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A Study of the Application of Laminar Flow Ventilation to Operating Rooms

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A Study of the Application of Laminar Flow Ventilation to Operating Rooms

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PUBLIC HEALTH MONOGRAPH

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Foreword

Postoperative infections in patients continue to be a serious health problem in hospitals today. The problem is due in part to bacterial contamination from the air within the operating room. Tests have shown that well-designed ventilation equipment can help prevent such contamination. However, many lives are still being lost annually because this problem has not been adequately solved.

The "laminar airflow" concept described herein has been shown to reduce viable bacteria in the air up to one-hundredth of that found in an ordinary operating room with normal dilution ventilation. Other possible applications for using this air handling technique to control infections exist not only in surgery, but also in postoperative intensive care facilities, and possibly in sterile supply areas and research animal rooms. Scientists working with this new approach to bacterial control in the medical environment feel that it is a significant contribution to medical progress.

We hope that this monograph contributes to the advancement of biomedical research and also stimulates investigators working in this field.

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Division of Research Services,
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Contents

Contents - Continued

List of Illustrations

List of Tables

List of Tables - Continued

Chapter 1. Introduction

A serious problem that the medical world has had to face in recent years is the evaluation and control of nosocomial or hospital acquired infections. One aspect of this problem that needs more attention is the relationship between control of airborne microorganisms and the number of nosocomial infections. While no definite relationship has been established between environmental contamination and hospital acquired infection, doctors, bacteriologists, engineers, sanitarians, and others recognize that reduction of pathogenic airborne organisms in the operating room is an important part of infection control. Many investigators have implicated aerial routes as the primary mode of transport and deposition of viable microbiological contaminants in a medical care facility, particularly in the operating room.

Michaelsen (*1*) has stated that the control of microbial contaminants in the air can be approached in two ways: reduce the numbers of viable organisms in the air and control air movement to minimize the transport of airborne contamination. The practicality and certainty of mechanical air handling systems in reducing airborne contamination in a hospital environment have been demonstrated by Blowers and Crew (*2*) and many others. Most mechanical systems have introduced the supply air through the ceiling of a room either by a single diffuser, a series of diffusers, or through a perforated ceiling. The air is usually exhausted at various locations around the periphery of the room, and this approach has had only limited success in keeping airborne contamination at a low level.

New technological advances in industry, as typified by the work of Whitfield (*3, 4*), have permitted development of extremely clean environmental chambers or rooms for assembly of electronic and missile parts. The "white rooms" in industry now incorporate a technique whereby essentially bacteria-free air is introduced through a perforated end wall or ceiling. The air is directed toward and exhausted through a similar end wall or floor on the opposite side of the room thus creating a uni-directional flow of air over the entire working area. Actual practice has demonstrated that this technique can reduce airborne contamination, such as dust or particulate matter, to a very low level expressed in terms of numbers of particles per cubic foot of air. Austin and Timmerman (*5*) report that, with the new technique, one can attain dust levels of 10^3 particles per cubic foot of air 0.32 microns and larger, compared with approximately 10^6 particles per cubic foot of air in previous attempts at controlling airborne contamination.

No attempt has been made to date to apply a true uni-directional or so-called laminar air flow system to the cross section of the hospital operating room; therefore, no information is available in the literature on the design features and operational characteristics of such applications in hospitals.

Problem to be Investigated

The ability of a uni-directional flow of air to prevent airborne microbiological contamination from being transported into the operating room's critical field depends upon two basic requirements. First, is the capability of an air handling system to provide microbe free air and to establish uni-directional airflow. Second, once this flow has been established, the system must maintain its efficiency in preventing airborne microorganisms from moving into the critical site under a variety of disrupting influences that are typically found in the modern operating room.

The first of these requirements is primarily a design consideration for which criteria have been developed and evaluated by Whitfield (*3*) and Daniel et al. (*6*)

among others. Both laminar downflow and laminar crossflow air handling systems in industrial settings have been successfully used in reducing particulate airborne contamination.

The second requirement is a broad area and forms the basis for this study. The system must maintain both its uni-directional flow characteristics and its efficiency in preventing transport of airborne microbiological contamination to the critical site under the disrupting influences of people and equipment in the airstream. In the hospital operating room, these disrupting influences include the surgeon and his assistants working with their hands or part of their bodies directly over the wound site, the circulating nurse moving about in the periphery of the operating room, and the people in close proximity to the operating table who are observing or waiting to take an active part in the procedure. Careful study and evaluation have been made of the effect these people have on disrupting the airstream and creating turbulent airflow that potentially increases the risk of introducing additional biological contamination into the surgical field.

The effect on airflow of equipment such as the operating table, overhead surgical lamp, instrument tables, and anesthesia machine has also been evaluated. While these items are usually considered movable equipment, for any given procedure they normally remain in a fixed position.

A major disturbance common to all hospital air distribution systems involves the operating room doors. Bourdillon and Colebrook (*7*) and Blowers et al. (*8*), among others, have demonstrated that the operating room should be under positive air pressure with respect to the surrounding less critical areas, thus establishing the importance of maintaining this pressurization with people entering and leaving the operating room during a surgical procedure.

Objective

The objective of this study was to determine empirically the ability of a uni-directional flow of air to prevent airborne contamination generated by people within the operating room from being transported to and deposited in the critical field at the operating table under a variety of influences. The objective was divided into three subobjectives:

Subobjective 1: Estimate the level of contamination at the wound site as influenced by the presence of obstructions and their positions relative to the direction of the flow of air.

