NOAA QUALITY ASSURANCE PROGRAM FOR MARINE ENVIRONMENTAL MEASUREMENTS

SUMMARY OF TECHNICAL WORKING GROUP

ON HUMAN PATHOGENS

Held at

National Oceanic and Atmospheric Administration
Northwest and Alaska Fisheries Center
2725 Montlake Boulevard East
Seattle, Washington 98112

January 1984

The National Oceanic and Atmospheric Administration (NOAA) has established five technical working groups to review current Quality Assurance (QA) Practices used for Marine Environmental Measurements. Following the reviews, the five technical working groups were asked to recommend actions that NOAA might consider to improve or maintain QA and to increase our knowledge of the estuarine and marine environments.

These technical groups include research areas in: (1) organic chemicals, (2) trace metals, (3) inorganic nutrients, (4) human pathogens, and (5) biological rate measurements. This report summarizes the review and discussions of the meeting of the technical working group on Human Pathogens which was held in Seattle, Washington, in January 1984. Scientists attending the meeting represented NOAA research laboratories, Universities, Gulf Coast Research Laboratories, and the Food and Drug Administration (Table 1).

Prior to the meeting, NOAA scientists, contractors, and grantees involved in Human Pathogen studies were asked to submit a written report on the methods and quality assurance practices following the outline listed in Table 2. Each of the five technical working groups followed this general outline in an attempt to standardize the responses. Even though this outline was prepared for chemical studies, all participants were asked to respond to the different points of the outline that applied to their specific research area.

Reports were received from all of the NOAA scientists known to be involved in Human Pathogen studies. In addition, responses were received from the some of the contractors and grantees supported by NOAA (Table 3). Scientists volunteered information on their Quality Assurance used in studies with bacteria, viruses, and protozoans (amoebae).

The reports from the different laboratories, however, varied considerably in length (ranging from 2 to 37 pages) and many of the reports referred to publications, manuals, and validated methodology for details. Because of these variations, the reports were used as points for discussions and the working group developed the following conclusions.

General Comments on Status of QA in Human Pathogen Studies

Each of the 13 reports submitted to the QA program referred to methods published in AOAC, Bacteriological Analytical Methods of FDA, or other validated methodology. When new methods were under investigation, spiked controls, intralaboratory comparisons, and other check points were used. After reviewing the reports and their attached publications and references, it was agreed that the different investigators preparing the reports were well aware of quality assurance. However, there were no QA programs commonly applied by all laboratories. This would aid the different laboratories to standardize their procedures and ensure comparability of the data.

The technical working group also concluded that the quality of research of any laboratory depends upon the integrity of the scientists and that this cannot be replaced by a quality assurance program. The group did conclude that a checklist or QA plan should be made available to the different laboratories. A Quality Assurance plan currently used by FDA was therefore reviewed. A similar plan (see attachment) should be prepared and made available to all NOAA laboratories as an "Umbrella Quality Assurance Plan." Specific QA plans (e.g., plans for tissue cultures, use of animals, etc.) should be prepared by individual laboratories. These "umbrella" and specific plans would be particularly useful to new

as well as established investigators and particularly valuable for students and visiting scientists. The plan, however, should not become too detailed or it would interfere with research and soon be discarded.

Specific Comments on Quality Assurance Plans

A good quality assurance plan should include (1) planning, (2) quality control, (3) quality assessment, and (4) handling of data and publications. All four steps of the process are integrated and cannot operate independently of the other.

Planning.

The intended use of the data should first be addressed. The investigator and associates must have proper training or obtain training for the specific study. An experimental design must be prepared, if possible with the assistance of a statistician and following consultation with other investigators studying the specific human pathogens. This in turn has a strong influence on the selection of methods and the number of samples to be examined. In field studies or surveillance studies, different options must be available and can be influenced by weather, availability of samples, etc.

Quality Control

Quality control in a laboratory centers on good laboratory practices. A Quality Control Plan of FDA is attached and should be considered, along with others, in the formulation of an overall Umbrella Plan. Again, specific plans should be considered for individual projects.

Quality Assessment

Quality assessment includes techniques and methods used to evaluate the precision and accuracy of measurements and the results. This should

involve the selection of a method that can be used to collect reliable data. Sometimes these methods are validated through intralaboratory or interlaboratory comparisons and published in AOAC, etc. In other cases, especially with recently recognized human pathogens, the suitability of the method must be established. This is especially true when one extends these methods to the determination of the presence of human pathogens in a natural environment such as estuarine and marine waters.

