parvovirus B19	Virus	0.022	0.2104	21.0
Proteus mirabilis	Bacteria	0.494	0.0680	6.8
Pseudomonas aeruginosa	Bacteria	0.494	0.0680	6.8
Reovirus	Virus	0.075	0.0892	8.9
RSV	Virus	0.19	0.0450	4.5
Rhinovirus	Virus	0.023	0.2057	20.6
Rhizopus spores	Fungi	6.928	0.4981	49.8
Rotavirus	Virus	0.073	0.0913	9.1
Rubella virus	Virus	0.061	0.1062	10.6
Serratia marcescens	Bacteria	0.632	0.0916	9.2
Staphylococcus aureus	Bacteria	0.866	0.1372	13.7
Staphylococcus epidermis	Bacteria	0.866	0.1372	13.7
Streptococcus pneumoniae	Bacteria	0.707	0.1057	10.6
Streptococcus pyogenes	Bacteria	0.894	0.1428	14.3
VZV	Virus	0.173	0.0469	4.7

Appendix A reproduces the information in Table 2 but arranges the microbes in order of decreasing removal rates. Figure 4 illustrates how the pathogen removal rates correlate with the microbe size. This chart essentially duplicates Figure 4, the performance curve for a MERV 6 filter.

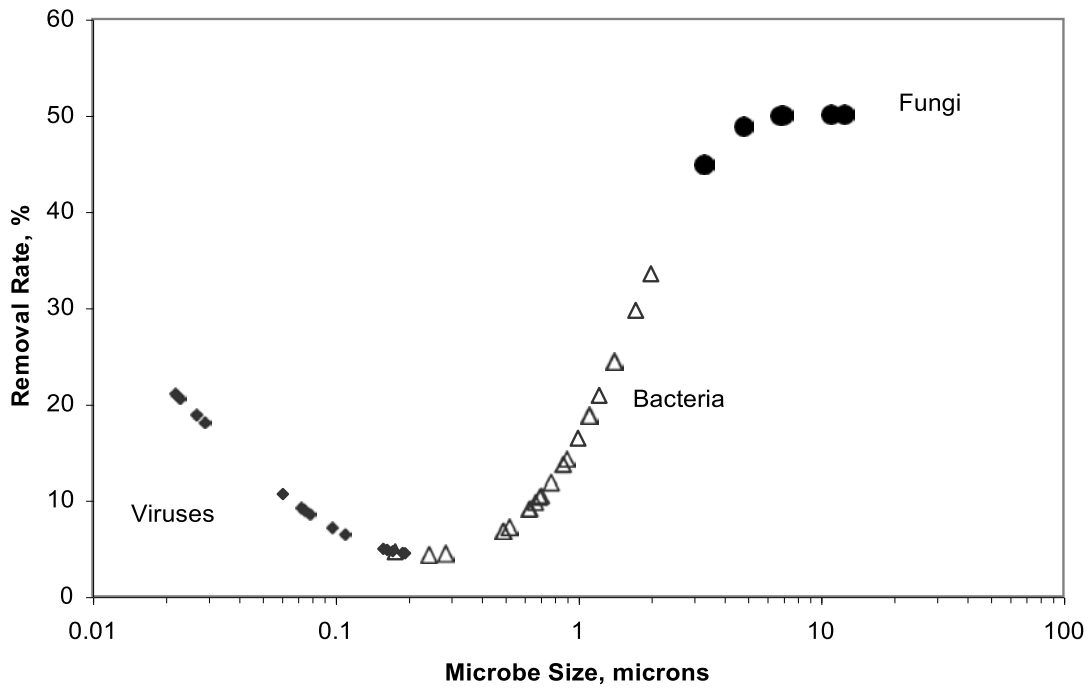


Figure 4: Removal rates for nosocomial pathogens arranged in a MERV 6 filter performance curve format (see Figure 3).

Table 3 lists the disinfection rates for airborne nosocomial pathogens based on the dose produced by the UV lamp. The 15 W lamp has been modeled (using the methods from Kowalski 2009) and found to produce a UV dose of 198 J/m² at 50 cfm. This dose is used to compute the disinfection rate based on the indicated UV rate constants listed in Table 3. Table 3 is reproduced in Appendix B where the pathogens are listed in order of decreasing removal rates.

Table 3: UV Disinfection Rates of Airborne Nosocomial Pathogens

Microbe	Type	UV k m ² /J	UV D90 J/m ²	Disinfection Rate, %
				15 W
Acinetobacter	Bacteria	0.16	14	100
Adenovirus	Virus	0.054	43	100
Aspergillus spores	Fungi	0.00894	258	83
Blastomyces dermatitidis spores	Fungi	0.01645	140	96
Bordetella pertussis*	Bacteria	0.0364	63	100
Clostridium difficile spores	Bacteria	0.0385	60	100
Clostridium perfringens spores	Bacteria	0.0385	60	100
Coronavirus (SARS)	Virus	0.377	6	100
Corynebacterium diphtheriae	Bacteria	0.0701	33	100
Coxsackievirus	Virus	0.111	21	100
Cryptococcus neoformans spores	Fungi	0.0167	138	96
Enterobacter cloacae	Bacteria	0.03598	64	100
Enterococcus*	Bacteria	0.0822	28	100
Fusarium spores	Fungi	0.00855	269	82
Haemophilus influenzae	Bacteria	0.11845	19	100
Haemophilus parainfluenzae*	Bacteria	0.03	77	100
Influenza A virus	Virus	0.119	19	100
Klebsiella pneumoniae	Bacteria	0.04435	52	100
Legionella pneumophila	Bacteria	0.2024	11	100
Measles virus	Virus	0.1051	22	100
Mucor spores	Fungi	0.01012	228	87
Mumps virus*	Virus	0.0766	30	100
Mycobacterium avium	Bacteria	0.04387	52	100
Mycobacterium tuberculosis	Bacteria	0.4721	5	100
Mycoplasma pneumoniae	Bacteria	0.2791	8	100
Neisseria meningitidis*	Bacteria	0.1057	22	100
Nocardia asteroides	Bacteria	0.0822	28	100
Norwalk virus*	Virus	0.0116	198	90
Parainfluenza virus*	Virus	0.1086	21	100
Parvovirus B19	Virus	0.092	25	100
Proteus mirabilis	Bacteria	0.289	8	100
Pseudomonas aeruginosa	Bacteria	0.5721	4	100
Reovirus	Virus	0.01459	158	94
RSV*	Virus	0.0917	25	100
Rhinovirus*	Virus	0.0142	162	94
Rhizopus spores	Fungi	0.00861	267	82
Rotavirus	Virus	0.02342	98	99
Rubella virus*	Virus	0.0037	622	52
Serratia marcescens	Bacteria	0.221	10	100
Staphylococcus aureus	Bacteria	0.5957	4	100
Staphylococcus epidermis	Bacteria	0.09703	24	100
Streptococcus pneumoniae	Bacteria	0.00492	468	62
Streptococcus pyogenes	Bacteria	0.8113	3	100
VZV (Varicella surrogate k)	Virus	0.1305	18	100
UV Dose, J/m ²		198		

Note: Asterisk means the UV rate constant is a predicted value based on the complete genome.

Table 4 lists the combined single pass removal rates for the array of nosocomial pathogens in the previous tables. This table is shown again in Appendix C where they have been rearranged in order of most susceptible to least susceptible.

Given the removal rates as listed in Table 4, the Zonal Protection Factor (ZPF) can be computed assuming the floor area coverage is 100 ft² and the zone has 15% outside air (from the normal ventilation system). The ZPF (aka BPF or Building Protection Factor) represents the theoretical protection offered to occupants by the UV24 System. It must be computed for each individual pathogen since each pathogen has a different removal rate (RR). The ZPF is computed by transient analysis of the airborne concentrations in the zone and is based on eight hours of breathing air in the occupied zone. The ZPF is the percentage of occupants likely to be protected from infection. The converse of the ZPF (1-ZPF) represents the number of likely infections. It is computed by assuming that the baseline condition has no air cleaning. The baseline condition assumes a release rate of pathogens sufficient to cause 99% infections. See Kowalski (2009) or Kowalski (2006) for more specific details on the computation of the BPF or ZPF.

Table 5 summarizes the predicted ZPF for each of the nosocomial pathogens under consideration and it indicates that very high protection factors are possible with the UV24 System, which could be expected since the removal rates are high for most pathogens and the airflow rate (50 cfm) is appropriate for the subject floor area (100 ft²). The maximum ZPF is 93% and this cannot be increased further without increasing airflow. The minimum acceptable ZPF for any system is about 50%, which means that half the occupants are protected from infection. Based on the results in Table 5, the ZPF is above the minimum for all pathogens, including bacterial and fungal spores.

The results in Table 5 are based on the nominal airflow rate of 50 cfm. The results will be proportionally lower for lower airflow rates, since the combined removal rates (filters plus UV) are largely maxed out. Table 5 is reproduced in Appendix C but rearranged in order of decreasing ZPF.

Table 4: Combined Single Pass Removal Rates

Microbe	Component Removal Rates		Overall Removal Rates
	MERV 6	15 W	MERV 6 + 15 W
	fraction	fraction	%
Acinetobacter	0.2089	1.0000	100.0
Adenovirus	0.0853	1.0000	100.0
Aspergillus spores	0.4476	0.8297	90.6
Blastomyces dermatitidis spores	0.5000	0.9615	98.1
Bordetella pertussis	0.0431	0.9993	99.9
Clostridium difficile spores	0.3353	0.9995	100.0
Clostridium perfringens spores	0.1643	0.9995	100.0
Coronavirus (SARS)	0.0643	1.0000	100.0
Corynebacterium diphtheriae	0.1040	1.0000	100.0
Coxsackievirus	0.1886	1.0000	100.0
Cryptococcus neoformans spores	0.4872	0.9634	98.1
Enterobacter cloacae	0.2442	0.9992	99.9
Enterococcus	0.2442	1.0000	100.0
Fusarium spores	0.5000	0.8160	90.8
Haemophilus influenzae	0.0443	1.0000	100.0
Haemophilus parainfluenzae	0.2973	0.9974	99.8
Influenza A virus	0.0709	1.0000	100.0
Klebsiella pneumoniae	0.0988	0.9998	100.0
Legionella pneumophila	0.0721	1.0000	100.0
Measles virus	0.0493	1.0000	100.0
Mucor spores	0.4983	0.8652	93.2
Mumps virus	0.0483	1.0000	100.0
Mycobacterium avium	0.1879	0.9998	100.0
Mycobacterium tuberculosis	0.0925	1.0000	100.0
Mycoplasma pneumoniae	0.0464	1.0000	100.0
Neisseria meningitidis	0.1190	1.0000	100.0
Nocardia asteroides	0.1879	1.0000	100.0
Norwalk virus	0.1809	0.8994	91.8
Parainfluenza virus	0.0447	1.0000	100.0
Parvovirus B19	0.2104	1.0000	100.0
Proteus mirabilis	0.0680	1.0000	100.0
Pseudomonas aeruginosa	0.0680	1.0000	100.0
Reovirus	0.0892	0.9444	94.9
RSV	0.0450	1.0000	100.0
Rhinovirus	0.2057	0.9399	95.2
Rhizopus spores	0.4981	0.8182	90.9
Rotavirus	0.0913	0.9903	99.1
Rubella virus	0.1062	0.5193	57.0
Serratia marcescens	0.0916	1.0000	100.0
Staphylococcus aureus	0.1372	1.0000	100.0
Staphylococcus epidermis	0.1372	1.0000	100.0
Streptococcus pneumoniae	0.1057	0.6225	66.2
Streptococcus pyogenes	0.1428	1.0000	100.0
VZV	0.0469	1.0000	100.0

Table 5: Zonal Protection Factors for Nosocomial Pathogens

Pathogen	Type	MERV6+15W	FA 100 ft ²
		Removal %	ZPF %
Acinetobacter	Bacteria	100.0	91
Adenovirus	Virus	100.0	91
Aspergillus spores	Fungi	90.6	89
Blastomyces dermatitidis spores	Fungi	98.1	90
Bordetella pertussis	Bacteria	99.9	91
Clostridium difficile spores	Bacteria	100.0	91
Clostridium perfringens spores	Bacteria	100.0	91
Coronavirus (SARS)	Virus	100.0	91
Corynebacterium diphtheriae	Bacteria	100.0	91
Coxsackievirus	Virus	100.0	91
Cryptococcus neoformans spores	Fungi	98.1	90
Enterobacter cloacae	Bacteria	99.9	91
Enterococcus	Bacteria	100.0	91
Fusarium spores	Fungi	90.8	89
Haemophilus influenzae	Bacteria	100.0	91
Haemophilus parainfluenzae	Bacteria	99.8	91
Influenza A virus	Virus	100.0	91
Klebsiella pneumoniae	Bacteria	100.0	91
Legionella pneumophila	Bacteria	100.0	91
Measles virus	Virus	100.0	91
Mucor spores	Fungi	93.2	89
Mumps virus	Virus	100.0	91
Mycobacterium avium	Bacteria	100.0	91
Mycobacterium tuberculosis	Bacteria	100.0	91
Mycoplasma pneumoniae	Bacteria	100.0	91
Neisseria meningitidis	Bacteria	100.0	91
Nocardia asteroides	Bacteria	100.0	91
Norwalk virus	Virus	91.8	89
Parainfluenza virus	Virus	100.0	91
Parvovirus B19	Virus	100.0	91
Proteus mirabilis	Bacteria	100.0	91
Pseudomonas aeruginosa	Bacteria	100.0	91
Reovirus	Virus	94.9	90
Rhinovirus	Virus	100.0	91
Rhizopus spores	Fungi	95.2	90
Rotavirus	Fungi	90.9	89
RSV	Virus	99.1	91
Rubella virus	Virus	57.0	73
Serratia marcescens	Bacteria	100.0	91
Staphylococcus aureus	Bacteria	100.0	91
Staphylococcus epidermis	Bacteria	100.0	91
Streptococcus pneumoniae	Bacteria	66.2	79
Streptococcus pyogenes	Bacteria	100.0	91
VZV	Virus	100.0	91
Average Protection Factor %			90

Table 6 provides the Zonal Protection Factors for a range of alternate airflows from 50 ft² to 300 ft², arranged in order of descending ZPF.