Subobjective 2: Estimate the level of contamination at the back instrument table as influenced by the presence of obstructions and their position relative to the direction of the flow of air.

Subobjective 3: Estimate the level of contamination at the instrument table as influenced by the presence of obstructions and their position relative to the direction of the flow of air.

Design of the Study

A test facility of appropriate size was constructed to simulate a hospital operating room equipped with a uni-directional airflow system. (The air handling equipment for this facility was purchased from a commerical supplier of industrial laminar flow room systems.) Construction and arrangement of the mock-up operating room furniture, in addition to determination of typical locations for various personnel during actual surgical procedures, were completed with the advice of several practicing surgeons and anesthesiologists. Generation of the simulated contamination and the physical collection of data were in accordance with an appropriate and proved method for studying distribution of airborne contamination (*9*). Treatment of the data followed appropriate statistical methods of analysis.

Significance of the Study

The significance of this study lies in (1) its evaluation of the effectiveness of an existing industrial method for controlling airborne particulate matter in a hospital operating room, (2) its assessment of whether the laminar flow principle provides a microbiologically cleaner surgical field than do other means now used, and (3) its analysis of these crucial elements in laminar flow

decontamination in the operating room: ability of a uni-directional flow of air to prevent the airborne contamination generated within the operating room from moving into the critical work area, conditions under which laminar airflow can be maintained in an operating room, and efficiency under the influence of several disruptive factors.

Potential applications of this study encompass many phases of medical care. In addition to many existing or proposed operating rooms, laminar flow may be applied to several other hospital areas that require strict airborne contamination control: patient care areas for burn patients, special environmental chambers for certain medical research techniques, pharmaceutical preparation areas, and nurseries for the newborn.

Limitations of the Study

While the orientations of people and equipment in this study simulate a number of surgical procedures, they clearly do not and cannot represent every situation, and frequently are but the best possible compromise. For example, the personnel in the test facility were placed in reasonably fixed positions and were not permitted to move about the room as they would during an actual procedure. Measuring and evaluating the efficiency of the air handling system were done with tracer substances disseminated in a manner approximating but not duplicating natural contamination disseminated from human beings. Operating room furniture in the test facility was built to represent the actual equipment. In addition, compromises had to be made on the exact size and shape of this equipment to imitate that which could be found in a variety of operating rooms.

The investigator clearly recognized that these factors would produce limitations and variables. However, he made every effort to minimize such influences and to qualify those portions of the work where such effects apparently influenced the final results.

Chapter 2. Review of the Literature

The Hospital Environment

The microbiological aspects of the hospital environment and their role in nosocomial infections have not been clearly defined until recently. Some contributions to knowledge of airborne infections in hospitals were made by efforts of Bourdillon and Colebrook (*7*) to identify specific pathogens (staphylococci and streptococci), and by samplings for the clostridial microorganisms by Duquid and Wallace (*10*) and Blowers and Crew (*2*).

It was not until Greene et al. (*11*) made qualitative and quantitative microbiological studies of hospital air that a clearer picture was gained. These investigators discovered that the distribution of various types of organisms in a hospital varies with the hospital area, the location within a given hospital area, and the overall level of the gross airborne microbial contamination. Most of the organisms they found were gram-positive cocci, which included among others *Staphylococcus aureus* and streptococci, which are normally considered indicative of human contamination. Approximately 85 percent of the gram-positive cocci were isolated in the surgical, obstetrical, and central supply areas. Other microorganisms which contributed to the overall microflora of the hospital were gram-positive rods, gram-negative rods, and molds. Twenty percent of the organisms found in the surgical areas were penicillin-resistant. Reports by Altemeier (*12*), Goddard (*13*), and Shaffer (*14*) have indicated that, in terms of postoperative infections, several members of the gram-negative bacilli (including *Escherichia coli, Proteus* species, and *Aerobacter aerogenes)* are frequently involved.

Greene et al. (*11*) have reported that the concentration of viable airborne contaminants, expressed in units of mean count per cubic foot of air, ranged from a high of 72.4 microorganisms in waste handling areas to 4.8 in obstetric-gynecology delivery rooms,

with an average of 20 for the entire hospital. Of these contaminants, the authors report approximately one-half were particles greater than 6 microns in diameter, about one-third were particles in the 2- to 6-micron range, and the remainder were less than 2 microns. Fraser (*15*) reports that the airborne particulate contamination typically found in a hospital operating room ranges from 1 to 10 microns in diameter, and that the size distribution curve for these particles has peak concentrations at the values of 2 and 10 microns. He assumes that the 2 micron size particles are separate and discrete, while the 10 micron size particles represent agglomerates made up of a number of the smaller particles.

The significance of the size of an airborne contaminant within an operating room may be found by investigating the ability of the particle to remain suspended in the air, its ability to be removed by mechanical filtration, its deposition in the respiratory tract or wound, and its ability to cause infection. Historically the significance of the size of airborne particles with regard to respiratory problems was determined from studies of silicosis. More recently, Decker et al. (*16*) and Wolf et al. (*17*) have reported on the selective action of the respiratory tract for particles of certain sizes. Those greater than 5 microns in diameter are effectively trapped in the upper respiratory tract; those in the 1- to 5-micron range and those from 1 micron down to 0.2 microns penetrate the deep pulmonary regions, with the smaller particles showing the greatest retention.

