REPORT

on

BIOSAFETY AT THE CENTER FOR DISEASE CONTROL

by

THE TASK FORCE ON LABORATORY SAFETY

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : Director, CDC

DATE:

FROM : Chairman, Task Force on Laboratory Safety

SUBJECT: Transmittal and Summary of Report

Transmitted herewith is the report of the Task Force on Laboratory Safety. The Task Force was given the mission of identifying biohazards at CDC and recommending ways of abating these. The report contains many recommendations; however, we wish to call to your attention in this memorandum the more important findings and recommendations.

1. New facilities which incorporate the safest engineering and design features for handling hazardous agents should be constructed as soon as possible. The present facilities at Clifton Road and Chamblee are not adequate to handle many of the kinds of organisms now being studied. Many laboratories do not meet the operational requirements published in Lab Safety at the CDC(1). Several stop-gap steps should be taken: a) Provide adequate containment equipment (BSC), b) Provide adequate autoclaving facilities, c) Establish and enforce restricted areas of access, d) Provide clean areas for eating, drinking, and smoking.

2. An Office of Biosafety with expanded staff and range of competence should be established and separated from other functions presently performed by the Office of Biosafety. Duties assigned to this Office should be exclusively those relating to the control of biohazards at all CDC stations. These duties should include monitoring, control, consultation, investigation, training, and research.

3. A Biohazard Control Committee should be established to serve as technical advisors to the Office of Biosafety. The Director of the Office of Biosafety should report the progress of the biosafety program to the Biohazard Committee at regular intervals. The Committee should be composed of a small number (possibly 5 or 6) of highly knowledgeable individuals, such as a virologist, bacteriologist, physician, epidemiologist and environmental engineer. The Committee would assist in identifying needs; provide support, advice, and guidance to all aspects of the CDC biosafety program; and report on a regular basis to the Director, CDC.

4. Longterm measures should include: a) Developing a functioning employee immunization program, b) Developing a plan for medical surveillance of illness among CDC employees, c) Establishing a biosafety training program, d) Revising the CDC Lab Safety manual, e) Reviewing and improving procedures for identifying infectious agents in animal quarters, f) Requiring protective garments to be worn while working in the lab and street clothing to be worn elsewhere, g) Prohibiting

infectious materials to be taken from the laboratory areas except in tightly closed containers, h) Opening all specimens suspected of containing Class 4 agents only in the Maximum Containment Laboratory, i) Centrifuging infectious materials only in safety cups or in centrifuges housed in containment cabinets.

In addition to the summaries in the attached report, all of the returned questionnaires and analyses, interview notes, employee written comments, and Task Force notes are available for further study and analysis.

The Task Force studied only safety problems directly related to biohazards; however, we received several comments about chemical hazards. Personnel in some chemistry laboratories (toxicology) are concerned about the possibility of being exposed to infectious agents in specimens submitted for chemical analysis; so a similar study for these hazards may be indicated.

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October 31, 1977
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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Center for Disease Control
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I. INTRODUCTION

Biosafety at the Center for Disease Control (CDC) has always been of primary concern to employees at all levels because of the nature of much of the research, diagnostic work, and training they conduct. Before the present facilities were constructed considerable thought and research went into planning and design of the physical arrangement and the air handling equipment. Also before occupying these facilities, procedures were established for handling and disposing of infectious materials representing various degree of hazards (1). However, during the 17 years in which the present facilities have been occupied, there have been numerous modifications of buildings and air handling systems. Safety procedures have also been revised and in some instances ignored. Etiologic agents of disease whose existence was unknown when the original planning was done are being isolated, identified, and studied. Numerous instances of illness have occurred among CDC employees which were related to their employment at CDC. The death of two employees from Rocky Mountain spotted fever (2) stimulated the formation of this task force to review the facilities, policies, procedures and practices relating to biosafety and to attempt to assess the gap between procedures and practices.

The Task Force was appointed by the Director, CDC, on March 9, 1977, as follows:

Dr. John V. Bennett	Dr. Robert H. Huffaker
Dr. Adrian Chappell	Mr. Norman J. Petersen
Mr. Robert J. Cotton	Mr. Leslie G. Schaum
Dr. Paul M. Feorino	Mr. Bradford P. Smith
Dr. John E. Forney, Chm.	Mr. David Weathers

Subsequently, Dr. William J. Martone was appointed to the Task Force by the Chairman.

The Task Force first met on March 14, 1977, and then daily for the next two weeks. During the first meeting, Dr. David J. Sencer, then Director, CDC, and Dr. Roslyn Q. Robinson, Director, Bureau of Laboratories, discussed with the Task Force some aspects of the biosafety program which they believed should be studied. The Task Force decided to collect data for use in preparing final recommendations by four means: (a) interviews with CDC employees, (b) personal observations and inspections, (c) review of records and published procedures, and (d) questionnaires distributed to all CDC employees including those stationed at Fort Collins, Colorado; Phoenix, Arizona; San Juan, Puerto Rico; Cincinnati, Ohio; and Morgantown, West Virginia.

INTERVIEWS

A. Members of the Task Force assisted by Mr. Jerry Brimberry and Mr. James D. Lewis, interviewed all but two or three employees from

Building 7 (virology laboratory building). Representative personnel from the Technical Services Branch and from Engineering Services were also interviewed (Exhibit 1).

B. The Task Force as a whole interviewed Dr. H. Bruce Dull, Chairman of the Medical Advisory Board; Dr. Richard E. Dixon, Chairman of the committee studying the circumstances surrounding the deaths of two employees from Rocky Mountain spotted fever; Dr. John Richardson, Director of the Office of Biosafety; Dr. George H. Connell, Chairman of the CDC Safety Committee; and Dr. Lonnie C. Jenkins, of the CDC clinic.

OBSERVATIONS AND INSPECTIONS

Members of the Task Force conducted a floor-by-floor inspection of Building 7, with special attention to the direction of airflow in each laboratory. The Task Force also directed its attention to the manner in which materials are handled in the central autoclave rooms. One member of the Task Force conducted a similar room-by-room and floor-by-floor inspection of Building 5, and Buildings 6, 7, and 21 at Chamblee.

PROCEDURES

The staffing and duty assignments of the Office of Biosafety were reviewed. Other documents studied were the CDC LABORATORY SAFETY manual (3), the operating procedures of the Data and Specimen Handling (DASH) activity and Technical Services, and the records of servicing the biological safety cabinets.

QUESTIONNAIRES

The Task Force broke into four subcommittees and prepared questionnaires for these four groups: nonlaboratory personnel, support and service personnel, laboratory bench workers, and laboratory supervisors. Ms. Jeannine Connell and Mr. Albert M. Barber helped prepare the questionnaires. Responses to items on the questionnaires covered the past six months. The numbers of questionnaires distributed and the percentages returned are:

6828

Nonlaboratorians	1,407	66%
Support and Service	383	48%
Bench Workers	460	99%
Supervisors	185	89%

Data from all questionnaires were stored in the computer. Comments received on many of the questionnaires have been summarized.

Problems identified fell into several broad categories:

a) Facilities and Equipment
b) Procedures
c) Medical Surveillance
d) Immunization
e) Training
f) Office of Biosafety

Therefore, the problems and recommendations will be presented under these headings.

Although data were collected from CDC locations other than 1600 Clifton Road, the Task Force's principal effort was directed toward the problems at 1600 Clifton Road. Insofar as similar problems exist at other sites, however, the same recommendations apply.

While the Task Force was collecting data, analyzing information and formulating recommendations, several memoranda were issued and several procedural changes made. These are presented in Exhibit 2.

II. FACILITIES AND EQUIPMENT

During the past 17 years the CDC facilities at 1600 Clifton Road have been frequently and, in some instances, extensively remodeled to provide space for new programs. In some instances, expediency has dictated the use of existing facilities rather than building ideal facilities to meet a functional need. As new techniques are developed for culturing etiologic agents of disease, more highly infectious agents can be and are being cultivated. Furthermore, for such purposes as antigen production, large quantities must be produced. Thus, any mishap or breach of technique has the potential for extensive contamination of workers and the environment. This is particularly of concern where expediency has required that organisms be handled in facilities with less than optimal containment.

Great reliance is placed upon a properly functioning air handling system which incorporates the principle of one-pass air through laboratories, with increased localized control created by negative pressure (Class 1) cabinets. The airflow in some areas is so delicately balanced that even a slight disruption or malfunction may reverse the direction of airflow in a laboratory or biological safety cabinet (BSC). This condition has been reported in the questionnaires, comments, and interviews, and by members of this Task Force.

PROBLEM

1. Building 7, 1600 Clifton Road

   A. This building is too readily accessible to the general public. Persons with no real need to be in the building can enter directly from the parking lot or the catwalks connecting it with other CDC buildings. The only barriers are warning signs on all outer doors and these are frequently ignored. Because of this easy access, even employees who work in the building have no "psychological" barrier and no sense of entering a more hazardous area. Furthermore, there is no barrier between office and administrative areas and laboratory areas, so management and clerical personnel are at risk of being directly exposed to infectious agents accidentally released into the environment.

   B. Building 7 is designed to have negative pressure in the laboratories relative to that in the corridors. However, because of extensive modifications which have been made in some areas, and some basic deficiencies in the building design, this condition does not always exist. Some labs always have positive pressure, (i.e., air blows out into corridors), and some have positive pressure at one time and negative pressure at another. In some laboratories the air flows from the small rooms that contain the BSC's into the main laboratory room. Therefore, the plan for airflow from the cleaner areas into the less clean areas is constantly compromised and the danger of infection is increased.

Air flow direction was checked in Building 5. Air from rooms 108, 131, 136, 318, and 319 flowed strongly outward into the corridor. Rooms B12, 234, 312, and 318 were being used with the corridor doors open so the direction of airflow was difficult to assess. An attempt should be made to readjust the airflow in this building also.

C. In Building 7 there is currently little or no differentiation among laboratories in which work with Class 2, Class 3, or potentially Class 4 agents is performed (4). Basically, the physical layout of all the Building 7 laboratories is the same, even though work is performed on viruses in 14 different CDC precaution categories. These categories reflect a large range of potential biohazards. The basic design of most of the labs is adequate only for working with low hazard viruses or other agents (Class 2); it is not adequate for working with moderate or high hazard viruses or agents (Clases 3 and 4).

D. The design of Building 7 is such that there is no real separation between clean and dirty areas; and because of the erratic airflow patterns, no particular area can be guaranteed clean. In fact, calling some areas "clean" leads to a false sense of security. The only "clean" lunch area is a small room which looks out upon racks of contaminated material waiting to be autoclaved.

E. Building 7 is poorly designed for virus work, crowded, and cluttered. The numerous places where dust and dirt can collect include light fixtures, the utility pipes, the air ducts, external shelves, cabinets that do not go to the ceiling, ledges that are cracked and discontinuous, and the tops of BSC's. Functions of different hazard levels cannot be properly segregated because the building is so crowded that all space has to be fully utilized. Because of a lack of storage space, the building is cluttered with glassware, and equipment is permanently stored on ledges and even in BSC's. Because of lack of adequate office space for professional personnel, work cubicles are jointly used for technical and office work.

F. Inspection of Building 5 and Buildings 6, 7, and 21 at Chamblee disclosed that Class 3 bacteria and fungi are being worked with in these locations. The facilities available for this purpose are inadequate because of problems with air handling, inadequate provision for terminal sterilization, and insufficient containment equipment.

RECOMMENDATION

We conclude (a) that Buildings 5 and 7 and Buildings 6, 7, and 21 at Chamblee are inherently unsafe for much of the work being performed in them, (b) that CDC should provide working facilities that are as safe as

possible for the employees, and (c) that because of CDC's worldwide stature it should have "showcase" facilities to demonstrate to health officials who come here, how hazardous work can best be performed. We therefore recommend that new facilities be constructed which will meet these requirements.

A high-level containment building suitable for handling Class 3 and 4 organisms and the large volumes of Class 1 and 2 organisms now being produced in Building 7 as well as in Building 5, and Buildings 6, 7, and 21 at Chamblee is essential and should ideally have at least the following design characteristics:

1. One-story style construction
2. Restricted areas, i.e., by card, airlock, or other type of barrier
3. Well-engineered air handling system
4. Intralaboratory decontamination and sterilization facilities
5. Facilities for terminal decontamination of liquid effluent from containment areas
6. Separation of laboratory and office space
7. Animal facilities including space for conducting aerosol experiments
8. Facilities for conducting training in containment of DNA experiments as well as other hazardous procedures
9. Preferably located in a sparsely populated area.

Buildings 8 and 9 meet many of these design characteristics, but they are too small to support the present workload of CDC laboratories with hazardous agents and therefore restrict work to only a few Class 4 viral agents.

We recognize the inevitable time lag in the funding and construction of new facilities. Therefore certain "stop-gap" alterations must be instituted to reduce the biohazards in the present facilities.

PROBLEM

2. Biological Safety Cabinets

A. There have been repeated reports of malfunctioning negative pressure cabinets (BSC), i.e., insufficient airflow, variation in airflow, and even reversal of airflow. Of the 149 laboratory supervisors who responded to the questionnaire, 33% of those who work with Class 3 agents and 43% of those who work with Class 4 agents reported instances of malfunction of cabinets. In interviews of 63 scientific personnel in Building 7 who work with cabinets, 57% did not believe the BSC to be functioning correctly. Members of the safety committee tested all of the BSC's in Building 7 and found that all but two were functioning

below 75 linear feet per minute, the airflow required to meet safety standards; indeed, all but two had airflow of less than 50 linear feet per minute and some showed essentially no air movement. Furthermore, most of the BSC's are in small rooms where door movements drastically affect airflow patterns.

B. Another difficulty associated with the BSC's is that the airflow is shut off in the evening between 4:30 and 5:00 p.m. as an economy measure. This often results in a loss of airflow while laboratorians are still working, exposing them to infectious material. Twenty-three percent of the laboratory workers in Building 7 who use BSC's indicated that this had occurred while they were using a BSC after 4:30. In addition, almost all workers using BSC's reported unscheduled shutdown of exhaust fans during the usual work day. Currently, the only exhaust air that is filtered is the air going through the BSC. When this airflow is stopped, contaminated air spills out into the room and eventually leaves the building without being filtered.

RECOMMENDATIONS

A. All BSC's should be critically and repeatedly checked for proper function. If they cannot be made to operate at 75 linear feet per minute air velocity, they should be repaired or replaced. Repair might consist of increasing airflow, installing larger motors and more effective fans or installing glove ports. If repair is not possible, the cabinets should be replaced with vertical laminar flow biological safety cabinets (Class II, type 1) that protect both the worker and the material being worked with. Many cabinets are in small rooms that are drastically affected by the opening of doors. The room air-cabinet interaction should be checked. All of this effort should be coordinated with a review of the hazard level of the work being performed so that hazard and containment level are in consonance.

B. Shutting off the building and BSC airflow at 4:30-5:00 p.m. saves energy, but creates a biohazard in the labs if work is still in progress. Either all work must stop at that time or a compromise be reached to leave the air on to a later time.

PROBLEM

3. Autoclaves

A. Personnel in five Virology Branches in Building 7, and three Mycology Branches, and four Bacteriology Branches in Building 5 work with Class 3 agents. None of the laboratories in which these employees work contains an autoclave for decontaminating discarded material. This means that highly infectious material

must be taken out of the laboratory, carted through the halls to the "dirty glassware" rack at the end of each floor (sometimes next to the elevators) and left there until space is available in the community autoclave. Consequently, infectious material may remain untreated overnight or over a weekend. This procedure affords multiple opportunities for accidents to occur, both through spillage and aerosol exposure. The proximity of dirty glassware to the elevator shaft is particularly distressing and raises serious speculations as to airborne hazards.

B. There is no autoclave for contaminated material in the SSB of Building 7. Therefore, contaminated material is carted down the hall, placed in an elevator, taken off at some other floor, and left on a dirty glassware rack to be autoclaved when space is available in a community autoclave. Since personnel in the two Branches located in the SSB work with Class 3 and Class 4 viruses, the biohazard is clearly evident and indefensible.

C. Condensate drains for almost all dirty glassware autoclaves are open to the autoclave room or pipechase. There is evidence as well as opinion that aerosols of infectious agents are discharged from the open drains as the autoclave cycle is begun. Since the temperature of the initially exhausted air-vapor mixture is not very high, it may contain infectious material.

RECOMMENDATIONS

A. Each laboratory in which work with Class 3 or 4 agents is performed should contain an autoclave so that contaminated material can be autoclaved before it leaves the laboratory area.

B. The condensate drains should be sealed as soon as possible.

C. Performance of autoclaves must be monitored during each cycle and periodically reviewed by the Office of Biosafety and checked by biological monitoring.

PROBLEM

4. Animal Quarters

A. Building 6 has the same problems with airflow, cabinets, and autoclaves as the other buildings. Air balance between animal quarters and office space is critical and every effort should be made to keep office areas under positive pressure in relation to the animal quarters.

B. There are no adequate containment facilities for especially infectious animals such as influenza-infected ferrets.

RECOMMENDATIONS

A. An engineering study should be made of the air handling equipment with particular attention to "fail-safe" and back up systems to prevent air from animal quarters being forced into office areas.

B. The need for BSC's in the animal quarters should be reviewed and appropriate cabinets purchased.

C. Autoclaves in this building should be monitored and modified as necessary.

PROBLEM

5. Centrifuges

Of 149 laboratory supervisors questioned, 30% indicated that at least one specimen container had been broken in the last six months while being centrifuged. This type of accident produces an extensive aerosol, and the centrifuge is difficult to decontaminate. Such accidents, therefore, present definite biohazards.

RECOMMENDATION

Purchase and use of safety screw cap centrifuge containers should be mandatory for centrifuging infectious agents as this will reduce aerosol formation to the zero level. In some situations the centrifuge should be housed in a containment cabinet with filtered exhaust.

PROBLEM

6. Discard pans

Employees complained that discard pans issued to the laboratories occasionally develop leaks. This permits contamination of the environment.

RECOMMENDATION

All discard pans should be checked under pressure in a water tank before being issued to the laboratories.

III. PROCEDURES

PROBLEM

1. Access to Laboratories

Persons other than those working in laboratory areas frequently visit those areas. Of the nonlaboratory personnel, 130 (9.7%) reported going into infectious disease labs for duty reasons and 19 (1.47%) went for social reasons. Laboratory workers reported receiving 294 duty visits and 227 social visits. They also received 235 visits from non-CDC persons. There were 54 reports of children being seen in the lab areas and 3 reports of children in the animal quarters. There were many unstructured comments on this subject emphasizing that access to CDC laboratories needs to be drastically restricted.

RECOMMENDATIONS

A. High hazard areas should be "off limits" except to authorized persons wearing a distinctive identification

B. As an alternative, high hazard areas should be locked, and entry permitted only by key or use of an electronic card

C. All non-CDC personnel should be escorted to laboratories after receiving necessary clearance from the laboratory supervisor

D. A conference area with several rooms or cubicles should be provided for meetings outside of high hazard areas

PROBLEM

2. Written Procedures - "Lab Safety at the Center for Disease Control"

Ignorance of the CDC Lab Safety manual was widely expressed. Fifty-nine percent of the service and support personnel said they had never seen the manual. Forty-three percent of the bench workers said they did not have a copy in their lab or did not know if they had one. As for supervisors 90% of the males and all of the females were knowledgeable about the CDC safety manual.