Table 6: Zonal Protection Factors for Nosocomial Pathogens at Alternate Room Areas

Pathogen	MERV6+15W	Zonal Protection Factor %						
	Removal	Area	Area	Area	Area	Area	Area	Area
	%	50 ft ²	75 ft ²	100 ft ²	125 ft ²	150 ft ²	200 ft ²	300 ft ²
Coronavirus (SARS)	100.0	93	92	91	90	88	85	80
Legionella pneumophila	100.0	93	92	91	90	88	85	80
Mycobacterium tuberculosis	100.0	93	92	91	90	88	85	80
Mycoplasma pneumoniae	100.0	93	92	91	90	88	85	80
Proteus mirabilis	100.0	93	92	91	90	88	85	80
Pseudomonas aeruginosa	100.0	93	92	91	90	88	85	80
Serratia marcescens	100.0	93	92	91	90	88	85	80
Staphylococcus aureus	100.0	93	92	91	90	88	85	80
Streptococcus pyogenes	100.0	93	92	91	90	88	85	80
Acinetobacter	100.0	93	92	91	90	88	85	80
VZV	100.0	93	92	91	90	88	85	80
Influenza A virus	100.0	93	92	91	90	88	85	80
Haemophilus influenzae	100.0	93	92	91	90	88	85	80
Coxsackievirus	100.0	93	92	91	90	88	85	80
Parainfluenza virus	100.0	93	92	91	90	88	85	80
Neisseria meningitidis	100.0	93	92	91	90	88	85	80
Measles virus	100.0	93	92	91	90	88	85	80
Staphylococcus epidermis	100.0	93	92	91	90	88	85	80
Parvovirus B19	100.0	93	92	91	90	88	85	80
Rhinovirus	100.0	93	92	91	90	88	85	80
Enterococcus	100.0	93	92	91	90	88	85	80
Nocardia asteroides	100.0	93	92	91	90	88	85	80
Mumps virus	100.0	93	92	91	90	88	85	80
Corynebacterium diphtheriae	100.0	93	92	91	90	88	85	80
Adenovirus	100.0	93	92	91	90	88	85	80
Mycobacterium avium	100.0	93	92	91	90	88	85	80
Klebsiella pneumoniae	100.0	93	92	91	90	88	85	80
Clostridium difficile spores	100.0	93	92	91	90	88	85	80
Clostridium perfringens spores	100.0	93	92	91	90	88	85	80
Enterobacter cloacae	99.9	93	92	91	90	88	85	80
Bordetella pertussis	99.9	93	92	91	90	88	85	80
Haemophilus parainfluenzae	99.8	93	92	91	90	88	85	79
RSV	99.1	93	92	91	89	88	85	79
Cryptococcus neoformans spores	98.1	93	92	90	89	88	85	79
Blastomyces dermatitidis spores	98.1	93	92	90	89	88	85	79
Rhizopus spores	95.2	92	91	90	88	87	84	78
Reovirus	94.9	92	91	90	88	87	84	78
Mucor spores	93.2	92	91	89	88	86	83	77
Norwalk virus	91.8	92	90	89	87	86	83	76
Rotavirus	90.9	91	90	89	87	86	82	76
Fusarium spores	90.8	91	90	89	87	86	82	76
Aspergillus spores	90.6	91	90	89	87	86	82	76
Streptococcus pneumoniae	66.2	83	81	79	77	74	69	61
Rubella virus	57.0	78	75	73	70	67	62	53

Summary and Discussion of Analysis Results

The analysis presented herein indicates that the UV24 System will produce high removal rates of all nosocomial pathogens including bacteria, fungi, and viruses. Analysis also shows that the risk of infection in areas where the unit is installed will be considerably reduced, based on predicted reduction in airborne concentrations of microbes. The combination of a 15 W UV lamp, a MERV 6 filter, and an airflow rate of 50 cfm will produce an average removal rates in excess of 97%, in a single pass, for all but two of the pathogens listed in Table 5. Table 7 provides a comparison of unitary UV systems operating between 30-100 cfm arranged in order of UV dose. The UV24 System provides a higher UV dose than most of these systems and has more efficient filtration than all but one of these systems.

Table 7: Comparison of Unitary UV Systems between 30-100 cfm

Manufacturer	Model	Airflow/CADR		Prefilter	Primary Filter	UVP W	Dose J/m ²	URV	Notes
		cfm	m ³ /min						
Virobuster	Steritube	44	1.25	G4	none	57	592	23	multispeed
Virobuster	Steritube	59	1.67	G4	none	57	443	22	multispeed
Virobuster	Steritube	74	2.083	G4	none	57	355	21	multispeed
sterilAir AG	LSK2036-U	29.2	0.83	none	none	30	315	21	
MI/Nuvo	UV24 System	50	1.42	Yes	MERV6	15	198	19	
sterilAir AG	UVR2250-1	88	2.50	optional	none	27	190	19	
sterilAir AG	LSK2018	11.8	0.33	none	none	7	173	19	
Holmes Group	BAP920-U	100	2.83	none	MERV15	22	69.2	17	PCO
Sanuvox	P-900	35	0.99	Yes	none	4.76	48	15	multispeed
Amcor	AM-45	30	0.85	none	none	1.96	26.9	13	
Amcor	AM-45C	31	0.88	Yes	none	25	23.2	13	PCO, carbon
Amcor	AM-45C	40	1.13	Yes	none	25	17.8	12	PCO, carbon
Amcor	AM-45C	45	1.27	Yes	none	25	15.9	12	PCO, carbon
Amcor	AM-45	60	1.70	none	none	1.96	13.5	11	

NOTE: CADR is approximately equal to the airflow for all systems.

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Appendix A: Filter Removal Rates of Airborne Nosocomial Pathogens

Microbe	Type	Size µm	Removal Rate %
			MERV 6
Blastomyces dermatitidis spores	Fungi	12.649	50.0
Fusarium spores	Fungi	11.225	50.0
Mucor spores	Fungi	7.071	49.8
Rhizopus spores	Fungi	6.928	49.8
Cryptococcus neoformans spores	Fungi	4.899	48.7
Aspergillus spores	Fungi	3.354	44.8
Clostridium difficile spores	Bacteria	2	33.5
Haemophilus parainfluenzae	Bacteria	1.732	29.7
Enterobacter cloacae	Bacteria	1.414	24.4
Enterococcus	Bacteria	1.414	24.4
Acinetobacter	Bacteria	1.225	20.9
Mycobacterium avium	Bacteria	1.118	18.8
Nocardia asteroides	Bacteria	1.118	18.8
Clostridium perfringens spores	Bacteria	1	16.4
Streptococcus pyogenes	Bacteria	0.894	14.3
Staphylococcus aureus	Bacteria	0.866	13.7
Staphylococcus epidermis	Bacteria	0.866	13.7
Neisseria meningitidis	Bacteria	0.775	11.9
Streptococcus pneumoniae	Bacteria	0.707	10.6
Corynebacterium diphtheriae	Bacteria	0.698	10.4
Klebsiella pneumoniae	Bacteria	0.671	9.9
Mycobacterium tuberculosis	Bacteria	0.637	9.3
Serratia marcescens	Bacteria	0.632	9.2
Legionella pneumophila	Bacteria	0.52	7.2
Proteus mirabilis	Bacteria	0.494	6.8
Pseudomonas aeruginosa	Bacteria	0.494	6.8
Haemophilus influenzae	Bacteria	0.285	4.4
Bordetella pertussis	Bacteria	0.245	4.3
Parainfluenza virus	Virus	0.194	4.5
RSV	Virus	0.19	4.5
Mycoplasma pneumoniae	Bacteria	0.177	4.6
VZV	Virus	0.173	4.7
Mumps virus	Virus	0.164	4.8
Measles virus	Virus	0.158	4.9
Coronavirus (SARS)	Virus	0.11	6.4
Influenza A virus	Virus	0.098	7.1
Adenovirus	Virus	0.079	8.5
Reovirus	Virus	0.075	8.9
Rotavirus	Virus	0.073	9.1
Rubella virus	Virus	0.061	10.6
Norwalk virus	Virus	0.029	18.1
Coxsackievirus	Virus	0.027	18.9
Rhinovirus	Virus	0.023	20.6
Parvovirus B19	Virus	0.022	21.0

Appendix B: UV Disinfection Rates of Airborne Nosocomial Pathogens

Microbe	Type	UV k m ² /J	UV D90 J/m ²	Disinfection Rate, %
				15 W
Coronavirus (SARS)	Virus	0.377	6	100
Legionella pneumophila	Bacteria	0.2024	11	100
Mycobacterium tuberculosis	Bacteria	0.4721	5	100
Mycoplasma pneumoniae	Bacteria	0.2791	8	100
Proteus mirabilis	Bacteria	0.289	8	100
Pseudomonas aeruginosa	Bacteria	0.5721	4	100
Serratia marcescens	Bacteria	0.221	10	100
Staphylococcus aureus	Bacteria	0.5957	4	100
Streptococcus pyogenes	Bacteria	0.8113	3	100
Acinetobacter	Bacteria	0.16	14	100
VZV (Varicella surrogate k)	Virus	0.1305	18	100
Influenza A virus	Virus	0.119	19	100
Haemophilus influenzae	Bacteria	0.11845	19	100
Coxsackievirus	Virus	0.111	21	100
Parainfluenza virus*	Virus	0.1086	21	100
Neisseria meningitidis*	Bacteria	0.1057	22	100
Measles virus	Virus	0.1051	22	100
Staphylococcus epidermis	Bacteria	0.09703	24	100
Parvovirus B19	Virus	0.092	25	100
RSV*	Virus	0.0917	25	100
Enterococcus*	Bacteria	0.0822	28	100
Nocardia asteroides	Bacteria	0.0822	28	100
Mumps virus*	Virus	0.0766	30	100
Corynebacterium diphtheriae	Bacteria	0.0701	33	100
Adenovirus	Virus	0.054	43	100
Klebsiella pneumoniae	Bacteria	0.04435	52	100
Mycobacterium avium	Bacteria	0.04387	52	100
Clostridium difficile spores	Bacteria	0.0385	60	100
Clostridium perfringens spores	Bacteria	0.0385	60	100
Bordetella pertussis*	Bacteria	0.0364	63	100
Enterobacter cloacae	Bacteria	0.03598	64	100
Haemophilus parainfluenzae*	Bacteria	0.03	77	100
Rotavirus	Virus	0.02342	98	99
Cryptococcus neoformans spores	Fungi	0.0167	138	96
Blastomyces dermatitidis spores	Fungi	0.01645	140	96
Reovirus	Virus	0.01459	158	94
Rhinovirus*	Virus	0.0142	162	94
Norwalk virus*	Virus	0.0116	198	90
Mucor spores	Fungi	0.01012	228	87
Aspergillus spores	Fungi	0.00894	258	83
Rhizopus spores	Fungi	0.00861	267	82
Fusarium spores	Fungi	0.00855	269	82
Streptococcus pneumoniae	Bacteria	0.00492	468	62
Rubella virus*	Virus	0.0037	622	52
UV Dose, J/m ²		198		

Note: Asterisk means the UV rate constant is a predicted value based on the complete genome.

