INVITATION TO SUBMIT A RESEARCH PROPOSAL ON AN ASHRAE RESEARCH PROJECT

1833-TRP, "Literature Review for Evidence of the Basis for Specified Air Change Rates (ACR) for Cleanrooms, Laboratories, laboratory animal facilities, and health care facilities with medium to high ACR"

Attached is a Request-for-Proposal (RFP) for a project dealing with a subject in which you, or your institution have expressed interest. Should you decide not to submit a proposal, please circulate it to any colleague who might have interest in this subject.

Sponsored by: MTG.ACR, Air Change Rates

Budget Range: $75,000 may be more or less as determined by value of proposal and competing proposals.

Scheduled Project Start Date: **TBD** or later.

All proposals must be received at ASHRAE Headquarters by 8:00 AM, EST, TBD. NO EXCEPTIONS, NO EXTENSIONS. Electronic copies must be sent to rpbids@ashrae.org. Electronic signatures must be scanned and added to the file before submitting. The submission title line should read: 1833-TRP, "Literature Review for Evidence of the Basis for Specified Air Change Rates (ACR) for Cleanrooms, Laboratories, laboratory animal facilities, and health care facilities with medium to high ACR", and "*Bidding Institutions Name*" (electronic pdf format, ASHRAE's server will accept up to 10MB)

If you have questions concerning the Project, we suggest you contact one of the individuals listed below:

For Technical Matters
Phil Naughton
Applied Materials Inc
9700 East US Highway 290
Austin, TX 78724
Phone: 512-272-0437
E-Mail: phil_naughton@amat.com

For Administrative or Procedural Matters:
Manager of Research & Technical Services (MORTS)
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Contractors intending to submit a proposal should so notify, by mail or e-mail, the Manager of Research and Technical Services, (MORTS) by TBD in order that any late or additional information on the RFP may be furnished to them prior to the bid due date.

All proposals must be submitted electronically. Electronic submissions require a PDF file containing the complete proposal preceded by signed copies of the two forms listed below in the order listed below. **ALL electronic proposals are to be sent to rpbids@ashrae.org.**

All other correspondence must be sent to ddaniel@ashrae.org and mvaughn@ashrae.org. Hardcopy submissions are not permitted. **In all cases, the proposal must be submitted to ASHRAE by 8:00 AM, EST, TBD.**
NO EXCEPTIONS, NO EXTENSIONS.

The following forms (Application for Grant of Funds and the Additional Information form have been combined) must accompany the proposal:

(1) ASHRAE Application for Grant of Funds (electronic signature required) and
(2) Additional Information for Contractors (electronic signature required) ASHRAE Application for Grant of Funds (signed) and

ASHRAE reserves the right to reject any or all bids.

State of the Art (Background)

Required ventilation rates for many kinds of spaces are selected to comply with published guidance specific to the industry served. These guiding documents have various levels of authority, from codes, to publications of professional societies, to design standards of the client's institution. In many cases, the HVAC designers and operators may be unaware of the reasons and justification for the published ventilation rates. These rates drive energy use and system sizing and other issues. This situation is prevalent in many "critical ventilation" applications, including cleanrooms, healthcare spaces including patient rooms, airborne infection isolation rooms, operating rooms, chemical and biological laboratories and other similar facilities. The ventilation rates are specified in terms of Air Changes per Hour (ACH) or other terms. Specified rates range anywhere between 4 to 300+ ACH.

For example:

- ASHRAE Standard 170, 4 ACH for patient rooms;
- ASHRAE Standard 170, 20 ACH for operating rooms;
- Design standard for NIH, 6 ACH at all time in laboratories;
- Design standard for U of California, 1cfm per square foot of floor space in laboratories;
- FDA Aseptic Guidance, 0.2 to 0.5 m/s for ISO Class 5;
- IEST RP 12, 20 to 200 ACH for ISO Class 7;
- ILAR Guide for Care and Use of Laboratory Animals, 10 to 15 ACH for animal holding rooms
- See additional references

Some of the pertinent guidelines, codes, regulations and standards for such specifications are decades old when the understanding of contamination generation rates and transport mechanisms may have been less understood and to provide a safe environment a high ACR was specified. These airflow rates were established based upon the judgment of experienced practitioners and likely upon controlling conditions in some circumstances which are no longer applicable such as control of explosive hazards from anesthesia fumes in operating rooms. It is important to identify whether these recommendations have any scientific basis and if that basis is still applicable. An understanding of associated risk and how it may have influenced historical practices and airflow specifications for various facilities has become essential to make the facilities safe, sustainable, and energy efficient.