Several employees commented that the safety manual is difficult to use, is inadequate, and needs to be revised.

RECOMMENDATION

The CDC safety manual should be revised and better organized. Authorship should be vested in one person with a technically knowledgeable Biohazards Control Committee providing much of the manuscripts. Consideration should be

given to dividing the manual into sections which would be of principal interest to (a) non-laboratorians (b) support and service personnel, (c) bench workers and (d) supervisors. A copy of the manual should be given to every new employee. Every employee should be required to sign a statement that he or she has read or had explained the appropriate portions of the manual, and the statement should be placed in the employee's personnel file.

PROBLEM

3. Personal Habits

This general problem has many aspects. First is the habit of smoking, eating, or drinking in a laboratory. Among service and support personnel 61% customarily eat in a lunchroom in the building where they work. Others eat in the following locations: clean lab --22 (12%), infectious lab--3 (1%), animal room--8 (4%), corridor to animal room--18 (10%), glassware wash room--18 (10%), sterile glassware processing room--12 (7%), glassware processing room--10 (6%), autoclave room--10 (6%), office in their building--91 (51%), corridor adjacent to infectious lab--18 (10%), restroom--48 (27%), cage-washing room--14 (8%), and pipe chase--18 (10%).

Approximately 75% of the bench workers eat and drink in the labs, and 56% frequently smoke. At the supervisory level the following responses were given:

	Low Hazard	Medium Hazard	High Hazard
Eat in lab	52%	28%	18%
Smoke in lab	35%	38%	42%
Drink in lab	63%	48%	42%

These responses show that many employees eat, drink, and smoke in areas where they may be exposed to infectious agents. While the risks to those working with low-hazard agents or those working in office space separated from the lab work areas is small, these practices nevertheless increase risks from infections.

RECOMMENDATION

Obviously, the cafeteria and "The Other Place" are not meeting the needs of all employees for a place to smoke, eat, and drink. These places would be inadequate if all employees took their coffee and coke breaks and ate their brown-bag lunches there. Therefore a room, or rooms with tables and chairs, and vending machines should be provided in a central location for smoking, eating, and drinking.

PROBLEM

4. Protective Clothing

Service and support personnel change clothes before leaving the work area 53% of the time. Bench workers discard their lab coats 62% of the time, but reuse them the rest of the time. Protective clothing is usually discarded into open laundry bags. The bags are collected and taken to the laundry where the contents are emptied, sorted, and inspected for items left in pockets. This procedure creates a hazard to the laundry workers if the clothing is contaminated.

The wearing and use of protective clothing is not a uniform practice. Some workers wear street clothes in the laboratory with no protective clothing and go anywhere else with those clothes on. Others wear protective clothing anywhere; while still others change protective clothing when they leave the lab and then wear a clean coat anywhere.

RECOMMENDATION

Protective clothing is designed for use only while working in the laboratory and even if not contaminated is socially unacceptable anywhere else such as the cafeteria, credit union, or bank. Ideally, a protective garment should be worn while working in the lab and street clothes be worn elsewhere.

PROBLEM

5. Infectious Cultures or Suspensions

Occasionally infectious culture materials must be taken from one lab to another or to and from the animal facilities. These are sometimes carried in the hand, or in open baskets, or wire racks. Thus they are easily dropped or spilled in corridors or on catwalks. The catwalks in particular may be slippery from rain or ice, since they are exposed to the elements.

RECOMMENDATION

Containers which can be closed tightly should be used for transporting infectious materials, tubes, syringes, etc., outside of laboratory areas. The catwalks leading to the animal quarters should be protected from rain and snow.

PROBLEM

6. Infectious Specimens

Specimens containing Class 4 agents have been received and unpacked in the main laboratory in Building 7 before being taken to the Maximum Containment Laboratory.

RECOMMENDATION

All packages of specimens suspected of containing Class 4 agents should be opened only in the Maximum Containment Laboratory.

PROBLEM

7. Care, Handling, and Disposal of Laboratory Animals

Among service and support personnel only 25 (14%) stated that they usually knew which infectious agents were being used in animal rooms where they work. They get this information as follows:

	No.	%
By asking lab person	25	14
From sign on door	28	16
From clipboard in room	15	9
From supervisor	20	11
From label on cage	14	8

These responses indicate that personnel in this work category are not well informed of the hazards in rooms where they work.

Only twenty-four (14%) of the respondents were aware that they could acquire "B virus" from monkeys. A similar number responded that they always report monkey bites and scratches to a supervisor.

RECOMMENDATION

Better ways of providing identification of those agents which are inoculated into animals should be studied. For example, the identification sign should be on the door or on the wall near the door.

Support and service personnel should be given additional training and orientation in the hazards of their work.

PROBLEM

8. Enforcement of Safety Procedures

Responses from service and support personnel to the stated question are shown below:

"Do you feel that safety for CDC is taken seriously by:

	Yes		No		Unknown	
	No.	%	No.	%	No.	%
Your supervisor	105	59	28	16	44	24
Section Chief	80	45	28	16	69	39

	Yes		No		Unknown	
	No.	%	No.	%	No.	%
Branch Chief	75	42	28	16	74	42
Division Director	71	40	25	14	81	46
Bureau Director	66	37	22	12	89	50
CDC Director	80	45	23	13	74	42
CDC Clinic	85	48	24	14	68	38

These figures indicate that except for the Director of CDC the further removed the supervisor is from the employee, the less confidence the employee has that the supervisor is concerned about safety.

Of the bench workers, 201 responded that they rigidly adhere to safety procedures but 122 responded "others" do not.

The supervisors responded affirmatively to the question: "Do you feel that there is adequate enforcement of biosafety requirements?" as follows:

< 1 year on job	35.7%
1-5 years	29.5%
> 5 years	20.0%

They stated a need for greater enforcement as follows:

< 1 year on job	14.3%
1-5 years	38.6%
> 5 years	47.1%

RECOMMENDATION

Safety enforcement should be "tightened-up" starting with enforcement by management and descending through the organizational level to the first line supervisor who has primary responsibility for enforcement. Evaluation of a supervisor's performance should include a statement of the degree to which he fulfills his responsibility for biosafety. Guidelines for disciplinary action should be developed in the event a supervisor fails in his responsibility. Such failure should be reviewed as necessary by the Biohazards Committee and an explanation obtained from the supervisor.

IV. SURVEILLANCE

PROBLEM

In interviews many employees expressed the view that managers at CDC are not sufficiently concerned about illnesses associated with laboratory work and that the CDC clinic personnel were not adequately caring for CDC employees. Over half (92, 55%) of the service and support personnel who responded to the questionnaire stated that they would go to the clinic for treatment of a minor cut, and 121 (75%) stated that they would go for a needle prick. Several employees said they would not go to the clinic even for a severe cut or animal bite.

There is a surprising lack of systematic effort to determine whether illness in an employee is caused by a laboratory-acquired infection. There is an obvious lack of consistency in perceived responsibilities for making such determinations, and in the actions supervisors take when they encounter suspected laboratory infections in employees. Supervisors of laboratories in which work with class 3 and 4 agents is being done generally assume a much greater responsibility for seeking consultation and evaluation of employees. A lack of confidence in the CDC clinic is reflected by the fact that supervisors working with the more hazardous agents refer employees to CDC clinic physicians less frequently than they do to other CDC physicians. The lack of consistency in providing diagnostic laboratory services for employees with infections, the infrequency with which employees have been instructed about symptoms expected from illness due to agents in their laboratories, and the lack of consistency in placing individuals potentially exposed to hazardous agents under surveillance all underscore the need for much clearer policies and instructions in these matters. Relatively few respondents are maintaining a record of agents used each day; a much larger number of supervisors said such a log should be kept. The same phenomenon is seen to a much less degree in sign-in, sign-out policies.

RECOMMENDATION

Responsibilities of the Office of Biosafety should be expanded to improve the surveillance of illness among CDC employees in order to relate illness to possible exposure while at work. Attached as Exhibit 3 is a report of a study conducted by Dr. William J. Martone. In this study he reviewed illness among CDC employees and made recommendations for a surveillance program.

V. IMMUNIZATION

PROBLEM

Employees' responses to questions concerning immunization policies and procedures were numerous.

Nonlaboratory personnel-

The divergence of opinion regarding primary responsibility for insuring that individuals have received appropriate immunizations before entering specific buildings and laboratories indicates a rather striking fragmentation of such responsibilities. Most employees (58 of 131, or 44%) said that they were primarily responsible for their own immunizations. Over half of the employees in the Bureau of Laboratories (69.2%) relied on the laboratory supervisor, but only 15.4% of those in the Bureau of Epidemiology did so.

Support and Service Personnel-

Seventy percent of those responding to the questionnaire said they did not know which immunizations are needed for their job. Their opinions on where responsibility lay were quite diverse.

In response to the question, "Are you willing to work in hazardous areas if you have received proper shots?" 77% stated "yes." When asked, "If shots are not available to protect you, are you willing to work under these conditions?", 77% said "no." During interviews several employees in this group said that if they were "vaccinated," they were safe. This opinion emphasizes a need for better education about the value of certain immunizations.

Laboratory Bench Workers-

Of the 200 people who responded, 26% said they did not have preexposure serum on file. Many respondents did not know if their immunizations were current.

Supervisors-

When asked the question, "Who is primarily responsible for ensuring that you are properly immunized?", answers were as follows:

	%
Yourself	39.7
Your supervisor	22.6
CDC Clinic	5.5
Biosafety Office	8.9
Other	9.5
Don't know	13.7

Many individuals do not know what immunizations they should be given nor where records should be maintained.

Four components are basically responsible for the present immunization system at CDC: The Office of Biosafety, CDC Clinic, Computer Systems Office, and user organizations.

The Office of Biosafety is responsible for the overall administration of the immunization program by: (1) periodically surveying the user organizations to ascertain that their organizational and/or individual immunization requirements correctly reflect the possibility of exposure to infection, (2) requesting and distributing a monthly list of personnel due immunizations to each user organization, (3) correcting or changing the system as necessitated by errors or revised immunization requirements.

The Clinic is responsible for (1) scheduling immunizations when contacted by the user organization, (2) administering immunizations, (3) keeping a record of immunizations in the individual's medical folder, (4) sending a coded notification to the Computer Systems Office that the immunization was given, and (5) notifying the Office of Biosafety of any apparent errors in the system or data.

The Computer Services Office is responsible for (1) producing reports on immunization as requested by the Office of Biosafety and (2) providing programming services for revising the immunization system--again as requested by the Office of Biosafety.

The user organization is responsible for (1) contacting the Clinic and asking that immunizations be scheduled when the monthly report of personnel due immunizations is received, (2) notifying organization personnel when to report to Clinic for immunization, (3) notifying the Biosafety Office of any changes or corrections needed in data in the system.

These lists of responsibilities indicate the system can break down in numerous places. In fact, the system appears to have broken down in so many places that personnel have very little confidence in its ability to provide accurate data on immunizations. This lack of confidence is evidenced by the fact that most of the organizations contacted have some sort of manual system upon which they rely for immunization data. Even so many employees neither know what immunizations they have had nor what immunizations they need.

The failure of the computerized immunization system seems to lie in the fact that there are no written descriptions of the system, no written instructions for operating it, and no written designations of responsibilities. Consequently, persons involved in the operation of the system do not know their responsibilities nor the responsibilities of persons in other parts of the system. With this complete lack of understanding, the system is likely to break down unnoticed at any time and stay broken down for any length of time.

Examples of system breakdown:

1. The Office of Biosafety from 1973 to 1977 did not review immunization requirements.

2. Monthly lists of personnel due to receive immunizations were not distributed for several months in 1976 because the Office of Biosafety employee who usually sent out the lists was on sick leave. No one else in the Office of Biosafety was trained to do this job, and no one in the Office was aware that the lists had not been distributed.

3. New Clinic personnel were not instructed by their predecessors on the need to make EDP entries for immunizations, so immunizations were not recorded on the computer.

4. Clinic Personnel did not make correct entries on EDP forms, so immunizations were not recorded on the computer.

5. User organizations have not attempted to correct the computer data because of lack of knowledge about the system. They simply discard the computer immunization data and use their manual system.

6. No description of the Immunization System has been prepared by the Computer Systems Office or the Office of Biosafety.

7. Computer lists have been distributed with no instructions concerning their disposition.

8. Computer lists containing data that users could not interpret have been distributed.

RECOMMENDATIONS

Despite the shortcomings of the present computer-controlled immunization system, the concept of computer control is valid for this use. Such a system, however, must have clearly written instructions and responsibilities must be clearly designated. All employees should be able to read the reports with ease. The reports should not contain unexplained codes and meaningless dates. Ideally, the system should annually generate a wallet-sized card showing current immunizations for each CDC employee. Finally, the system must be kept current and accurate at all times to overcome the justifiable lack of confidence that has been built up by most user organizations.

An ad hoc committee composed of Bob Falter, Clinic; Kathy McCormack, Office of Biosafety; Forrest Thornton, Computer Systems Office; and Les Schaum, Engineering Services Office, is working on modifying the Immunization System to provide a more reliable system.

#697

Initial steps to be taken include:

1. Revising report schedules to reduce data lag and resultant redundant information.

2. Setting up reports to run automatically so that reports will be put out even if the coordinator is absent.

3. Revising report format as follows to make it more readable:

   a. Making titles more descriptive of report content.

   b. Numbering pages of reports.

   c. Printing dates on all reports.

   d. Deleting dummy code dates on reports distributed to user organization.

4. Having the computer print instructions for disposition of reports on the reports.

5. Preparing a complete system description with flow charts showing responsibilities for each component and distributing to all persons having system responsibilities.

6. Assigning immunization responsibility for user organizations at Division or Branch level to minimize contact points and to fix responsibility.

These changes, together with close attention to the ongoing operational aspects of the systems should result in a more reliable, accurate, and manageable Immunization system. The system should be reviewed periodically by the Biohazards Control Committee and the Office of Biosafety.

VI. TRAINING

PROBLEM

In preliminary interviews with several employees, deficiencies in the laboratory safety training offered at CDC became evident. This problem was explored further through the questionnaires.

Nonlaboratory personnel-

Of the 15 nonlaboratory and nonlaboratory support personnel who on occasion do laboratory work, a number appear not to have received appropriate training in biosafety. As previously mentioned, six did not know if written protocols existed for routine laboratory procedures and nine did not know if written protocols were included in safety procedures. Forty percent did not know if they adhered to laboratory safety procedures, and 13% specifically claimed not to adhere to laboratory safety procedures. In no instance had knowledge of biosafety been derived from a CDC sponsored course, 14 of 15 (93%) received most of their training on the job or before joining CDC. Only 2 of the 15 received specific instructions on symptoms to be expected from an illness due to agents used in their laboratory; 12 of the 15 claimed to know what symptoms to expect on the basis of prior professional training.

Service and Support personnel-

Thirty-six percent stated that they had not received safety orientation in their present job. Orientation, when given, was by:

	#	%
Experienced worker	23	20
Supervisor	65	56
Safety Office	20	17
Classroom instruction	8	7

This group of respondents made two comments:

a) Persons working in high risk areas should be given special training.
b) All service personnel should be trained and oriented about hazardous areas.

Laboratory Bench Workers-

Half of this group responded that they received training during the first month of employment. Training was received from:

	%
Coworkers	37
Supervisor	43
Safety Office	4
Films	11
Structured course	5

When asked the question, "Have you received any subsequent safety training?", 203 (69%) said "yes" and 93 (31%) said "no." The 203 said they received the subsequent training as follows: 17%, from coworkers; 20%, supervisor; 14%, Office of Biosafety; 36%, films; and 13%, structured course. When answers to this question are compared with answers to the previous question, it becomes obvious that after the first month the Office of Biosafety, films and structured courses increase as sources of additional safety training and coworkers and supervisors decrease as sources.

In response to the question, "Do you believe that the safety training you have received has been adequate?", 173 (61%) said "yes" and 110 (39%) said "no." This points up a need for (1) more and better safety training and (2) reinforced safety training to assure laboratorians that they are in fact adequately trained or more probably, some mixture of both categories of training with emphasis on better safety training.

Twenty-two respondents stated that safety training was substandard.

Supervisors-

Supervisors indicated on-the-job training to be their primary source of biosafety knowledge. This source became more important as the length of time at CDC and length of time on the present job at CDC increased. In regard to the latter the figures are: those employed less than 1 year, 40%; 1 to 5 years, 48%; and more than 5 years, 72%. Almost all supervisors responded on the questionnaire that they thought they were adequately trained in biosafety.

No training source in biosafety is readily available outside CDC, so most employees obtain such knowledge after coming on duty at CDC. Special efforts need to be directed towards biosafety training for supervisors of nonmicrobiology laboratories. Supervisors strongly reaffirmed their primary responsibility for training members of their laboratory staffs in biosafety, but the data suggest that their subordinates do not believe they are fulfilling this role.

RECOMMENDATIONS

A. All new employees should receive safety training appropriate to their jobs as a part of their initial orientation within the first month. After completing training, the employee should sign a statement to that effect, and it should be placed in his or her personnel file.

B. If reassignment results in a significant change in duties, recommendation No. 1 should again apply.

C. The immediate first-line supervisor should be responsible for seeing that employees receive the training described in recommendations 1 and 2.

D. A segment of every lab training course should be devoted to safety training. This segment should appear in the course schedule.

E. One person or committee should coordinate all safety training, for CDC employees, trainees, and students.

F. A continuing program of safety education and training should be developed.

VII. OFFICE OF BIOSAFETY

Generally, this office develops and implements a broad program designed to protect CDC employees and the public from a variety of hazards. Some of the specific official functional areas are: physical security (guards); fire safety; supervision and enforcement of parking regulations; driver's licenses, building passes, and I.D. cards; radiation safety; computer security; biological and chemical safety in laboratories; safety training (in-house and extramural); regulation of importation and shipment of etiologic agents; disposal of hazardous wastes (chemical, biological, and radiological); administering the immunization program; processing claims for and against the government; and accident investigation. Professional staff members, and particularly the Director, serve as members of CDC, as well as national and international, committees related to several aspects of safety, including recombinant DNA research, chemical carcinogens, and design of containment facilities for hazardous agents. The Director also serves as CDC Veterinary Public Health Coordinator and as coeditor of the monthly publicaion Veterinary Public Health Notes.

In addition, because of CDC's position as the recognized leader in public health research and service, the Office of Biosafety receives numerous requests for information and consultation. They are also asked to visit and consult with clinical laboratories, hospitals, universities, and other government institutions. This is especially true with respect to procedures for safe handling and disposal of hazardous materials and design and operation of special containment facilities for hazardous biological agents.

The staff of the Office of Biosafety now includes three professionals, including the Director (whose time is almost entirely devoted to administrative and consultative duties), two technicians, and a supporting staff including one secretary, one part-time clerk, one staff assistant, and 10 guards. One professional and one technician, because of their many other duties, do not routinely work in areas of laboratory safety. The remaining professional and technician spend most of their time on laboratory safety-related projects.

