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Standard Operating Procedure **NHX/SOP-300-004**

Title: Monitoring and Maintaining Cleanliness of the ACS Inorganic Clean Lab Facility

Source: Research Triangle Institute

U.S. Environmental Protection Agency
Office of Research and Development
Human Exposure & Atmospheric Sciences Division
Human Exposure Research Branch

STANDARD OPERATING PROCEDURE	RESEARCH TRIANGLE INSTITUTE POST OFFICE BOX 12194 RESEARCH TRIANGLE PARK, NC 27709-2194	NHX/SOP-300-004 Page 1 of 21

TITLE: STANDARD OPERATING PROCEDURES FOR MONITORING AND MAINTAINING CLEANLINESS OF THE ACS INORGANIC CLEAN LAB FACILITY

SOURCE: Research Triangle Institute
Post Office Box 12194
Analytical and Chemical Sciences
Research Triangle Park, NC 27709-2194

AUTHOR(s):

R Jurado _____ Date: 05.31.95

_____ Date: _____

_____ Date: _____

APPROVED BY:

Principal Investigator: E Pellizzari _____ Date: 6/2/95

QA Officer: DJ Smith _____ Date: 6/15/95

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MONITORING AND MAINTAINING CLEANLINESS OF THE ACS INORGANIC CLEAN LAB FACILITY

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1.0 INTRODUCTION

Clean rooms are designed to control and limit the airborne particles in the working environment. The ACS Clean Lab Facility, located in room 193 of the Dreyfus building, is specially designed to eliminate the contamination problems in trace and ultra trace metal analysis. The purpose of this SOP is to provide guidelines to all laboratory personnel for proper monitoring and maintenance of the facility to preserve its cleanliness. A floor diagram of the facility is provided in Figure 1.

The level of cleanliness is specified by the maximum allowable particles per cubic foot of air as defined by Federal Standard 209E. The class designation is taken from the maximum allowable number of particles, 0.5 μm or larger, per cubic foot of air (see Table 1). A properly functioning air handling system will ensure that the number of particles in the air is minimized, that the cleanliness class specifications are met, and that the movement of air between rooms minimizes contamination. In essence, any particulate matter that is created by the movement of people, operation of equipment, etc., is rapidly removed from the room, and movement of air between rooms is always from a region of more clean air to less clean air. For example, the flow of air should not proceed from the ante room to the Class 100 room, or from the instrument room to the ante room. These effects are made possible by properly functioning air handling equipment and filters, as well as proper cleanroom use by personnel. The specific air handling parameters to be monitored are listed in the following sections of this SOP.

2.0 INITIAL TESTING AND CERTIFICATION OF THE CLEAN LAB FACILITY

The certification of the Clean Lab Facility was performed by an independent company (Contamination Control Technologies Inc.) certified by the National Environmental Balancing Bureau. A copy of the certified document is attached (Appendix I). The certification procedure involved the measurement of particle counts in the facility in an "as built" condition. It reflects the performance of the air handling system of the Clean Lab Facility with one person in the laboratory. Particle counts will be monitored periodically to ensure that the initial standards are maintained.

3.0 MONITORING THE CLEANLINESS OF THE CLEAN LAB FACILITY

Monitoring the cleanliness of the clean lab facility requires measurement of two sets of parameters. The first set are physical parameters that indicate if the air handling system is functioning properly. It includes measurement of temperature, static pressure, relative humidity, and the alarm status of various fans and motors. The second set are chemical parameters that indicate if the Clean Lab Facility is sufficiently clean in selected analytes to enable contaminant-free analyses. It includes measurement of chemical concentrations in acid baths and settled particulates.

The Clean Lab Facility is equipped with an electronic monitoring system for measuring and recording the physical parameters. Sensors in each room of the suite are interfaced to a computer system that provides continuous display of measured parameters on a control panel in the service room. The computer also updates a database and prints reports of measured parameters at a frequency specified by the laboratory manager. The frequency of each activity and the parameter criteria are specified in the following sections.

3.1 More Frequently Monitored Parameters

The physical parameters that indicate the proper operation of the air handling system (temperature, static pressure, relative humidity, alarm status) will be monitored continually by the electronic system. Failure of the system due to fan or motor shutdown, excess heat, etc., will generate an audible alarm and printed diagnostic message. The laboratory manager will contact John Berkley or the person in charge at RTI Heating, Ventilation, and Air Conditioning. In the event that the laboratory manager is not available, a printed message with instructions for other personnel is located near the alarm switch.

The electronic monitoring system will print reports of temperature, static pressure, and relative humidity on a weekly basis (or more frequently). The laboratory manager or designated personnel will review the printed parameter reports weekly.