Noble et al. (*18*) relate that many organisms associated with human disease are carried on nonviable airborne particles and acted upon by the force of gravity. This has the effect of removing them from the air by sedimentation, in accordance with Stoke's Law. While there is little information in the literature as to the proportion of airborne particles that carry a viable organism, these authors suggest that with an increase in particle size the chance that a particle will carry a viable organism will also increase. The most hazardous particles in the average hospital vary in size from 4–20 microns in diameter.

In a given hospital environment, there are a great many variables which exert a greater or lesser effect on the level of airborne microbiological contamination. Bond et al. (*19*), in an extensive survey of environmental microbial contamination in a number of surgical suites, attempted to define patterns and normal levels of microbial contamination not only within a single hospital, but among several hospitals. These authors found gradations in contamination levels within the surgical suite: the operating room was the least, and the doctor's locker room the most contaminated. Levels of contamination among hospitals varied appreciably for a given location, whereas the contamination for a given location in any one hospital was not necessarily correlated to that found in other areas of the same hospital. They conclude there are varying degrees of correlation among the levels of air and surface microbiological contamination, especially in areas such as the surgical suite in which age, condition of the floor, traffic and dress control procedures, housekeeping procedures, the air handling system, and the number of personnel are significant variables.

Extensive microbiological sampling of the air by Vesley and Brask (*20*) indicated that for a given location in the hospital the number of organisms per cubic foot of air usually depends on four parameters: (1) the quality of the air entering the location, (2) the amount of personnel activity during a period of time, (3) the relative amount of biological contamination associated with the objects or personnel in the activity, and (4) the rate at which clean air being introduced into the area effectively replaces contaminated air.

These investigators also demonstrated that the high airborne bacterial counts found in hospitals during the day are correlated with peak hours of personnel traffic and activity; conversely, counts taken in the same location drop appreciably during periods of little activity. They conclude that it is possible to maintain a low level of airborne contamination in such critical hospital areas as surgery and obstetrics by supplying clean air, minimizing activity, and providing a high rate of ventilation. Greene et al. (*21*) found a similar relationship between levels of airborne

bacteria and activity. Hall (*22*), who has graphically illustrated the typical fluctuations in airborne contamination levels before, during, and after surgery, attributes the peaks to several variables including increased human activity, rapid movement of nonsterile drapes, and cleaning of the room after surgery. Michaelsen (*23*) and others (*17*) report similar peaks in contamination levels.

Kethley et al. (*24*) and Duquid and Wallace (*10*), have shown that the amount of bacterial particulate contamination disseminated by human beings in a room depends upon the use and type of protective clothing, and the amount of activity. These investigators demonstrated that the number of particles was minimized when the subject sat quietly with little talking. Dissemination increased rapidly with increasing levels of activity. They have also shown that tightly fitting aseptic gowning similar to those worn in the operating room sharply lower the contamination. Specifically, the average number of airborne bacterial particles liberated per person per minute was found to be 50,000 for loose surgical gowning and much activity, as contrasted with 7,400 for loose fitting gowning and little activity, 3,200 for tight fitting gowning and much activity, and 1,500 for tight gowning and little activity.

Additional variables that influence the amount of airborne microbial contamination in operating rooms, reported by Blowers and Wallace (*25*) and others, include medical and nursing aseptic techniques, the amount of contaminated air entering the operating room, the amount of contamination on unsterilized blankets, sheets, and instruments in the operating room, and the amount of turbulence in the ventilation system. Greene and Vesley (*26*) found typical surgical masks more than 95 percent efficient in removing contamination in all particle size ranges expelled by a human subject.

Lidwell and Williams (*27*), Kethley et al. (*28*), and others reported on a variety of ventilation arrangements for the introduction and exhaust of air to prevent a buildup in airborne contamination generated by the surgical team within a hospital operating room. These mechanical aspects of controlling fluctuations in airborne contamination are discussed in greater detail in a following section.

Altemeier (*29*) has praised the development of improved aseptic techniques, but he is quick to point out that surgeons and practitioners have relied too heavily and indiscriminately on antibiotic agents, with consequent relaxation of well-established surgical principles and increased numbers of infections. Hospital patients now run the danger of infection with newly emerged bacterial strains resistant to any antibiotic.

Although there has been very little quantitative evaluation of the magnitude of human introduction and spreading of microbial contaminants into the air, the significance of this dissemination is attested by Lidwell and Williams (*27*), Walter and Kundsin (*30*), Blowers and Crew (*2*), Wolf et al. (*17*), Nahmias et al. (*31*), Williams et al. (*32*), Blowers and Wallace (*25*), and others. These authors conclude, in general, that contamination may be spread by the patient who is either already infected at the time he is admitted to the hospital or may become infected during his confinement. Conversely, infectious agents that come originally from other patients, visitors, or members of the hospital staff may be carried to a wound site by dirty hands, unsterile dressings, clothing, or instruments. Simultaneously, contamination settled on the floor and other horizontal surfaces may be resuspended in the air by people walking and working in the area. Even though the precise relationship between the microbiological flora of an operating room and the rate of nosocomial infections has yet to be defined, there is strong evidence to suspect that potentially pathogenic bacterial aerosols are constantly being generated by all people in the hospital.