Opinions expressed in interviews, comments, and responses to questionnaires indicate mixed attitudes toward the role and effectiveness of the Office of Biosafety. Overall, only about half of the respondents believed the Office of Biosafety to be responsive to their needs. Supervisors and laboratorians working with more hazardous agents were more likely than others to consult with the Office of Biosafety. A fairly high percentage of respondents said they believed the Office of Biosafety should have more authority to enforce safety regulations. Respondents seemed to feel that the Office of Biosafety is not visible enough in its daily contact with laboratories, and this is recognized to be at least partially due to the small staff.

The consensus of the responses and observations leads to the following conclusions:

1. CDC employees do not clearly understand the duties and role of the Office of Biosafety.

2. The Office of Biosafety needs to be more visible and more responsive to the needs of laboratorians. (These needs may require definition, and they can best be defined by personal contact of safety personnel with laboratorians).

3. The duties and responsibilities of the Office of Biosafety are excessive for the size of the staff.

RECOMMENDATIONS

A. The Office of Biosafety should be reorganized and expanded. The present Office of Biosafety is a misnomer because all CDC safety responsibilities are now centered there, such as plant security, parking lot control, and chemical and radiological safety. We recommend that an office be established with responsibility solely for biosafety, and that other functions not related to biosafety be assigned to a separate office.

B. The Director, CDC, should reaffirm in writing the limits of authority and responsibilities of the Office of Biosafety.

C. A Biohazard Control Committee composed of individuals who are technically knowledgeable about biosafety should be organized to advise and support the Biosafety Officer.

D. Resources should be made available for research, for testing, and for development of biosafety equipment, facilities, and procedures. This is urgent if CDC is to be a center of excellence in regard to biosafety.

E. The following additional staff should be added immediately to the Office of Biosafety:

1. A technician (safety specialist)

2. A microbiologist knowledgable about biohazard control

3. An industrial hygienist

4. A medical epidemiologist

5. One additional full-time clerk-typist

Additional staff should be added as additional needs and responsibilities are identified.

REFERENCES

1. Committee for Development of Operational Procedures for Central Services Activities in the New CDC Installation (Connell GH, chairman, Asher TH, Eschenbrenner AL, Fodor AR, Majors RH, Pinson HE). Report: 1957-58. Center for Disease Control, Public Health Service, U. S. Department of Health, Education, and Welfare, Atlanta, Ga.

2. MMWR: Morbidity and Mortality Weekly Report, Vol. 26, No. 10, March 11, 1977, p.84.

3. Lab Safety at the Center for Disease Control, DHEW Publication No. CDC 76-8118, Center for Disease Control, Public Health Service, U. S. Department of Health, Education, Welfare, Atlanta, Ga.

4. Classification of Etiologic Agents on the Basis of Hazard, Office of Biosafety, Center for Disease Control, Public Health Service, U. S. Department of Health, Education, and Welfare, Atlanta, Georgia.

Exhibit 1

CDC Personnel Interviewed Regarding Biohazards

Virology Division

Lorene H. Adams
Marja H. Barron
Sally P. Bauer
Patricia Bingham
Renee A. Black
Denise R. Brown
Helen L. Casey
Roy W. Chamberlain
Avis L. Cherry
Nancy J. Cox
Kathryn M. Crane
Theresa Cromeans
Walter R. Dowdle
Helen M. Engelman
Joseph Esposito
Rudolph G. Falcone
Paul M. Feorino
Bert K. Fiedler
Mary R. Flemister
Judith C. Galphin
Jared J. Gardner
George W. Gary, Jr.
Anna D. Hall
Bette A. Hall
Alyne K. Harrison
Milford H. Hatch
Kenneth L. Herrmann
John T. Heyward
John Hierholzer
Susan K. Hollingshead
Brian P. Holloway
Margaret L. Hopping
Dorreth D. Humphrey
Harriet D. Hutchinson
Karl M. Johnson
Harold S. Kaye
Alan P. Kendal
James V. Lange
Beverly C. Lawrence
Vester J. Lewis
Helen S. Lindsey
George E. Marchetti
Mary Lane Martin
Joseph E. McDade
Donna L. Miller
Shannon H. Mitchell
Frederick A. Murphy
James H. Nakano
Verne F. Newhouse
Gary R. Noble
Baldev K. Nottay
John F. Obijeski
Erskine L. Palmer
Joanne L. Patton
Rosemarie B. Petrucci
Martha A. Redus
Luna F. Roumillat
Karen C. Sanderlin
Donna R. Sasso
John W. Scott
Charles C. Shepard
Steven L. Shore
Marianne D. Stapp
John A. Stewart
Yvonne O. Stone
Wayne L. Thacker
Martha L. Thieme
James C. Trimier
Rosalind M. Vanlandingham
Laura L. Walker
Donna T. Warfield
Patricia A. Webb
Bernice D. Werner
Paul White
Sylvia G. Whitfield
Herta T. Wulff
Wilma B. Yarbrough
Donald W. Ziegler

Biological Products Division

Charlotte Black
Adrian Chappell
Avis G. Daugharty
Martha B. Fears
Barbara Forrester
Charlotte Freeman
William C. Gamble
Edwin H. George
Henrietta E. Hall
Diane Mundhenk
Don J. Phillips
Charles B. Reimer
Dane W. Sanderlin
Helen C. Snodgrass
Ted Tzianabos
Thomas W. Wells
Lendell A. White

Scientific Services

Tom Chadwick
Wilbert L. Cosby
Harvey J. Johnson
John L. Johnson
Elmer Knox
Willie B. Melson
Alamas Richardson
Theodore C. Wright

Engineering Services

Paul T. Cheek, Jr.
Lester Manker
Larry J. Payne

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : All Employees, Virology Division, BL DATE: March 14, 1977

FROM : Director, Virology Division

SUBJECT: Laboratory Safety

The deaths of Mr. Flowers and Mr. Dubingon have been a blow to all of us. George Flowers was known for many years as a dependable, helpful and courteous fellow employee with a high sense of loyalty to the people in Building 7. Above all, to many of us he was a good friend. Robert Dubingon had not been here as long and was not as well known, but he had already established friendships with many in the building. The cause of these two deaths was established last week as Rocky Mountain Spotted Fever. How or where they may have acquired this infection is not known. It may never be known, but there is little doubt that their deaths were work-related.

Today, Dr. Robinson is convening a task force to inspect microbiological containment equipment and review the microbiological safety rules and practices in the Bureau of Laboratories. The task force will consist of representatives from the Scientific Services Division, Biological Products Division and Virology Division, Bureau of Laboratories; the Bacterial Diseases Division and Phoenix Laboratories, Bureau of Epidemiology; and the Engineering Services. Dr. John Forney, General Bacteriology Consultant, Laboratory Training and Consultation Division, will serve as chairman. Dr. Feorino will represent the Virology Division. I urge each of you to cooperate fully with the task force in expediting their review.

I do not know what the final recommendations of the task force will be. But we do not need to wait 2-3 weeks for the report in order to put into practice those things which we already know; that is, the basic common sense rules of safety:

1. No mouth pipetting of etiologic agents or sera (CDC Laboratory Safety Manual, page 75).

2. No eating, smoking, or drinking in the laboratory. In almost every Branch, clean areas have been designated for such activities.

3. Dispose of infectious materials promptly and correctly (CDC Laboratory Safety Manual, page 125).

4. Maintain biological safety cabinets clean and free from extraneous glassware and equipment.

Page 2, All Employees, Virology Division, BL

Because of our unblemished safety record over the past 17 years this building has been in operation, it is understandable that some of us may have become somewhat casual in our attitudes towards safety. It has been brought home to us these past weeks in the saddest possible way that safety rules must be observed. We don't have the right to ignore the rules simply because they happen to be inconvenient or do not suit us. No one wants to be responsible for the illness of a fellow worker. To assure that this does not happen in the future, willful disregard of these common sense safety rules will be considered grounds for disciplinary action.

Walter R. Dowdle, Ph.D.

cc: Dr. Robinson

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO :

DATE: March 24, 1977

FROM : Director, Virology Division, BL

SUBJECT: Rocky Mountain Spotted Fever Vaccination

Some years ago, vaccination against Rocky Mountain spotted fever (RMSF) was a requirement at the CDC for laboratory personnel working with, or exposed to, rickettsia. In the late 1960's, the efficacy of the vaccine came under question. In several institutions, including the CDC, the emphasis gradually shifted from vaccination to more reliance on containment facilities, restricted access to laboratories, and safety education. Generally quoted in support of this approach is the report by Dupont et al., Journal of Infectious Diseases 128:340, 1973, which showed that no protection was afforded by a primary course of the commercially (Lederle) available vaccine produced from infected yolk sacs. The subjects were challenged by a minimal number of guinea pig infectious doses. The egg-grown vaccine had been assumed to be effective for man based on data from protection studies in guinea pigs. The Dupont study represents the only controlled efficacy data available, although earlier data from field trials reported by Parker, American Journal of Tropical Medicine 21:369, 1941, suggested that vaccines produced from infected ticks tissue reduced the severity of naturally acquired RMSF and perhaps reduced the evidence of infection. Recently, data from the Walter Reed unit at Fort Detrick has shown that a course of the commercial vaccine reduced the severity of infections in rhesus monkeys. In short, then, protection from RMSF vaccine may be better than that demonstrated by Dupont et al., but it is likely no more than minimally effective. Because of the recent tragic events, the theoretical advantages of the vaccine are being reconsidered by the CDC. The vaccine should not be viewed as a primary barrier to infection, but rather as a part of the total armamentarium for providing a possible extra margin of safety.

The RMSF vaccine manufactured by Lederle is a killed vaccine prepared from yolk sacs infected with *Rickettsia rickettsi*. Mild, local reactions are reported as common. Persons who are allergic to eggs, that is, those who cannot eat eggs, should not take the vaccine. The primary series for immunization consists of three 1-ml doses 7 to 10 days apart. A booster dose of 1 ml is recommended after 1 year and annually for a total of perhaps 3 years for those with heaviest exposure.

In accord with the CDC Laboratory Safety Manual (II-46), the vaccine will be required for the following: (a) persons who work directly with the disease agent in the laboratory, (b) persons who work in the same

laboratory or who come into the room while work is in progress, and (c) caretakers of infected animals. The vaccine is also being offered to all others in Building 7 who wish to receive it. It will not be required, but personnel should consider being vaccinated if their anticipated collaboration or equipment-sharing may take them into the rickettsial laboratories on "B" floor. These laboratories will be "off limits" to unvaccinated personnel.

Vaccinees will be asked to contribute pre- and post-vaccination bloods for evaluation of vaccine efficacy. If you are not among those for whom the vaccine is required, please let Mrs. Adams know if you wish to be vaccinated. Scheduling of personnel for prevaccination bloods and vaccination should begin next week.

Our records show the following information (if incorrect, contact Mrs. Lorene Adams, Ext. 3574):

/_/ You have received the initial vaccine series and require a booster dose.

/_/ You have not previously received this vaccine and will require a primary series of three doses.

Walter R. Dowdle, Ph.D.

Chief, Virology Division March 29, 1977

Chief, Technical Services Branch

Proposed Memorandum on RMSF Immunization

The following lists of names represent Technical Services Branch personnel that must receive RMSF immunization if your suggested memorandum is promulgated.

Lab. Svcs. Sect.	Equip. Dev. Sect.
Elmer Knox	Robert Osgood
Wilbert Cosby	James Moore
James Sullivan	Charles Smith
Robert Fitzpatrick	James Weaver
Dorothy Hall	Karl Branch
Homer Pinson	J.B. Smith
Frances Pinson	Robert Cotton
	L.B. Wilmon

There are two additional things that probably bear your consideration:

1. Laboratory coats come from your building to my laundry without being decontaminated. Should my laundry people receive RMSF immunization?

2. My laboratory glassware transfer carts go into your laboratories and come back out and leave the building without being decontaminated. They pass through hallways, up and down elevators, and frequently are used by others of my people to go to other CDC laboratories. Do you see this as a possible means of contamination to second or third parties re: RMSF?

B P Smith

Brad Smith

BPSmith:abh: 3/29/77
cc: Dr. John Forney
Dr. John Richardson

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : SEE BELOW

DATE: May 9, 1977

FROM : Director, Office of Biosafety
Director, Bureau of Laboratories

SUBJECT: Laboratory Safety

The Interim Report of the Task Force on Laboratory Safety requested that the attached excerpt of Laboratory Safety (pages II-3 through II-8) be distributed to all laboratory personnel. You are asked to evaluate your laboratory activities involving infectious agents in terms of the containment and operational procedures described on page II-6.

If deficiencies are noted in your containment capability or operational procedures, or if you need assistance in evaluating individual laboratory activities, please communicate directly with the Office of Biosafety at extension 3883.

Roslyn Q. Robinson, Ph.D.
Director, Bureau of Laboratories

John H. Richardson, D.V.M.
Director, Office of Biosafety

Attachment

ADDRESSEES:
All Employees:
  Bureau of Laboratories
  Bureau of Tropical Diseases
  NIOSH, Morgantown
  NIOSH, Cincinnati
Bureau of Epidemiology
  Epidemiologic Investigations Lab
  Phoenix Laboratory Division

INTRODUCTION

This section presents certain safety requirements for handling specific hazardous micro-organisms. These requirements derive from judgment based on present knowledge; as further knowledge accumulates and additional vaccines are developed, the requirements for some agents will change. The operational requirements are also based, in part, on the existing facilities and resources at CDC. Similar precautions probably would not be feasible in many other institutions. Information on required vaccines appears on pages II-11 through II-64.

In the following tables on operational requirements for safety in the laboratory, no attempt was made to cover all microbiologic agents. All known micro-organisms that are not listed, however, can be handled safely in the laboratory without special equipment, techniques, or immunization of personnel.

Precautions are indicated only when they are clearly required for the safety of laboratory workers or others. Optional or debatable items have been excluded; only those items deemed absolutely necessary for safety are presented. Thus, the following table of operational requirements presents only minimal safety criteria. For example, it is highly desirable that all laboratories be under negative air pressure; however, the absence of negative air pressure in laboratories working with certain agents may not be associated with an infection hazard.

Several additional operational principles and habits might be routine in laboratories even though they may not be required for safety with all micro-organisms. As a general principle, doors to laboratories should be kept closed except for necessary entrances and exits, and visits by extraneous persons should be discouraged. Eating, drinking, or smoking in the laboratory is undesirable. Handwashing by laboratory personnel should be encouraged, and bulb pipetting, a good laboratory procedure, can be generally recommended. Disinfection of work surfaces after working with a disease agent is strongly recommended as a routine measure. All of these general recommendations are desirable, even if they are not specifically needed for the safe handling of certain agents.

The following index table (Table 1) lists hazardous micro-organisms within the basic categories of Bacteria, Parasites, Viruses (including Rickettsia and Bedsonia), and Fungi. Each agent has been given a number and an alphabetic letter that identifies its "Precaution Category" (PC). The letter appears immediately to the right of the name of the agent. Table 2, the operational requirements table, contains precaution categories in alphabetic order ; the specific requirements for handling a particular agent are indicated by "+" entries under the various columns. Micro-organisms that require the same set of precautions are grouped within the same precaution category and, to conserve space, are identified by their code numbers.

Comments on each column heading in Table 2 follow the table.

Table 1

INDEX TO OPERATIONAL REQUIREMENTS

OID**	BACTERIA	***	OID**	BACTERIA	PC***
1	Actinobacillus-all species (except *A. mallei*)	D	23	Mycobacteria-all other species	D
			24	Mycoplasma-all species	D
2	*Actinobacillus mallei*	BB	25	*Neisseria gonorrhoeae* and *N. meningitidis*	D
3	Antinomyces-all species	D			
4	*Aeromonas salmonicida*	D	26	*Pasteurella pestis,** *tularensis,** *multocida* (Type B)	AA
5	*Arizona arizonae*-all serotypes	D			
6	*Bacillus anthracis**	AA	27	Pasteurella-all other species	D
7	Bartonella-all species	N			
8	Bordetella-all species	D	28	*Pseudomonas pseudomallei*	BB
9	Brucella-all species	BB	29	*Salmonella typhi**	G
10	*Clostridium botulinum**	AA	30	Salmonella-all other species	D
11	*Clostridium tetani**	G			
12	Clostridia-other species	D	31	Shigella-all species	D
13	*Corynebacterium diphtheriae**	G	32	*Sphaerophorus necrophorus*	D
14	Corynebacteria-other species	A	33	*Staphylococcus aureus*	D
15	*Erysipelothrix insidiosa*	D	34	*Streptobacillus moniliformis*	D
16	*Haemophilus ducreyi, H. gallinarum H. influenzae*	D	35	*Streptococcus pneumoniae*	D
			36	*Streptococcus agalactiae S. equi, S. equisimilis S. pyogenes* of Lancefield's Groups A, B, C, G	D
17	*Herellea vaginicola*	A			
18	Klebsiella-all species	A			
19	Leptospira-all species	D	37	*Treponema pallidum, pertenue, carateum*	D
20	Listeria-all species	D			
21	*Mima polymorpha*	A	38	*Vibrio comma**	K
22	*Mycobacterium avium, bovis, johnei, tuberculosis*	CC	39	*Vibrio fetus*	D
			40	*Yersinia enterocolitica*	D

OID**	PARASITES	PC***	OID**	PARASITES	PC***
41	*Echinococcus granulosus*	C	52	*Pneumocystis carinii*	T
42	*Echinococcus multilocularis*	C	53	*Shistosoma haematobium*	H
43	*Leishmania braziliensis*	N	54	*Shistosoma japonicum*	H
44	*Leishmania donovanii*	N	55	*Shistosoma mansoni*	H
45	*Leishmania mexicana*	N	56	*Taenia solium*	B
46	*Leishmania tropica*	N	57	*Toxoplasma gondii*	T
47	*Naegleria gruberi*	L	58	*Trypanosoma cruzi*	N
48	*Plasmodium falciparum*	F	59	*Trypanosoma gambiense*	D
49	*Plasmodium malariae*	F	60	*Trypanosoma rangeli*	B
50	*Plasmodium ovale*	F	61	*Trypanosoma rhodesiense*	D
51	*Plasmodium vivax*	F			

OID**	VIRUSES, RICKETTSIA, BEDSONIA	PC***
62	Adenoviruses-all types	I
63	Arboviruses-general	Y
64	B. virus	CC
65	Coxsackie A & B-all types	J
66	Cytomegalovirus	I
67	Echoviruses-all types	I
68	Encephalomyocarditis virus	L
69	Hepatitis-infectious & serum	I
70	Herpesviruses except B	L
71	Infectious bronchitis-like virus	L
72	*Influenza virus-all types**	I
73	K virus	P
74	Langat	R
75	Lassa virus	EE
76	Marburg virus	EE
77	*Measles virus**	K
78	Murine viruses, including ectromelia, LCM, murine hepatitis, etc.	E
79	*Mumps virus**	K
80	Newcastle Disease virus	I
81	*Polioviruses**	M
82	Psittacosis, LGV	U
83	*Q Fever,* R. prowazeki*, and* all other rickettsia except *R. rickettsii*	Z
84	Rabies-Fixed & attenuated	I
85	*Rabies-Street virus**	S
86	Reoviruses	I
87	Respiratory syncytial virus	J
88	Rhinovirus	I
89	*Rickettsia rickettsii**	DD
90	*Rubella**	K
91	Simian viruses, (except B virus and Marburg)	J
92	*Smallpox virus Major and Minor**	DD
93	Tacaribe group viruses except Tamiami	EE
94	Tamiami virus	L
95	Tick-borne viral encephalitis: *(Russian-Spring-Summer-Encephalitis** and all other viruses of complex except Langat)	X
96	*Vaccinia**	P
97	Varicella	J
98	Venezuelan encephalitis virus-exotic strains	Y
99	VEE-domestic and vaccine strains	W
100	Vesicular stomatis & other rhabdoviruses	V
101	*Yellow Fever**	X

OID**	FUNGI	PC***
102	*Blastomyces dermatididis*	O
103	*Cryptococcus neoformans*	O
104	Paracoccidioides	O
105	*Histoplasma capsulatum*	O
106	*Coccidioides immitis*	O
107	*Sporothrix schenckii*	O

*Vaccines for these agents are described on pages II-13 through II-64.