Quality assessment also involves the effect of different technicians, different equipment, and repeatability of measurements. Sampling procedures, storage conditions, temperature of samples, sample identification and history, and changes in custody are extremely important in human pathogen studies. For example, it is often assumed that the best procedure for handling microbiological samples is to refrigerate the samples to prevent microbial multiplication and/or die-off between collection and analysis. For certain pathogens, e.g., Vibrio cholerae and viruses, this could cause a great reduction in the specific population. The periodic use of samples spiked with the specific pathogen(s) under study should be included to assure that the methodology is adequate to detect the microorganisms in question in the environmental sample. Also the use of collaborative tests, reference samples, and the exchange of samples are important in validating a procedure. Significant error can also be introduced if a known human pathogen received from other laboratories is used without additional confirmation of purity and authenticity.

Handling of Data and Publications

Many tax dollars and scientific hours are involved in the collection of research data. The data therefore should be collected, recorded, and

stored in such a manner that it can be useful for future reference. The use of peer review for scientific publications is encountered when one submits manuscripts for publication in journals. If possible, peer review by specialists in the field is desirable prior to submission to a journal.

Because of limited space and the costs of scientific publication, the methodology section is often abbreviated. Investigators therefore should have details of methodology that could be available in future years.

Conclusions and Recommendations

1. Based upon the reports received from the different laboratories, investigators are well aware of the importance of quality assurance in research.

2. NOAA should develop a Quality Assurance Plan for Human Pathogen Study to standardize procedures and ensure comparability of results. This should consist of an umbrella plan that could be used by all laboratories including safety procedures for studies with human pathogens. QA plans for specific pathogenic studies should be prepared by individual laboratories. These plans should not be cumbersome requiring a lot of extra paper work.

3. Contractors and grantees should be furnished with NOAA umbrella QA plan, and specific QA plans should be submitted by the investigators along with how QA will be maintained by the investigator.

4. NOAA should encourage periodic meetings of the investigators working with human pathogens to discuss methodologies, problems, and other specific topics concerning human pathogens associated with the marine environment.

5. NOAA should encourage intra- and interlaboratory comparisons and set up mechanisms for these comparisons including sources of human pathogens. This would be especially useful for new grantees or contractors.

6. With increasing pollution of our coastal and ocean waters, there is a growing and urgent need to develop, establish, and standardize methodologies for the monitoring of human pathogens in such large bodies of water. NOAA should take the lead to fund long-term research of Human Pathogens in the estuarine and marine environment. These studies should focus on the following areas:

A) Determining whether present methodologies for detecting pathogens are adequate for organisms that are "nonrecoverable" with current culture procedures, but still viable.

B) Use of conventional tests for accepted indicators of fecal pollution as well as recently developed methods for enumerating specific pathogenic bacteria, viruses, and protozoans.

C) Through a coordinated study, establish a set of data for a variety of estuarine and coastal water systems to determine what human pathogens (bacteria, viruses, amoebae) are present and which organism or organisms best indicate survival of human pathogens from faecal pollution.

D) Determining the effects of seasonal variation, geographic location, oceanographic factors, salinity, industrial pollution, thermal pollution, etc., on human pathogens.

E) Studying pathogens in the marine environment on an annual basis is inadequate and should be conducted on a long-term basis considering variables listed under D) above.

F) Caution in interpreting the relationship of the data to the safety hazards in humans. For example, is the specific organism found in the marine environment pathogenic?

G) To determine whether the discharged waste materials selectively enriches for naturally occurring (autochthonous) pathogens. Also the need to know which pathogens are affected and how they are affected.

h) Development of more efficient recovery methods for studies on the distribution and survival of human pathogens in the marine environment. This should include rapid, reliable tests to assess the virulence of pathogens recovered from the marine environment. It should also include development of methods for the detection of some human enteropathogenic viruses which are noncultivable or difficult to grow in cell cultures.

REFERENCES

Huai-Shu Xu, N. Roberts, F. L. Singleton, R. W. Attwell, D. J. Grimes, and R. R. Colwell. 1982. Survival and viability of nonculturable Escherichia coli and Vibrio cholerae in the estuarine and marine environment. Microbiol. Ecol. 8:313-323.