Justification and Value to ASHRAE

ASHRAE members design, commission, operate, monitor and maintain HVAC systems to satisfy the published ventilation requirements studied in the project. These requirements strongly affect design, construction, operation and maintenance of the systems. To properly serve clients, the HVAC designer needs to judge when to adhere to the guidance and when to deviate. This is only possible if the reasons for the ventilation rates are known.
ASHRAE Multi Task Group (MTG) is formed on this topic of Air Change Rates (MTG.ACR). This group is comprised of representatives from various Technical Committees including TC2,2, TC2.4, TC5.3, TC9.02, TC9.06, TC9.10, and TC9.11. In addition, representatives SSPC 170 are also part of this MTG.ACR. All these committees are looking for this research and answers to the questions stated above. This research will lead to valuable addition and improvements to various ASHRAE Standards, design guidelines and respective Chapters in the ASHRAE Handbooks. Secondly, this is the first step in determining the scientific basis for ACH. MTG.ACR intends to develop further research projects based on the outcome of this literature survey.

This project will foster and engage ASHRAE relationships with other organization memberships and in turn strengthen member value proposition. This project creates a learning endeavor that could be emulated to additional standards or activities within ASHRAE and outside of ASHRAE and to help promote ASHRAE as a leader in ventilation guidance.

Objectives

The main objectives of the proposed research are as follows:

1. Provide an understanding of the meaning and use of terminology such as ventilation effectiveness, ventilation rates, etc. associated with ventilation of spaces of differing applications.
2. Identify basis for ventilation rate specifications for cleanrooms, laboratories, laboratory animal facilities, and healthcare facilities by reviewing literature and contacting sources of the guidance.
3. Identify various terminologies employed in describing the ventilation effectiveness for these spaces.

4. Identify and document scientific experiments and analyses correlating ventilation effectiveness with ACH. Include research focused on people exposure control, infection control, and contamination control,
5. Identify and analytically summarize using recommended criteria above for historical data and evidences for the existing recommendations for ventilation rates cleanrooms, laboratories, laboratory animal facilities, and healthcare facilities.
6. Classify the researched data in the literature as field evaluations, laboratory experiments, simulations and numerical analysis, and consensus determination.
7. Publish results and recommend additional research.

NOTE: It is not the goal of this research to reduce ventilation rates. The goal is to set them with sound reasons and justification. If lower rates result and energy is saved, that's good. If existing high rates are justified, that's also a successful project.

Scope:
Tasks

Task 1
Literature Search for meaning of key terminology. Refer to latest edition of ASHRAE Terminology Glossary of Terms as the baseline identifying missing or conflicting sources.

- Ventilation
- Ventilation Effectiveness
- Ventilation Rate
- Ventilation Requirements
- Ventilation Air
- Ventilation Effectiveness Concentration

See, https://www.ashrae.org/resources--publications/free-resources/ashrae-terminology
Investigator shall research history and changes terminology meanings providing assessment and root cause of any significant changes leading to current understanding of the terms. Investigator shall note any differences in meaning between the various ASHARE publications and identify a consensus definition

Types of literature for review. Peer reviewed literature shall take priority over non-peer reviewed literature.

- Books
- Booklets
- Journals and Periodicals
- Technical Papers and Symposia
- Specifications and Standards
- Codes
- Regulations

Sources. Periodical Database Searches covering publication of the following:

- Government Agencies: Limited to United States and European Union
- National Labs
- Research Institutions
- Trade or Industry Organizations (e.g. ASHRAE) Documents including Symposia, Journals and Periodicals covering public health, industrial hygiene,
- Patents

Original Language Source

- English
- Japanese (Translated into English)
- German (Translated into English)
- United States English
- United Kingdom English

Application of Terms in primary and secondary applications
The objective of the search is to understand the current and historical basis or evidence for the terms noted above. The Investigator may find evidence that indicates the use and definition of the terms have varied over time based

upon the space in question. For example, ventilation rates for operating rooms may include an understanding of fresh air or recirculation air but for cleanrooms the ventilation may only refer to recirculation air. The investigator shall note differences by primary application, cleanroom, laboratories, and healthcare but also within subcategories within the primary category. Investigator should reference ASHRAE Application Handbook for a list of potential subcategories.