3.1.1 The air pressure of each room in the Clean Lab Facility will be recorded twice daily by the electronic monitoring system and printed weekly. Lab personnel will check printed reports each week to ensure that the proper gradient exists. From most positive pressure to least positive pressure the order should be:

Class 100 > Ante Room > Class 10000 > Service Room = Office Room.

In the event the measured gradient is different from the above gradient, the laboratory manager will contact John Berkley or the person in-charge at RTI Heating, Ventilation and Air Conditioning.

3.1.2 The temperature in the Clean Lab Facility will be monitored by lab personnel continuously through the electronic monitoring system and data will be printed on a daily basis. In the event the temperature makes the facility uncomfortable to the working personnel, HVAC will be contacted by the laboratory manager for corrective actions (refer to section 3.1.1 for a contact person).

3.2 Less Frequently Monitored Parameters

These include physical and chemical properties that are measured less frequently.

3.2.1 Particle measurements will be made in both Class 100 and Class 10000 areas once every year and will be compared to those obtained at the initial certification. The laboratory manager is responsible for making necessary arrangements to have the particle measurements made as specified. The measurements must be made at locations where an open sample would be located, and will include, but not limited to, inside the 8′ hood and on top of the 11′ bench in the Class 100 room.

3.2.2 All of the parameters mentioned above (under sections 3.1. and 3.2.1) are good parameters for monitoring the air handling efficiency of the Clean Lab Facility. However, they do not provide direct information on contamination levels of various metals of interest within the laboratory. Lead (Pb), arsenic (As) and cadmium (Cd) are chosen as the contamination monitoring agents. These three elements will be measured in laboratory blanks and controls once every six months to establish the cleanliness of the Clean Lab Facility with respect to trace metals. Suitable sample locations will be chosen and two samples will be taken from each location along with blanks. One sample will be tested for As by hydride generation atomic fluorescence spectrometry and the other will be tested for Pb and Cd by GFAAS. Sampling will be done by placing four clean Teflon beakers, two open (samples) and two covered (blanks) at each sampling location. The sampling locations and acceptable limits are given in Tables 2 and 3.

4.0 MAINTENANCE OF THE CLEAN LAB FACILITY

All routine maintenance performed will be recorded in clean lab maintenance log books. All periodic maintenance schedules are prepared as checklists and are given in Appendix II.

4.1 All exposed bench surfaces and hood surfaces in the Class 100 room will be wiped with a lint-free, static-free wipe wetted with deionized water on a daily basis prior to any laboratory activities. (Appendix II, Page 16)

4.2 The floor in the Class 100 room will be mopped with tap water on the first working day of every week. A suitable metal-free detergent may be used when necessary. (Appendix II, Page 16)

4.3 The cleaning procedure described in Section 4.1 will be carried out in the Class 10000 area as well but with the exception that it will be performed once a week. (Appendix II, Page 17)

4.4 The cleaning procedure described in Section 4.2 will be carried out in the Class 10000 area as well but with the exception that it will be performed only once each month. (Appendix II, Page 17)

4.5 Sticky mats that are kept at entry doors of Class 100 and 10000 areas must be replaced when soiled. Proper maintenance of these sticky mats will minimize the entry of dirt into the clean area from chemist's feet. (Appendix II, Page 18)

4.6 All fume hoods will be inspected by the custodian for their proper operation regularly. The static pressure through the filter(s) in the fume hood will be monitored once a week and recorded in the log book (Appendix II, Pages 19-21)

4.7 The entrance and exit procedures and the transfer of items (samples, reagents, labware, apparatus etc.) from one area to another also play an important role in maintaining the cleanliness of the Clean Room Facility. These issues will be addressed by separate documents (NHX/SOP-300-006 and NHX/SOP-300-007).

5.0 CORRECTIVE ACTIONS

If any of the measured physical or chemical parameters indicate any sign of degradation of the cleanliness of the Clean Lab Facility it should be reported to the laboratory manager immediately. The laboratory manager is responsible for taking appropriate corrective actions to re-establish the cleanliness of the Clean Lab Facility.

TABLE 1. AIRBORNE PARTICULATE CLEANLINESS CLASSES

Class Name[a]	Class Limits[b] (particles/ft^3)
1	1.00
10	10.0
100	100
1,000	1,000
10,000	10,000
100,000	100,000

[a] Concentration limits for intermediate classes can be calculated, approximately, from the following equation:

$$\text{Particles}/m^3 = N_c(0.5/d)^{2.2}$$

Where "N_c" is the numerical designation of the class based on English (U.S. customary) units, and "d" is the particle size in µm.

[b] Class limits designate specific concentrations (particles per unit volume) of airborne particles with sizes equal to and larger than 0.5 µm diameter.