**OID = Organism Identification Number

***PC = Precaution Category

EXPLANATION OF COLUMN HEADINGS IN TABLE 2

Column 1: **Precaution Category** – The explanation is given on page II– 6 .

Column 2: **Geographic Isolation** – The action of isolating in a separate room or building in which no other work is concurrently conducted. A ventilating system to the room that prevents recirculation of air is implied. Exhaust air may be passed though High Efficiency Particulate Air (HEPA) filters or incinerated. For extremely hazardous agents, an air lock should also be used.

Column 3: **Controlled Access** – The exclusion of extraneous persons from areas where certain agents are being handled. Such control decreases the probability of distractions resulting in accidents and limits the number of exposed individuals should an accident occur.

The degree to which access is limited depends upon the risk associated with being in the area: the greater the hazard, the more restrictive the entrance requirements.

Corridors are the least hazardous of any locations in restricted laboratory areas. Areas in which the work is associated with a greater degree of risk are marked by signs reading "Caution, do not enter without current immunization against (name of disease)" or "Caution, infectious agents, do not enter without authorization from (name of investigator)." These signs are posted only while the risk is present.

Entrance to some areas should be restricted to the staff assigned to it. Access to areas in which very hazardous agents are being used should be controlled with locks and keys. No-access areas should be posted with signs reading "Warning: Highly Infectious Material: *Keep Out.*" In temporary situations, such as following an accident, a large sign with bright red printing reading "Danger: DO NOT ENTER: Contaminated Areas" is posted. Areas posted with either of these signs are off limits to *all* personnel except the investigator who posted the sign. One should not pass these signs for *any* reason, not even to fight fire.

Questions about the location of areas of restricted access, the hazards in the areas and the risk of infection, the times when restricted areas can be visited, or the immunizations required for access should be directed to the Biohazards Control Officer.

Column 4: **Negative Air Pressure** – Ideally, the air pressure in all laboratories should be negative in relation to the pressure in surrounding corridors, thus helping to prevent agents from leaving the work area. When negative pressure is required, as shown in Table 2, it is essential for safety. Even when cultures are manipulated under hoods, negative pressure in the general lab area in relation to that in surrounding corridors is still highly desirable. In addition, doors to all laboratories should be closed except for necessary entrances and exits.

Column 5: **Hood and Cabinets** – These include protected work areas such as the CDC Bio-Safety Cabinet, glove boxes, laminar flow safety cabinets, and gastight isolators.

Column 6: **Disinfections** – Standard methods suitable for disinfection of work surfaces, entire work area, and material before leaving work area have not been presented. Disinfection should routinely take place when work with agents is completed, and each laboratory should be cleaned, work surfaces decontaminated, and all contaminated material either covered in discard pans or autoclaved at the end of the work day. The Biohazards Control Officer should be contacted for specific instructions.

Column 7: **Bulb Pipetting** – This heading is self-explanatory.

Column 8: **Protective Equipment**

Gloves, including gloves on cabinet or hood ports, should be worn whenever one is handling organisms which call for this precaution. Gloves prevent the direct invasion of micro-organisms through intact skin and greatly reduce the hazards of indirect spread.

Masks should be worn to protect against the aerosol spread of certain organisms. Such masks should be worn except when the work is done in: a) a sealed cabinet in rooms with isolated ventilation systems with exhaust control, or b) effective immunizing agents have been given to all who might be exposed. High efficiency, disposable surgical masks are recommended; they are capable of reducing by 2 logs the number of airborne micro-organisms that are inhaled. Special respirators or supplied air equipment may have essentially complete respiratory protection.

Other Special Clothing or Guards – Face masks or shields, caps, safety gloves, booties, or even complete changes of clothing may be indicated for aerosol work with certain very hazardous agents. No attempt has been made to specify which special equipment may be needed for which special agents. The Biohazards Control Officer should be consulted for advice and guidance.

Column 9: **Special Precautions with Work Involving Insects and Animals** – These precautions have been stipulated for hazardous agents that might be capable of spread to humans through insects and animal vectors. Containment facilities should be secure before work is begun. The excretions and secretions of infected animals and insects may be infectious to humans, and personnel who must come in contact with them should routinely use special protective equipment. In some instances, discharges are capable of establishing disease in nature. These wastes must be decontaminated before they are released from the facility.

Column 10: **Special Aerosol Precautions** – Centrifuges, blenders, and other equipment capable of creating aerosols should be operated in separate "isolation" rooms or hoods. Special care should be taken in loading centrifuges to avoid accidental breakage during operation. Safety equipment to prevent the formation of aerosols is available and should be used. The Biohazards Control Officer should be consulted for further information.

Column 11: **Immunization Available and Required** – Immunization is generally recommended for all diseases against which effective, safe, and licensed vaccines have been developed. However, there are no vaccines against many highly virulent organisms, and some vaccines for such agents are investigational and without clear documentation of efficacy in humans. Nonetheless, in certain circumstances, the seriousness of the disease and the absence of other effective therapy may dicatate their use.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Center for Disease Control
Atlanta, Georgia 30333

May 9, 1977

CDC GENERAL MEMORANDUM NO. 77-5

LABELING OF EQUIPMENT TO BE REMOVED FROM A LABORATORY OR SERVICED IN THE LABORATORY

To assure that all equipment to be removed from a laboratory is free from dangerous chemicals or infectious organisms, the laboratory supervisor is responsible for Form CDC 0.593 being completed and affixed to the equipment. This applies to all equipment that is to be removed from the laboratory for maintenance, repair, transfer, surplus, or any other purpose. Also, equipment that must be serviced on site in the laboratory must bear the same label. The form will be removed from the equipment at the time of return to the laboratory or at the time servicing on site is completed.

If electronic or other specialized complex equipment must be decontaminated by extraordinary methods before repairs, maintenance, or other disposition can be made, the Office of Biosafety (telephone extension 3883) should be contacted for assistance or advice.

Form CDC 0.593 (a self-adhesive form) is illustrated on the reverse of this page. Copies of the form are available:

(1) at each of the maintenance and repair shops
(2) by telephone request to Engineering Services Office, extension 3216
(3) from the Office of Biosafety, extension 3883
(4) from the collateral duty safety inspector for facilities other than at the Clifton Road facility

This memorandum supersedes CDC General Memorandum No. 73-8, Labeling of Equipment Sent for Maintenance/Repairs.

James D. Bloom
Executive Officer

DISTRIBUTION: Mailing List No. 1, Codes 2 and 3

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : Director, Office of Biosafety

DATE: May 17, 1977

FROM : Chief, Technical Services Branch

SUBJECT: Decontamination of Potentially Infectious Glassware and Related Items

Now that I have had the hoses removed from all of the central autoclave rooms at the Clifton Road facility, it is necessary to rethink, change, and reissue the decontamination protocols.

Prior to the removal of the hoses it was possible to add water to discard pans in the autoclave rooms just before autoclaving. Since this is no longer possible, it will be necessary to add some aqueous solution to the discard pans in the laboratories before transporting them to the central autoclave rooms.

My thinking relative to this procedural change is as follows:

a. In those instances where it has always been the practice for laboratorians to autoclave glassware and related items that they produce, and the Laboratory Services Section (LSS) personnel only picked up the already autoclaved material and returned it to the LSS washroom area, no changes in protocol are necessary. This is only true if all such laboratorians realize the importance of, and in fact do, add approximately one inch of some aqueous solution to the discard pans prior to autoclaving. Such solutions can be water, or a liquid germicide, or for that matter, since it is their own business, any liquid that will volatilize during the initial stage of autoclaving and drive the air up and out of discard pans.

b. In those instances where it has in the past been the practice of LSS personnel to add water to discard pans that do not contain any liquid, and then autoclave the pans and return them to the LSS washroom area, it will now be necessary for laboratorians to add some liquid to the pans prior to delivering them to the central autoclave rooms.

c. The LSS personnel will continue, as in the past, to autoclave the discard pans and return them to the LSS washroom.

d. I personally believe that unless it is logistically impractical to purchase, stock, and supply laboratories with the germicide of choice against the organism with which they work, that they should be so supplied.

e. Further, the new protocol should make a particular point of stating that only approximately one inch of liquid be placed in pans so that during transport and handling prior to autoclaving the chance of it slopping out of the pans will be minimized.

f. Lastly, the point should be equally, strongly made that the transportation of discard pans from the laboratory to the central autoclave room remains the responsibility of the laboratorians.

Last Friday, May 13, 1977, I instructed that the hoses be removed, and by the end of the working day all had been. I further contacted a representative of each Bureau of Laboratories Division plus a Bureau of Epidemiology representative and requested that they inform all laboratorians in their respective organizations that the hoses were being taken out of the central decontamination autoclave rooms and that it has thus become the responsibility of laboratorians to add liquid to their discard pans prior to pans leaving the laboratories.

Brad

Brad Smith

cc:
Dr. Forney
Mr. Pinson

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : Bureau Director and
Branch Chief

DATE: June 22, 1977

FROM : US PHS Outpatient Clinic
Atlanta, Georgia

SUBJECT: Services provided by PHS Clinic for CDC employees

(1) Physical Examinations for Employees forty and over.
This exam is offered to employees every two years. The examination includes CXR, EKG, U/A, VDRL, CBC, SMA 12. Other types of physicals performed include PHS annual and separation, WHO, fit-for-duty, pre-employment, and annual retired military.

(2) On the job injury and illness.
We request that supervisors call the clinic before sending employees. This allows our staff to prepare for emergencies and to give appointments to non-emergencies. A two way memo should be sent with employees seen for on the job illnesses. Forms 304 and CA-16 should be sent with injured employees.

(3) Blood Pressure Screening.

(4) Allergy Shots.
Offered twice a week. Employees are asked to bring instructions on how injections are to be administered. The first injection should be given by employee's private physician.

(5) Immunizations and boosters required by CDC laboratories.

(6) Medical records on employees are sent to private physicians at the employee's request. A release form must be signed before records are sent out. Please give 2 weeks notice on requests for medical records.

(7) Medications are provided for on the job illnesses and injuries when indicated. Medication is also provided to employees who forget to take needed medications.

(8) When employees are referred from the clinic to consultants, either BEC or the patient is responsible for the bill. The clinic pays the bills for PHS officers.

(9) The clinic functions on an appointment basis; however, emergencies are given priority over scheduled clinic operations. Drop-ins are handled as soon as scheduling permits.

CLINIC SCHEDULE

	TIME	DAY
Allergy Shots	10 AM	Mon. Fri.
Yellow Fever Shots	10 AM	Tues.
BP Screening	1 PM	Weds. Fri.

If you have questions concerning clinic procedures, don't hesitate to call: 3385 - 3386.

Lonnie C. Jenkins, M.D.
Director

Robert G. Falter, M.B.A.
Deputy Director

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : All Course Coordinators and Branch Chiefs
Laboratory Training and Consultation Division

DATE: August 2, 1977

FROM : Director, Laboratory Training and Consultation Division

SUBJECT: Briefing of Students on Laboratory Safety

The responsibility for laboratory safety for students attending CDC courses rests with the course coordinators. Only the course coordinator is fully aware of the day-to-day activities in the training laboratory and the potential hazards of these activities. It is the coordinator's responsibility to instruct the students in the proper safety practices pertinent to their training while at CDC and to make certain that these instructions are followed. To facilitate this instruction, each course schedule must contain a portion of time specifically designated and identified as being devoted to the instruction of students on the subject of laboratory safety. It is the Branch Chief's responsibility to assure that instructions are given.

John H. Krickel, Ed.D.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : All Employees, LT&C Division

DATE: AUG 8 1977

FROM : Director, LT&C Division, BL

SUBJECT: Briefing of Incoming Personnel on Laboratory Safety

The primary responsibility for laboratory safety rests with the first line supervisor. Only he or she is fully aware of the day-to-day activities in his or her laboratory and the potential hazards of these activities. It is the supervisor's responsibility to instruct the employee in the proper safety practices and to make certain that these instructions are followed. It is the Branch Chief's responsibility to assure that instructions are given.

Overall responsibility for laboratory safety rests with the Office of the Director. It is my responsibility to make certain that each new person coming to work in the Division is informed of ongoing laboratory activities, restricted areas, vaccine requirements, rules prohibiting mouth pipetting, smoking, eating or drinking in the laboratory, and procedures for reporting illnesses.

Effective immediately, all new or transfer employees, visiting scientists, and trainees coming to work in the Division should be scheduled for a briefing in this office before undertaking their Branch assignments. Dr. Dan Sudia will conduct the briefing in my absence.

W D Sudia

for John H. Krickel, Ed.D.

Identical memo was distributed to employees of each Division, Bureau of Laboratories.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO :

DATE: August 10, 1977

FROM : Director, Office of Biosafety

SUBJECT: Computer Print-out of Immunization Requirements for Personnel

With the assistance of the Task Force on Laboratory Safety and the CDC Clinic, revisions have been made to the immunization program. The attached print-out has been revised to include instructions. All immunizations due should be scheduled with the Clinic on Form CDC 0.697 by the 15th day of the current month. Send the original of the form to the Clinic. Keep the second copy for your record. CDC 0.697 is available at the Office of Biosafety and after September 1 thru the Self-service Store, Building 4, Sub-basement Floor. A completed copy is attached as a sample for your information.

Other changes have been made in the program which will provide an individual immunization history and an individual immunization requirements listing for your personnel. These listings should come off the computer and be available for distribution within the next month.

Many people have input into the system; therefore, there are errors. If your listing has errors or if you have other problems with the immunization program, please contact Kathy McCormack, Office of Biosafety, extension 3883.

I am attaching a listing of the Immunization Liaison Officers for your information. A meeting of all Immunization Liaison Officers has been scheduled for Monday, September 12 at 9:00 am in Classroom I. Please plan to attend.

John H. Richardson

John H. Richardson, D.V.M.

Attachments

IMMUNIZATION LIAISON OFFICERS

NAME	BUREAU/DIVISION/STAFF SERVICE	BUILDING, ROOM NUMBER		EXTENSION
Kathy McCormack	Office of Biosafety	4	232	3883
Ellis Britt	Engineering Services Office	11	110	3462
David Atkins	Mail and Messenger Section	1	SB104	3208
Charlotte McClendon	Materiel Management Branch	Pfy	306	6719
Don Mackel	Epidemiology, Bacterial Diseases Division	1	B370	3813
Myron G. Schultz	Epidemiology, Parasitic Diseases Division	1	5421	3676
Henry M. Colvin	Laboratories, Office of the Director	1	1106	3260
Raul H. Lopez-Correa	Laboratories, San Juan Laboratories	San Juan		809-781-3636
John A. Magill	Laboratories, Bacteriology Division	1	1116	3663
Robert J. Ellis	Laboratories, Biological Products Division	6	284	3356
Dayton T. Miller	Laboratories, Clinical Chemistry Division	1	1202	3434
O. W. van Assendelft	Laboratories, Hematology Division	1	1323	3914
Fay Neal	Laboratories Laboratory Training and Consultation Division Office of the Director	6	291	3232
Lois Jennings	Bacteriology Training Branch	1	2266	3646
Anne B. Wyatt	Clinical Chemistry and Hematology Training Branch	6	292	3991

NAME	BUREAU/DIVISION/STAFF SERVICE	BUILDING,	ROOM NUMBER	EXTENSION
Cynthia Hand	Diagnostic Immunology Training Branch	1	B206	3230
Cynthia Hand	Mycology Training Branch	1	B206	3230
China E. Christian	Parasitology Training Branch	1	SB215	3220
Geraldene M. Stedman	Venereal Disease Training Branch	6	256	3764
Linda Frank	Virology Training Branch	1	B223	3278
	Laboratories			
Timothy Groza	Licensure and Proficiency Testing Division	6	315	3871
Sherri Nash	Mycology Division	5	B13	3547
	Laboratories			
	Parasitology Division			
Irving G. Kagan	Office of the Director	4	SB2	3423
George R. Healy	General Parasitology Branch	5	B37	3227
Shirley E. Maddison	Parasitic Immunochemistry Branch	5	SB15	3710
Kenneth W. Walls	Parasitic Serology Branch	5	SB6	3856
Carol Price	Laboratories, Pathology Division	1	2301	3623
	Laboratories			
	Scientific Services Division			
George Williams	Data and Specimen Handling Activity	4	SB35	3933
Brad Smith	Technical Services Branch	6	415	3878
Sam Adams	Animal Breeding and Holding Section	Lawrenceville		963-5264
J. Roger Broderson	Research Animal and Veterinary Pathology Section	6	415	3876
Gerald C. Taylor	Tissue Culture and Media Section	6	418	3879
Paul White/Lorene Adams	Laboratories, Virology Division	7	SB10	3574

SCHEDULE OF IMMUNIZATIONS

TO: USPHS Outpatient Clinic
Building 1, Room 658

	NAME (In full) (Last) (First) (Middle)	D. O. B.	IMMUNIZATION REQUIRED	DATE THIS IMMUNIZATION LAST RECEIVED	DATE THIS IMMUNIZATION WILL BE NEEDED NEXT:	REMARKS
1	RICHARDSON, John H.	N.A.	RMSF Smallpox			
2	WEBB, William L.	N.A.	Rabies Polio			
3						
4						
5						
6						
7						
8						
9						
10						

SAMPLE

FROM: (Bureau, Div., Prog., Unit, Staff Svc.)

Office of Biosafety

Signature of person responsible for scheduling immunizations — Phone Ext.

3883

0.697 4-74

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Center for Disease Control
Atlanta, Georgia 30333

August 12, 1977

CDC GENERAL MEMORANDUM NO. 77-9

PROCEDURES AND PRACTICES FOR LABORATORY ACTIVITIES USING RABIES VIRUS

A. INTRODUCTION

Recently, a case of laboratory-associated rabies in a State health department laboratory technician was reported. Information on the case of rabies and important issues raised by the case are provided later in this memorandum. This case prompted a review of the procedures and practices in CDC laboratory activities which involve the use of rabies viruses.