Historical Reference – Several of the terms may have been used during the 125 year history of ASHRAE, provide a brief etymology of each subject word and their application in cleanrooms, laboratories, and healthcare facilities since early 20th century. In general ventilation guidance started with public health concerns in public spaces, progressed to cover healthcare spaces as evidence of correlation between ventilation and infection spread became better known. Industrial environments and Industrial Hygiene for worker protection was being researched leading to expansion from the factory floor to the laboratory space. Finally, with the advent of clean rooms in the 1950's ventilation added product protection into the meaning.
Application Reference – Note any differences in word etymology for cleanrooms, laboratories, and healthcare facility applications

Task 2 – Scientific basis of ventilation guidance for cleanrooms, laboratories, laboratory animal facilities, and healthcare facilities
Upon completion of the task 1 a consensus definition of each critical term shall be recommended by the PI and approved by the PMS. The consensus definition shall be used for evaluating the scientific basis of ventilation guidance including air change rates, ventilation effectiveness, and minimum ventilation rates.
Avoidance of duplication of effort. ASHRAE Joint Research Project RP CO-RP 3, Evidence Based Research Project: Literature Review for ASHRAE Standard 170-2013 is scheduled to issue its final report in 2018. PI shall review the results of RP CO-RP 3 and extract relevant findings in lieu of duplicating the literature search of RP CO RP 3.

Task 3 – Summary of results for each industry/application segment. Using results from task 2 provide a summary of findings for each application, cleanrooms, laboratories, laboratory animal facilities, and healthcare and subcategories showing interrelationships that may exist. List specific instances where results from one application has been used to improve conditions in another. Classification of data under various categories such as field evaluations, laboratory experiments, simulations and numerical analysis, and consensus determination.

Task 4 – Propagation of terms and guidance into various forms of publication. For example, explain the propagation for air change rates for use in healthcare facility practices to building codes and government regulations citing possible causal events. Identify overlaps between public health and industrial hygiene which may have led to creation of guidance in other industries. For example, how did operating room ventilation rates influence recommended ventilation in bio-safety labs.

Task 5 – Final Publication of results. Prepare complete bibliography including English Language version of foreign language sources when available. Summarize findings into a technical paper to be presented at an ASHRAE meeting to be agreed to between PI and PMS

Deliverables:

Findings of the research and literature review will be disseminated through special publications, ASHRAE Handbooks, ASHRAE conferences and other special conferences on the subject. The outcome of these efforts will be communicated to ASHRAE standards committees, regulatory authorities, and other similar organizations to facilitate any modifications in their codes and standards.

Task 1 Deliverables shall include:

1. Complete and comprehensive bibliography of cited sources.
2. Assessment report of findings of search results and recommendation going into task 2.
3. Recommended consensus definitions of each critical term shall be submitted in report format by the PI and approved by the PMS. The consensus definition shall for the basis of evaluation the scientific basis of ventilation guidance including air change rates, ventilation effectiveness, minimum ventilation rates

Task 2-5

1. Summary of scientific findings and/or basis covering air change rates, ventilation effectiveness, and minimum ventilation rates for multiple examples of applications in cleanrooms, laboratories, and healthcare facilities. If the results of the search for scientific basis varies within each primary application, e.g. Pharmaceutical Cleanrooms versus Semiconductor Cleanrooms, or Bio-Safety Labs versus Radiological Lab or Animal Labs or teaching Labs or Clinical Labs the Investigator shall note these differences. Investigator shall use the latest ASHRAE Application Handbook to help identify subcategories of each primary application.
2. Final report to be presented in a publication method as defined by the PMS and ASHRAE Publications, e.g. special publication, technical report, Journal Article, etc.
3. Optional Presentation of findings at an ASHRAE Annual or Winter Meeting upon approval by PMS. During the bid process, the cost to present at an annual meeting shall be noted and ASHRAE shall decide if this remains in the contract.

Progress, Financial and Final Reports, Technical Paper(s), and Data shall constitute the deliverables ("Deliverables") under this Agreement and shall be provided as follows:

a. Progress and Financial Reports

Progress and Financial Reports, in a form approved by the Society, shall be made to the Society through its Manager of Research and Technical Services at quarterly intervals; specifically on or before each January 1, April 1, June 10, and October 1 of the contract period.