Airborne Infection

There appears to be considerable confusion in the medical profession about the nature and epidemiology of hospital acquired infection, especially postoperative infections. The mechanisms and transmission routes of mi-

crobiological contamination are well recognized, but final identification of the source (exogenous or endogenous) of a nosocomial infection becomes difficult and confusing.

Much of this confusion lies in the lack of well-defined terms. The term "airborne infection" as used herein is restricted to infection which arises from transmission of microbiological agents by droplet nuclei and dust. This is Langmuir's definition (*33*) and refers to droplet nuclei as residues from the evaporation of droplets which remain suspended in the air as contrasted to droplets which are larger particles projected from the nose or mouth. This distinction is made to exclude that disease transmission mechanism which effects the direct spread of the agent between two persons in close association by the spread of droplets or direct contact. The basis for this distinction is that control of droplet or direct-contact infection depends almost entirely on good personal hygiene and individual protection. Control of infection due to droplet nuclei and dust is based on such factors as mechanical ventilation, filtration, and dust suppression.

Although the historical aspects of airborne disease and the evolving attitudes of epidemiologists towards this mode of transmission have received attention (*34*), there is, with several exceptions, a noticeable lack of work relating to the magnitude and importance of the role of airborne microorganisms. Important exceptions are Altemeier and Hart: Altemeier (*12*) reports that reducing the number of viable airborne organisms with ultraviolet light did not show a corresponding decline in the postoperative infection rate, thus suggesting that air is a minor source of contamination. The converse has been shown by Hart (*35*), who reported that as early as 1936 the continuous use of ultraviolet radiation proved effective and safe in decontaminating air in the operating room. In 1942, he reported that ultraviolet light effected improvement in wound healing, a large drop in the number of deaths from unexplained infections in clean wounds, and a reduction in the level and duration of elevated temperatures in postoperative patients. Hart believes that the aerial route for the transmission of disease organisms is the greatest single factor in the contamination of otherwise clean surgical wounds and sterile supplies.

Investigators (*7*) report a drop in incidence of burn patient infections when the bacterial content of the air in the bandage-changing room was decreased. Others (*8*) have demonstrated a decreased infection rate in a thoracic surgery unit coincident with an increase in clean air. Lidwell and Blowers (*36*) conclude that the risk of airborne infection in an operating suite is significant enough to warrant serious consideration of effective controls. The basis for such control is simply that the contaminated air be diluted and replaced by air essentially bacteria free.

Despite some evidence to the contrary (Kinmouth et al. (*37*) indicate that the rate of postoperative infections bears little relationship to the presence or absence of certain pathogenic microorganisms in the air), the general belief is that introduction of clean air is essential for maintaining low concentrations of airborne contamination. Additional evidence for this comes from Wolf et al. (*38*), Lidwell (*39*), and Gaulin (*40*).

Mechanical Ventilation

The importance of reducing the risk of infection from sources external to critical areas such as surgery and obstetrics is obvious. Mechanical filtration is perhaps the best understood and most widely applied means of removing airborne biological contaminants.

Airborne bacteria in a hospital operating room may come from outside or inside the room or both. External sources of contamination include the ventilation system, doors, windows, and air leakage because of wind and thermal effects between the inside and outside of the building. Considering the operating room alone, the remainder of the hospital can be thought of as a potential source of airborne contamination, particularly when the operating room is under a negative pressure with respect to adjacent areas.

It has been reported (*16*) that with the exception of the presence of some spores of *Clostridium perfringens* and *Clostridium*

tetani, the outside air contains few viable microorganisms and only a small fraction of these are pathogenic. However, as Michaelsen (*41*) has pointed out, the contamination potential of each location for a supply air intake must be evaluated by its geographic location, by its relative location to various air exhaust ducts, surrounding industrial plants, and traffic, and by its height above the ground.

Contamination generated within the operating room, as discussed previously, includes pathogenic organisms that may be shed from infected wounds, from skin, hair, clothing, the respiratory tracts of the room occupants, and resuspended dust from the floor. Mechanical control of internal contamination has not yet reached the sophistication of external contamination control. Much of the available knowledge must be attributed to several British investigators (*7, 8, 25*). The early work (*7*) on air hygiene with burn cases showed that the air in the bandage-changing area was highly contaminated with viable microorganisms. There were two sources of these organisms: (1) wound dressings, blankets, and personnel and (2) the ventilation system. Since the ventilation system was not capable of removing an accumulation of airborne contamination, a supply of properly filtered air was introduced into the room in quantities sufficient to provide 10 to 20 air changes per hour. By supplying more air than was exhausted, the amount of sepsis was appreciably reduced. The excessive amount of clean air, by creating a positive air pressure in the room with respect to the adjacent areas, imposed an effective barrier against the free movement of airborne contamination entering the room.

Additional studies (*25*) were done on removing organisms liberated in the room by directing the supply of incoming air in three specific ways. The first method directed a stream of air either horizontally or obliquely toward the operating table in order to create an area of turbulent airflow directly over the patient. This system was intended to prevent a buildup of contamination in the stagnant air space bounded by the overhead lamp and the surgical team around the table. A second method introduced air at the ceiling in such a way that only mild turbulence was created as the supply air was mixed with the room air and then exhausted. In this way, the level of airborne contamination was controlled by a process of constant dilution. The third method was essentially the same as the second, except for producing minimal turbulence and mixing with the room air. The contaminated air in this case was removed by a downward displacement or piston effect. In each of these systems, the exhaust air was removed through ports located on each wall near the floor.