B. SAFETY PRACTICES

As a result of this review, additional steps to reduce the hazard to personnel in rabies laboratories are recommended. Therefore, the following safety practices will be implemented immediately in CDC laboratories:

1. Any procedure which can produce virus aerosols will be performed in a biological safety cabinet or other physical containment system. The procedures would include homogenization, pellet resuspension, and sonication. Centrifugation, which can also generate aerosols, will be performed using sealed cups opened only in a biological safety cabinet or similar barrier system.

2. Activities involving work with large volumes of rabies virus, regardless of viral strain or titer, will be conducted in a biological safety cabinet or other physical containment system.

3. Protective gloves will be worn when performing any operation which might result in spillage of an infectious virus.

4. No person will work with rabies virus in the laboratory, even on a temporary basis, who has not demonstrated a seroconversion following immunization: a titer of 1:16 by the rapid fluorescent focus inhibition test or an equivalent titer by another test is considered as evidence of seroconversion.

5. Antibody levels in persons working with rabies virus will be tested at least annually; revaccination will be given if the titer is below 1:16.

6. Earlier safety recommendations (1) regarding rabies laboratory hazards will remain valid.

C. INFORMATION ON REPORTED RABIES CASE

The information stated below on the reported rabies case was published in the Morbidity and Mortality Weekly Report (MMWR), Volume 26, No. 31, August 4, 1977, issue. The safety practices stated above also were published in that issue.

Followup on Rabies - New York: On June 3, a case of laboratory-associated rabies in a New York State Health Department laboratory technician was reported (2). The patient, a 32-year-old man, was hospitalized but is showing continued improvement. Motor function recovery has been particularly remarkable since mid-July; he is ambulatory but has occasional periods of agitation and spasticity. Although he remains aphasic, he is awake and appears to recognize family members. He has experienced mild recurring urinary tract infections; Escherichia coli has been isolated in each instance, and he has responded to therapy.

Serum antibody levels are being monitored at approximately 2-week intervals; the antibody titer remains at approximately 1:175,000--unchanged since it peaked at that level in mid-May.

Editorial Note: This case of laboratory-associated rabies, in which infection may have resulted from exposure to an aerosol, raises several questions regarding current laboratory practices. This is the second case of probable airborne infection with a laboratory-adapted strain of virus and the first case of rabies in an immunized individual with pre-existing serum neutralizing rabies antibodies.

Important issues raised by this rabies case are: 1) the risk of airborne exposure to rabies virus for laboratory personnel; 2) the protective value of serum neutralizing antibodies against airborne exposure; and 3) the human pathogenicity of laboratory-adapted strains of rabies virus, both fixed and attenuated.

There is only limited information available on the risk of airborne exposure. Three earlier human cases have been reported, 2 following exposure in bat caves and 1 resulting from exposure to an aerosol generated by a tissue homogenizer (3). These cases and the limited data on airborne infection in animals (4) indicate that persons exposed to airborne virus appear to be at increased risk.

Serum neutralizing antibody is well documented as a conventional protective measure against subsequent challenge by inoculation or bite exposure. The relationship between serum neutralizing antibody levels and protection against aerosol exposure is not known.

It is known that fixed virus strains (challenge virus standard and production virus) are pathogenic for man. The pathogenicity of attenuated vaccine strains varies with the site of inoculation, strain of virus, and species exposed. Attenuated strains which have been further manipulated, as by tissue culture or animal passage, are of unknown virulence and must be considered pathogenic until proven otherwise.

References:

1. MMWR 21:179, 1972

2. MMWR 26:183, 1977

3. MMWR 26:113-114, 1972

4. Winkler WG, Baker EF, Hopkins CC: An outbreak of non-bite transmitted rabies in a laboratory animal colony. AM J Epidemiol 95:267-277, 1972

Roslyn G. Robinson

for William H. Foege, M.D.
Assistant Surgeon General
Director, Center for Disease Control

DISTRIBUTION: Mailing List No. 1, Codes 2 and 3

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : All Scientific Services Division Personnel DATE: September 28, 1977

FROM : Director, Scientific Services Division Kenneth D. Quinn

SUBJECT: Division Biosafety Rules

It is important that you be knowledgeable about biosafety rules which apply to all Division personnel, plus specific biosafety rules which apply to certain positions in the Division.

All new Division employees will receive orientation concerning these rules prior to beginning work. Orientation will begin in the Division Director's Office and proceed to specific orientation by the Immediate Supervisor. Current employees must familiarize themselves with the biosafety rules listed in this memorandum and its attachment.

Scientific Services Division (SSD) Branch Chiefs are asked to obtain the signature of each employee to indicate that the employee has received orientation on the biosafety rules in effect for SSD employees.

General Biosafety Rules to be observed by all Division employees:

1. Hazard warning signs indicate areas of general and specific risk. Every employee will obey these signs at all times. Under no circumstances will any employee enter a restricted area without special clearance from the Laboratory Supervisor of the area.

2. SSD personnel are not permitted to eat, drink, or smoke in any CDC laboratory.

3. Every employee is responsible for observing proper safety practices such as the wearing of protective clothing, showering, and hand washing. Requirements for protective clothing, if required, will be stated in the Specific Biosafety Rules (attached).

In addition to the above general rules all Division employees will have a serum specimen on file in the Serum Bank Section and will receive designated immunizations prior to beginning specific work programs.

All personnel are encouraged to bring to the attention of their Immediate Supervisor any observed breaches of CDC biosafety rules.

I have read the General and Specific Biosafety Rules that pertain to my job, have reviewed them with my Immediate Supervisor and understand them.

Also, my Immediate Supervisor has discussed with me the portions of the CDC safety manual, "Lab Safety at the Center for Disease Control" that pertain to my job.

_____
Signature

_____
Date

_____
Branch Chief

_____
Date

Attachment

October 3, 1977

DATA AND SPECIMEN HANDLING ACTIVITY (DASH)

SPECIFIC BIOSAFETY RULES

DASH is an Activity in the Office of the Chief, Technical Services Branch.

A. Reference diagnostic specimens will be picked up by DASH personnel in the mail room at approximately 8:15 a.m. and in the early afternoon.

B. The various types of shipping containers will be opened in the Biological Safety Cabinets (BSC) provided. (A permissible exception to this rule is the clearly marked parasitology specimen--these may be opened on the table.)

C. Acceptable safety procedures must be used at all times in the DASH Activity.

1. Our quarters have been carefully planned by Engineering Services and by the Biohazards Control Officer.

2. Biological Safety Cabinets provide negative airflow to protect the workers, and must be used with the glass down and fan running.

3. Laboratory coats are to be worn by workers opening specimens and must not be worn to lunch.

4. Gloves and protective masks will be worn when handling leaked and broken specimens and/or hazardous spills. A discard bag is provided for soiled lab coats.

D. All known or suspected infectious material is to be handled in the BSC, except when enroute to the individual laboratories.

1. Enroute to the laboratories, each rack of cultures will be enclosed in a disposable plastic bag closed with a rubber band or wire tie.

2. Bags are opened at the lab of destination and the test tube rack and bag are returned to DASH where the rack is reissued.

3. Used bags are discarded with the shipping containers.

E. Shipping containers will be accumulated in large wheeled trash containers.

1. Contaminated containers will be disposed of in accordance with the procedure for discarding broken or leaking specimens.

2. At the end of each workday, work surfaces of tables and of BSC's will be wiped down with an approved disinfectant.*

F. No eating, drinking, or smoking is permitted in the specimen handling area.

G. No persons except those opening specimens, xeroxing 3.203 reports, and supervising the operations or servicing equipment and facilities are to enter the specimen handling area.

H. Other laboratory people who need to leave specimens or to discuss a problem must deposit their specimens in the appropriately marked spot outside the specimen handling area and must see the Activity Chief in the Data Handling area.

I. The specimens are packaged in sealed plastic bags and delivered to the laboratory units.

The sealed bag is to prevent contamination in the event that specimens are dropped during delivery.

J. In the event of a leaking or broken specimen, the following guidelines are to be followed:

1. Serology Specimens and Parasitology Specimens

a. While the serum specimens may be infectious, the risk to people opening shipping containers is small.

b. Even though we are temporarily forced by necessity to open some serum specimens and parasitology specimens on some occasions on the table top, we can minimize possible exposure by using good judgement.

(1) Open serum samples and parasitology specimens over a folded cloth towel, saturated with disinfectant.* Have a discard pan filled with disinfectant* within arm's reach of the technician.

(2) A leaking serum specimen or fecal specimen is to be placed immediately into the discard pan. The 3.203 information form may be saved only if there is certainty that it has not been contaminated. A fellow technician can complete substitute 3.203 if there is any question about contamination of the accompanying 3.203.

*Issued phenolic diluted according to instructions on container.

(3) Notify the Activity Chief or his substitute so the State Health Department can be notified that the specimen was discarded. He will phone the State so there will be no unnecessary delay in getting another specimen. He will also send a written report.

2. Cultures and Specimens Assumed to be Infectious

a. This category includes blood, animal and human tissues for isolation purposes, cultures, swabs, sputum, feces for bacteriology, cerebrospinal fluid, and other body exudates or fluids.

The technician is at risk while opening the specimen shipping container if breakage or leakage has occurred.

b. Specimens more likely to be hazardous (addressed to Mycology Special Pathogens Lab) will be opened in the BSC in the small lab, not in the main room.

c. Open all cultures and types of specimens listed above in a functioning biological safety cabinet.

(1) The glass front must be down and the fan on.

(2) Also open in the BSC all shipping containers on which the sender has failed to indicate whether the specimen is "serum" or "other."

(3) Opening the specimen in the BSC over a disinfectant* soaked cloth towel folded to a size of approximately 8 inches square is advisable but optional.

A discard pan containing an appropriate disinfectant must be in each BSC.

(4) If you find a leaking or broken specimen, have someone call the DASH supervisor or his alternate who will use his judgement as to the need for further action.

He will phone the Biohazards Control Officer and/or a resource person from Bacteriology, Mycology, or Virology if he has any question about the danger of a situation.

*Issued phenolic diluted according to instructions on container.

3. Damaged Specimens

a. A broken specimen vial or tube, or a leaking specimen is to be discarded into the disinfectant in the discard pan, and the pan and contents autoclaved.

b. An acceptable substitute is to wrap the leaking or broken specimen in lab toweling, then enclose the entire mess in a disposable plastic bag.

c. This bag must be hand carried without delay to the incinerator, and the technician must stay at the incinerator until the specimen is placed inside and incineration begun.

d. If the 3.203 is incorrectly wrapped around the specimen vial or tube and is contaminated, discard with the specimen. Make no effort to salvage a contaminated 3.203.

e. If the 3.203 is wrapped around the inner shipping container and is not contaminated, it may be retained.

f. All handling of a broken or leaking specimen will take place inside the BSC, and there is no reason to evacuate the area.

g. The DASH supervisor will notify by phone and in writing the State laboratory of the problem, and that the specimen was discarded.

4. Accidental Spills of Infectious Specimens Outside of the BSC

a. If a spill occurs outside the BSC in the specimen handling area, and if there is any doubt whatsoever as to the nature and danger of the spilled material, evacuate the specimen handling rooms immediately.

(1) Leave all lab coats which might have been contaminated in the rooms.

(2) Call the DASH supervisor for assistance, and phone the Biohazards Control Officer.

b. As specimens are moved from the BSC to the appropriate laboratory, an accidental spill could occur.

(1) The racks containing the specimens will be contained in individual plastic bags to contain any infectious material in the event that the rack is dropped and breakage occurs.

(2) The person delivering specimens throughout Buildings #1, #5, and #7 will use a laboratory cart and will have with them five clean cloth towels, a supply of plastic bags and a plastic bottle of disinfectant.

(3) He will plan his delivery schedule so that specimens are delivered to each building separately.

c. If a spill occurs in a hallway, he will cover the spill with disinfectant-soaked towels and phone the Biohazards Control Officer immediately, then the DASH supervisor.

(1) If needed, he will get assistance from the nearest laboratory and will stay with the mess only long enough to warn people of the danger.

(2) He should also ask someone to notify the responsible Branch Chief. (Personal clean-up is described in the next paragraph.)

d. A technician upon whose person infectious material has splashed should wipe clean with disinfectant and then proceed to the nearest bathroom and wash the affected area.

(1) Soap and water is effective in removing infectious material from skin surfaces.

(2) Regular hand washing in the DASH areas should be a routine procedure.

(3) Clothes (lab coats, trousers, etc.) contaminated with spills will be placed in the cloth discard bag.

(4) Before the bag is removed from the DASH, it will be placed in a second laundry bag.

(5) The double bag must be autoclaved before being sent to the laundry.

K. Specimens delivered to CDC laboratories:

1. The Activity Chief plus two selected employees will normally be given sufficient immunizations to make deliveries to Building #7. This will reduce the number of DASH personnel required to take the maximum number of immunizations.

All DASH staff can make deliveries to Buildings #1 and #5.

2. All deliveries made are to be made to those laboratories and/or rooms so designated by the laboratory unit as areas of pickup and deliveries, and for no reason are persons making deliveries to stop, enter, or visit in, pick up, or touch anything in laboratories and/or rooms not so designated.

3. All deliveries will be made with a fully safety equipped cart.

L. Immunization requirements - DASH personnel are required to have the following immunizations and/or tests:

1. Tests

PPD TB skin test annually.

2. Immunizations

a. Polio every 20 years.
b. Smallpox every three years.
c. Tetanus and diphtheria every 10 years.
d. Typhus as recommended by the CDC Safety Office.
e. Rickettsia series and annual booster for those designated to work and deliver specimens to Building #7.
f. Yellow Fever every 10 years.

3. Blood sample in Serum Bank every 20 years.

M. Work connected injuries and illnesses:

1. All injuries will be reported to your supervisor.

a. The injured employee should be sent to the Clinic for prompt treatment.

b. In cases where injuries are severe and patient cannot be moved, the Clinic should be called (extension 3385) giving the Clinic the following information if possible: employee's name, where the patient can be found, building and room number, etc., and type of injury.

2. If illness occurs during working hours report it to your supervisor.

a. Judgement can be made at that time whether illness is job related.

b. You can choose to see your personal physician or a memo to the Clinic can be sent by your supervisor.

3. <u>If illness occurs after hours and requires a physician:</u>

   a. Be sure that you or someone in your family informs your doctor that you work at CDC and the type of hazardous material you come in contact with.

   b. If illness is severe you should, or someone in your family should, contact your immediate supervisor. (Mr. George R. Williams, home phone - area code 404 - 972-2286.)

October 3, 1977

EQUIPMENT DEVELOPMENT SECTION

SPECIFIC BIOSAFETY RULES

A. Equipment brought to Equipment Development Section (EDS) areas for repair will be received only if it is tagged with form HSM 0.593 CDC.

B. Equipment to be serviced by EDS personnel in the laboratories will be similarly tagged or will not be serviced.

1. In those laboratory areas that are posted as restricted entry areas, Section employees will contact the area Supervisor to obtain clearance prior to entering the area to service equipment.

2. When working in a restricted area Section employees will abide by all area requirements such as protective clothing, personal hand washing, etc. during their time in the area and immediately upon leaving.

C. All Section personnel are required to receive such immunizations as have been accepted and approved by the Office of Biosafety that pertain to the areas where they are required to work.

D. Employees of the EDS are required to bring to the attention of their Immediate Supervisor any observed instances of breaches of biosafety rules, regardless of where such breaches are observed to occur.

1. Entry into Bldg. #7, Clifton Road Facility is permitted only if one has received a smallpox vaccination within the last three years. This is the only such building restriction in the metropolitan Atlanta area.

2. However, additional restrictions do pertain to specific areas of certain buildings and employees must be constantly alert to restriction signs and abide by them.

October 3, 1977

LABORATORY SERVICES SECTION

SPECIFIC BIOSAFETY RULES

A. Unless your job specifically requires it, you have no legitimate reason to enter any laboratory. If your job does require you to enter a laboratory, and only supervisors, clerical, and delivery personnel and their substitutes are required to do this, you must be aware of the following requirements:

1. Restricted buildings:

Any CDC employee can enter any building in the metropolitan Atlanta area for business purposes except Bldg. #7 at the Clifton Road Facility. In order to enter this building you must have had a smallpox vaccination within the last three years. If you haven't had such an immunization, stay out of Bldg. #7.

2. Restricted corridors in buildings:

The basement floor of Bldg. #7 has a restricted corridor. It is the eastern most north-south corridor on the basement floor. In order to enter this corridor you must have a current Rocky Mountain Spotted Fever inoculation and a current Typhus inoculation. If you don't have both of these inoculations, stay out of that corridor even though you have a current smallpox vaccination and are allowed in Bldg. #7.

3. Restricted laboratories and laboratory areas:

All other CDC restricted laboratories and laboratory areas in the metropolitan area that work with human disease-causing organisms may from time to time be posted as restricted areas. This is done when the work that is going on at the time requires it.

Placards are posted on the laboratory doors and even sometimes on the corridor doors when this type of work is being done. These posted notices would be in Buildings #1, #5, and #7 at the Clifton Road Facility and possibly even at Chamblee and Lawrenceville.

It is your responsibility to be aware of this situation, recognize all such placards and obey them whenever and wherever they are posted.

Some examples where this happens are:

a. Building #7, first floor, westerly north-south corridor:

(1) This corridor is sometimes placarded that you need a Polio inoculation to use the corridor.

(2) This same corridor is sometimes placarded stating that you need a Yellow Fever inoculation to use the corridor.

b. Building #7, second floor, easterly north-south corridor is sometimes placarded that to enter the corridor you need current Rabies inoculation.

c. Building #5, all floors are on occasion placarded on a laboratory by laboratory basis telling everyone, except those who work there to keep out unless they have had a specific immunization, and the name of the disease is on the placard.

d. Building #1, south wing, first floor, easterly north-south corridor, room 1383 is sometimes posted warning you that you must have Anthrax protection before you can enter the laboratory.

As stated before, these are but some of the examples, others can and will, from time to time, occur. Also, as stated before, it is your responsibility to recognize such signs and placards and to obey them without fail. Your family and friends must rely on your good judgement in this regard because they have no way of knowing if you elected to enter a posted area knowing that you shouldn't have done so.

B. Eating, drinking, and smoking can be done in any Laboratory Services Section spaces except as otherwise posted.

C. Protective clothing is provided for all Section personnel except clerical personnel. Delivery personnel who must enter other buildings, and on occasion laboratories, are required to wear protective clothing. Gloves are required to be worn at all times when picking up discarded material.

Do not remove containers of discarded materials from autoclaves unless the indicator tape shows that decontamination temperatures have been reached during the autoclave cycle. Always wash your hands thoroughly after working with discarded materials.

D. Do not remove from container or sort soiled wearing apparel unless you are wearing gloves and a mask. Wash your hands thoroughly after completing this task and discarding gloves versus putting them someplace for reuse.

E. When working on a discard pickup job, always report to your Immediate Supervisor any observed instances of improperly placed discard materials.