Appendix C: Combined Single Pass Removal Rates

Microbe	Component Removal Rates		Overall Removal Rates
	MERV 6	15 W	MERV 6 + 15 W
	fraction	fraction	%
Coronavirus (SARS)	0.0643	1.0000	100.0
Legionella pneumophila	0.0721	1.0000	100.0
Mycobacterium tuberculosis	0.0925	1.0000	100.0
Mycoplasma pneumoniae	0.0464	1.0000	100.0
Proteus mirabilis	0.0680	1.0000	100.0
Pseudomonas aeruginosa	0.0680	1.0000	100.0
Serratia marcescens	0.0916	1.0000	100.0
Staphylococcus aureus	0.1372	1.0000	100.0
Streptococcus pyogenes	0.1428	1.0000	100.0
Acinetobacter	0.2089	1.0000	100.0
VZV	0.0469	1.0000	100.0
Influenza A virus	0.0709	1.0000	100.0
Haemophilus influenzae	0.0443	1.0000	100.0
Coxsackievirus	0.1886	1.0000	100.0
Parainfluenza virus	0.0447	1.0000	100.0
Neisseria meningitidis	0.1190	1.0000	100.0
Measles virus	0.0493	1.0000	100.0
Staphylococcus epidermis	0.1372	1.0000	100.0
Parvovirus B19	0.2104	1.0000	100.0
RSV	0.0450	1.0000	100.0
Enterococcus	0.2442	1.0000	100.0
Nocardia asteroides	0.1879	1.0000	100.0
Mumps virus	0.0483	1.0000	100.0
Corynebacterium diphtheriae	0.1040	1.0000	100.0
Adenovirus	0.0853	1.0000	100.0
Mycobacterium avium	0.1879	0.9998	100.0
Klebsiella pneumoniae	0.0988	0.9998	100.0
Clostridium difficile spores	0.3353	0.9995	100.0
Clostridium perfringens spores	0.1643	0.9995	100.0
Enterobacter cloacae	0.2442	0.9992	99.9
Bordetella pertussis	0.0431	0.9993	99.9
Haemophilus parainfluenzae	0.2973	0.9974	99.8
Rotavirus	0.0913	0.9903	99.1
Cryptococcus neoformans spores	0.4872	0.9634	98.1
Blastomyces dermatitidis spores	0.5000	0.9615	98.1
Rhinovirus	0.2057	0.9399	95.2
Reovirus	0.0892	0.9444	94.9
Mucor spores	0.4983	0.8652	93.2
Norwalk virus	0.1809	0.8994	91.8
Rhizopus spores	0.4981	0.8182	90.9
Fusarium spores	0.5000	0.8160	90.8
Aspergillus spores	0.4476	0.8297	90.6
Streptococcus pneumoniae	0.1057	0.6225	66.2
Rubella virus	0.1062	0.5193	57.0



BIOLOGICAL INACTIVATION OF UV24 SYSTEM

FINAL REPORT

PROTOCOL NO. AER 09112013 Rev 3

LABORATORY PROJECT ID #13016311

Organism: *Bacillus atrophaeus*

Contact time: 1 hr., 4hr, 8 hr. and 24 hr.

SUBMITTED BY

AEROBIOLOGY LABORATORY
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BIOLOGICAL INACTIVATION OF THE UV24 SYSTEM

COMPLIANCE STATEMENT

Information on the structure and activation of UV24 system resides with the sponsor of the study.

QAU STATEMENT

TITLE: Biological Inactivation of UV24 (UV24)

PROTOCOL AER 09112013 Rev 3

LAB PROJECT 13016311

EVALUATION STUDY Study II

TEST DATE 10.27.2013

DATE QAU INSPECTED 10.28.2013

DATE REPORTED 10.29.2013

STUDY OBJECTIVES

Evaluate the inactivation efficiency of the UV24 system in terms of % reduction or Log reduction of microorganism in a simulated room in the same manner as the critical care facility areas in hospital settings. The system is designed to operate quietly with 100% disinfection while delivering highly purified air. The protocol described herein determines the inactivation efficiency of the system against spore forming and vegetative bacteria which represents a wide range of applications.

The test was conducted based on the EPA protocol "Biological Inactivation Efficiency by HVAC In-Duct Ultraviolet Light Systems". The Quality Assurance Unit of Aerobiology Laboratory has inspected the lab project # 13016311 in compliance with the current GLP Regulations and the reported results accurately reflect the raw data.

INTRODUCTION

This report describes the procedure and results of the biological inactivation efficiency of the UV24 system during an increased challenge of aerosolized inoculum of clinically relevant microorganisms. A medical grade nebulizer is used to deliver the accurate and consistent number of pathogens into the simulated room. The UV24 system is turned on for specified contact time during which the aerosolized microorganism comes in contact with the UV system resulting in reduction and release of purified air into the room. This test procedure is developed for a challenge level of greater than 10^8 colony forming units (CFU), which provides 1000 times higher challenge than would be expected in normal use. This method employed the fundamentals of the EPA method "Biological Inactivation Efficiency by HVAC In-Duct Ultraviolet Light Systems".

JUSTIFICATION

The surface air sampler (SAS) or impactor provides a number of advantages over other methods for test because it can simulate inhalation of aerosolized contaminants at controlled air flow rate. The SAS pulls in 500 l of air which is represented as 219 impaction holes on the media placed within the SAS. High volume of air causes multiple impaction which skews the data interpretation. The use of medical grade delivery nebulizer allows a high concentration of aerosol challenge to be aerosolized into the room. The actual count of challenging microorganism is predetermined by colony count, while the volume of the challenge aerosol is tightly controlled by monitoring the air flow and air pressure through the nebulizer. Aerosols are self-contained and they do not pose any bio-safety concerns.



DESCRIPTION OF TEST PROCEDURE

Sample conditioning and calibration

The Zipwall® is constructed as per manufacture instruction. The spacing of the poles is based on the movement of air in the room. The air flow is typical for commercial air space environment. Four glove box areas are specified in the Zipwall® room for nebulizer placement and for 3 SAS samplers. The UV24 unit is installed in the ceiling as per instructions and plugged in. At nominal design airflow of 50 cfm, with a MERV 6 filter and a UV lamp, the UV24 emits 15 watts of UV radiation at 253.7 nm. The SAS and the nebulizer are placed at the appropriate glove box. The SAS will operate at the flow rate of 100 lpm for 5 minutes for a total of 500 L.

Challenge phase

Unplug the UV24 system. Connect nebulizer to the PARI compressor. An appropriate media plate is also placed in each of the SAS. Add 8ml of inoculum to the sterile nebulizer. Attach the nebulizer to the connector and to the hose of the PARI compressor. Set timer for 15 minute. Turn on PARI compressor. The nebulizer aerosolizes the inoculum and the compressor is turned off after 15 min. The SAS are turned on for 5 min for sample collection. Three sets of samples are taken outside the simulated clean room using the SAS at 5 min to verify contamination of outside air by the indicator organism.

Contact time

The UV24 system is turned on after the baseline samples are taken. Samples are taken after the contact times of 1hr, 4 hr, 8 hr and 24 hr during, which the aerosolized inoculum comes in contact with UV24 system.

Recovery phase

After sampling at specified time intervals, the plates are then placed in the incubator at 35°C for 24 hrs to recover the challenge microorganism.

Plate count/ Result recording

Examine plates after 24 hours for growth, and colony count. If necessary, incubate plates for an additional 24 hours. After the colonies have grown, choose countable plate. Record control counts to determine the accuracy of the challenge and the inhibitory efficiency of the UV24 system. The raw colony counts are compared to the 219-hole surface air sampler (SAS) positive hole correction chart to get positive hole corrected colony count for the respective samples (Attachment 1).

TEST MATERIALS

Testing Area (Room area)	8ft x9ft x10ft
Equipment Source	UV24 System
Equipment	Surface air sampler
Date Received	(SAS) 10.21.13
Start Date	10.27.13
Lab study completion date	10.29.13
Report Issue Date	10.29.13

TESTS CONDITIONS

Test Matrix	6 samples
Organism	<i>Bacillus atrophaeus</i> ATCC 9372
Inoculum	10 ⁸ cfu/ml
Media	Tryptic Soy Agar with 5% sheep's blood
Set up	Protocol no. 09112013 Rev 3 (Diagram 1)
Challenge Device	Nebulizer Pro NEB ULTRA II
Delivery Time	15 min
Challenge Volume	8ml
Internal Control	Pre-samples taken outside and inside the Zipwall room
"Base line"	Immediately after aerosolization for 15 min with UV24 off
Contact time	1 hr, 4hr, 8 hr, and 24hr
Incubator	35°C
Recovery	24hr in Incubator at 35°C

CALCULATION - LOG REDUCTION

1. Conversion raw count to colony forming units per cubic meter (cfu/m³).
 - Raw count converted to positive hole corrected value using the SAS (219-Hole impactor correction table).
 - Minimum reporting limit (MAL): 1000 divided by the volume of air collected by SAS (500 L)
The MAL (detection limit) for the testing will be <2cfu/m³ of air.
 - Total colony forming units per cubic meter (cfu/m³): positive hole corrected count x MRL
2. Log reduction were calculated using following equation:
Log reduction = Log (Avg of Baseline - Avg for each specified contact time)
3. All statics were calculated using MS Excel static package.

The t-test was performed by the following

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\frac{S_p^2}{n_1} + \frac{S_p^2}{n_2}}}$$

where

- All Statistics were calculated by the MS Excel statistic package.

The data and results of log recovery are represented in Table 1 and Table 2 respectively.

RESULTS

TABLE 1: RECOVERY OF BACILLUS ATROPHAEUS AT DIFFERENT TIME INTERVALS

SAS	TIME										
	Baseline (cfu*)	Pos. hole**	cfu/m ³	1 HR (cfu)	cfu/m ³	4HR (cfu)	cfu/m ³	SHR (cfu)	cfu/m ³	24HR (cfu)	cfu/m ³
SAS 1	219	1307	2614	56	112	1	2	2	4	4	8
	208	646	1292	60	120	8	16	4	8	2	4
	219	1307	2614	32	64	2	4	3	6	4	8
SAS2	219	1307	2614	48	96	2	4	3	6	5	10
	219	1307	2614	52	104	3	6	1	2	6	12
	219	1307	2614	25	50	2	4	3	6	4	8
SAS3	219	1307	2614	72	144	5	10	1	2	4	8
	219	1307	2614	48	96	5	10	4	8	3	6
	219	1307	2614	52	104	6	12	1	2	4	8

* Positive corrected value as per the 219-hole SAS value chat

** Colony forming units

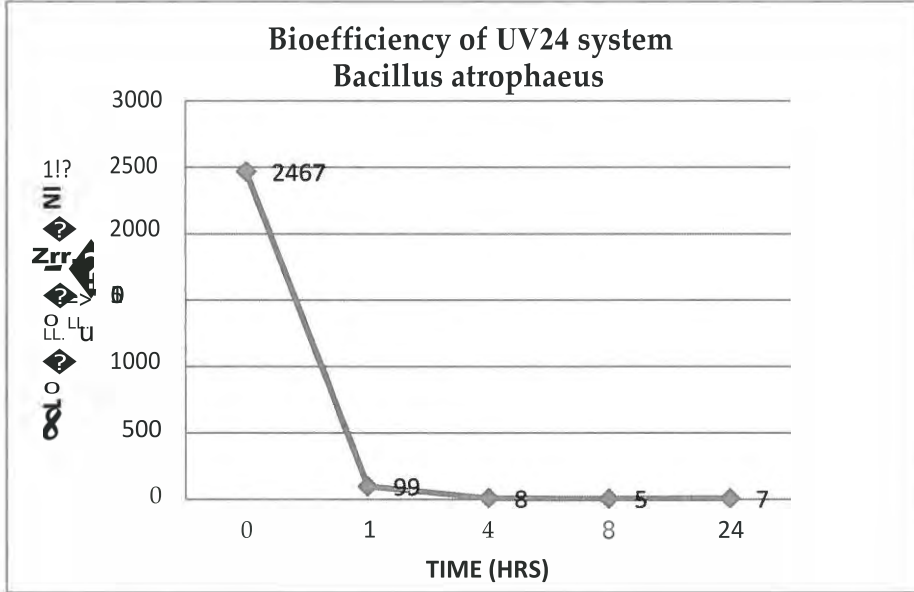


TABLE 2:
STATISTICAL ANALYSIS AND LOG REDUCTION AT EACH TIME INTERVAL FOR BACILLUS ATROPHAEUS

SAS	TIME				
	Baseline (cfu/m3)	1 HR (cfu/m3)	4 HR (cfu/m3)	8HR (cfu/m3)	24 HR (cfu/m3)
SAS 1	2614	112	2	4	8
	1292	120	16	8	4
	2614	64	4	6	8
SAS2	2614	96	4	6	10
	2614	104	6	2	12
	2614	SO	4	6	8
SAS3	2614	144	10	2	8
	2614	96	10	8	6
	2614	104	12	2	8
Average	2467	99	8	5	7
STD Dev.	73.44	22	2	3	1
Log 10	3.39	2.00	0.88	0.69	0.87
% Red		95.9	99.6	99.7	99.7
Log Red		1.40	2.51	2.70	2.53

CONCLUSION

The baseline samples showed growth of *Bacillus atrophaeus* and after the specified contact time of 1 hr there was 95.9% reduction in growth and after 4hr showed 99.6% reduction. After 8 hr and 24 hr with the UV24 system on, the samples showed 99.7% in the colony count compared to the baseline counts.