The following deliverables shall be provided to the Project Monitoring Subcommittee (PMS) as described in the Scope/Technical Approach section above, as they are available:

Furthermore, the Institution's Principal Investigator, subject to the Society's approval, shall, during the period of performance and after the Final Report has been submitted, report in person to the sponsoring Technical Committee/Task Group (TC/TG) at the annual and winter meetings, and be available to answer such questions regarding the research as may arise.

b. Final Report

A written report, design guide, or manual, (collectively, "Final Report"), in a form approved by the Society, shall be prepared by the Institution and submitted to the Society's Manager of Research and Technical Services by the end of the Agreement term, containing complete details of all research carried out under this Agreement, including a summary of the control strategy and savings guidelines. Unless otherwise specified, the final draft report shall be furnished, electronically for review by the Society's Project Monitoring Subcommittee (PMS).

Tabulated values for all measurements shall be provided as an appendix to the final report (for measurements which are adjusted by correction factors, also tabulate the corrected results and clearly show the method used for correction).

Following approval by the PMS and the TC/TG, in their sole discretion, final copies of the Final Report will be furnished by the Institution as follows:

-An executive summary in a form suitable for wide distribution to the industry and to the public.
-Two copies; one in PDF format and one in Microsoft Word.

c. *Science & Technology for the Built Environment* or ASHRAE Transactions Technical Papers

One or more papers shall be submitted first to the ASHRAE Manager of Research and Technical Services (MORTS) and then to the "ASHRAE Manuscript Central" website-based manuscript review system in a form and containing such information as designated by the Society suitable for publication. Papers specified as deliverables should be submitted as either Research Papers for HVAC&R Research or Technical Paper(s) for ASHRAE Transactions. Research papers contain generalized results of long-term

archival value, whereas technical papers are appropriate for applied research of shorter-term value, ASHRAE Conference papers are not acceptable as deliverables from ASHRAE research projects. The paper(s) shall conform to the instructions posted in "Manuscript Central" for an ASHRAE Transactions Technical or HVAC&R Research papers. The paper title shall contain the research project number (1833-RP) at the end of the title in parentheses, e.g., (1833-RP).

All papers or articles prepared in connection with an ASHRAE research project, which are being submitted for inclusion in any ASHRAE publication, shall be submitted through the Manager of Research and Technical Services first and not to the publication's editor or Program Committee.

d. Data

Data is defined in General Condition VI, "DATA"

e. Project Synopsis

A written synopsis totaling approximately 100 words in length and written for a broad technical audience, which documents 1. Main findings of research project, 2. Why findings are significant, and 3. How the findings benefit ASHRAE membership and/or society in general shall be submitted to the Manager of Research and Technical Services by the end of the Agreement term for publication in ASHRAE Insights

The Society may request the Institution submit a technical article suitable for publication in the Society's ASHRAE JOURNAL. This is considered a voluntary submission and not a Deliverable. Technical articles shall be prepared using dual units; e.g., rational inch-pound with equivalent SI units shown parenthetically. SI usage shall be in accordance with IEEE/ASTM Standard SI-10.

Level of Effort

It is estimated that the project will require two (2) professional-months for the Principal Investigator and nine (9) months effort of a research assistant, with a project duration of nine (9) months at a cost of $75,000. Research team is expected to be proficient and knowledgeable in the fields of ventilation and contamination control.

Other Information to Bidders (Optional):

With the parallel literature search into ASHRAE 170, ASHRAE Joint Research Project RP CO-RP 3, Evidence Based Research Project: Literature Review for ASHRAE Standard 170-2013, the bidders shall provide a breakout in their costs for activities that may be performed by RP CO-RP 3 such that the cost and effort for this portion of the work may be easily subtracted from the overall scope of work.

Project Milestones:

No.	Major Project Completion Milestone	Deadline Month
1	Literature Search for meaning of key terminology. Refer to latest edition of ASHRAE Terminology Glossary of Terms as the baseline identifying missing or conflicting sources. • Ventilation • Ventilation Effectiveness • Ventilation Rate • Ventilation Requirements • Ventilation Air • Ventilation Effectiveness Concentration Coordination with results from ASHRAE Joint Research Project RP CO-RP 3	1
2	PMS Review and Approval of Task 1 deliverables	2
3	Scientific basis of ventilation guidance for cleanrooms, laboratories, laboratory animal facilities, and healthcare facilities	3
4	Summary of results for each industry/application segment. Using results from task 2 provide a summary of findings for each application, cleanrooms, laboratories, laboratory animal facilities, and healthcare and subcategories showing interrelationships that may exist. List	5