F. Always notify your Immediate Supervisor if you believe an accident may have exposed you to any contaminated material.

G. Check with your Immediate Supervisor as to the location of acceptable clean places to eat in your Section spaces.

Your Immediate Supervisor will advise you if it is necessary to have immunizations for a specific portion of your job.

October 3, 1977

SERUM BANK SECTION

SPECIFIC BIOSAFETY RULES

The Serum Bank laboratory area is relatively clean when one compares inherent hazards with those existing in Bldgs. #1, #5, and #7. There is a possibility that Bank personnel may be exposed to hepatitis when handling and processing commercial blood products, solicited convalescent specimens, and serum collections. There is also an outside chance of exposure to viremia in convalescent bloods. Most bloods, however, are collected after the viremic stage of the disease.

A. Handling of Blood Products

1. All personnel are instructed to treat all bloods being received as potentially hazardous. This includes products tested by commercial suppliers and reported by them to be negative.

2. Bench tops are to be wiped daily with Amphyl solution. Disposable toweling with plastic backing is used to cover work sites thereby minimizing actual contamination of the bench top surfaces. Toweling is disposed of in discard pans and subjected to steam sterilization.

3. Surgical gloves are to be worn when working with materials known to be contaminated, and bench tops are to be wiped with Amphyl immediately after working with materials known to be contaminated.

4. All supplies, glassware, needles, etc. used in processing blood products are autoclaved by Laboratory Services personnel. Discards are placed in appropriate pans, labeled with building and room number, and taped with indicator tape. Water is added to pans just prior to pickup.

B. Delivery of Products to Other Laboratory Areas

1. Delivery services are not usually provided. Any delivery deemed necessary will be made to office areas only.
(If office is in restricted area, immunizations may be necessary.)

C. Liquid Nitrogen Activities

1. Eye protection (shields, glasses) will be worn when dispensing LN_2 or retrieveing specimens from storage.

2. Retrieval of pathogenic specimens from storage could be extremely hazardous. Liquid nitrogen leaking into an improperly sealed or cracked vial that is stored in the liquid phase could cause the vial to explode if removed and immediately subjected to room

temperature. As a necessary precaution all specimens to be removed are elevated from the liquid to the vapor stage area of the freezer and held there for at least one hour before transfer to room temperature and/or a 37°C water bath.

D. Immunizations

Anyone required to enter Building #7 must have had a smallpox vaccination within the last three years.

E. Equipment Repair

1. Decontaminate with Amphyl.

2. Maintenance personnel are required to get assurance of decontamination from Serum Bank Office prior to working on equipment or removing for repair in maintenance shop.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : All CDC Employees

DATE: October 20, 1977

FROM : Director, CDC

SUBJECT: Laboratory Safety

In 30 years of operation, our laboratories have had an exemplary record for the safety of the people who work in them. In February of this year, two employees died suddenly and tragically. Their deaths were caused by Rocky Mountain Spotted Fever. Their infection was almost certainly acquired in the area in which they worked. They were the first laboratory-related deaths in the history of CDC.

Following the two deaths, a thorough evaluation of our safety procedures was initiated to determine if there were additional steps that could be taken to assure that safety procedures were as complete as possible. One part of this evaluation involved a complete investigation of the circumstances surrounding the two deaths. I now have a final report of this investigation. It is available to any interested employee. A second part of the evaluation was the formation of a Task Force on Laboratory Safety. While this Task Force has not completed its final report, I am aware of its major deliberations. There are several actions that will be initiated immediately. They are:

1. Restrict Access to Laboratories. When our work force was smaller, our mission less complex, and we worked with fewer potentially dangerous agents, it was possible to rely on warning signs and written procedures to restrict unnecessary access to laboratories. This is no longer so. It is now necessary to assure that access is restricted to authorized personnel by locking laboratory doors and developing a system of identification. The highest priority areas will be buildings 7, 8, and 9, but other laboratories will be evaluated to see if restrictions should be imposed. The Office of Biosafety is responsible for accomplishing this action.

2. Safety Training. The Safety Manual and the Etiologic Agents Manual serve as the basic reference documents for laboratory safety. Both will be reviewed and updated. Steps will be taken to assure that all appropriate supervisors and employees are aware of and have access to these manuals. Additional attention will be given to formal training in laboratory safety. The

Office of Biosafety will be responsible for updating the manuals and the Personnel Management Office will be responsible for assuring that proper training in laboratory safety is provided.

3. Immunization of Employees. To assure that employees are adequately immunized against agents with which they might come in contact, we must have an effective system to determine which employees need to be immunized against various agents, to identify these employees, and then to monitor compliance with the requirements. An ad hoc group has already looked at our current procedures. The Office of Biosafety will develop this system.

4. Surveillance of Employee Illness. It is essential that we have a surveillance system to identify, on a daily basis, any ill workers who might have been in contact with highly pathogenic agents. A comprehensive program to collect such health information, evaluate it, and follow up as appropriate will be instituted. The Bureau of Epidemiology will develop a surveillance system and a follow-up action plan.

5. Monitoring of Laboratory Safety. To carry out these recommendations and to generally strengthen our monitoring of laboratory safety, the staff of the Office of Biosafety will be increased by four additional positions.

Laboratory safety concerns all of us, and I am well aware that many positive actions have been taken, both individually and collectively, since February. The formal actions being announced today, coupled with those earlier activities, and further suggestions expected from the Task Force, will assure us that all appropriate steps are taken to provide the safest possible conditions for all CDC employees. Continuing suggestions from employees for further improvements are welcomed and should be directed to the Office of Biosafety.

William Foege

William H. Foege, M.D.
Assistant Surgeon General

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : All CDC Laboratorians

DATE: October 28, 1977

FROM : Chief, Technical Services Branch

SUBJECT: Biosafety and Control of Discard Materials

The purpose of this memorandum is to gather together in one paper various issuances pertaining to discard procedures, biosafety rules, protocols, and suggested techniques relative to your association with the Laboratory Services Section. It supersedes and replaces all such previous memorandums.

> It is recommended that this memorandum be posted in the laboratory as a ready reference in training new employees and for periodic review by others.

A. Each discard pan is inspected for pin holes and leaks before it is distributed by the Laboratory Services Section. We check these pans by totally immersing them upside down in a deep sink of water. If there is a leak, however small, a readily discernible stream of bubbles appears, and the pan is sent to Engineering Services metal shop for repair and return. Pans which can't be repaired are discarded, and repaired ones are rechecked and returned to the system.

However, this method of checking is not an absolute guarantee that you won't receive an occasional discard pan that leaks. Every leak has to start somewhere sometime and it may be that it will start in your laboratory. If you do find a pan that leaks, place a piece of tape on it stating that it leaks so that we, in turn, can either have it repaired or throw it away.

All contaminated containers should have their closures loosened before being placed into the appropriate size discard pan. These stainless steel pans are allocated as follows: size 6" x 8" x 11" for needles, syringes, and other small items; size 4" x 8" x 18" for pipets and tubes; size 8" x 8" x 18" for bottles, beakers, and other large containers.

Each discard pan must have approximately 1" of water or other aqueous solution added to it before it is taken from the laboratory to be autoclaved. The liquid not only drives the air up and out of the pan during

the beginning of the autoclave cycle, thus permitting live steam to enter the pan and come into contact with all surfaces of the pan contents, but also provides sufficient moisture during the last stage of the autoclave cycle so that material doesn't become so baked to glassware that it is difficult to remove in our washing procedures.

It is the responsibility of each laboratorian who uses discard pans to add water or an aqueous germicidal solution to discard pans before they leave the laboratory for autoclaving. Laboratory Services Section personnel have been directed not to look into pans to see if there is sufficient liquid in them. This is a grave responsibility and should be treated as such.

All disposable items, whether glass or plastic, can be discarded in the same container but should never be placed in a discard pan with reusable items. When we receive a pan of autoclaved disposable items we can simply dump the contents into a garbage can. However, if reusable items are intermixed with disposables our staff is exposed to hand stabs and cuts as we attempt to sort them.

Reusable needles and syringes require special treatment so that we can recover as high a percentage of them as possible. After they are used, they should be placed in 6" x 8" x 11" pans and as a general rule should not be accompanied by other items because of the risk of needle stabs during sorting. Syringe plungers and barrels should be carefully separated so that steam can come into contact with all surfaces, and both should be totally immersed in water or some aqueous solution as soon as possible after use to prevent material from drying on surfaces.

Disposable needle and syringe units need not be separated, but can be discarded intact into disposable items discard pans.

Also very important is remembering not to place heavy items on the top of light, fragile items in a discard pan. These pans all have to be transported across doorway thresholds and on and off elevators and receive some relatively sharp bumps in the process.

Stainless steel items such as 6" x 6" baskets, test tube racks, petri dish canisters, and pipet canisters in which you receive materials from Media and Glassware may become contaminated in your main laboratory or when used in a Biological Safety Cabinet. When the Laboratory Supervisor judges that such contamination has occurred, it is his responsibility to ascertain that these items are decontaminated by some acceptable method before being returned to the Laboratory Services Section for reuse and reissue.

The principle stated above can and should be applied to any items that enter your laboratory which must subsequently be handled by non-scientific support personnel.

B. Because hundreds of individuals are involved in these discard procedures, and all of us do make mistakes, we must have a system of identifying the source of improperly discarded materials. The purpose of this identification is corrective, not punitive.

After the appropriate authority, usually the Laboratory Chief, has made the decision that the contents of discard pans should or should not be autoclaved, the pans should be marked as follows:

1. To-be-autoclaved pans:

   a. A discard pan to be autoclaved should have the appropriate white "BUILDING AND ROOM NUMBER" label placed on one end of the pan.

   b. In addition to the above label, a 5" to 8" strip of "AUTOCLAVE TAPE" should be affixed vertically to the same end of the pan and should extend onto the horizontal surface of the pan lid, thereby identifying pan and lid as one unit.

2. Not-to-be autoclaved pans:

   a. A discard pan that does not require autoclaving should have the appropriate white "BUILDING AND ROOM NUMBER" label placed on one end of the pans.

   b. In addition, a green "DO NOT AUTOCLAVE" label should be placed on the same end of the pan.

Every discard pan, regardless of category, must have a lid on it so that pans can be stacked. This is your responsibility. If a piece of laboratory glassware is so large that it cannot be placed in a pan, treat it individually and label it accordingly.

<u>Do not place</u> either the white "BUILDING AND ROOM NUMBER" label or the green "DO NOT AUTOCLAVE" label on the lid of the pan. Always place labels on the same end of the pan.

<u>Further, laboratorians are responsible for transporting all pans containing discards to the autoclave room whether their Chief instructs them to do the autoclaving or the autoclaving is left to Laboratory Services Section personnel.</u>

All CDC Laboratorians 4

It is the policy, and responsibility, of this Branch that all autoclaves at CDC used for decontaminating glassware and other materials which subsequently come to the Laboratory Services Section have the efficacy of their operating cycle confirmed once each month with Kilit ampules.

C. Laboratory Services Section personnel will continue, as in the past, to deliver glassware and media to your laboratories and clean discard pans to the autoclave rooms. However, when your laboratory doors are posted, or placarded, with restricted entry signs because of the nature of the work being done, it is requested that one of your own laboratory carts be placed immediately outside your closed laboratory door so that delivered material can be placed on it rather than expecting our personnel to enter your laboratory. If this is not practical or possible, place a sign on your door explaining where the delivery can be put.

The necessity of observing safety precautions and the desire to comply must be instilled in each laboratorian. Laboratory Chiefs are responsible for the prevention schemes and protective equipment incidental to the work in their laboratories.

The problem of safety in its simplest form is one of control because the state of the art is sufficiently well advanced to have determined aseptic techniques and to have evolved excellent control equipment. Control can best be assured by the participation and personal involvement of all employees. Reasonable involvement of all employees on a periodic basis will do much to ensure a well-integrated safety program.

A variety of hazards may be encountered by persons working in non-scientific jobs, not the least of which may be those dangers that arise out of the employees' lack of knowledge of "things microbiological." However, it is the right of such employees to assume that all apparatus received by them from laboratories is microbially and pathogenically safe unless they are specifically informed to the contrary.

It is the moral duty of the laboratorian to have knowledge of the materials and equipment he uses and to take

due precautions based on this knowledge to protect non-laboratory personnel.

In order to bring about the above, it is necessary to have a program with adequate guidelines for a continuous, aggressive, comprehensive, and responsible effort by all employees to reduce and keep to a minimum the waste of manpower, materials, and other monetary losses caused by accidents. Planning for accident prevention should be a part of all research, development, maintenance, repair, and construction, as well as of the daily procedures of every laboratory.

T H E B O T T O M L I N E

Remember, each Laboratory Chief is responsible for the safety of all those who enter his laboratory, plus all those who come in contact with materials generated by his laboratory.

B F Smith

Brad Smith

EXHIBIT 3

1

A Review of Laboratory Accidents and Laboratory-Associated Infections at CDC for the Period 1947-1976.

William J. Martone, M.D.

SUMMARY

From 1947 through 1976, 124 laboratory-acquired infections were identified at CDC. Bacteria and viruses caused 63% of the cases. Accidents preceded only 33% of the illnesses.

INTRODUCTION

Reports of laboratory-acquired infections have appeared frequently in the literature. Most are reports of individual case or epidemiologic studies of isolated outbreaks. Surveys of laboratory-acquired infections which have occurred in a given time frame (1-4) and in particular laboratories (5-9) have contributed to our knowledge of common patterns of transmission, clinical presentation and treatment, and they indicate the wide variety of agents which have been involved.

There are, however, relatively few reports concerning infection rates among laboratorians, and in recent years, attention has apparently shifted to the risk of health care personnel acquiring hepatitis or tuberculosis (10-17). As a result, it is difficult to clearly define areas of high risk or to determine changing patterns of illness among laboratory workers. Significant changes in infection frequencies are often obscured by small numbers of yearly cases, absence of standard guidelines for reporting, and the lack of well-defined populations at risk.

In this report, laboratory-acquired infections which have occurred at the CDC since 1947 are reviewed. Much of this information was gathered in an extensive survey conducted by the Office of Biosafety, CDC, in 1973 and was incorporated in a previous publication (4). Also included in this report is the first attempt to determine crude infection and laboratory accident frequencies at CDC for the years 1970-1976. This approach should serve as a guideline for future surveillance activities both at the CDC and other institutions. Deficiencies encountered in reporting infections and high-risk accidents, and problems of data acquisition and access are indicated; methods to correct these deficiencies are recommended.

METHODS

In identifying cases for the 1947-73 period the Office of Biosafety used the following sources of information: 1) CDC Accident Report forms (#CDC 0.304), 2) compensation claims forms (CA1 and CA2), and 3) personal

interviews with laboratorians and laboratory supervisors. Individuals who had been ill and were still employed at the CDC were also queried. Information obtained included: date of acquisition, method of confirmation (for example, serology and culture), most likely source of infection, and duration of illness. Cases detected solely by personal interview for the years 1970-73 were tabulated separately.

Infections occurring from 1974 to 1976 were identified by methods similar to those outlined above; however, except in a few cases, personal interviews were not conducted.

For the 1947-76 period, a case was defined as an individual with a history of known or potential exposure to an infectious agent during field investigation or laboratory activity who developed an apparent or inapparent infection, with definitive diagnostic evidence of such infection (for example, isolation or demonstration of agent in clinical specimens, seroconversion, or skin-test conversion).

For crude estimates of laboratory and field accident and infection rates, population data were derived from personnel staffing lists for the 30th of June of each year from 1971 through 1976, and for the 31st of December, 1970. The populations at risk included employees of the Ecologic Investigation Program, Epidemiology Program, Laboratory Division, Malaria Program, State and Community Services Division, Bureau of Tropical Diseases, Bureau of Epidemiology, and Bureau of Laboratories in the following categories: laboratory workers; animal caretakers; insectary workers; laboratory equipment operators; warehousemen in the Bureau of Laboratories; biological sciences employees; medical, dental, hospital, and public health employees; veterinarians; and engineers. The presence of visiting scientists, students, and other short-term laboratory personnel, as well as staffing changes that occurred after the 30th of June of any year, may have resulted in variations in population estimates.

All laboratory and field accidents occurring in the period 1970-76 which resulted in injury and/or possible exposure to microbiological agents were derived from CDC Accident Report forms (#CDC 0.304) and employee compensation claim forms (CA1 and CA2). Laboratory and field accidents (and/or exposures) considered high-risk for acquisition of infection were tabulated separately. The criteria used for the selection of high-risk accidents were as follows:

1. Inoculations, ingestion, or conjunctival exposure of material known to contain infectious agents (including HAA + sera).

2. Spills, splashes, or accidental aerosolizations of agents in categories L, O, P-R, T-Z, AA-EE*.

3. Spills, splashes, or accidental aerosolizations of agents in categories G, K, M, and S involving unimmunized or inadequately immunized individuals*.

4. Inoculations of material from, or bites by, known infectious insect vectors.

5. Bites of laboratory animals known to be infected with pathogenic agents.

Yearly population totals were multiplied by 2080 Equivalent Hours/Year/ Employee (17), with the assumption that each person worked 40 hours each week for the entire year. Resultant values were expressed as Equivalent Hours (X100,000). Infection and accident rates were calculated by dividing the number of infections or accidents occurring per year by the Equivalent Hours. These frequencies were expressed as the Number Infections/100,000 person-hours Number Accidents/100,000 person/hours. Accidents were separated into total and high-risk categories.

Facility and building designations other than those currently in use were converted to the present designations.

RESULTS

From 1947 to 1976, there were 124 laboratory and field acquired infections (Figure 1). Of these, 109 had been previously identified by the Office of Biosafety for 1947-1973; the remaining 15, occuring in 1974-76, were found by review of CDC Accident Report forms and employee compensation forms CA1 and CA2. For the sake of completeness, the total included 3 illnesses due to Ascaris sensitivity and 1 unspecified wound infection following a laboratory animal scratch. Laboratory acquired infections accounted for 103 of 124 (83%) illnesses; field-acquired infections accounted for the remaining 21 (17%). The largest number of illnesses occurred in 1966, when 1 field and 9 laboratory acquired infections were recognized. No deaths directly attributable to these illnesses were noted.

For the period 1947-76, an antecedent laboratory accident was identified in only 34 (33%) of the 103 laboratory acquired illnesses (Table 1). Of these accidents, autoinoculation (21%) and mouth pipetting

*Categories as described in Lab Safety at the Center for Disease Control, DHEW Publication No. CDC 76-8118, Center for Disease Control, Public Health Service, U. S. Department of Health Education, and Welfare, Atlanta, Georgia, pp II-4, through II-6.

(15%) were the most common (Table 2). Similarly, only 4 of the 21 (19%) field acquired infections were attributable to a field-associated accident; all 4 were the result of an insect vector bite.

Classification of illnesses by agent revealed the wide variety of pathogens involved (Table 3). Including 1 case of acute glomerulonephritis following work with type 12 Streptococcus and an unspecified wound infection following a scratch by a laboratory animal, bacterial infections accounted for 42 of the 124 infections (34%). Diseases due to viral agents were the second most common (36 of 124 cases, or 29%). Together, bacterial and viral infections accounted for 63% of the laboratory and field-associated infections at the CDC for this period.