L. H. Keith, W. Crummett, J. Deegan, Jr., R. A. Libby, J. K. Taylor, and G. Wentter. 1955. Principles of environmental analysis. Anal. Chem. 55:2210-2218.

Compendium of Methods for the Microbiological Examination of Foods. 1976. American Public Health Association, Washington, DC. Bacterial Analytical Manual, FDA, 1977.

Standard Methods for the Examination of Water and Wastewater. 15th Ed. 1980. APHA-AWWA-WPCF.

Microbiological Methods for Monitoring the Environment. Environmental Protection Agency. EPA-600/8-78-017.

Handbook for Sampling and Sample Preservation of Water and Wastewater. EPA-600/4-82-029. December 1982.

Part 15 - Sample Control Procedures and Chain of Custody

Part 16 - Quality Assurance

Manual for the Interim Certification of Laboratories Involved in Analyzing Public Drinking Water Supplies. EPA-600/8-78-008. May 1978.

Bureau of Foods Laboratory Quality Assurance Manual. FDA. 1982.

Table 1. NOAA Quality Assurance Committee on Human Pathogens

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Table 2. Outline: Information Requested from NOAA Scientists and NOAA Contractors/Grantees

1.0 Parameters of Interest

Human Pathogens

2.0 Matrices of Interest

- 2.1 Sediments, including flocculent material
- 2.2 Water, including interstitial water
- 2.3 Tissues, including edible and non-edible tissues
- 2.4 Surface films
- 2.5 Particulate matter, including suspended and settling matter

3.0 Rationale

- 3.1 Purpose of this study or research and intended use of the data
- 3.2 Level of precision and accuracy sought and level actually achieved
- 3.3 Limit of detection achieved and its mathematical definition

4.0 Methods, Procedures, and Practices of Interest

- 4.1 Sample collection
  - 4.1.1 Type of gear, unique deployment techniques
  - 4.1.2 Contamination prevention procedures
- 4.2 Sample transportation, including chain-of-custody procedures
- 4.3 Sample storage
- 4.4 Sample analysis
  - 4.4.1 Number of analyses in a typical year
  - 4.4.2 Determination of reagent purity
  - 4.4.3 Pretreatment
  - 4.4.4 Extraction, separation, purification
  - 4.4.5 Analytical instrumentation and techniques
- 4.5 Data reduction and analysis
- 4.6 Calibration, standardization, and testing
  - 4.6.1 Calibration studies
  - 4.6.2 Blank samples
  - 4.6.3 Spiked samples
  - 4.6.4 Replicate analysis
  - 4.6.5 Blind standards
  - 4.6.6 Standard Reference Materials
  - 4.6.7 Interlaboratory comparison
- 4.7 Publications
  - 4.7.1 Provide copies of publications dealing with the methods, procedures, and quality assurance practices described in Sections 4.1 and 4.6
  - 4.7.2 Provide list of publications containing data obtained by use of the methods, procedures, and quality assurance practices described in Sections 4.1 and 4.6

Table 3. List of Participants that Submitted Reports to Human Pathogens Quality Assurance Program

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Quality Assurance Plan
For the
Food and Cosmetics Microbiology Branch
And the Microanalytical Branch
Bureau of Foods, FDA

Amended April 29, 1982

Room No._____
Responsible Individual_____
Inspection Date_____

A. Historical Background

Using the check list supplied in the Phase II Report of the Bureau of Foods' Quality Assurance Task Force and the requirements of the Director of the Division of Microbiology, the Division's two Branches in DC conducted inspections of the Division's facilities in Federal Building 8 during October 1981. A safety inspection, using the check list supplied by the Bureau's Safety Office, was conducted simultaneously since there is overlap between QA and Safety requirements. Following the inspections, the Bureau's check list and the Division Director's requirements were modified into single plans for each Branch. The findings of the October inspections determined what modifications would be appropriate for a given Branch. In general simultaneous QA and Safety inspections were judged to be advisable in terms of thoroughness and efficiency. Inspections of one Branch by the other were judged advisable on occasion

B. The Working Plan

a. An internal inspection will take place quarterly.

b. Divisional QA Committee will designate inspection teams in such a manner that there will be no self inspection

C. Inspections will be conducted according to the QA/Safety Check List* that constitutes Part F of this document. This list should be modified as required by circumstances, but standards must not be comprised.

D. The findings of each inspection should be documented and the report made available to the inspected individual and to the Branch Chief.