Prepared by

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Maryn

Date 10-29-13

Reviewed by

.....
Suzanne J. Blue

Date 10.29.13

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**Correction Table to Adjust Colony Count from a 219-Hole Impactor
Using Standard 55 mm Contact Plates and 90 mm Petri Plates**

r = colony forming units count Pr = probable count

r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr
1	1	41	45	81	101	121	175	161	289	201	542
2	2	42	46	82	102	122	178	162	293	202	554
3	3	43	48	83	104	123	180	163	297	203	567
4	4	44	49	84	106	124	182	164	301	204	580
5	5	45	50	85	107	125	185	165	305	205	595
6	6	46	51	86	109	126	187	166	309	206	611
7	7	47	53	87	110	127	189	167	313	207	627
8	8	48	54	88	112	128	192	168	317	208	646
9	9	49	55	89	114	129	194	169	322	209	666
10	10	50	57	90	116	130	196	170	326	210	687
11	11	51	58	91	117	131	199	171	331	211	712
12	12	52	59	92	119	132	201	172	335	212	739
13	13	53	60	93	121	133	204	173	340	213	770
14	14	54	62	94	122	134	206	174	344	214	807
15	15	55	63	95	124	135	209	175	349	215	851
16	17	56	64	96	126	136	212	176	354	216	905
17	18	57	66	97	128	137	214	177	359	217	978
18	19	58	67	98	130	138	217	178	364	218	1088
19	20	59	69	99	131	139	220	179	370	219	1307
20	21	60	70	100	133	140	222	180	375		
21	22	61	71	101	135	141	225	181	381		
22	23	62	73	102	137	142	228	182	387		
23	24	63	74	103	139	143	231	183	393		
24	25	64	76	104	141	144	234	184	399		
25	26	65	77	105	142	145	237	185	405		
26	28	66	78	106	144	146	240	186	412		
27	29	67	80	107	146	147	243	187	418		
28	30	68	81	108	148	148	246	188	425		
29	31	69	83	109	150	149	249	189	432		
30	32	70	84	110	152	150	252	190	439		
31	33	71	86	111	154	151	255	191	447		
32	34	72	87	112	156	152	258	192	455		
33	36	73	88	113	158	153	261	193	463		
34	37	74	90	114	160	154	265	194	471		
35	38	75	92	115	162	155	268	195	480		
36	39	76	93	116	165	156	271	196	489		
37	40	77	95	117	167	157	275	197	499		
38	42	78	96	118	169	158	278	198	508		
39	43	79	98	119	171	159	282	199	519		
40	44	80	99	120	173	160	286	200	530		

Biological Inactivation of the UV24 System

Protocols: Biotest using UV lamp - Simulation of Field Performance


Purpose: To test the inactivation efficiency of the UV24 System during an aerosol challenge of a quantified inoculum of clinically relevant microorganisms.

Written by:

Manju Pradeep 

Date: 09.05.13

Reviewed by:

Suzanne Blevins 

Date: 09.09.13

Approved by:



Date: '-/-  0-13

Study Completion Date: 10.30.2013

1.0 Scope and Application

The UV24 System, a UV disinfection system is incorporated into a patented fluorescent ceiling fixture and is used to disinfect bacteria, viruses and fungi in hospital settings. This equipment is intended to be used in all critical care areas of the facility. The system is designed to operate quietly with 100% disinfection while delivering highly purified air. The protocol described herein determines the inactivation efficiency of the system against spore forming and vegetative bacteria which represents a wide range of applications.

2.0 Protocol Description: Surface Air Sampler (SAS) testing - Air challenge.

The UV24 System includes a High Output UV emitting lamp, a filter and a fan array which creates differential pressure to recirculate the air locally. The SAS impactor will allow bioaerosols containing microorganisms to be actively drawn into the microbial impaction sampler.

The generation of the bio aerosol will be aerosolized in a Zipwall® room with glove boxes. The generation of the bioaerosol is continuous. A defined amount of Tryptic Soy Broth containing a pre-determined inoculum is used and delivered by the nebulizer inside the Zipwall® room. Appropriate agar plates will be placed in the three SAS impactors to verify the performance of the SASes. Equipment placement as shown in Diagram 1.

The SAS will operate at the flow rate of 100 lpm for 5 minutes for a total of 500 L.

The Pro/Neb Ultra nebulizer delivers the inoculum directly into the Zipwall® room. The nebulizer is filled with 8ml of inoculum in TSB and delivers a constant rate of 7.5 lpm. The flow rate of the bioaerosol is maintained by calibrated PARI compressor. The SAS draws the mixture of air and the bio aerosol for 5 minutes and impacts on the plates.

The inoculum concentration is maintained and documented between 10^8 cfu/ml for all tests.

Before challenge:

- The Zipwall[®] is constructed as per manufacture instruction. The spacing of the poles is based on the movement of air in the room. The air flow is typical for commercial air space environment.
- Four glove box areas are specified in the Zipwall[®] room for nebulizer placement and for 3 SAS samplers.
- The UV24 unit is installed in the ceiling as per instructions and plugged in. At nominal design airflow of 50 cfm, with a MERV 6 filter and a UV lamp, the UV24 emits 15 watts of UV radiation at 253.7 nm.
- The SAS and nebulizer are decontaminated before testing.
- The room ceiling is decontaminated before testing.

Challenge:

- The air flow and the UV emittance from the AUKV24 system are continuous.
- The nebulizer is placed in one of the glove box with orifice facing towards the inside of the Zipwall[®] room.
- Each of the SAS samplers with appropriate agar plates is placed in the other three glove box spaces to collect the air samples.
- The ambient air is sampled before the inoculum is nebulized into the Zipwall[®] room. The UV24 system is turned off.
- Add 8 ml of inoculum to the sterile nebulizer. Attach the nebulizer to the connector and to the hose of the PARI compressor.
- Set timer for 15 minute. Turn on PARI compressor.
- Turn off nebulizer after 15 minute and the SAS'es are run for 5 min to collect 500 L of air as the baseline sample.
- The procedure is repeated at different time intervals of 1 hr., 4 hrs, 8hrs and 24 hrs after the UV24 system is turned on.

- The testing is done in replicates of 3 for each interval of time.
- The procedure is repeated for 3 consecutive times to get 6 sets of data for each organism at different time intervals.

After challenge:

- The impacted plates are placed in an incubator at 35°C, examine plates after 24 hours for growth, and count colonies. If necessary, incubate plates for an additional 24 hours. After the colonies have grown, choose countable plate. Record control counts to determine the accuracy of the challenge and the inactivation efficiency of the UV24 system.

Test organisms:

- *Serratia marcescens* ATCC14756
- *Bacillus atrophaeus* ATCC 9372

3.0 Preparation of the Inoculum/Control

1. Grow the organisms for 18-24 hours at 37°C in sterile TSB in a 5 mls sterile tube before use.
2. Turn on turbidometer and check the system using control standards.
3. Dilute 1 ml of culture grown overnight into 9 mls of sterile TSB and take 1 ml from this dilution and read the absorbance in the turbidometer. Compare the turbidity to a Mcfarland 1 standard.
4. Remove 1 ml of the diluted mixture and serially dilute to 10⁻⁸ and plate 100µl of this dilution onto sterile Tryptic soy agar plates for stock count verification.
5. Incubate plate for 24 hours at 35°C. Count colonies to verify growth of stock culture. Multiply cfu (colony forming units) count by dilution to determine cfu/ml in diluted stock culture.
6. Make certain that biological safety cabinet blower is on and the surface is cleaned and dried with 10% bleach.

7. Operator should wear sterile gloves and gown before handling spray generator and test materials.
8. Set-up sterile materials in the BSC. Perform the testing steps in the BSC.

Inoculum

Each inoculum is prepared using basic growth methods and growth media optimal to each organism. The organisms are grown in broth and turbidity is verified using a turbidometer according to McFarland standards. Organisms are serially diluted and plated to determine viability and numeration. All organisms will be handled according to the biosafety level of which it has been assigned. Organisms will be acquired from American Type Culture Collection (ATCC) and the test strains used will not have been cultured beyond 5 passages. All bio hazardous waste will be sterilized and disposed of properly.

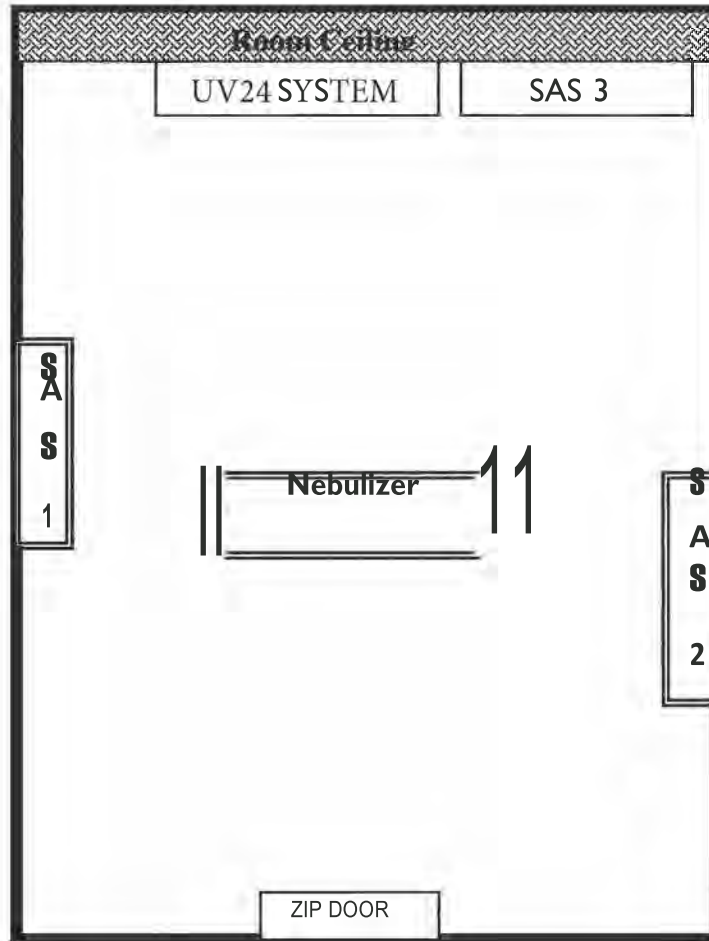
4.0 Recording and Interpreting Results:

All tests are performed according to GLP (good laboratory standards). Tests performed in triplicate. The sensitivity of the recovery method test is assumed to be 2 colony-forming units. Final numbers averaged and compared to the baseline time. Recovered organisms are counted and the colony forming units recorded. Recovery at each time interval is subtracted from recovery colony-forming units (cfu) of the baseline.

Airborne inactivation efficiency (%) = 100 (1 - survival rate)

Diagram 1: Air Bio test: Simulation of Field Performance

ZIPWALL® ROOM



References:

1. "Biological Inactivation Efficiency by HVAC In -Duct Ultraviolet Light Systems":
EPA, Office of Research And Development National Homeland Security Research Center.
2. Report on the performance of the uv24 System: total ceiling solutions
ZIPWALL® package Insert: Home Depot
- 3.



Website: www.aerobiology.net

BIOLOGICAL INACTIVATION OF THE UV24 SYSTEM

FINAL REPORT

PROTOCOL NO. AER 09112013 Rev 3

LABORATORY PROJECT ID #13016309

Organism: *Serratia marcescens*

Contact time: 1 hr., 4hr, 8 hr. and 24 hr.

SUBMITTED BY

AEROBIOLOGY LABORATORY
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Dulles, VA 20166
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BIOLOGICAL INACTIVATION OF UV24 COMPLIANCE STATEMENT

Information on the structure and activation of UV24 system resides with the sponsor of the study.