The investigations indicated that downward displacement achieved the most rapid removal of organisms. The turbulent systems, although quite efficient in removing contamination, brought a much greater amount of contaminated air in contact with the wound site, thus presumably increasing the risk of lodging an organism in or on the patient. This may be explained by the fact that the number of organisms coming into contact with the wound site depended largely upon air contaminant concentration and the amount of air passing over the site. In the turbulent scheme, both of these parameters tended to be large. The concentration of organisms was increased because they were not being removed as rapidly as they were introduced. In addition, in the turbulent case, a contaminant had more than a single opportunity to contact the wound site due to the random and nondirectional movement of the air.

An additional comparison (*2*) of turbulent and downward displacement methods indicated that, for contamination distributed throughout a room, the "displacement air" or piston distribution was much superior in terms of rapid removal of airborne contamination. For localized contamination, turbulent flow was better if the contamination was directly over the table; if the contamination was elsewhere such as on the lower part of the clothing or the floor, the displacement system was better. This study concluded that the most rapid removal of airborne bacteria and the lowest contamination of exposed surfaces can be achieved by a ventilation system that produces minimal

turbulence, thus causing the contamination to be removed in a piston-like manner rather than with dilution.

Lidwell and Williams (*27*), working with nitrous oxide tracer gas at the potential wound site, found mildly turbulent airflow better when the generating point of contamination was close to or above the elevation of the operating table. Conversely, downward displacement was better for contamination liberated either away from or below the table.

Kethley et al. (*28*) reported that with the ventilation systems commonly used today in hospital operating rooms, it is very likely that airborne particles generated by people can be transported great distances by the airstream and readily distributed throughout the room. Specifically, particles of 50 microns or greater in diameter can be carried for horizontal distances up to 8 feet. These authors assume that, if this is true, turbulent airflow can carry smaller particles at least the same distance.

Evaluation of Ventilation Effectiveness

Primary concerns in evaluating a ventilation system are air pattern functions, air velocities, room air ventilation rates, and types of air supply and exhaust systems for transporting and distributing contaminated particulate matter throughout a room. However, there is no single measurement that will give quantitative indication of actual ventilation effectiveness, and, indeed, the precise function of these parameters is not well defined. There is general agreement that, first, the ventilation system must be able to rapidly remove the widespread contamination that increased activity causes at the beginning and end of an operation, and, secondly, any contamination from a localized source, such as the nose and throat of the surgeon should be removed without being carried into the critical area.

On the basis of the above, Blowers and Crew (*2*) give two performance measures for a ventilation system—the Equivalent Ventilation Rate and Sedimentation Index. The Equivalent Ventilation Rate measures the rate at which an initial concentration of airborne microorganisms is removed from a room; it compares, in air changes per hour, the performance of a given ventilation system with that of a standard system. A standard system has been defined as one in which uniform turbulence creates complete and rapid mixing of the clean supply air with contaminated room air and has a mechanical ventilation rate of 17 changes per hour. The authors report that this rate gives the number of air changes per unit time required for the given system to be of similar performance, and provides a numerical value to ventilation performance which is directly proportional to the rapidity with which airborne contamination is being removed: a higher value means a better performance. The Equivalent Ventilation Rate is calculated by plotting time against the logarithm of the bacterial counts and constructing the line of best fit between the points. Between any two points on this line a quantity called the disappearance rate of organisms may be calculated from all causes including ventilation, sedimentation, and natural die-off. The formula for this calculation given below, was developed by Bourdillon et al. (*42*)—

$$\text{equivalent air changes/hr., } K = \frac{(\log n_1 - \log n_2)\ 138,}{t}$$

where n_1 and n_2 are the number of bacteria present during time t expressed in minutes and 138 is the unit conversion factor.

The Sedimentation Index (S.I.) indicates the amount of contamination that an open wound site receives as the contamination is being removed. Thus, a lower value for this index means higher performance of the ventilation system. Since the Sedimentation Index depends only upon initial concentration and amount of contamination that settles out of the air into the wound, it is defined as

$$\text{S.I.} = \frac{\text{particles settling/sq. ft./min.}}{\text{particles/cu. ft. at start of run}}$$

Although Blowers and Crew (*2*) base their performance measurements on a comparison with a standard system, the reported values are not conceptually clear.

Kethley et al. (*43*), employing the same definitions as Blowers and Crew, developed

both a Performance Index and a Sedimentation Ratio. Kethley et al. form ratios with the theoretical or expected situation thus yielding a more meaningful index. The Performance Index is a ratio of the concentration of airborne bacteria at a particular room site to the theoretical concentration at the same site in a completely turbulent room under the assumption that the only loss of particles is due to unhindered and natural settling. Thus, the smaller values of this index represent better performance in terms of rapid removal of airborne contamination. The Sedimentation Ratio compares the number of particles that settle per minute per square foot to the number that would theoretically settle in the turbulent case. Therefore, if the value of this ratio is greater than one, large amounts of contamination are being deposited.