The category of agent causing most illnesses in a particular building or facility correlated strongly with the predominant category of agent maintained and investigated in that facility (Table 4). In instances where primary responsibility for a particular agent shifted to a new facility, illness due to that agent reemerged in the new facility.

Five of 9 illnesses at Fort Collins (56%) and 7 of 10 illnesses at Kansas City (70%) were acquired in the field. The relatively high proportion of field-acquired infections at Fort Collins and Kansas City were, in part, a reflection of the heavy assignment of field activities at these facilities. All of the field-acquired illnesses at Kansas City were due to H. capsulatum, and 4 of 5 field-acquired illnesses at Fort Collins were due to Colorado Tick Fever virus.

The yearly high-risk and total accident rates for the seven combined CDC facilities remained fairly constant for the period 1970-76, the only exceptions being 1971 and 1972 when the total accident rates rose slightly. The mean total accident rate of 4.5 accidents/100,000 person-hours/year was 76% higher than the mean high-risk accident rate of 1.1 accidents/100,000 person-hours/year (Tables 5 and 6, Figure 2). In contrast to the accident rates for the combined facilities, the rates varied considerably from facility to facility in a given year and from year to year in a given facility. Of the 119 high-risk accidents occurring from 1970 through 1976, 5 resulted in laboratory-acquired infections.

Except for Phoenix, where the infections were sporadic, the number of yearly infections by facility was of a low order (Table 7). The overall yearly infection rates for the seven combined CDC facilities remained constant, ranging from 0.2 - 0.4 infections/100,000 person-hours/year, with a mean of 0.3 infections/100,000 person-hours/year (Table 7, Figure 2). The frequency of infections preceded by high-risk accidents can be estimated to be 10-15% of the mean infection frequency, since, as previously noted, five high-risk accidents for 1970-76 resulted in infection.

The mean infection rates for the 7-year period were higher for the Fort Collins and Phoenix facilities than for the Chamblee or Clifton Road

facilities. When field-acquired infections were excluded from the detemination of the Fort Collins rate (not shown in the tables), however, the average yearly rate approximated that of the Clifton Road facility.

Of the 23 cases for 1970-73, only 9 were reported on CDC Accident Report forms or employee compensation forms; 14 (61%) were discovered only after personal interview of laboratorians and laboratory supervisors. All cases reported on forms CA1 and CA2 for this period were also reported on Accident Report forms. Of the 15 cases occurring from 1974-76, all but 1 was reported on Accident Report forms.

DISCUSSION

One of the most outstanding characteristics of the study results involved the overall number of illnesses which investigators could not attribute to an accident. Other reports have similarly described a large proportion of infections which were not actually preceded by accidents (1-4). Unrecognized aerosolizations of microbiological agents have been thought to contribute to most of these infections (18-19). Doubtlessly, errors not recognized as accidents have also been involved. Technological advances aimed at decreasing these potentials should continue to improve laboratory safety records.

Although CDC high-risk accident and infection rates for 1970-76 appear to have been relatively constant, these rates are, at most, crude estimates. The assumption that all individuals included in the population totals were continuously at risk (that is, worked 40 hours/week in the laboratory), and the failure to exclude immunized or otherwise immune individuals from these determinations, resulted in minimal rates The accuracy of these estimates for individual facilities was variable, since some facilities had more clearly defined populations than others. Any conclusion which might have been drawn concerning small differences in accident and illness rates between these facilities was thus judged unreasonable.

Similar underestimates in the number of infections were likely, especially for infections occurring from 1974 through 1976 when detection of a case depended solely on voluntary reporting. The deficiencies of a largely passive surveillance system for the identificaiton of laboratory-acquired infections were indicated by the observation that for 1970-73, 61% of infections were discovered only after personal interview with laboratorians and laboratory supervisors. Thus, the frequencies for 1974-76 might have been higher had the same method of case detection been used for this period.

Phillips compared estimated frequency rates for laboratory-acquired infections among various institutions and concluded that typical values of 1.0-5.0 infections/1,000,000 man-hours could be found where adequate reporting existed (20). Although his estimate of 1.3 infections/1,000,000

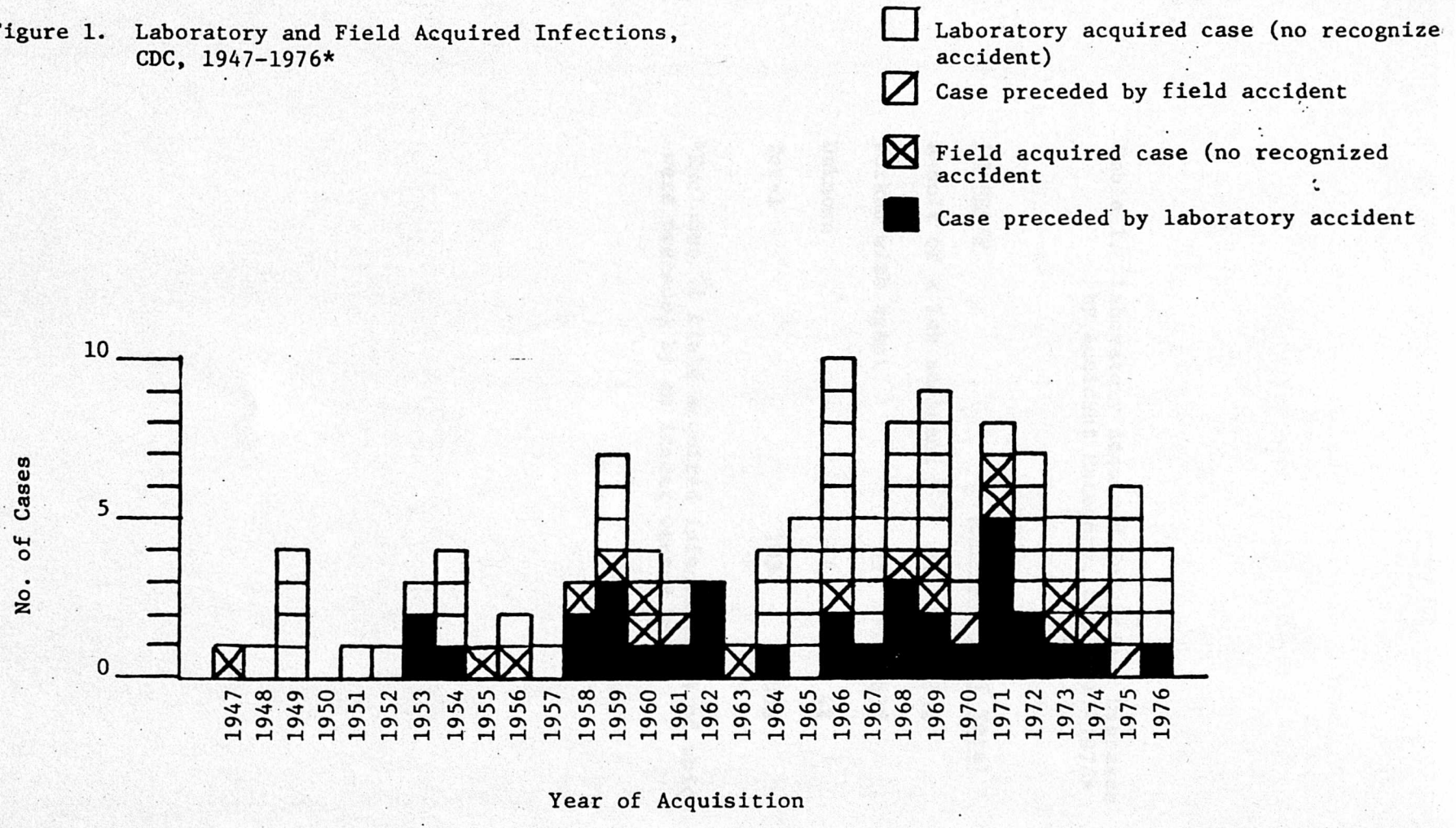
man-hours for the CDC for 1959-62 was slightly lower and involved a different time frame than that of this investigation, he did not describe the methods used to arrive at this figure.

In part, any measure of the effectiveness of training or biosafety programs must be based on accurate determinations of yearly frequencies of accidents and infection. Significant deviations above or below expected values might thus signify the need to investigate special situations or the overall success of such programs. Similarly, with such determinations the impact of technological and procedural biosafety improvements may be more accurately documented.

A successful system for determining yearly rates of infection and high-risk accidents would depend largely on three major areas of investigation: 1) detecting and confirming the case; 2) developing criteria for identifying the population at risk; and 3) developing criteria for high-risk accidents with the efficient reporting and follow-up of these accidents.

Surveillance of laboratory-acquired infections at CDC could be expanded to include other institutions. Uniformity in collecting data should enable participating institutions to compare illness and accident rates and to assess differences in their biosafety programs (17).

Figure 1. Laboratory and Field Acquired Infections, CDC, 1947-1976*



*Five laboratory acquired cases (no recognized accident) not shown because of indeterminant acquisition date.

Table 1. Laboratory Acquired Infectious Diseases by Accident Category, CDC, 1947-1976*

Category	Number	% of Total
Result of a lab accident	34	33%
Worked with agent	65	63%
Unknown	4	4%
Total	103	100%

*Excludes 21 field acquired infections, 4 of which were preceded by an insect vector bite.

Table 2. Laboratory Acquired Infectious Diseases Preceded by an Accident by Accident Category and Agent, CDC, 1947-1976

Accident	Number	Agent
Auto-inoculation	7	Group A Streptococcus (1), Clostridia septicum (1), SLE virus (1), West Nile virus (1), Omsk Hemorrhagic Fever virus (1), Toxoplasma gondii (2)
Mouth pipetting	5	Salmonella sp. (1), Shigella sp. (1), Leptospira interrogans (2), Rio Bravo virus (1).
Skin Contamination	4	Corynebacterium diphtheriae (1), Leptospira interrogans (1), VEE virus (2)
Blenders and Centrifuges	3	Group A Streptococcus (1), VEE virus (2)
Laboratory Animal Bites	3	Rio Bravo virus (1), Ossa virus (1) unspecified wound infection (1).
Mechanical Failure of BSC*	2	Rickettsia mooseri (2)
Pre-existing Wound Infection	2	Group A Streptococcus (1), Salmonella sp. (1)
Breaks and Spills	1	Shigella sp. (1)
Other	7	Group A Streptococcus (1), Salmonella sp. (2), Neisseria meningiditis (1) Rickettsia mooseri (1), Histoplasma capsulatum (2)
Total	34	

*Biological safety cabinet

Table 3. Laboratory and Field Acquired Infections by Agent, CDC, 1947-1976

BACTERIAL (40)

Mycobacteria tuberculosis (8)

Group A Streptococcus (7)

Shigella sp. (6)

Brucella sp. (5)

Leptospira interrogans (4)

Salmonella sp. (4)

Neisseria meningiditis (1)

Clostridia septicum (1)

Borrelia sp. (1)

Pseudomonas pseudomallei (1)

Corynebacterium diphtheriae (1)

Atypical mycobacteria (1)

VIRAL (36)

Venezuelan Encephalitis Virus (6)

Hepatitis A (6)

Colorado Tick Fever Virus (4)

Hepatitis B (4)

Hepatitis A or B (3)

Rio Bravo Virus (2)

Newcastle Disease Virus (2)

Simian Adenovirus X (1)

Ossa Virus (1)

West Nile Virus (1)

Omsk Hemorrhagic Fever Virus (1)

Saint Louis Encephalitis Virus (1)

Dengue virus (1)

Group B Tick Borne Encephalitis Virus (1)

California Encephalitis Virus (1)

Swine Influenza Virus (A/New Jersey/76) (1)

FUNGAL (19)

Histoplasma capsulatum (13)

Coccidioides immitis (3)

Candida albicans (1)

Blastomyces dermatitidis (1)

Sporotrichum shencki (1)

RICKETTSIAL AND CLAMYDIAL (18)

Clamydia psittaci (9)

Rickettsia mooseri (6)

Coxiella burnetii (3)

PARASITIC (9)

Toxoplasma gondii (4)

Ascaris lumbricoides sensitivity (3)

Giardia lamblia (1)

Trypanasoma cruzi (1)

OTHER (2)

Acute glomerulonephritis following work with Group A Streptococcus (type 12) (1)

Unspecified wound infection following a laboratory animal scratch (1)

Table 4. Laboratory and Field Acquired Infections by Agent and Facility, CDC, 1947-1976*

Class of Agent	1600 Clifton Road				Chamblee	Fort Collins	Kansas City	Montgomery	Phoenix	Unknown	Total
	Building 1	Building 5	Building 6	Building 7							
Bacterial	18(3)**	6	1	0	11	3(1)	0	0	0	0	39(4)
Viral	1	2	1	8	1(1)	6(4)	0	4	10	2(2)	35(7)
Fungal	2	5	0	0	0	0	10(7)	0	0	2(1)	19(8)
Parasitic	0	6	0	0	3(1)	0	0	0	0	0	9(1)
Rickettsial/ Clamydial	0	0	0	1	6	0	0	9	0	1(1)	17(1)
Other	0	0	1***	1****	0	0	0	0	0	0	2
Total	21(3)	19	3	10	21(2)	9(5)	10(7)	13	10	5(4)	121(21)

* Las Cruces (1 viral), Savannah (1 rickettsial), and Lawrenceville (1 bacterial) are not shown.

** Numbers in parentheses refer to illnesses acquired as a result of field investigation in which the illness corresponds to the particular agent being studied by that facility or by that particular group.

*** Unspecified wound infection following a laboratory animal scratch.

****Acute glomerulonephritis following work with Group A Streptococcus (type 12)

Table 5. Total Laboratory Accident Rates by Facility and Year, CDC, 1970-1976 (1)

	1970				1971				1972				1973				1974				1975				1976				Average 1970-1976		
	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours
Clifton Road Building 1	356	7.4	26	3.5	385	8.0	43	5.4	395	8.2	48	5.9	393	8.2	35	4.3	397	8.2	37	4.5	438	9.1	34	3.7	410	8.5	29	3.4	8.2	36.0	4.4
Clifton Road Building 5	80	1.7	5	2.9	107	2.2	10	4.5	119	2.5	18	7.2	128	2.7	8	3.0	111	2.3	13	5.7	117	2.4	7	2.9	128	2.7	11	4.1	2.4	10.3	4.3
Clifton Road Building 6	101	2.1	21	10.0	93	1.9	11	5.8	82	1.7	7	4.1	55	1.1	6	5.5	39	0.8	3	3.8	40	0.8	3	3.8	38	0.8	5	6.3	1.3	8.0	6.2
Clifton Road Building 7	82	1.7	9	5.3	84	1.7	11	6.5	89	1.9	8	4.2	80	1.7	11	6.5	68	1.4	8	5.7	73	1.5	15	10.0	78	1.6	10	6.3	1.6	10.3	6.4
Chamblee	15	0.3	0	0.0	12	0.3	0	0.0	14	0.3	3	10.0	14	0.3	3	10.0	77	1.6	5	3.1	79	1.6	0	0.0	90	1.9	4	2.1	0.9	2.1	2.3
Fort Collins	48	1.0	1	1.0	48	1.0	5	5.0	49	1.0	5	5.0	41	0.9	2	2.2	52	1.1	5	4.5	56	1.2	8	6.7	59	1.2	5	4.2	1.1	4.4	4.0
Phoenix	44	0.9	0	0.0	30	0.6	0	0.0	35	0.7	0	0.0	34	0.7	0	0.0	27	0.6	0	0.0	31	0.6	1	1.7	30	0.6	4	6.7	0.7	0.7	1.0
TOTAL (all facilities)	726	15.1	62	4.1	759	15.8	80	5.1	783	16.2	89	5.5	745	15.5	65	4.2	771	16.0	71	4.4	834	17.3	68	3.9	833	17.3	68	3.9	16.1	71.9	4.5

(1) Includes field investigation accidents and laboratory animal accidents

Table 6. High-Risk Laboratory Accident Rates by Facility and Year, CDC, 1970-1976

	1970				1971				1972				1973				1974				1975				1976				Average 1970-1976		
	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours	Equivalent hours (X100,000)	Number accidents	Number accidents per 100,000 person-hours
Clifton Road Building 1	356	7.4	7	0.9	385	8.0	6[1]	0.8	395	8.2	8	1.0	393	8.2	6	0.7	397	8.2	9	1.1	438	9.1	3	0.3	410	8.5	9	1.1	8.2	6.9	0.8
Clifton Road Building 5	80	1.7	4	2.4	107	2.2	6	2.7	119	2.5	7	2.8	128	2.7	3	1.1	111	2.3	5	2.2	117	2.4	5	2.1	128	2.7	2	0.7	2.4	4.6	1.9
Clifton Road Building 6	101	2.1	1	0.5	93	1.9	0	0.0	82	1.7	2	1.2	55	1.1	0	0.0	39	0.8	0	0.0	40	0.8	2[2]	2.5	38	0.8	1	1.3	1.3	0.9	0.7
Clifton Road Building 7	82	1.7	5	2.9	84	1.7	3	1.8	89	1.9	4	2.1	80	1.7	3	1.8	68	1.4	2	1.4	73	1.5	6	4.0	78	1.6	2	1.3	1.6	3.6	2.3
Chamblee	15	0.3	0	0.0	12	0.3	0	0.0	14	0.3	0	0.0	14	0.3	0	0.0	77	1.6	1	0.6	79	1.6	0	0.0	90	1.9	0	0.0	0.9	0.1	0.1
Fort Collins	48	1.0	0	0.0	48	1.0	0	0.0	49	1.0	0	0.0	41	0.9	1	1.1	52	1.1	1	0.9	56	1.2	2[3]	1.7	59	1.2	2	1.7	1.1	0.9	0.8
Phoenix	44	0.9	0	0.0	30	0.6	0	0.0	35	0.7	0	0.0	34	0.7	0	0.0	27	0.6	0	0.0	31	0.6	1	1.7	30	0.6	0	0.0	0.7	0.1	0.1
TOTAL (all facilities)	726	15.1	17	1.1	759	15.8	15	0.9	783	16.3	21	1.3	745	15.5	13	0.8	771	16.0	18	1.1	834	17.3	19	1.1	833	17.3	16	0.9	16.1	17.0	1.1