QAU STATEMENT

TITLE: Biological Inactivation of UV24 System

PROTOCOL AER 09112013 Rev 3

LAB PROJECT 13016309

EVALUATION STUDY Study I

TEST DATE 10.24.2013

DATE QAU INSPECTED 10.25.2013

DATE REPORTED 10.28.2013

STUDY OBJECTIVES

Evaluate the inactivation efficiency of the UV24 system in terms of % reduction or Log reduction of microorganism in a simulated room in the same manner as the critical care facility areas in hospital settings. The system is designed to operate quietly with 100% disinfection while delivering highly purified air. The protocol described herein determines the inactivation efficiency of the system against spore forming and vegetative bacteria which represents a wide range of applications.

The test was conducted based on the EPA protocol "Biological Inactivation Efficiency by HVAC In-Duct Ultraviolet Light Systems". The Quality Assurance Unit of Aerobiology Laboratory has inspected the lab project # 13016309 in compliance with the current GLP Regulations and the reported results accurately reflect the raw data.

INTRODUCTION

This report describes the procedure and results of the biological inactivation efficiency of UV24 system during an increased challenge of aerosoled inoculum of clinically relevant microorganisms. A medical grade nebulizer is used to deliver the accurate and consistent number of pathogens into the simulated room. The UV24 system is turned on for specified contact time during which the aerosolized microorganism comes in contact with the UV system resulting in reduction and release of purified air into the room. This test procedure is developed for a challenge level of greater than 10^8 colony forming units (CFU), which provides 1000 times higher challenge than would be expected in normal use. This method employed the fundamentals of the EPA method "Biological Inactivation Efficiency by HVAC In-Duct Ultraviolet Light Systems".

JUSTIFICATION

The surface air sampler (SAS) or impactor provides advantages over other methods for test because it can simulate inhalation of aerosoled contaminants at controlled air flow rate. The SAS pulls in 500L of air which is represented as 219 impaction holes on the media placed within the SAS. High volume of air causes multiple impactions which skews the data interpretation. The use of medical grade delivery nebulizer allows a high concentration of aerosol challenge to be aerosolized into the room. The actual count of challenging microorganism is predetermined by colony count, while the volume of the challenge aerosol is tightly controlled by monitoring the air flow and air pressure through the nebulizer. Aerosols are self-contained and they do not pose any bio-safety concerns.

DESCRIPTION OF TEST PROCEDURE

Sample conditioning and calibration

The Zipwall® is constructed as per manufacture instruction. The spacing of the poles is based on the movement of air in the room. The air flow is typical for commercial air space environment. Four glove box areas are specified in the Zipwall® room for nebulizer placement and for three SAS samplers. The UV24 is installed in the ceiling as per instructions and plugged in. At nominal design airflow of 50 cfm, with a MERV 6 filter and a UV lamp, the UV24 emits 15 watts of UV radiation at 253.7 nm. The SAS and the nebulizer are placed at the appropriate glove box. The SAS will operate at the flow rate of 100 lpm for 5 minutes for a total of 500 L.

Challenge phase

Unplug the UV24 system. Connect nebulizer to the PARI compressor. An appropriate media plate is also placed in each of the SAS. Add 8ml of inoculum to the sterile nebulizer. Attach the nebulizer to the connector and to the hose of the PARI compressor. Set timer for 15 minute. Turn on PARI compressor. The nebulizer aerosolizes the inoculum and the compressor is turned off after 15 min. The SAS are turned on for 5 min for sample collection. Three sets of samples are taken outside the simulated clean room using to SAS at 5 min to verify contamination of outside air by the indicator organism.

Contact time

The UV24 system is turned on after the baseline samples are taken. Samples are taken after the contact times of 1hr, 4 hr, 8 hr and 24 hr during which the aerosolized inoculum comes in contact with UV24 system.

Recovery phase

After sampling at specified time intervals, the plates are then placed in the incubator at 35°C for 24 hrs to recover the challenge microorganism.

Plate count / Result recording

Examine plates after 24 hours for growth, and colony count. If necessary, incubate plates for an additional 24 hours. After the colonies have grown, choose countable plate. Record control counts to determine the accuracy of the challenge and the inhibitory efficiency of the UV24 system. The raw colony counts are compared to the 219-hole surface air sampler (SAS) positive hole correction chart to get positive hole corrected colony count for the respective samples. (Attachment 1). The No growth sample is assumed to be <1 colony forming unit per sample and cfu/m³ of air will be less than <2 cfu/ m³ per analysis.

TEST MATERIALS

Testing Area (Room area)	8ft x9ft x10ft
Equipment Source	(UV24 system) Surface air
Equipment	sampler (SAS) 10.21.13
Date Received	10.24.13
Start Date	
Lab study completion date	10.26.13
Report Issue Date	10.28.13

TESTS CONDITIONS

Test Matrix	6 samples
Organism	<i>Serratia marcescens</i> ATCC 14756
Inoculum	10 ⁸ cfu/ml
Media	Tryptic Soy Agar with 5% sheep's blood
Set up	Protocol no. 09112013 Rev 3 (Diagram 1)
Challenge Device	Nebulizer Pro NEB ULTRA II
Delivery Time	15 min
Challenge Volume	8ml
Internal Control	Pre-samples taken outside and inside the Zipwall room
"Base line"	Immediately after aerosolisation for 15 min with UV24 off 1
Contact time	hr, 4hr, 8 hr, and 24hr
Incubator	35°C
Recovery	24hr in Incubator at 35°C

CALCULATION - LOG REDUCTION

1. Conversion raw count to colony forming units per cubic meter (cfu/m³).
 - Raw count converted to positive hole corrected value using the SAS (219-Hole impactor correction table).
 - Minimum reporting limits (MRL): 1000 divided by the volume of air collected by SAS (500 L). The MRL (detection limit) for the testing will be <2cfu/m³ of air.
 - Total colony forming units per cubic meter (cfu/m³): positive hole corrected count x MRL
2. Log reduction were calculated using following equation:
Log reduction= Log (Avg of Baseline - Avg for each specified contact time)
3. All statics were calculated using MS Excel static package.

The t-test was performed by the following

$$t = \frac{\bar{X}_1 - \bar{X}_2}{S_p \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}} \quad \text{where } S_p = \sqrt{\frac{S_1^2 + S_2^2}{2}}$$

- All Statistics were calculated by the MS Excel statistic package.

The data and results of log recovery are represented in Table 1 and Table 2 respectively.

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RESULTS

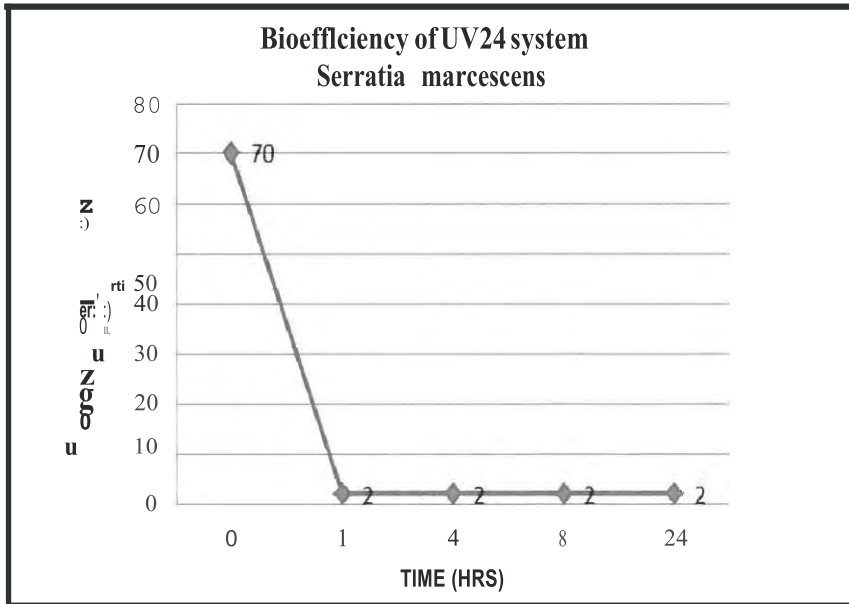
TABLE 1: RECOVERY OF SERRATIA MARCESCENS AT DIFFERENT TIME INTERVALS

SAS	TIME										
	Baseline (cfu**)	Pos. hole*	cfu/mA3	1 HR (cfu)	cfu/mA3	4HR (cfu)	cfu/mA3	SHR (cfu)	cfu/mA3	24HR (cfu)	cfu/mA3
SAS1	44	49	98	NG***	<2	NG	<2	NG	<2	NG	<2
	7	7	14	NG	<2	NG	<2	NG	<2	NG	<2
	13	13	26	NG	<2	NG	<2	NG	<2	NG	<2
SAS2	65	77	154	NG	<2	NG	<2	NG	<2	NG	<2
	5	5	10	NG	<2	NG	<2	NG	<2	NG	<2
	5	5	10	NG	<2	NG	<2	NG	<2	NG	<2
SAS3	75	92	184	NG	<2	NG	<2	NG	<2	NG	<2
	5	5	10	NG	<2	NG	<2	NG	<2	NG	<2
	2	2	4	NG	<2	NG	<2	NG	<2	NG	<2

* Positive corrected value as per the 219-hole SAS value chart

**colony forming units

*** NG assumed to be <1 cfu for raw count per plate and calculated as <2 for cfu/m3 of air.



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TABLE 2:
STATISTICAL ANALYSIS AND LOG REDUCTION AT EACH TIME INTERVAL FOR SERRATIA MARCESCENS

SAS	TIME				
	Baseline (cfu/m3)	1 HR (cfu/m3)	4HR (cfu/m3)	SHR (cfu/m3)	24HR (cfu/m3)
SAS1	98	2	2	2	2
	14	2	2	2	2
	26	2	2	2	2
SAS2	154	2	2	2	2
	10	2	2	2	2
	10	2	2	2	2
SAS3	184	2	2	2	2
	10	2	2	2	2
	4	2	2	2	2
Average	70	2	2	2	2
STD Dev.	66.36	0	0	0	0
Log 10	1.85	0.30	0.30	0.30	0.30
%Red		97.0	97.0	97.0	97.0

CONCLUSION

The baseline samples showed growth of *Serratia marcescens* and after the specified contact time of 1 hr., 4hr, 8 hr., and 24 hr with the UV24 system on, the samples showed complete reduction in the colony count. The Pre samples taken after 48hrs showed no *Serratia marcescens* indicating complete elimination of the indicator organism that was aerosolized into the simulated room for 15 minute.

Prepared by


Manju Pradeep

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Date 10. 9s. 13

Reviewed by

Suzanne Blevins

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Date 10. 9s. 13

**Correction Table to Adjust Colony Count from a 219-Hole Impactor
Using Standard 55 mm Contact Plates and 90 mm Petri Plates**

r = colony forming units count **Pr** = probable count

r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr
1	1	41	45	81	101	121	175	161	289	201	542
2	2	42	46	82	102	122	178	162	293	202	554
3	3	43	48	83	104	123	180	163	297	203	567
4	4	44	49	84	106	124	182	164	301	204	580
5	5	45	50	85	107	125	185	165	305	205	595
6	6	46	51	86	109	126	187	166	309	206	611
7	7	47	53	87	110	127	189	167	313	207	627
8	8	48	54	88	112	128	192	168	317	208	646
9	9	49	55	89	114	129	194	169	322	209	666
10	10	50	57	90	116	130	196	170	326	210	687
11	11	51	58	91	117	131	199	171	331	211	712
12	12	52	59	92	119	132	201	172	335	212	739
13	13	53	60	93	121	133	204	173	340	213	770
14	14	54	62	94	122	134	206	174	344	214	807
15	15	55	63	95	124	135	209	175	349	215	851
16	17	56	64	96	126	136	212	176	354	216	905
17	18	57	66	97	128	137	214	177	359	217	978
18	19	58	67	98	130	138	217	178	364	218	1088
19	20	59	69	99	131	139	220	179	370	219	1307
20	21	60	70	100	133	140	222	180	375		
21	22	61	71	101	135	141	225	181	381		
22	23	62	73	102	137	142	228	182	387		
23	24	63	74	103	139	143	231	183	393		
24	25	64	76	104	141	144	234	184	399		
25	26	65	77	105	142	145	237	185	405		
26	28	66	78	106	144	146	240	186	412		
27	29	67	80	107	146	147	243	187	418		
28	30	68	81	108	148	148	246	188	425		
29	31	69	83	109	150	149	249	189	432		
30	32	70	84	110	152	150	252	190	439		
31	33	71	86	111	154	151	255	191	447		
32	34	72	87	112	156	152	258	192	455		
33	36	73	88	113	158	153	261	193	463		
34	37	74	90	114	160	154	265	194	471		
35	38	75	92	115	162	155	268	195	480		
36	39	76	93	116	165	156	271	196	489		
37	40	77	95	117	167	157	275	197	499		
38	42	78	96	118	169	158	278	198	508		
39	43	79	98	119	171	159	282	199	519		
40	44	80	99	120	173	160	286	200	530		



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BIOLOGICAL INACTIVATION OF THE UV24 SYSTEM

FINAL REPORT

PROTOCOL NO. AER 09112013 Rev 4

LABORATORY PROJECT ID# 13017604

Organism: *MRSA BAA 44*

Contact time: 1 hr., 4hr, 8 hr. and 24 hr.