The work of Wells (*44*) contains similar indices for the effectiveness of a ventilation system. He first states that air change, that is, room volume replacement, is a measure of the ventilation per occupant in a given enclosure. However, he goes on to say that a single air change cannot completely replace all the air in the enclosure, since the supply air is diluted to some degree by the air being replaced in the enclosure. Wells also reports the proportion of original room air that remains after one air change is the reciprocal of the Naperian base, e, or 1/2.718 which is equal to 36.8 percent. The concept of air change is the unit of measure he uses for "sanitary ventilation." Therefore, the disappearance rate of room contamination by mechanical means of purification is expressed in terms of number of air changes that yield the same reduction in concentration of the contaminant by dilution with fresh air.

Wells also formulates the rate of contamination removal by sedimentation, expressing it in terms of a known settling rate for the particles and the fraction of the room height through which the particle travels. For example, he expresses the "sanitary equivalent ventilation" as sedimentation of dust particles that settle at a rate of 1 foot per minute in a room 10 feet high as an air change every 10 minutes or six equivalent changes per hour.

Sampling Techniques

Sampling of airborne microbial particles in hospitals—particularly operating rooms—has been increasingly emphasized in recent years. Microbiological sampling (*22*) has sought to define qualitative aspects of the environment (hazards associated with airborne microbial contamination, movements of such contamination, influence of people and objects on the microbial quality of the air) and to determine the ability of air-cleaning devices to remove airborne contamination. Much of the work involved study of already existing contamination in an operating room, regardless of source, in an effort to delineate hospital microflora. Wolf et al. (*45*) have reported biological air sampling equipment and associated techniques required for this type of analysis.

In other studies (*27*), a gaseous tracer was liberated in a carefully controlled simulated operating room to evaluate a given ventilation system without the variables (viability, biological decay, and the effects of temperature, and humidity on the viable agent) associated with biological air sampling.

The criteria to be applied in selecting the appropriate tracer substance, the limitations of its use, and the alternatives available in the generation and analysis of such a tracer are discussed in detail in a later chapter of this monograph.

Development of Laminar Flow Rooms

An ever increasing need for cleaner environments during assembly of missile components and electronic equipment led industry (*3, 4*) to re-evaluate existing "clean rooms," which could not meet the cleanliness standards (in terms of suspended particulate matter) specified for these materials. Ceiling diffusers at various locations in the conventional clean room introduced large volumes of clean and conditioned air that passed downward and was exhausted through wall grilles near the floor around the room's periphery. A turbulent airflow (*2, 25*) was created as the supply air, bounced off walls, floor, tables, equipment, and personnel. Emphasis was placed on limiting the amount of contamination in the new air by con-

trolling personnel, activities, and types of material used within the room.

This clean room presented a number of problems. First, it had no self-cleaning capabilities to offset the contamination generated—faster than it could be removed —by people and equipment in the enclosure. A large portion of this contamination settled on the floor or on horizontal work surfaces which then permitted the reintroduction of settled contamination into the air by air current changes and personnel activity in the room. Ultimately this contamination had to be removed manually. Secondly, the airflow patterns were neither uniform nor directed to carry off particulate matter from the critical field. In addition, rigid control of personnel, clothing, and activity were needed to lessen contamination.

It soon became apparent that total control of the air (temperature, humidity, cleanliness of the supply, and direction of flow) within the enclosure was required.

To solve these problems, new methods were developed for introducing clean air into the room and for removing contaminated air. Large volumes of clean air were introduced into the room through a very large diffuser or perforated panel; this method reduced the velocity of the incoming air, thereby preventing agitation and reintroducing settled contamination into the air. It also decreased the contamination blown off personnel and equipment. At the opposite side of the room, the air was removed through a perforated area of the same size as the inlet diffuser.

This new concept of total air control used a single-pass technique in which either one wall or the ceiling consisted of a bank of ultra-high efficiency particulate air filters. In this manner, the air made a single uniform traverse of the room in either a vertical (laminar downflow) or horizontal (laminar crossflow) pattern. Since the air flowed from the inlet to the outlet throughout the full cross-sectional area of the enclosure, there could be no reverse flow within the enclosure that would carry contaminants generated at one point within the enclosure to any point further upstream. The contaminants were therefore carried directly downstream and out of the enclosure. In this case, the emphasis was on performing the task in an undisturbed flow of clean air. The restrictions on personnel, equipment, and materials were minimized. Figure 1 shows a schematic sketch of each clean room system.

Uni-directional or laminar airflow may be thus visualized: consider several sheets of glass, one on top of the other, sliding down an inclined plane. While each individual sheet may move down the plane with a somewhat different velocity relative to the other sheets, each is confined to its own plane and does not enter the plane of any other. On the other hand if these sheets were broken into small pieces and allowed to slide down the same inclined plane, the pieces from one sheet would intermix with pieces of other sheets in a random manner. This latter condition is called turbulent flow. The laminar airflow is defined in Federal Standard No. 209 as ". . . airflow in which the entire body of the air within a confined area moves with uniform velocity along parallel flow lines with a minimum of eddies."

Technically, the term "laminar flow" applied to this mechanical air handling system is incorrect. Based on information from Daugherty and Ingersoll (*46*), laminar or streamline flow is characterized by laminations of an infinitesimal thickness, sliding relative to adjacent laminations in a definite and observable path. The velocity required for these airflow characteristics can be calculated for any enclosure size. For example, in a rectangular room 20 feet long, 15 feet wide, and 8 feet high, with the air moving in the long dimension of the room, the velocity range is 0.15 to 3.75 linear feet per minute. This range is several orders of magnitude less than the velocity required for directional airflow that is subjected to other forces (thermal effects, movements of people) and obstructions (tables, desks, and chairs).