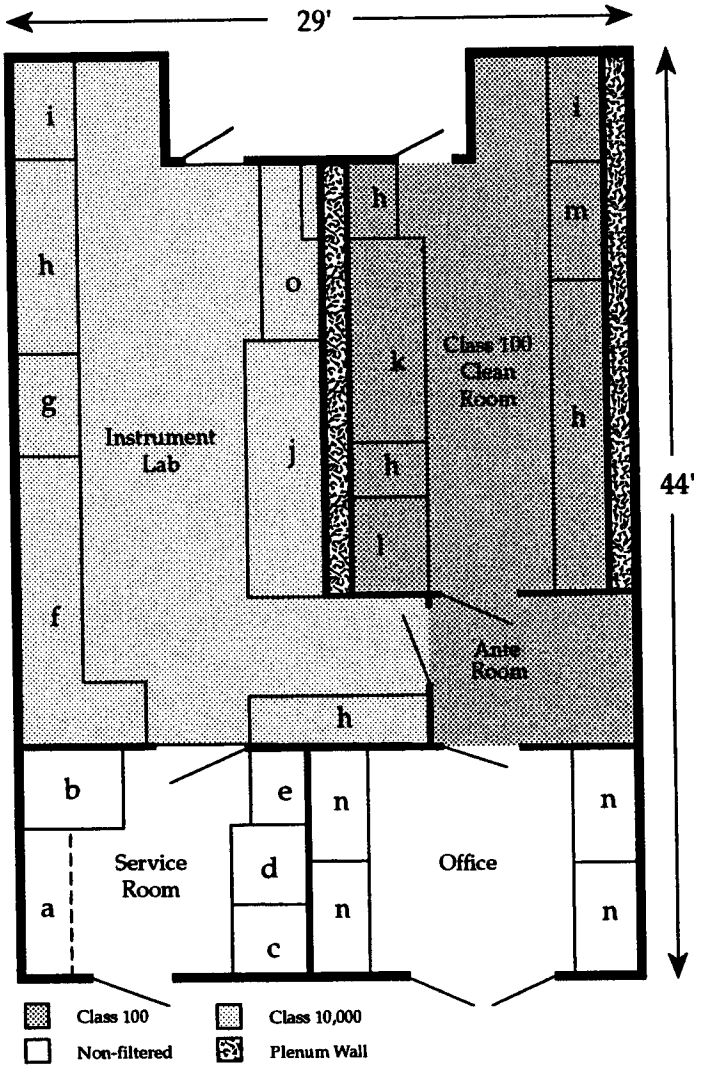
TABLE 2. SAMPLING LOCATIONS

Sampling Locations	No. of Samples
Class 100 Room	
11′ Bench	2
8′ Hood	2
Class 10,000 Room	
4′ Hood	1
On top of the GFAA Autosampler	1

TABLE 3. ACCEPTABLE CONTAMINANT LIMITS

Element	Limit[a] ($ng/cm^2/24$ h)
Pb	1.0
As	0.1
Cd	0.1

[a] Concentrations are given in ng of analyte per cm^2 of exposed area per 24 hours of sampling.



a.	Gas Cylinders	f.	PE 5100 ZL	k.	8′ HEPA Hood
b.	D. I. Water	g.	4′ HEPA Hood	l.	Non-HEPA 4′ Exhausting Hood
c.	Freezer	h.	Bench	m.	6′ Acid Baths
d.	Refrigerator	i.	Sink	n.	Desk
e.	Clean Room Supplies	j.	ICP	o.	Questron V6 AFS

Figure 1. ACS inorganic class 100/10,000 clean lab facility.

APPENDIX I

Introduction

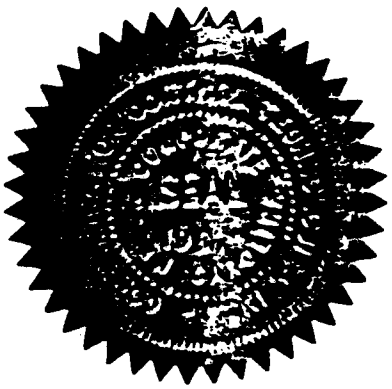
The purpose of this report is to provide an evaluation of the environmentally controlled areas at the **Research Triangle Institute** facility located in Research Triangle Park, North Carolina. This report provides data acquired April 25, 1994, by **Contamination Control Technologies, Inc.**, of Morrisville, North Carolina.

The data presented in this report is indicative of the performance of the mechanical systems, facility design, and installation of the environmentally controlled areas as of time and date tested. Testing was performed using Federal Standard 209E as general procedural guidelines.

The cleanrooms were tested in an "as built" state with the test technician being the only person present in the rooms during the evaluation.