SUBMITTED BY

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BIOLOGICAL INACTIVATION OF THE UV24 SYSTEM COMPLIANCE STATEMENT

Information on the structure and activation of UV24 system resides with the sponsor of the study.

QAU STATEMENT

TITLE: Biological Inactivation of UV24 (UV24)

PROTOCOL AER 09112013 Rev 4

LAB PROJECT 13017604

EVALUATION STUDY Study IV

TEST DATE 11.19.2013

DATE QAU INSPECTED 11.21.2013

DATE REPORTED 11.21.2013

STUDY OBJECTIVES

Evaluate the inactivation efficiency of the UV24 system in terms of % reduction or Log reduction of microorganism in a simulated room in the same manner as the critical care facility areas in hospital settings. The system is designed to operate quietly with 100% disinfection while delivering highly purified air. The protocol described herein determines the inactivation efficiency of the system against spore forming and vegetative bacteria which represents a wide range of applications.

The test was conducted based on the EPA protocol "Biological Inactivation Efficiency by HVAC In-Duct Ultraviolet Light Systems". The Quality Assurance Unit of Aerobiology Laboratory has inspected the lab project # 13017604 in compliance with the current GLP Regulations and the reported results accurately reflect the raw data.

INTRODUCTION

This report describes the procedure and results of the biological inactivation efficiency of UV24 system during an increased challenge of aerosoled inoculum of clinically relevant microorganisms. A medical grade nebulizer is used to deliver the accurate and consistent number of pathogens into the simulated room. The UV24 system is turned on for specified contact time during which the aerosolized microorganism comes in contact with the UV system resulting in reduction and release of purified air into the room. This test procedure is developed for a challenge level of greater than 10^6 colony forming units (CFU), which provides 1000 times higher challenge than would be expected in normal surrounding. This method employed the fundamentals of the EPA method "Biological Inactivation Efficiency by HVAC In-Duct Ultraviolet Light Systems".

JUSTIFICATION

The surface air sampler (SAS) or impactor provides advantages over other methods for test because it can simulate inhalation of aerosoled contaminants at controlled air flow rate. The SAS pulls in 500L of air which is represented as 219 impaction holes on the media placed within the SAS. High volume of air causes multiple impactions which skews the data interpretation. The use of medical grade delivery nebulizer allows a high concentration of aerosol challenge to be aerosolized into the room. The actual count of challenging microorganism is predetermined by colony count, while the volume of the challenge aerosol is tightly controlled by monitoring the air flow and air pressure through the nebulizer. Aerosols are self-contained and they do not pose any bio-safety concerns.

DESCRIPTION OF TEST PROCEDURE

Sample conditioning and calibration

The Zipwall® is constructed as per manufacture instruction. The spacing of the poles is based on the movement of air in the room. The air flow is typical for commercial air space environment. Four glove box areas are specified in the Zipwall® room for nebulizer placement and for three SAS samplers. The UV24 is installed in the ceiling as per instructions and plugged in. At nominal design airflow of 50 cfm, with a MERV 6 filter and a UV lamp, the UV24 emits 15 watts of UV radiation at 253.7 nm. The SAS and the nebulizer are placed at the appropriate glove box. The SAS will operate at the flow rate of 100 lpm for 5 minutes for a total of 500 L.

Challenge phase

Unplug the UV24 system. Connect nebulizer to the PARI compressor. An appropriate media plate is also placed in each of the SAS. Add 8ml of inoculum to the sterile nebulizer. Attach the nebulizer to the connector and to the hose of the PARI compressor. Set timer for 15 minute. Turn on PARI compressor. The nebulizer aerosolizes the inoculum and the compressor is turned off after 15 min. The SAS are turned on for 5 min for sample collection. Three sets of samples are taken outside the simulated clean room using to SAS at 5 min to verify contamination of outside air by the indicator organism.

Contact time

The UV24 system is turned on after the baseline samples are taken. Samples are taken after the contact times of 1hr, 4 hr, 8 hr and 24 hr during which the aerosolized inoculum comes in contact with UV24 system.

Recovery phase

After sampling at specified time intervals, the plates are then placed in the incubator at 35°C for 24 hrs to recover the challenge microorganism.

Plate count/ Result recording

Examine plates after 24 hours for growth, and colony count. If necessary, incubate plates for an additional 24 hours. After the colonies have grown, choose countable plate. Record control counts to determine the accuracy of the challenge and the inhibitory efficiency of the UV24 system. The raw colony counts are compared to the 219-hole surface air sampler (SAS) positive hole correction chart to get positive hole corrected colony count for the respective samples. (Attachment 1). The No growth sample is assumed to be <1 colony forming unit per sample and cfu/m³ of air will be less than <2 cfu/ m³ per analysis.

TEST MATERIALS

Testing Area (Room area)	8ft x9ft x10ft
Equipment Source	(UV24 system) Surface air
Equipment	sampler (SAS) 10.21.13
Date Received	11.19.13
Start Date	
Lab study completion date	11.21.13
Report Issue Date	11.21.13

TESTS CONDITIONS

Test Matrix	6 samples
Organism	<i>MRSA BAA44</i>
Inoculum	10 ⁶ cfu/ml
Media	Tryptic Soy Agar with 5% sheep blood
Set up	Protocol no. 09112013 Rev 4 (Diagram 1)
Challenge Device	Nebulizer Pro NEB ULTRA II
Delivery Time	15 min
Challenge Volume	8ml
Internal Control	Pre-samples taken outside and inside the Zipwall room
"Base line"	Immediately after aerosolisation for 15 min with UV24 off 1
Contact time	hr, 4hr, 8 hr, and 24hr
Incubator	35°C
Recovery	24hr in Incubator at 35°C



CALCULATION - LOG REDUCTION

1. Conversion raw count to colony forming units per cubic meter (cfu/m³).
 - Raw count converted to positive hole corrected value using the SAS (219-Hole impactor correction table).
 - Minimum reporting limits (MRL): 1000 divided by the volume of air collected by SAS (500 L). The MRL (detection limit) for the testing will be <math><2\text{cfu/m}^3</math> of air.
 - Total colony forming units per cubic meter (cfu/m³): positive hole corrected count x MRL
2. Log reduction were calculated using following equation:
Log reduction= Log (Avg of Baseline -Avg for each specified contact time)
3. All statistical analysis were calculated using MS Excel static package.

The data and results of log recovery are represented in Table 1 and Table 2 respectively.

RESULTS

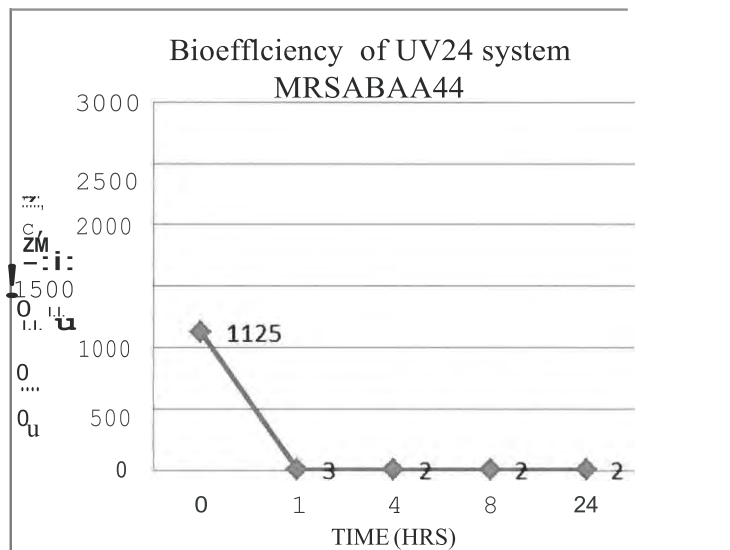
TABLE 1: RECOVERY OF MRSA AT DIFFERENT TIME INTERVALS

SAS	TIME										
	Baseline (cfu*)	Pos. hole**	cfu/ m ³	1HR** (cfu)	cfu/ m ³	4HR** (cfu)	cfu/ m ³	SHR** (cfu)	cfu/ m ³	24HR** (cfu)	cfu/ m ³
SAS 1	168	317	634	3	6	1	2	1	2	1	2
	125	185	370	1	2	1	2	1	2	1	2
	168	317	634	1	2	1	2	1	2	1	2
SAS2	219	1307	2614	1	2	1	2	1	2	1	2
	200	530	1060	2	4	1	2	1	2	1	2
	196	489	978	1	2	1	2	1	2	1	2
SAS3	176	354	708	1	2	1	2	1	2	1	2
	152	258	516	3	6	1	2	1	2	1	2
	219	1307	2614	1	2	1	2	1	2	1	2

* Positive corrected value as per the 219-hole LAS value chart

** colony forming units

*** NG assumed to be <1 cfu for raw count per plate and calculated as <2 for cfu/m³ of air.



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TABLE 2:
STATISTICAL ANALYSIS AND LOG REDUCTION AT EACH TIME INTERVAL FOR MRSA

SAS	TIME				
	Baseline (cfu/m3)	1 HR (cfu/m3)	4HR (cfu/m3)	8HR (cfu/m3)	24HR (cfu/m3)
SAS 1	634	6	2	2	2
	370	2	2	2	2
	634	2	2	2	2
SAS2	2614	2	2	2	2
	1060	4	2	2	2
	978	2	2	2	2
SAS3	708	2	2	2	2
	516	6	2	2	2
	2614	2	2	2	2
Average	1125	3	2	2	2
Log Red		2.56	2.75	2.75	2.75
%Red		99.7	99.8	99.8	99.8

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CONCLUSION

The baseline samples showed growth of *MRSA* and after the specified contact time of 1 hr., 4hr, 8 hr. and 24 hr. with the UV24 system on, the samples showed complete reduction in the colony count. The samples taken after 48hrs showed no *MRSA* indicating complete elimination of the target organism that was aerosolized into the simulated room for 15 minute.

Prepared by

Manju Pradeep

Date *11-11-13*

Reviewed by

Suzanne Blevins *St* *d.*

Date *11-11-13*



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BIOLOGICAL INACTIVATION OF UV24 SYSTEM

FINAL REPORT

PROTOCOL NO. AER 09112013 Rev 4

LABORATORY PROJECT ID #13016792

Organism: *Staphylococcus aureus*

Contact time: 1 hr., 4hr, 8 hr. and 24 hr.

SUBMITTED BY

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BIOLOGICAL INACTIVATION OF UV24 SYSTEM COMPLIANCE STATEMENT

Information on the structure and activation of UV24 system resides with the sponsor of the study.

QAU STATEMENT

TITLE: Biological Inactivation of UV24 (UV24)

PROTOCOL AER 09112013 Rev 4

LAB PROJECT 13016792

EVALUATION STUDY Study III

TEST DATE 11.12.2013

DATE QAU INSPECTED 11.14.2013

DATE REPORTED 11.15.2013

STUDY OBJECTIVES

Evaluate the inactivation efficiency of the UV24 system in terms of % reduction or Log reduction of microorganism in a simulated room in the same manner as the critical care facility areas in hospital settings. The system is designed to operate quietly with 100% disinfection while delivering highly purified air. The protocol described herein determines the inactivation efficiency of the system against spore forming and vegetative bacteria which represents a wide range of applications.

The test was conducted based on the EPA protocol "Biological Inactivation Efficiency by HVAC In-Duct Ultraviolet Light Systems". The Quality Assurance Unit of Aerobiology Laboratory has inspected the lab project # 13016792 in compliance with the current GLP Regulations and the reported results accurately reflect the raw data.

INTRODUCTION

This report describes the procedure and results of the biological inactivation efficiency of UV24 system during an increased challenge of aerosoled inoculum of clinically relevant microorganisms. A medical grade nebulizer is used to deliver the accurate and consistent number of pathogens into the simulated room. The UV24 system is turned on for specified contact time during which the aerosolized microorganism comes in contact with the UV system resulting in reduction and release of purified air into the room. This test procedure is developed for a challenge level of greater than 10^6 colony forming units (CFU), which provides 1000 times higher challenge than would be expected in normal use. This method employed the fundamentals of the EPA method "Biological Inactivation Efficiency by HVAC In-Duct Ultraviolet Light Systems".