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*"yes" and "NA" are acceptable; "no" is contrary to Branch requirements.

E. The Branch Chief or his designee will conduct unannounced follow-up inspections to determine whether deficiencies have been remedied and will take further action as required.

F. Quality/Assurance/Safety Check List for Laboratory Work.

THE ENVIROMENT

1. The Laboratory is in compliance with the Bureau of Foods Laboratory Safety Check List (see attachment).

2. Plumbing, heating, lighting, ventilation, etc. are routinely checked and monitored in a qualitative manner by labortory personnel for adequacy work being conducted.

( )Yes ( )No ( ) NA

3. Good housekeeping is practiced in terms of crowding, acess, safety factors and requlariti of cleaning. A designated individual will continue the above practices during abscences.

( )Yes ( ) No ( ) NA

4. Decontamination systems and procedures are adequate for the the type of work conducted.

( )Yes ( )No ( ) NA

5. Measure are taken to prevent, eliminate or reduce infestation by vermin such as insects and rodents.

( )Yes ( )No ( )NA

Microbiology Branch

6. Policy related to sample integrity and enviromental conditions is established concerning smoking, eating, and drinking in the laboratories; there will be no such activities at work benches or where interference with work could occur.

( )Yes ( )No ( )NA

(a) Animal facilities are arranged to facilitate cleaning, good housekeeping and the well being of the animals; animal areas are restricted to only those persons working with animals.

( )Yes ( )No ( )NA

(b) The Bureau wide requirements for animal quarantine, animal food storage, caging, labeling and reporting to the Veterinarian Medical Officer (HFF-6) are abhered to. Except that mice intended for totulism experiments be exempt from the quarantine requirements, since these mice are immediately used and discarded.

8. For bacteriology and mycology laboratories where work is done on open benches, the microbiological quality of the air is determined bi-weekly and the results are recorded. (This can be done by exposing an opened plate of non-selective general purpose medium to the air for 15 minutes. The colony count after incubation should not exceed 15. Included the specific negative environmental control where applicable). Where colony counts exceed 15 laboratory work is stopped and the entire roome is sanitized.

( )Yes ( )No ( )NA

9. Environmental and safety deficiencies beyond the control of group leaders are promptly reported to line management.

( )Yes ( )No ( )NA

II. PLANNING

1. Work plans (Protocols) include technical plans, experimental designs, methods have been developed for projects, and objectives are defined.

( )Yes ( )No ( )NA

2. Responsibilities in the work plans are detailed.

( )Yes ( )No ( )NA

3. All laboratories staff and working guest have received orientation in the Branch's quality assurance plan and are kept apprised of changes in laboratory procedures.

( )Yes ( )No ( )NA

4. Team leaders establish project priorities at least annually in consultation with Branch Chief and Division Director; priorities are reexamined quarterly.

( )Yes ( )No ( )NA

5. Work is monitored thoroughly by team leader at least ~~on a monthly basis and by Branch Chief at least~~ quarterly.

( )Yes ( )No ( )NA

6. Written reports are submitted by team leaders to Branch Chief on quarterly basis at minimum.

( )Yes ( )No ( )NA

II Materials

1. (a) Chemicals, media, and reagents are dated when received or prepared. Chemicals are dated and initialed when opened. If efficacy tests are performed on media, the results are entered into a numbered, bound notebook. Outdated chemicals, media and reagents are discarded according to proper procedures. If reaents/chemicals/etc. are retained past their expiration date or a receipt and/or opened date is not known, the container will be marked with a red dot 1/4-12" diameter which signfies that the item is for testing (preliminary) studies only. Review of dated reagent will be done on a quarterly basis. Red dotted items are not to be used for quantitative work final studies, or regulatory samples because age and/or purity is not known.

( )Yes ( )No ( )NA

(b) Purities of chemicals, reagent, toxin and antibodies are to be within tolerance for the studies being conducted.

( )Yes ( )No ( )NA

2. Biological standards, such as bacterial stocks strains, which are kept in culture or storage are checked for purity/authrnyivity before use. The results are entered into a numbered, bound notebook.

( )Yes ( )No ( )NA

3. When solutions are prepared and standarized (or restandardized), the date, analyst, weights, volumes, calculations and others appropriate data (temperature, lot number etc.) are recorded.