As applied to clean rooms, this type of airflow is more properly designated uni-directional airflow, rather than laminar airflow. Although fully cognizant of this misuse of this latter term, the author uses it in this work only to conform to popular nomenclature.

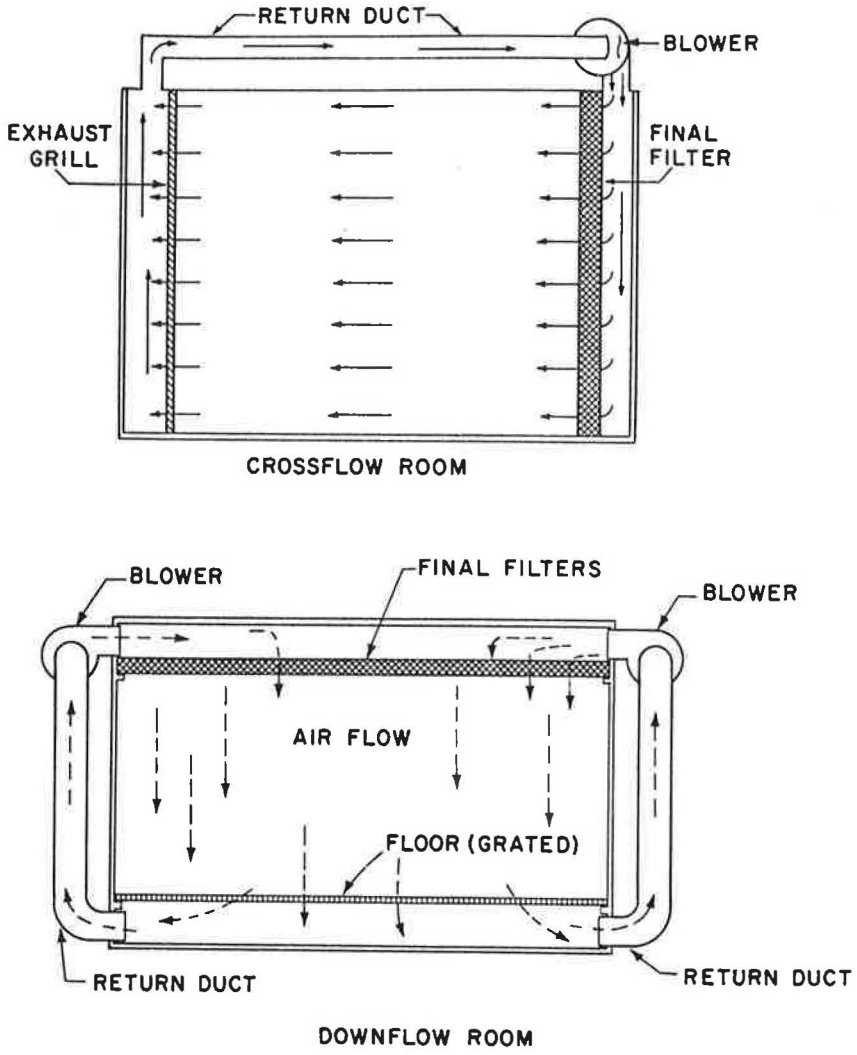

Figure 1. Diagrammatic drawing of laminar crossflow and downflow rooms

The laminar crossflow design based on the work of Daniel et al. (*6*) requires an air velocity of 100 linear feet per minute across an area determined by the cross-sectional area of the room measured perpendicular to the flow of air. The room dimension in the direction of the airflow then determines the minimum path of any particle; the maximum path will depend upon the number and projected area of the obstructions which it encounters in traversing the room. With the crossflow system, the laminar flow contours at the normal working surface are affected by all upstream obstructions, including equipment on the floor. Therefore, the cleanliness at any point in the room depends to a large extent on the upstream activity and inherent contamination. The crossflow scheme requires staging of work, that is, those procedures which need the cleanest air must be carried out in the area nearest the air supply.

The laminar downflow design requires an air velocity of 50–75 linear feet per minute (*6*) across an area determined by the floor area. The height of the room in this case determines the minimum path of any particle; the maximum path is similar to that for the crossflow design.

The geometry of the room size and the volume of supply air required for the crossflow versus the downflow systems present an interesting contrast. Consider a room 20 feet by 20 feet, with a 10-foot ceiling. As-

suming for purposes of illustration an air velocity of 100 linear feet per minute for both systems, the crossflow room will require 20,000 cfm versus 40,000 cfm for the downflow room.

Daniel et al. (*6*) also state that in terms of mechanical access requirements the downflow room needs access next to one wall of the room, while the crossflow scheme requires access space on two opposite walls. However, since the filter bank for a downflow system is located in the ceiling, cleaning and maintenance of the air handling equipment are more difficult than with a crossflow scheme. In addition, because of the weight of the filters, the downflow system requires a stronger structural supporting system than does the crossflow system. For a given size room and a given heat load, the downflow system requires a much lower air velocity to maintain a constant temperature within the room. Control of humidity in both systems is not a problem, since the velocity required to maintain the temperature conditions is far greater than that needed for humidity control.