JUSTIFICATION

The surface air sampler (SAS) or impactor provides advantages over other methods for test because it can simulate inhalation of aerosoled contaminants at controlled air flow rate. The SAS pulls in SOOL of air which is represented as 219 impaction holes on the media placed within the SAS. High volume of air causes multiple impactions which skews the data interpretation. The use of medical grade delivery nebulizer allows a high concentration of aerosol challenge to be aerosolized into the room. The actual count of challenging microorganism is predetermined by colony count, while the volume of the challenge aerosol is tightly controlled by monitoring the air flow and air pressure through the nebulizer. Aerosols are self-contained and they do not pose any bio-safety concerns.

DESCRIPTION OF TEST PROCEDURE

Sample conditioning and calibration

The Zipwall® is constructed as per manufacture instruction. The spacing of the poles is based on the movement of air in the room. The air flow is typical for commercial air space environment. Four glove box areas are specified in the Zipwall® room for nebulizer placement and for three SAS samplers. The UV24 is installed in the ceiling as per instructions and plugged in. At nominal design airflow of 50 cfm, with a MERV 6 filter and a UV lamp, the UV24 emits 15 watts of UV radiation at 253.7 nm. The SAS and the nebulizer are placed at the appropriate glove box. The SAS will operate at the flow rate of 100 lpm for 5 minutes for a total of 500 L.

Challenge phase

Unplug the UV24 system. Connect nebulizer to the PARI compressor. An appropriate media plate is also placed in each of the SAS. Add 8ml of inoculum to the sterile nebulizer. Attach the nebulizer to the connector and to the hose of the PARI compressor. Set timer for 15 minute. Turn on PARI compressor. The nebulizer aerosolizes the inoculum and the compressor is turned off after 15 min. The SAS are turned on for 5 min for sample collection. Three sets of samples are taken outside the simulated clean room using to SAS at 5 min to verify contamination of outside air by the indicator organism.

Contact time

The UV24 system is turned on after the baseline samples are taken. Samples are taken after the contact times of 1hr, 4 hr, 8 hr and 24 hr during which the aerosolized inoculum comes in contact with UV24 system.

Recovery phase

After sampling at specified time intervals, the plates are then placed in the incubator at 35°C for 24 hrs to recover the challenge microorganism.

Plate count / Result recording

Examine plates after 24 hours for growth, and colony count. If necessary, incubate plates for an additional 24 hours. After the colonies have grown, choose countable plate. Record control counts to determine the accuracy of the challenge and the inhibitory efficiency of the UV24 system. The raw colony counts are compared to the 219-hole surface air sampler (SAS) positive hole correction chart to get positive hole corrected colony count for the respective samples. (Attachment 1). The No growth sample is assumed to be <1 colony forming unit per sample and cfu/m³ of air will be less than <2 cfu/ m³ per analysis.

TEST MATERIALS**Testing Area (Room area)** 8ft x9ft x10ft**Equipment Source** (UV24 system) Surface air**Equipment** sampler (SAS) 10.21.13**Date Received** 11.12.13**Start Date****Lab study completion date** 11.14.13**Report Issue Date** 11.15.13**TESTS CONDITIONS****Test Matrix** 6 samples**Organism** *Staphylococcus aureus* ATCC 6538**Inoculum** 10⁶ cfu/ml**Media** Tryptic Soy Agar with 5% sheep blood**Set up** Protocol no. 09112013 Rev 4 (Diagram 1)**Challenge Device** Nebulizer Pro NEB ULTRA II**Delivery Time** 15 min**Challenge Volume** 8ml**Internal Control** Pre-samples taken outside and inside the Zipwall room**"Base line"** Immediately after aerosolisation for 15 min with UV24 off**Contact time** 1 hr, 4hr, 8 hr, and 24hr**Incubator** 35°C**Recovery** 24hr in Incubator at 35°C



CALCULATION- LOG REDUCTION

1. Conversion raw count to colony forming units per cubic meter (cfu/m³).
 - Raw count converted to positive hole corrected value using the SAS (219-Hole impactor correction table).
 - Minimum reporting limits (MRL): 1000 divided by the volume of air collected by SAS (500 L). The MRL (detection limit) for the testing will be <math><2\text{cfu/m}^3</math> of air.
 - Total colony forming units per cubic meter (cfu/m³): positive hole corrected count x MRL
2. Log reduction were calculated using following equation:
Log reduction= Log (Avg of Baseline -Avg for each specified contact time)
3. All statistical analysis were calculated using MS Excel static package.

The data and results of log recovery are represented in Table 1 and Table 2 respectively.

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RESULTS

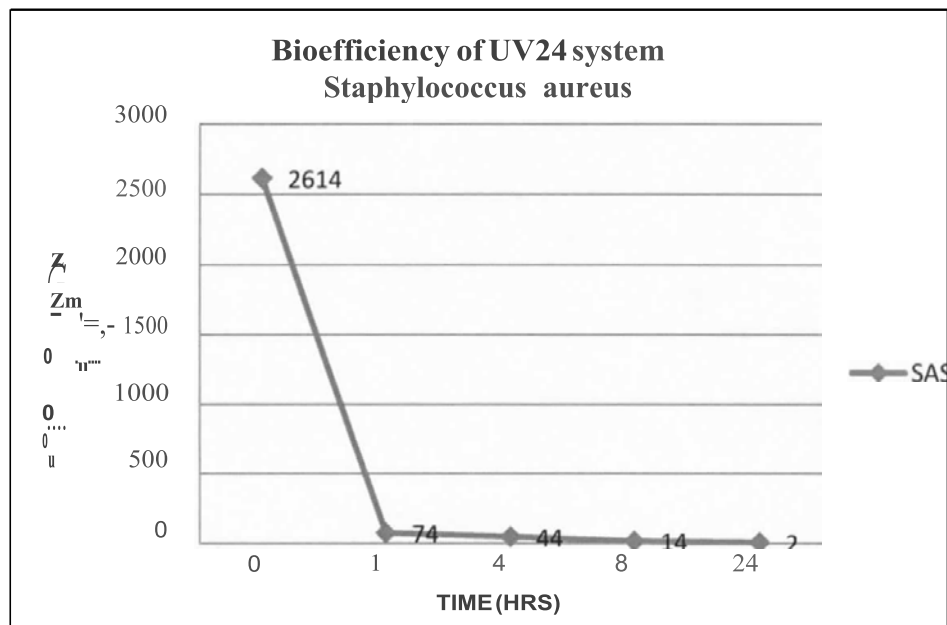
TABLE 1: RECOVERY OF STAPHYLOCOCCUSAUREUS AT DIFFERENT TIME INTERVALS

SAS	TIME										
	Base line (cfu*)	Pass hole**	cfu/ m ³	1 HR** (cfu)	cfu/ m ³	4 HR** (cfu)	cfu/ m ³	8 HR** (cfu)	cfu/ m ³	24HR** (cfu)	cfu/ m ³
SAS 1	219	1307	2614	30	60	31	62	4	8	1	2
	219	1307	2614	15	30	31	62	15	30	1	2
	219	1307	2614	44	88	29	58	34	68	1	2
SAS 2	219	1307	2614	49	98	10	20	1	2	1	2
	219	1307	2614	39	78	3	6	3	6	1	2
	219	1307	2614	54	108	19	38	1	2	1	2
SAS 3	219	1307	2614	54	108	12	24	1	2	1	2
	219	1307	2614	19	38	25	50	1	2	1	2
	219	1307	2614	28	56	39	78	2	4	1	2

* Positive corrected value as per the Z19-hole SA value chart

**colony forming units

*** NG assumed to be <1 cfu for raw count per plate and calculated as <2 for cfu/m³ of air.





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TABLE 2:

STATISTICAL ANALYSIS AND LOG REDUCTION AT EACH TIME INTERVAL FOR STAPHYLOCOCCUS AUREUS

SAS	TIME				
	Baseline (cfu/m3)	1 HR (cfu/m3)	4HR (cfu/m3)	SHR (cfu/m3)	24HR (cfu/m3)
SAS 1	2614	60	62	8	2
	2614	30	62	30	2
	2614	88	58	68	2
SAS2	2614	98	20	2	2
	2614	78	6	6	2
	2614	108	38	2	2
SAS3	2614	108	24	2	2
	2614	38	50	2	2
	2614	56	78	4	2
Average	2614	74	44	14	2
Log Red		1.55	1.77	2.28	3.12
%Red		97.2	98.3	99.5	99.9



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CONCLUSION


The baseline samples showed growth of *Staphylococcus aureus* and after the specified contact time of 1 hr., 4hr, and 8 hr. with the UV24 system on, the samples showed gradual reduction in the colony count. After 24 hrs, there was complete reduction in the colony count. The samples taken after 48hrs showed no *Staphylococcus aureus* indicating complete elimination of the target organism that was aerosolized into the simulated room for 15 minute.

Prepared by

Manju Pradeep

Date 11/5/13

Reviewed by

Suzanne Blevins 

Date 11/5/13

Predicted Value of the UV D90 for MERS Virus and Performance of the UV24 Unit

Prepared by Dr. Wladyslaw Kowalski
On 05-13-14

Executive Summary

The predicted D90 value for MERS Virus is **13.7 J/m²**, with a 95% confidence interval between J/m². This prediction is based on genomic analysis of the NCBI genome for MERS Coronavirus, genome number NC_019843. The input data and analysis results are shown on the following pages.

The predicted D90 is for water applications but the values are conservative to use for air and surface disinfection applications. Details on the genomic model are available from Kowalski 2009, 2009a, 2009b, 2009c, 2009d, & 2011). The specific genomic model used in this analysis is as yet unpublished, but is similar to the previously published models and is slightly more accurate. Analysis was performed using the Aerobiological Engineering proprietary program GSA (Genomic Sequence Analyzer) 1.0.1, Copyright 2014.

Also included is an evaluation of the performance for the UV24 unit against the MERS virus. This evaluation indicates the MERS virus will be eradicated at a very high rate and will be virtually sterilized from the UV24 airstream in a single pass.

1.1 Single Stranded RNA Viruses

The Middle Eastern Respiratory virus is an ssRNA virus and has no known measured UV rate constant or D90 value. The complete genome (NC_019843) was analyzed and compared to the existing ssRNA virus model. The genomic model for all ssRNA viruses is shown in Figure 1.1, where it can be seen that the r^2 value for the curve fit of the model is 94.09%. The relative dimerization value, D_v , for MERS virus is 0.055858, which plots out on Figure 1.1 to be about 13.7 J/m^2 . Appendix A summarizes the input and output data for the genomic model of MERS Coronavirus.

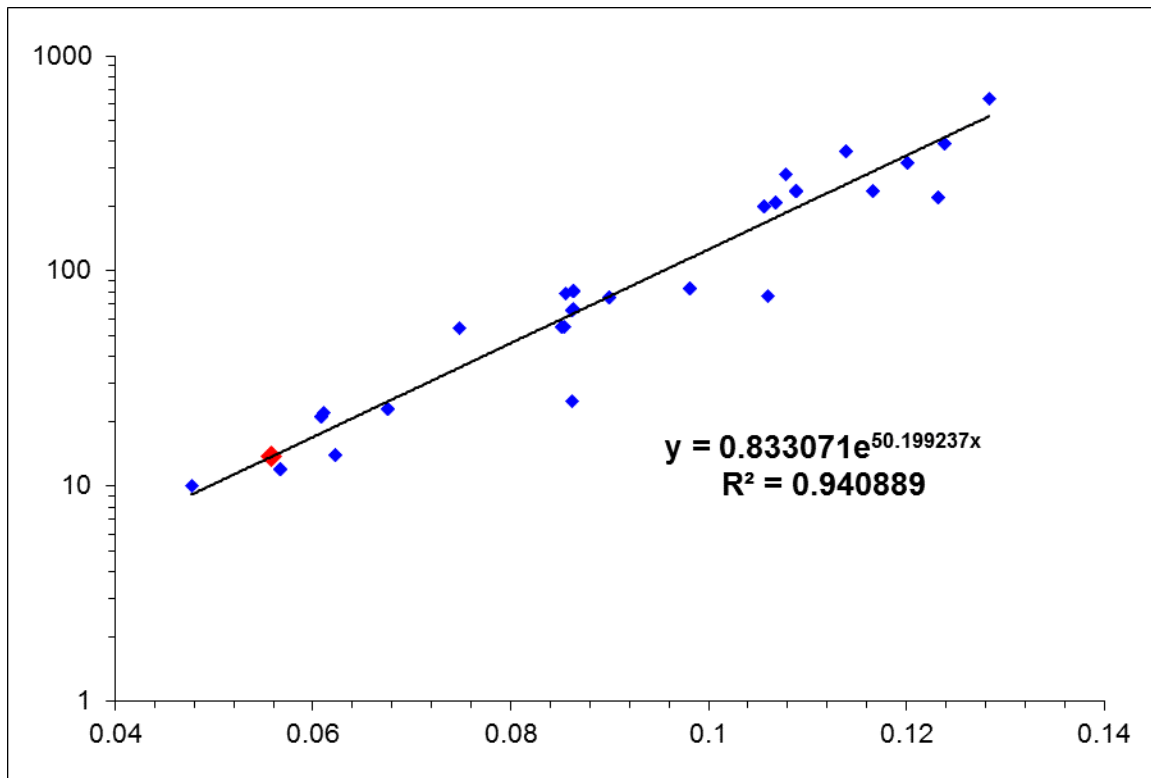


Figure 1.1: Genomic model for 27 ssRNA viruses (62 data sets). Based on Kowalski et al 2014 (unpublished). Red dot indicates the location of MERS Virus.