	specific instances where results from one application has been used to improve conditions in another. Classification of data under various categories such as field evaluations, laboratory experiments, simulations and numerical analysis, and consensus determination.	
5	Propagation of terms and guidance into various forms of publication. For example, explain the propagation for air change rates for use in healthcare facility practices to building codes and government regulations citing possible causal events. Identify overlaps between public health and industrial hygiene which may have led to creation of guidance in other industries. For example, how did operating room ventilation rates influence recommended ventilation in bio-safety labs.	7
6	Final Publication of results. Prepare complete bibliography including English Language version of foreign language sources when available. Summarize findings into a technical paper to be presented at an ASHRAE meeting to be agreed to between PI and PMS	9

Proposal Evaluation Criteria

Proposals submitted to ASHRAE for this project should include the following minimum information:

No.	Proposal Review Criterion	Weighting Factor
1	Experience with understanding impact of ventilation in cleanrooms, laboratories, laboratory animal facilities, and healthcare facilities	25%
2	Access to and ability to comprehend and assess non-English document sources	15%
3	Proposal scope of work description and method for conducting research	25%
4	Proposed Schedule	15%
5	Proposed level of effort	20%

References

1. ASHRAE, 2015 HVAC Applications Handbook, Chapter 16 Laboratory Systems
   Laboratory Ventilation Systems Minimum ventilation rates of 10 to 15 ACH for animal housing rooms, 6 to 10 ACH for Biosafety Level 2.
2. OSHA, 29 CFR Part 1910.1450 Occupational Exposure to Hazardous Chemicals in Laboratories
   Appendix A - National Research Council Recommendations Concerning Chemical Hygiene in Laboratories C. The Laboratory Facility 4. Ventilation (f) Performance “Rate: 4-12 room air changes/hour is normally adequate general ventilation if local exhaust systems such as hoods are used as the primary method of control.
3. ASHRAE, 2011 Handbook - HVAC Applications, Laboratories, Pg. 14.16, Containment Laboratories: Biosafety Level 2 Federal guidelines for these laboratories contain minimum facility guidelines however typical HVAC design criteria can include the following: • 100% outdoor air systems • 6 to 15 air changes per hour
4. Institute of Laboratory Animal Research, Commission on Life Sciences, National Research Council, Guide for the Care and Use of Laboratory Animals, Eight Edition, 2011: Provision of 10 to 15 fresh air changes per hour in animal housing rooms is an acceptable guideline to maintain macroenvironmental air quality by constant volume systems and may also ensure microenvironmental air quality.
5. Guidelines for Design & Construction of Hospital & Health Care Facilities. The American Institute of Architects Academy of Architecture for Health U.S. Department of Health & Human Services, Ventilation Requirements for Areas Affecting Patient Care in Hospitals & Outpatient Facilities – Minimum air changes of outdoor air per hour 3 Minimum total air changes per hour 6 to 15 total ACH and 2 to 3 ACR of outdoor air, depending on area designation.
6. US NFPA (National Fire Protection Association) Standard 45. A.8.2.2: A minimum ventilation rate for unoccupied laboratories is 4ACH. Occupied laboratories typically operate at rates of greater than 8ACH.
7. German Standard DIN 1946-7 “Ventilation and air conditioning - Part 7: Ventilation systems in laboratories”. This standard includes a recommendation but not a requirement for minimum lab ventilation of 25 m3 /hr./m2. This minimum ventilation flow recommendation corresponds to about 9.1 ACH for a 9 foot ceiling or an 8.2 ACH rate for a 10 foot ceiling space.
8. FDA Aseptic Guidance, page 11
   "Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice"

9. Pharmaceutical Inspection Co-operation Scheme (PIC/S). Guide to good manufacturing practice for medicinal products. PE 009-13 (Annexes) 1 January 2017
10. World Health Organisation. Expert Committee on Specifications for Pharmaceutical Preparations. Technical Report Series, No. 961. Forty-fifth report. Annex 5. Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. October 2011. ISBN 978-92-4-12096
11. EU GMP. The Rules Governing Medicinal Products in the European Union
Volume 4
12. EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use
13. Annex 1 Manufacture of Sterile Medicinal Products
14. IEST-RP-CC012.1,2,3: Considerations in Cleanroom Design, Institute of Environmental Sciences and Technology; 1827 Walden Office Square, Suite 400 • Schaumburg, IL 60173.