The testing and evaluation was performed by the following Contamination Control Technologies, Inc. personnel:

Ulrich R. Dietrich
Director, Controlled Environment Testing



Contamination Control Technologies, Inc. is certified by the National Environmental Balancing Bureau as a Cleanroom Performance Testing Contractor.

Airborne Particle Count
Laser Particle Counter Method

PURPOSE:

This test is performed to measure the airborne particulate levels within the Class 100 and 10,000 Cleanrooms, the Anteroom, the two HEPA filtered workstations and the one exhaust hood and to identify potential problem areas.

INSTRUMENTATION:

Laser Particle Counter with Built-in Recorder
Manufacturer: Particle Measuring Systems, Inc. Model: LPC-525A
Calibration: November 15, 1993 SN: 12005-1287-14

PROCEDURE:

Sampling duration for each count is one minute, with a total sample volume of 1.0 cubic foot. Sampling height is approximately 46 inches above the floor. Three counts are taken at each sampling location. Counts are recorded for all particles greater than or equal to 0.5 micrometers and for all particles greater than or equal to 5.0 micrometers. A 95% upper confidence level (UCL) is calculated for each room for counts greater than or equal to 0.5 micrometers and for all particles greater than or equal to 5.0 micrometers as described in Federal Standard 209E.

RESULTS:

The rooms were tested in an "as built" condition, i.e., only testing personnel were present during the particle count sampling.

The Class 100 Cleanroom meets requirements for an English (U.S. customary) class 100 (at 0.5 µm and 5.0 µm) or a SI (metric) class M3.5 (at 0.5 µm and 5.0 µm) classification under "as built" conditions.

The Class 10,000 Cleanroom meets requirements for an English (U.S. customary) class 10,000 (at 0.5 µm and 5.0 µm) or a SI (metric) class M5.5 (at 0.5 µm and 5.0 µm) classification under "as built" conditions.

Particle count locations, particle counts, and the statistical analyses of the counts are provided on the following pages.

APPENDIX II

ROUTINE MAINTENANCE OF THE CLASS 100 LAB

1. Wiping of all surfaces (bench tops and hood areas) with a wetted (with deionized water) clean room wipe must be done at the beginning of each working day.
2. Mopping of the clean lab floor with tap water must be done on the first working day of every week.

Please sign and put check marks where appropriate after performing duties.

Month/Year: ....

Day	Date	Name	Wipe surfaces	Mop the floor	Initial
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					
Saturday					
Sunday					
Monday					
Tuesday					
Wednesday					
Thursday					
Friday					

ROUTINE MAINTENANCE OF THE CLASS 10,000 LAB

1. Wiping of all surfaces (bench tops and hood areas) with a wetted (with deionized water) wipe must be done on the first working day of every week.

2. Mopping of the clean lab floor with tap water must be done once every five weeks.

Please sign and put check marks where appropriate after performing duties.

Period: MM/YY - MM/YY

Date	Name	Wipe surfaces	Mop the floor	Initial

June 1995

ROUTINE MAINTENANCE PROCEDURE FOR HOODS IN THE CLEAN LAB FACILITY

Please notify R. Fernando (Room 192, Ext. 6730) in the event of any problem or malfunction of the hood operation.

Hood Type: 8' hood in the Class 100 Lab. Period: MM/YY - MM/YY.

Date	Pressure (i.w.g.)	Indicator Light		Comments	Initial
		Normal	Caution/Alert		

June 1995

ROUTINE MAINTENANCE PROCEDURE FOR HOODS IN THE CLEAN LAB FACILITY

Please notify R. Fernando (Room 192, Ext. 6730) in the event of any problem or malfunction of the hood operation.

Hood Type: 4' hood in the Class 100 Lab. Period: MM/YY - MM/YY.

Date	Pressure (i.w.g.)	Indicator Light		Comments	Initial
		Normal	Caution/Alert		

June 1995

ROUTINE MAINTENANCE OF THE CLEAN LAB FACILITY

- STICKY MAT REPLACEMENT -

Please record the date when a fresh sticky mat is exposed.

Location: CLASS 10,000 LAB		Location: ANTE ROOM	
Date	**Initial / Comments**	**Date**	**Initial / Comments**

June 1995

ROUTINE MAINTENANCE PROCEDURE FOR HOODS IN THE CLEAN LAB FACILITY

Please notify R. Fernando (Room 192, Ext. 6730) in the event of any problem or malfunction of the hood operation.

Hood Type: 4' hood in the Class 10,000 Lab. Period: MM/YY - MM/YY.

Date	Pressure (I.w.g.)	Indicator Light		Comments	Initial
		Normal	Caution/Alert		

June 1995