Figure 1.2 shows the estimates of the upper and lower confidence interval for 95% of the data. The 95% confidence interval is 6.3-20 J/m^2 . The maximum value, 20 J/m^2 is suggested as a conservative value to use for design purposes.

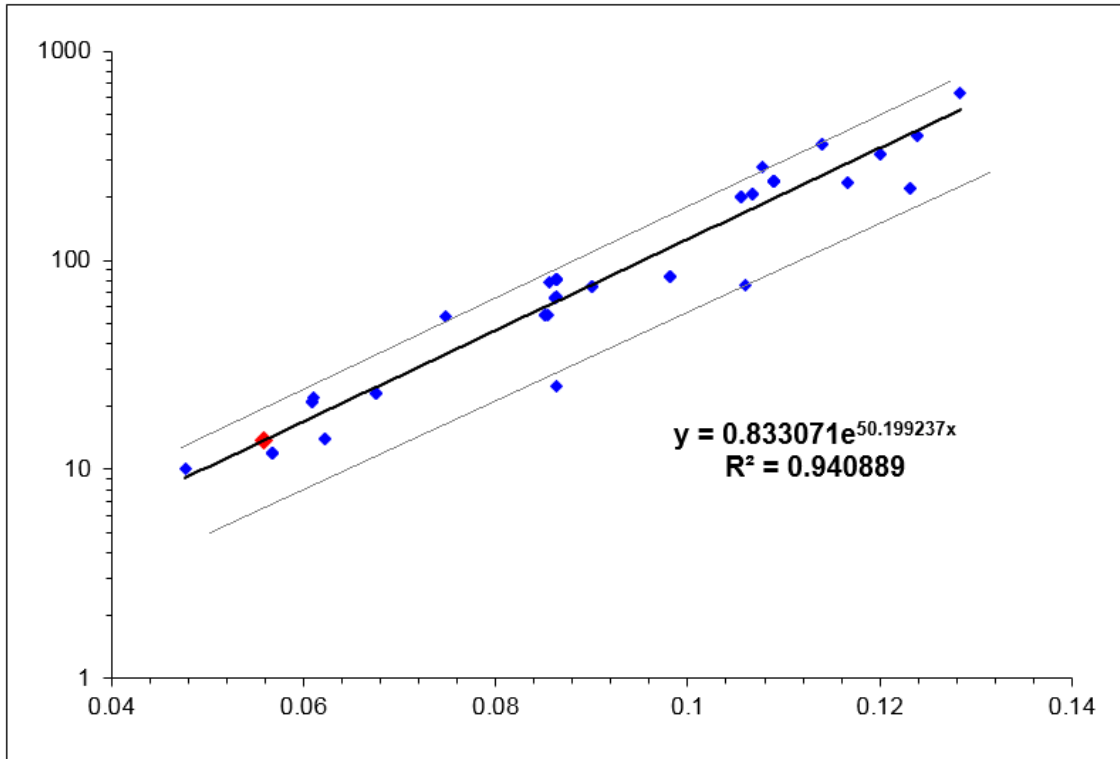


Figure 1.2: 95% confidence interval range for 62 data sets. Upper limit is 20 J/m², and lower limit is 6.3 J/m².

2.1 Performance of the UV24 Against MERS Virus

The UV24 system has two components, an ultraviolet light and a MERV 6 filter. The performance curve for a typical MERV 6 filter is shown in Figure 2.1, with the curve extended via modeling into the virus size range. MERS Coronavirus sits within the Most Penetrating Particle (MPP) size range of this, and all other MERV filters. The removal rate by the MERV 6 filter is seen to be approximately 0.05 or 5%.

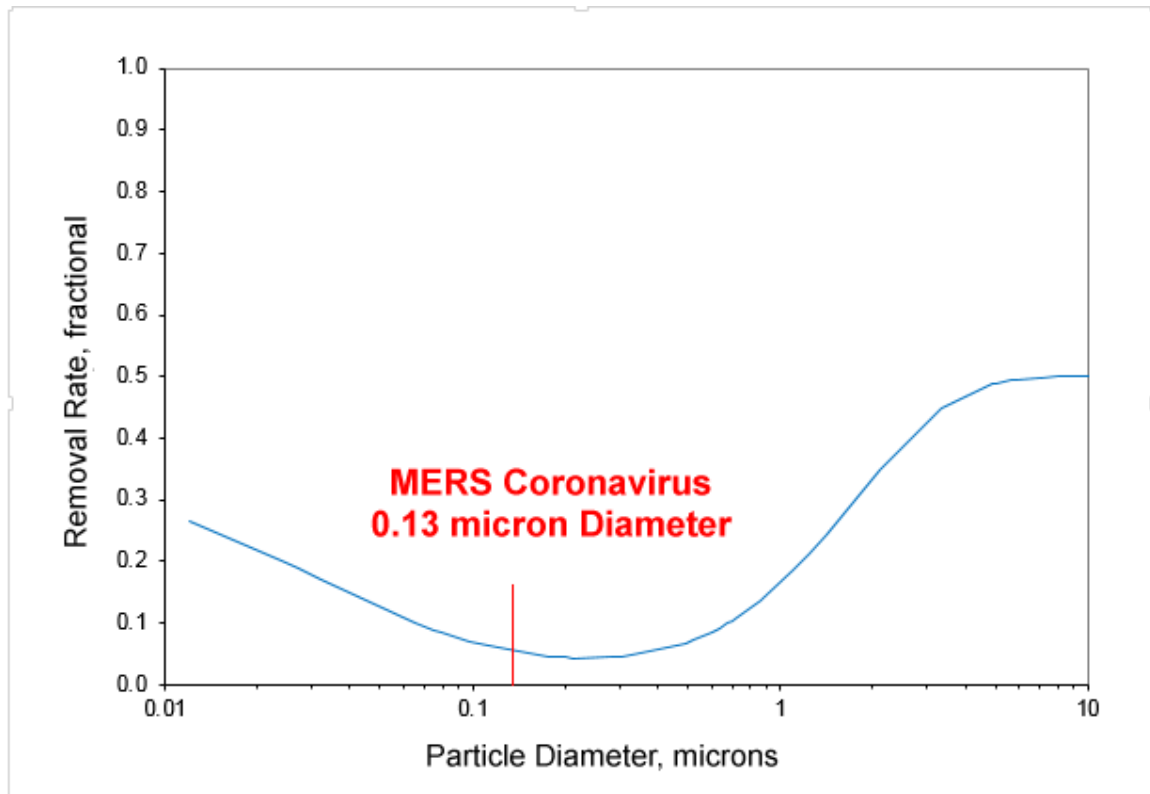


Figure 2.1: Filter Performance Curve for a Typical MERV 6 Filter, extended into the virus size range (Kowalski 2009). MERS Coronavirus is shown to be within the Most Penetrating Particle size range.

The UV component of the UV24 has an established UV dose of 198 J/m². The D90 dose for MERS Coronavirus is 13.7 J/m². This converts to a first stage UV rate constant of

$$k_1 = -\ln(0.10)/D_{90} = 0.16807 \text{ m}^2/\text{J}$$

The virus survival at 198 J/m² is then computed to be

$$S = \exp(-k \ 198) = 3.527 \times 10^{-15}$$

The inactivation rate is seen, therefore, to approach zero, and to be well over six logs of reduction, or virtual sterility. Figure 2.2 shows the survival curve

of MERS virus when exposed to ultraviolet radiation. Based on this evaluation, the UV24 will produce over six logs of reduction of any airborne MERS virus.

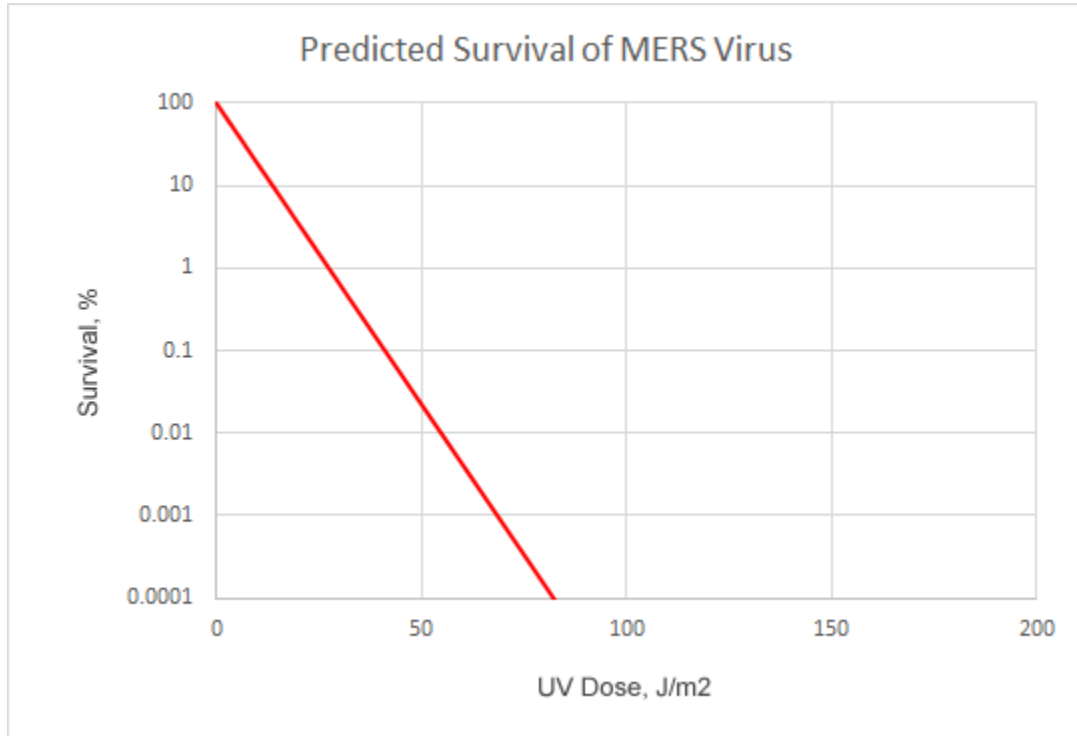


Figure 2.2: Predicted Survival of MERS Virus under UV exposure.

3.0 References

- Kowalski, W. J. (2009). *Ultraviolet Germicidal Irradiation Handbook: UVGI for Air and Surface Disinfection*. Springer, New York.
- Kowalski, W., Bahnfleth, W., and Hernandez, M. (2009). "A Genomic Model for Predicting the Ultraviolet Susceptibility of Bacteria and Viruses." *IUVA*, Amsterdam
- Kowalski, W., Bahnfleth, W., and Hernandez, M. (2009a). "A Genomic Model for the Prediction of Ultraviolet Inactivation Rate Constants for RNA and DNA Viruses." *IUVA*, Boston, MA
- Kowalski, W. J. (2009b). "Genomic Modeling of Ultraviolet Susceptibility for Viruses and Bacteria." (*unpublished manuscript*)
- Kowalski, W., Bahnfleth, W., and Hernandez, M. (2009c). "A Genomic Model for Predicting the Ultraviolet Susceptibility of Viruses." *IUVA News* 11(2), 15-28.

Appendix A: Genomic Parameters for MERS Virus

Name: MERS
RefSeq: NC_019843.2
Type: Single Stranded DNA
Strand: Template

Size: 30111 bp
T: 9815
A: 7897
C: 6096
G: 6303
GC: 12399
TA: 17712
Y: 15911
R: 14200

TT Pairs: 5326
TC Pairs: 3404
CT Pairs: 4606
CC Pairs: 2082
YR Pairs: 7966
Total Pairs: 23384
S: 16231

TT Hyperprimers: 1221.201672
TC Hyperprimers: 1008.970165
CT Hyperprimers: 1208.451832
CC Hyperprimers: 514.5694284
YR Hyperprimers: 2368.0
Total Hyperprimers: 6321.4568

Clusters: 2805
Mean Cluster Size: 5.784390591589451

=====

Hyperprimer Lookup Values:

Hy	Hc
1	0.0
2	0.0
3	0.5
4	0.75
5	0.88
6	0.983023614611054
7	0.994644615260238
8	1.0