( )Yes ( )No ( )NA

4. Prepared solutions shall be marked with the following information: solution/reagent, concentration, date, name of preparer, use before _____, any special information such as storage conditions. Some solutions and stock chemicals may not degrade with time and therefore may be marked "expiration date indefinate" or in some similar manner indicating that there is no minimum time by which the solution should be used.

( ) Yes ( ) No ( ) NA

5. Many solvents/reagents such as methanol, ethanol, etc. are bought in "large" containers and then poured without dilution into small glass or plastic bottles for use at the bench. It would have little meaning if these small "bench bottles" were dated since the only date which could be used would be the date when the bottle was last filled. Therefore, bench bottles will be clearly marked with the name of the solvent/reagent and the name of the user.

( ) Yes ( ) No ( ) NA

6. All reference materials meet the following established performance specifications: they are (a) well characterized, (b) in the same quality state as the test item being compared, (c) of known stability, and (d) properly labeled.

( ) Yes ( ) No ( ) NA

7. Reagent blanks and/or recovery controls are utilized as part of the analyses.

( ) Yes ( ) No ( ) NA

8. All volumetric implements used for measuring, and not precalibrated, are calibrated on a routine and/or periodic basis.

( ) Yes ( ) No ( ) NA

9. Implements are appropriately clean prior to use.

( ) Yes ( ) No ( ) NA

10. Chipped, corroded excessively worn implements are discarded.

( ) Yes ( ) No ( ) NA

IV. INSTRUMENTS AND EQUIPMENT

1. All pieces of equipment are located in an appropriate environment which will assure proper functioning.

( ) Yes ( ) No ( ) NA

2. All pieces of equipment are properly operated in consultation with manufacturer's recommendations.

( ) Yes ( ) No ( ) NA

3. Instruments are calibrated/standardized prior to use, and as needed during use. These calibration/standardization records are kept.

( ) Yes ( ) No ( ) NA

a. Balances are checked for accuracy and adjusted before use and have appropriate sensitivity (e.g., $\pm$ 0.1 g with a 200 g load for common beam balances). Each balance will be calibrated annually using a primary standard.

( ) Yes ( ) No ( ) NA

b. Refrigerators not supplied with temperature recorders are equipped with an indicating thermometer partially immersed in water. The temperture in each refrigerator in use is recorded and initialed at leaast once daily during the workweek. During absences adesignated individual will record temperature and initial record book. The record of temperatures is kept in the laboratory for at least 6 months prior to discard.

( )Yes ( )No ( )NA

c. Incubators that do not have temperature recorders when in use shal be equipped with theromometer(s) immersed in water. Tempertures are read and recorded at least daily during the workweek and a record is kept in the laboratory for at least 6 months. During absence adesignated individual will record temperature and initial record book.

( )Yes ( )No ( )NA

d. Moisture levels in bacteriological/mycological incubators are such that agar in petri dishes does not lose more than 15% in weight during a 48-hour period in the incubators. Tests are done at least once in 3 months and records kept in the laboratory.

( )Yes ( )No ( )NA

e. Where recorders are used in autoclaves, incubators and refrigerators, the charts are changes before overprinting occurs. Pens and ink are check daily.

( )Yes ( )No ( )NA

f. All thermomrters shall be calibrated for the temperature range in which they are used. Results chall be recorded in a permament record kept in the laboratory. Wherever practicable.

corrections shall be indicated on a card attached to the thermometer.

( ) Yes ( ) No ( ) NA

4. a. Instrument and equipment manuals are kept in a location readily accessible to laboratory personnel. The laboratory has a program of preventive maintenance for instruments and equipment that can be maintained by laboratory personnel. Any irregularity in equipment function shall be immediately reported to the supervisor(s). All equipment not in regular use or not properly functioning is tagged immediately.

( ) Yes ( ) No ( ) NA

b. This information is recorded.

( ) Yes ( ) No ( ) NA

c. Principal user(s) or monitor(s) for delicate instruments and equipment are identified.

( ) Yes ( ) No ( ) NA

d. Personnel are familiar with procedures for obtaining instrument/equipment repair.

( ) Yes ( ) No ( ) NA

V. DOCUMENTATION OF SAMPLES AND WORK

1. Original data are properly and completely recorded and stored in designated repositories in the lab following active use. Bound books are used unless inappropriate.

( ) Yes ( ) No ( ) NA

2. Integrity of data which cannot be recorded in bound laboratory notebooks is maintained (e.g., cross reference computer data, tapes, graphs, charts, etc.).