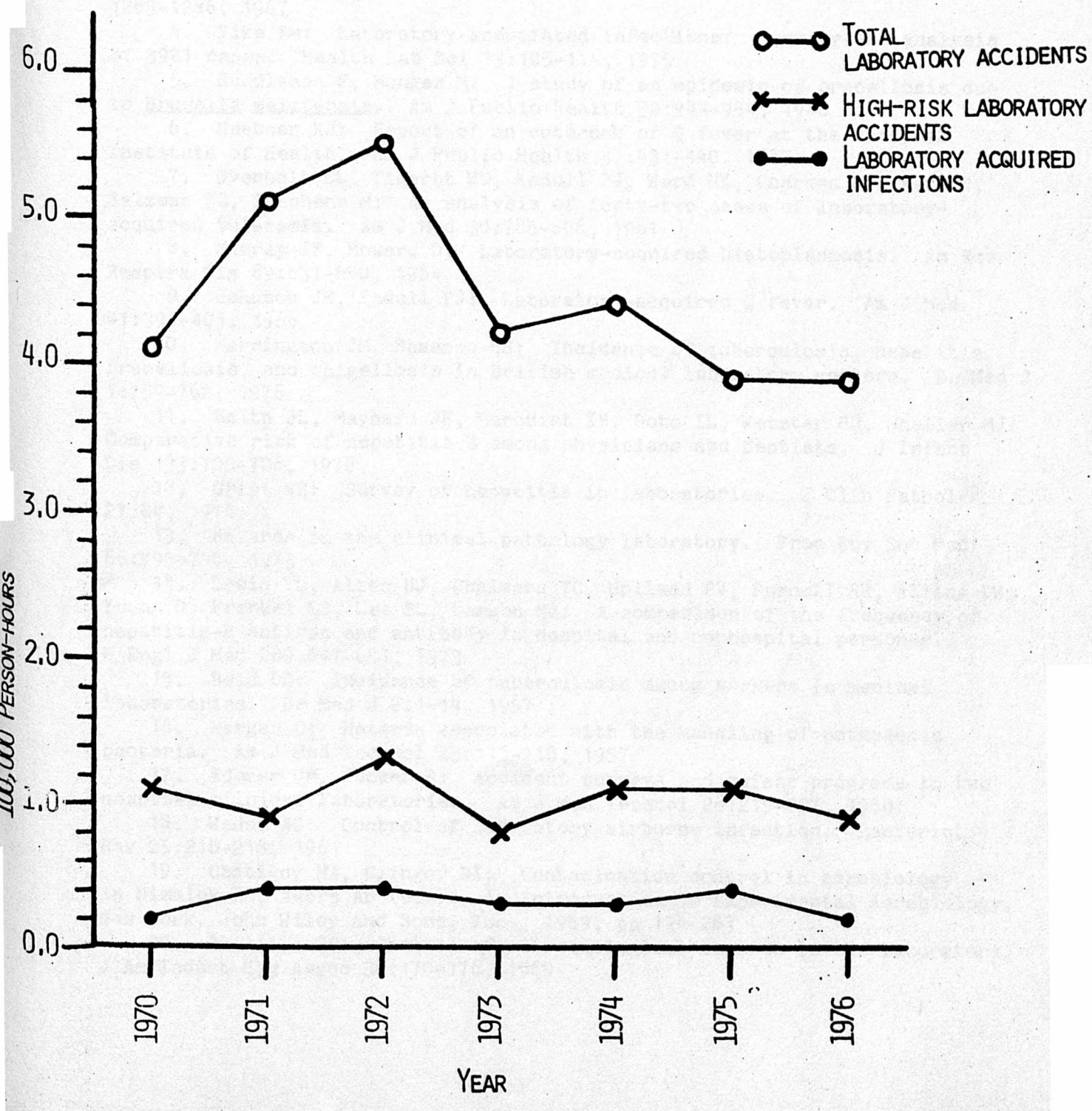
(1) Animal bite; infected with *Babesia microti* - (1)
(2) Animal bite; infected with B virus - (1)
Animal bite; infected with *B. anthracis* - (1)
(3) Animal bite; infected with CIF virus - (1)

Table 7. Laboratory, Laboratory Animal, and Field Acquired Infection Rates by Facility and Year, CDC, 1970-1976

	1970				1971				1972				1973				1974				1975				1976				Average 1970-1976		
	Number employees at risk	Equivalent hours (X100,000)	Number infections	Number infections per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number infections	Number infections per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number infections	Number infections per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number infections	Number infections per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number infections	Number infections per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number infections	Number infections per 100,000 person-hours	Number employees at risk	Equivalent hours (X100,000)	Number infections	Number infections per 100,000 person-hours	Equivalent hours (X100,000)	Number infections	Number infections per 100,000 person-hours
Clifton Road Building 1	356	7.4	0	0.0	385	8.0	2(1)*	0.3	395	8.2	1	0.1	393	8.2	1(1)	0.1	397	8.2	1	0.1	438	9.1	0	0.0	410	8.5	1	0.1	8.2	0.9	0.1
Clifton Road Building 5	80	1.7	1	0.6	107	2.2	2	0.9	119	2.5	1	0.4	128	2.7	2	0.7	111	2.3	0	0.0	117	2.4	3	1.3	128	2.7	1	0.4	2.4	1.4	0.6
Clifton Road Building 6	101	2.1	0	0.0	93	1.9	0	0.0	82	1.7	0	0.0	55	1.1	0	0.0	39	0.8	1	1.3	40	0.8	0	0.0	38	0.8	0	0.0	1.3	0.1	0.1
Clifton Road Building 7	82	1.7	0	0.0	84	1.7	1	0.6	89	1.9	0	0.0	80	1.7	1	0.6	68	1.4	0	0.0	73	1.5	1	0.7	78	1.6	1	0.6	1.6	0.6	0.4
Chamblee	15	0.3	0	0.0	12	0.3	1	3.3	14**	0.3	1	3.3	14	0.3	0	0.0	77	1.6	1(1)	0.6	79	1.6	0	0.0	90	1.9	0	0.0	0.9	0.4	0.4
Fort Collins	48	1.0	2(1)	2.0	48	1.0	1(1)	1.0	49	1.0	0	0.0	41	0.9	1(1)	1.1	52	1.1	1(1)	0.9	56	1.2	2(1)	1.7	59	1.2	0	0.0	1.1	1.1	0.9
Phoenix	44	0.9	0	0.0	30	0.6	0	0.0	35	0.7	4	5.7	34	0.7	0	0.0	27	0.6	1	1.7	31	0.6	0	0.0	30	0.6	0	0.0	0.7	0.7	1.0
Total (all facilities)	726	15.1	3	0.2	759	15.8	7	0.4	783	16.2	7	0.4	745	15.5	5	0.3	771	16.0	5	0.3	834	17.3	6	0.4	833	17.3	3	0.2	16.1	5.1	0.3

*Numbers in parentheses refer to illness acquired as a result of field investigations in which the illness corresponds to the particular agent being studied at that facility or by that particular group.
**Estimate

FIGURE 2. TOTAL ACCIDENT, HIGH-RISK ACCIDENT AND LABORATORY ACQUIRED INFECTION RATES, CDC, 1970-1976



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RECOMMENDATIONS

Medical surveillance, and, within certain limits, medical care of CDC personnel should be a CDC responsibility. Official duties may require that individuals work with infectious agents, enter laboratories containing infectious agents, or work with potentially contaminated laboratory discards, such as used glassware. In other instances, individuals may inadvertently enter restricted areas without appropriate immunizations.

Because many of the agents under investigation are highly infectious and/or not native to the United States, insuring that the community is adequately protected against the unauthorized as well as inadvertent release of these organisms should also be a CDC responsibility. An organized medical surveillance and medical care scheme for CDC personnel would fulfill one facet of this obligation, namely, to safeguard against unknowing release of organisms as a result of inapparent or unrecognized human infection. The scheme would also generally upgrade preventive medical services for employees.

Minimum Guidelines for Medical Surveillance and Medical Care

An effective medical surveillance plan must take into account and attain specific goals in at least these following four situations: 1) high- risk laboratory accidents, 2) laboratory-acquired infections, 3) absenteeism, and 4) entries into restricted areas by individuals who are not properly immunized.

For the purposes of this report, a high-risk laboratory accident can be viewed as one which places the involved individual or individuals at unusual risk of acquiring an infection with agents being used in the laboratory. The criteria may vary depending on 1) the nature of the accident, 2) the class of agent involved, and 3) the immune status of those exposed. All accidents involving laboratorians must be reported to the immediate supervisor, and the supervisor should be responsible for deciding within pre-existing guidelines, whether the accident is high-risk. If the supervisor decides that it is high risk, he or she would then be responsible for reporting the incident to the CDC Medical Epidemiologist (see proposal below). If a high-risk accident occurs, those at risk must be identified, and monitored and appropriate preventive measures must be applied. Efforts to counter the eventuality of person-to-person, and in certain cases, person-to-vector transmission must be viewed within the context of agent class. The Office of Biosafety must investigate to determine if the accident was due to malfunctioning equipment, inadequate facilities, or procedural error, and any deficiencies must be corrected. When decontamination of facilities is warranted, Office of Biosafety officals should supervise the decontamination. If an infection should occur, there must be an assurance that the individuals involved receive expert medical care and consultation.

If the laboratory-acquired illness is not preceded by an accident, it must be assumed that the cause was due to a microbiological aerosol, and those who are potentially at risk, but who are not ill, should be carefully identified and monitored (1). Appropriate preventive measures can be applied as indicated. Co-primary cases should be carefully sought. If person-to-person transmission is likely, all those in contact with cases should be identified and monitored. Where applicable, appropriate prophylactic therapy must be supervised, and adequate preventive measures taken to assure that further person-to-person and/or person-to-vector transmission is kept at a minimum. Office of Biosafety officials must investigate and correct potential sources of infection. Decontamination procedures must be monitored to insure their adequacy and effectiveness.

To expediently identify unrecognized laboratory-acquired infections, absenteeism must be systematically evaluated for laboratorians, laboratory supervisors, laboratory support individuals, or those who, because of official duties, have occasion to enter certain laboratories working with hazardous agents. Each of these persons must be knowledgeable of the signs and symptoms of the diseases caused by hazardous agents worked with in laboratories to which they are exposed. Absent employees must notify or otherwise inform the supervisor of the nature of the absence. If an employee fails to contact the supervisor, the supervisor should be responsible for determining the reason for the absence. Although absentee reporting probably need not go beyond the level of the immediate supervisor for those working with Class I or II agents, immediate consultation with the CDC Medical Epidemiologist in the Office of Biosafety should be sought for those working with Class IV and perhaps Class III agents. Efforts to exclude the possibility of laboratory acquired infection should be more rigorous with agents in higher classes; special diagnostic resources at the CDC should be made available to individuals working with them.

Entries into restricted areas without appropriate immunizations must also be reported and monitored. Such entries would automatically be minimized with limited access and with a system (such as color coded badges and laboratory entrance doors) that would permit easy identification of infractions of immunization requirements. The individual's prompt reporting is dependent upon 1) knowledge that such an entry is hazardous, 2) knowledge of immunization status, and 3) motivation to report the incident should the entry have been unobserved. An assessment must be made. The risks posed to that individual must be assessed, with the agent class and the status of laboratory work at that time taken into account.

Deficiencies in the Present System

The results of the Task Force investigation on existing practices regarding medical surveillance and medical care very clearly document serious deficiencies. Data sources included personal interviews, the laboratory safety questionnaire survey, written comments submitted with the laboratory safety questionnaire, and a review of laboratory accidents and

infections at the CDC. For discussion purposes, the results of the investigation are conveniently divided into the following topics: 1) reporting, 2) accident and illness investigations, and 3) medical care.

Reporting

The disturbingly high frequency of unreported laboratory-acquired infections at the CDC has been discussed above. Of 23 laboratory-acquired infections occurring in the period 1970-73, only 9 were officially reported to the Office of Biosafety; the remainder were disclosed only after personal interviews with laboratorians. The number of unreported illnesses in the period 1974-76 is unknown, since no interviews were conducted for this period. However, 1 swine influenza infection occurring in 1976, which is on record in the Bureau of Employee Compensation, was unknown to the Office of Biosafety.

The potential consequences of unreported illnesses are readily apparent. No systematic investigation can be undertaken to determine the source of infection; there is opportunity for further illnesses in other workers. Prophylaxis of co-workers who may have had a similar exposure is neglected. Finally, there is no way to interrupt a potential person-to-person or person-to-vector transmission cycle.

Serious deficiencies were also disclosed in the reporting of laboratory accidents for all groups targeted by the laboratory safety questionnaire survey. Most notable were the responses of the laboratorians and laboratory supervisors. For the 6 months covered by the questionnaire, 383 laboratorians admitted to a total of 352 unreported accidents. This is an unquestionably large number of incidents which did not even receive the benefit of supervisory evaluation. Similar deficiencies have been documented in the supervisor's willingness to report accidents to the Office of Biosafety.

Reports of entries into restricted laboratory areas without appropriate immunizations are rarely reported to the Office of Biosafety, though questionnaire responses documented this to be a fairly common infraction. From January 1970-March 1977, only 1 such incident is officially on record in the Office of Biosafety. For the 6 month period covered by the laboratory safety survey questionnaire, however, 16 of 130 (12.3%) Group 1 individuals, (i.e., non-laboratory and non- laboratory support personnel), entering laboratories claim to have entered restricted areas without the benefit of immunizations required for laboratorians.

Accident and Illness Investigation

An important part of effective accident and illness investigation involves ready access to a log of agents being used in the laboratory. Such a log, updated daily, would be particularly valuable in determining whether an illness in a laboratorian could be due to an agent being used in the laboratory. Only 32.6% of supervisors, however, were aware of a

separate log record of agents being used each day in their laboratories. In marked contrast, a higher proportion of supervisors felt that such a log should be kept, with strong correlation according to agent class: Class 1 and 2, 31%; Class 3, 44.4%; and Class 4, 85.7%.

Only 43.8% of supervisors stated that active efforts were systematically undertaken to determine if an illness in an employee represented a potential laboratory-acquired infection, regardless of agent class. In contrast, 67.9% of the supervisors indicated that they were primarily responsible for initially determining if an illness might be related to a laboratory exposure. A suspected laboratory-acquired infection in an employee absent from work, however, generally resulted in a much greater willingness on the part of the supervisor to arrange, or refer the employee to sources of medical consultation and evaluation. The perceived responsibilities of laboratory supervisors increased with increasing agent class.

A disturbingly low proportion (40.5%) of laboratory supervisors were satisfied with the follow-up of accidents reported to the Office of Biosafety. Paradoxically, more of those working with Class 3 or 4 agents were satisfied than were those working with less hazardous agent. The percentages and classes were: 24%, Class 1 and 2 agents; 53.3%, Class 3; and 46.7%, Class 4. Likewise, only 48% of laboratorians considered the Office of Biosafety a valuable resource in helping them perform their jobs in such a way as to provide maximum safety to themselves and others. Perceptions on the adequacy of the Laboratory Accident Investigation Board were too few to be reliably judged. These observations underscore the need for the expansion of the staff and skills of the office of Biosafety.

Medical Care

The rapid detection of possible laboratory-acquired illness depends, in part, on the worker's awareness of signs and symptoms to be expected from infection with the agents with which he is working. Only 55.4% of 134 laboratory supervisors, however, knew that their employees were informed of such symptoms and signs. Surprisingly, there is no trend with agent class.

CDC supervisory referral practices and attitudes indicated a lack of confidence in the CDC Clinic's ability to diagnose and manage rare infectious diseases. In instances of suspected laboratory-acquired infection, 76.9% of supervisors sought or directed employees to seek medical evaluation from CDC clinic physicians. However, there was clearly an increasing trend for supervisors to utilize alternative medical resources with increasing agent class (Table 2).

Sources of Medical Evaluation Utilized in
Instances of Suspected Laboratory-Acquired Infection

Source	Agent Class 1 and 2	3	4
Clinic	83%	77%	50%
Other CDC Physician	12%	20%	44%
Private M.D.	5%	0%	6%
Other	0%	3%	0%

Although there was an apparent increasing awareness by supervisors that diagnostic expertise for rare agents might be found other than at the CDC Clinic, these supervisors provided no more diagnostic services for their employees than those working with lower agent classes.

The lack of consistency in providing diagnostic laboratory services for employees with suspected infections, the infrequency with which employees are instructed about symptoms expected from illness due to agents in their laboratories, and the lack of consistent referral patterns, underscore the need for much clearer policies and instructions in these matters.

Proposals

The Task Force on Biosafety has identified serious deficiencies in medical surveillance and medical care of CDC employees. Adequate safeguards against infection fall short of what the Task Force has determined to be the minimum procedural guidelines to be followed for laboratory accidents, laboratory infection, absenteeism, and unauthorized laboratory entries. There is a lack of consistency regarding medical care of proved, suspect, or potential cases of laboratory-acquired infection.

To correct deficiencies documented in the preceding material, the Task Force proposes that a medical officer trained in epidemiology and infectious diseases, with a supporting staff of Biohazard Control Officers from the Office of Biosafety be assigned the specific responsibilities of medical surveillance and coordination of medical care. The duties of the medical officer would solely involve biosecurity responsibilities and in conjunction with the Biohazard Control committee would include:

1. Developing an efficient and effective reporting system for accidents and infections.

2. Refining standard definitions and/or procedural guidelines for the following reportable items:

   a. High-risk laboratory accidents

   b. Entries into restricted areas without appropriate immunizations

   c. Absenteeism

3. Identifying the population at risk, given either accidental exposure or infection.

4. Monitoring those identified in Item 3

5. Acting as an infectious diseases consultant (but not a primary care physician) for individuals with suspected laboratory-acquired illness, arranging for the collection and distribution of appropriate diagnostic specimens, and recommending prophylaxis if indicated and if available.

6. Triaging to appropriate quarantine or hospital facilities those individuals with suspected or documented infection in which person-to-person and/or person-to-vector spread pose a threat.

7. Assisting in the coordination of investigations of infections, facilities, equipment, and procedures.

8. Assisting the Systematic monitoring of safety practices and policies.

9. Determining yearly accident and infection rates at CDC.

10. Developing a sign-in, sign-out policy for laboratorians and others having responsibilities requiring them to enter certain laboratories.

11. Cooperating with a variety of persons with different skills and interests will be required for the successful operation of the medical epidemiologist and his staff. One way of enhancing cooperation and ensuring the input of the views and interests of a variety of organizational units is the formation of a Biohazard Control Committee. Representatives knowledgeable in epidemiology, clinical infectious disease, various subspeciality areas of microbiology, and environmental control should serve as committee members. In addition, management and organizations providing support services to laboratories should be represented. The medical epidemiologist would report data, problems, and activities to the committee on a regular (probably monthly) basis. The committee, or subcommittees thereof, would assist in the development of standards, guidelines, and policies. The committee should regularly prepare a report for the Center Director. The

report should succinctly summarize deliberations, actions, and recommendations of the committee. Copies of the report should be distributed to each major organizational unit represented on the committee as well as to those specific divisions, branches, sections, and units that have been requested by the committee to undertake actions.

Additional functions of the medical epidemiologist would include agent registration, immunization, monitoring, and periodic review of facilities and equipment. A long range plan must include national surveillance.

The assessment of the risk of acquiring an infection given either a laboratory accident, entry into a restricted area without immunizations, or absenteeism would involve a knowledge of agents being used in that particular laboratory or facility. Agent registration is a concept already being put to practical use at the National Institutes of Health (NIH) (2). There is a need to review the program at NIH and to adopt a similar program for the CDC.

Current knowledge of the immune status of workers having contact with laboratories is an indispensable facet of both medical care and medical surveillance of employees. There is clearly a need for a centralized, current, and efficient mechanism to monitor the immunization status of employees.

The adequacy of existing medical facilities and medical personnel must be systematically reviewed. The intent of the review should be to provide a basis for recommending appropriate changes that will guarantee the availability of expert medical care for individuals at risk of acquiring and/or transmitting a laboratory infection.

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