( )Yes ( )No ( )NA

3. All data records are appropriately indexed and identified by name, date, number, etc.

( )Yes ( )No ( )NA

4. Laboratory reports and manuscripts on completed work are reviewed by approriate supervisors.

( )Yes ( )No ( )NA

5. A means of recording receipt and accountability of research, survey, investigational, sonsumer complaint, interdivisional, etc., samples is established.

( )Yes ( )No ( )Na

6. When a system for accountability of reference standards for regulatory or ordinary samples is established:

(a) The system defines the standards specifications.

( )Yes ( )No ( )NA

(b) It includes a respository (or repositories).

( )Yes ( )No ( )NA

(c) It documents purity or identity, use individual using standard, and other data which establish standard authenticity.

( )Yes ( )No ( )NA

7. When a means of identifying regulatory samples is established:

   a. An individual(s) is designated as responsible for making this identification.

   ( ) Yes ( ) No ( ) NA

   b. A sample accountability record is always used.

   ( ) Yes ( ) No ( ) NA

8. All laboratory personnel and supervisors who work on regulatory samples are familiar with the information found in Chapter 7-40 of Part 7 of the Regulatory Procedures Manual (RPM) and the Analyst Operations Manual (AOM), Chapter 9.

   ( ) Yes ( ) No ( ) NA

   a. Copies of the pertinent portions of these manuals are readily available.

   ( ) Yes ( ) No ( ) NA

   b. Regulatory sample analyses are conducted in accordance with these manuals to insure sample integrity and accountability throughout receipt, storage, handling, preparation and analyses.

   ( ) Yes ( ) No ( ) NA

9. There is a checking system to insure that analyst's worksheets for regulatory samples are properly filled out and utilized in accordance with AOM procedures.

   ( ) Yes ( ) No ( ) NA

10. Check analyses are run on violative regulatory samples by the same method or another official method, if possible.

    ( ) Yes ( ) No ( ) NA

LABORATORY SAFETY CHECKLIST

GENERAL

Corridors, aisles and walkways are maintained clear of obstructions.

( ) Yes ( ) No ( ) NA

Caution and warning signs posted on lab door windows as needed. Other vision obstructing material is not posted.

( ) Yes ( ) No ( ) NA

Two unobstructed exits are provided from each lab.

( ) Yes ( ) No ( ) NA

Materials and supplies, which could create a falling hazard, are not stored on top of cabinets, refrigerators, etc.

( ) Yes ( ) No ( ) NA

Fire extinguishers are mounted, inspected each year and easily accessible.

( ) Yes ( ) No ( ) NA

Compressed gas cylinders are securely strapped at all times.

( ) Yes ( ) No ( ) NA

Compressed gas cylinders are transported with regulators removed and cylinder caps in place.

( ) Yes ( ) No ( ) NA

Areas where mercury is used or stored (in manometers, polarographs, vacuum diffusion pumps, etc.) are visually free of mercury contamination.

( ) Yes ( ) No ( ) NA

Heat producing appliances are used only on noncombustible surfaces.

( ) Yes ( ) No ( ) NA

Pressurized glass vessels such as vacuum desicators are shielded.

( ) Yes ( ) No ( ) NA

Water is maintained in the traps of cupsinks.

( ) Yes ( ) No ( ) NA

Glass vacuum systems are taped or shielded.

( ) Yes ( ) No ( ) NA

Compressed air used for cleaning is limited to 30 psig or less.

( ) Yes ( ) No ( ) NA

Laboratory stools are in good condition.

( ) Yes ( ) No ( ) NA

Use 1% hypochlorite solution to wipe laboratory table tops before and after work.

( ) Yes ( ) No ( ) NA

Use cotton plugged pipets for nontoxic materials e.g., spores but use propipets or other devices for pipetting toxic materials.

( ) Yes ( ) No ( ) NA

Use biohazard hood for transfer of toxic materials.

( ) Yes ( ) No ( ) NA

Centrifuge toxic materials in a hermetically closed centrifuge with safety cups.

( ) Yes ( ) No ( ) NA

Personally take all bacterial toxic materials to the autoclave and see that it is sterilized immediately.

( ) Yes ( ) No ( ) NA

Do not work alone with anesthetic solvents, explosive solvents and dangerous equipment in the laboratory or animal rooms after hours or weekends.

( ) Yes ( ) No ( ) NA

In a very visible location list phone numbers where specific therapeutic antitoxin related to your work can be obtained in case of emergency.

( ) Yes ( ) No ( ) NA

SAFETY EQUIPMENT

All laboratory personnel should wear lab coats, safety glasses, protective gloves and masks when necessary.

( ) Yes ( ) No ( ) NA

Visitor spectacles are available for transients.

( ) Yes ( ) No ( ) NA

Closed-toe shoes (but not ~~sneakers or~~ slippers) are worn in laboratories.

( ) Yes ( ) No ( ) NA

Emergency respirators are unobstructed and maintained.

( ) Yes ( ) No ( ) NA

Eyewash stations are installed and access to them is unobstructed.

( ) Yes ( ) No ( ) NA

Emergency shower is unobstructed and checked twice/year.

( ) Yes ( ) No ( ) NA

Fire blankets are available nearby.

( ) Yes ( ) No ( ) NA

TLD badges are worn by radiation workers.

( ) Yes ( ) No ( ) NA

CHEMICAL HAZARDS

Laboratory work benches are clear of excess chemicals.

( ) Yes ( ) No ( ) NA

Food and drink are not stored in laboratory refrigerators along with reagents, radioactive materials or bacteriological cultures.

( ) Yes ( ) No ( ) NA

Laboratory chemicals are not stored on floors.

( ) Yes ( ) No ( ) NA

Chemical storage shelves are anchored firmly to prevent tipping.

( ) Yes ( ) No ( ) NA

Laboratory hood ventilation has been checked within the past year and arrows indicating adequate air flow are affixed to the sash.

( ) Yes ( ) No ( ) NA

Hazardous chemicals are used inside laboratory hoods.

( ) Yes ( ) No ( ) NA

Laboratory hoods are not used for general storage.

( ) Yes ( ) No ( ) NA

All chemical containers are labeled as to their content.

( ) Yes ( ) No ( ) NA

Quantities of solvents are limited to 1 gal./lab unless stored in flammable storage cabinet.

( ) Yes ( ) No ( ) NA

Explosion resistant refrigerators/freezers are used for the storage of flammable chemicals requiring refrigeration.

( ) Yes ( ) No ( ) NA

Peroxide forming chemicals, ethyl ehter, chloroform are receipt dated. Also watch for MT ether evaporating cans.

( ) Yes ( ) No ( ) NA

Mechanical pipetting devices are used.

( ) Yes ( ) No ( ) NA

Caustic and flammable chemicals are stored low.

( ) Yes ( ) No ( ) NA

Chemicals with a limited shelf life are receipt dated and disposed of when shelf life has expired.

( ) Yes ( ) No ( ) NA

Chemical spill cleanup kits are available where needed.

( ) Yes ( ) No ( ) NA

ELECTRICAL - MECHANICAL

Power cords are in good condition (free of any obvious breaks in insulation).

( ) Yes ( ) No ( ) NA

Pigtail adapters are not used.

( ) Yes ( ) No ( ) NA

Hot water/constant temperature bath units are independently grounded. If not three prong plug.

( ) Yes ( ) No ( ) NA

Extension cords are not used as a replacement for permanent wiring.

( ) Yes ( ) No ( ) NA

Portable laboratory equipment, such as dryers, variacs, blenders, mixers, etc., are properly grounded with a three prong grounded plug.

( ) Yes ( ) No ( ) NA

Water and vacuum pumps, electric stirring machines, and electric motors have a suitable belt guard, or are enclosed in an instrument.

( ) Yes ( ) No ( ) NA

Metal desk lamps are <u>not</u> used on metal surfaces near water sources.

( ) Yes ( ) No ( ) NA

Animal Care and Breeding

STANDARD OPERATING PROCEDURE

1. All newly received animals from outside sources shall be placed in quarantine until their health status has been evaluated.

2. Moribund and dead animals shall be sacrificed and diagnosed for cause of illness.

3. Cages, racks and accessory equipment shall be cleaned and sanitized at weekly intervals.

4. Feed and water shall be checked daily.

5. Mice after quarantine and in satisfactory health shall be placed in holding cages 15♀ and 5 ♂. No more than 20 mice per holding cage.

6. Holding cages shall be numbered and identified by investigator name, date or arrival, date mated.

7. Mice, 16-18 days pregnant shall be transferred from holding cage to individual plastic shoe boxes.