In considering the settling of particulate matter for the two systems, the downflow room presents no problems since the flow of air is in the same direction as the gravitational force. The crossflow room, on the other hand, presents problems with respect to settling of particles. The larger particles (100 microns or greater) will settle onto the floor or work surfaces within a few feet of their point of introduction. Particles of approximately 50 microns can travel several feet in the airstream before settling. The 50–100 micron size particles, therefore, present a problem of gradual contamination buildup. Those particles less than 30 microns in size do not settle out at the air velocities required to maintain the desired conditions of temperature and humidity.

Throughout the literature on laminar flow clean rooms there is little information about their actual evaluation and performance. Most references merely state this equipment can meet the class 10,000 requirements in Federal Standard No. 209, namely, that the number of airborne particles of the size 0.5 microns and larger shall not exceed a total of 10,000 per cubic foot of air nor shall there be any more than 65 particles per cubic foot of air of size 5.0 microns and larger. In a performance evaluation of a laminar crossflow clean room, Flinn and Gosma (*47*) found only 2,850 particles per cubic foot of air in the size range of 0.3 to 10 microns, which is well below the limits described above. These tests were conducted when up to seven people were carrying out normal work procedures in the room, but the authors say these people made no significant contribution to the contamination. Typical of the results of such evaluations is the work of Whitfield (*3*), who has shown that airborne contamination levels in conventional clean rooms, in terms of particles per cubic foot 0.32 microns and greater, averages one million; the counts in a laminar flow clean room average 7,500 per cubic foot.

A diligent review of the literature reveals as yet no definitive comparison of the economic factors in the crossflow versus the downflow air handling system. However, it appears (*6*) that initial construction costs for the crossflow system are less, because of its simpler structure. From the long term operational point of view, the downflow system is less expensive because less air volume is needed to maintain its temperature and velocity requirements.

Comparison of Clean Rooms and Operating Rooms

A comparison of industrial clean rooms and modern hospital operating rooms becomes important in considering the basis for measuring "cleanliness" or contamination and the numbers and activity of people working in these two spaces.

Operating room contamination is determined in part by bacterial content of the air measured in organisms per cubic foot. While standards of air cleanliness have not been formally established for hospital operating rooms, it is reported (*48*) that the acceptable range suggested by several investigators is from one-tenth to 10 organisms per cubic foot of air. The measure of cleanliness in clean rooms, on the other hand, is dust concentration measured in particles per cubic foot of air. Air quality standards for these

rooms, depending upon type and class, range from 10,000 to 250,000 particles (less than 10 microns in diameter) per cubic foot, as discussed previously.

Michaelsen and Vesley (*48*) observe that clean rooms tend to be larger than the typical 20-foot by 20-foot operating room, and with fewer people working in them. In general, the operating room is not only smaller but more crowded: during a given procedure, it has greater physical activity and more people entering and leaving.

Another study (*49*) comparing the two types of rooms noted that conventional industrial clean rooms, under present techniques, were indeed cleaner: they showed a lower mean microbial count and a smaller range of microbial counts. This study would indicate that the principles of air distribution, limitations of personnel and activity, and dust-free clothing could profitably be applied to a hospital operating room with consequent reduction of airborne contamination and—assuming a relationship between the latter and postoperative infections—a corresponding drop in such infections.

Chapter 3. The Physical Facilities

Laminar Flow in Operating Rooms

The typical operating room in most hospitals is square and measures 20 feet by 20 feet, giving a free floor area of 400 square feet. However, rapid developments in surgery, particularly cardiac and neurosurgery, are increasing the demand for larger operating rooms, for new instrumentation, including heart-lung machines, hypothermia equipment, electro-encephalographs, electrocardiographs, and many other electronic devices, and for additional personnel to control and monitor this equipment. These new surgical procedures frequently require larger incisions that are kept open to the air for extended periods, thus increasing the chance for infection from airborne contamination. These factors underscore the need for a cleaner and fully controlled environment in the operating room.

Selection of a crossflow or a downflow system for environmental control of a hospital operating room depends upon many specific factors. There are advantages and disadvantages with either horizontal or vertical airflow. Downward flow of air will prevent transport of airborne contamination from one part of the room to another in a horizontal direction, but may deposit on the wound site contamination generated by the head and arms of the surgical team. The overhead surgical lamp offers an obstruction to the downward airflow and thus creates turbulence which may direct the contamination toward the wound site. The volumes of air required in the typical operating room, as discussed previously, will be less for the crossflow system as compared to the downflow system.

Within the limitations of the budget for this work and the previous discussion, the crossflow system appeared more feasible at the time.

Description of Test Facility

The fundamental design requirements for a laminar airflow room are that the air shall flow with a uniform velocity and direction through any given cross section of the room and that all of the air entering the room shall have passed through the high efficiency particulate air filters.

Overall performance of a laminar flow facility is keyed to the performance of individual components. The elements of a laminar airflow room include the basic room enclosure; the air distribution system consisting of ducts and plenums; the mechanical air handling devices, such as blowers and air conditioners; and the filtration system. Planning and construction of the facility used in this study (fig. 2) followed the design specifications established by Whitfield et al. (*50*).

The configuration of the basic room enclosure requires only that the interior wall surface be parallel to the direction of the airflow; the cross section of the room remains constant; and the walls have a minimum of ledges, protrusions, offsets, and other obstructions to the air stream. The interior dimensions of the test facility were 20 feet long, 14 feet, 8 inches wide, and 8 feet, 3

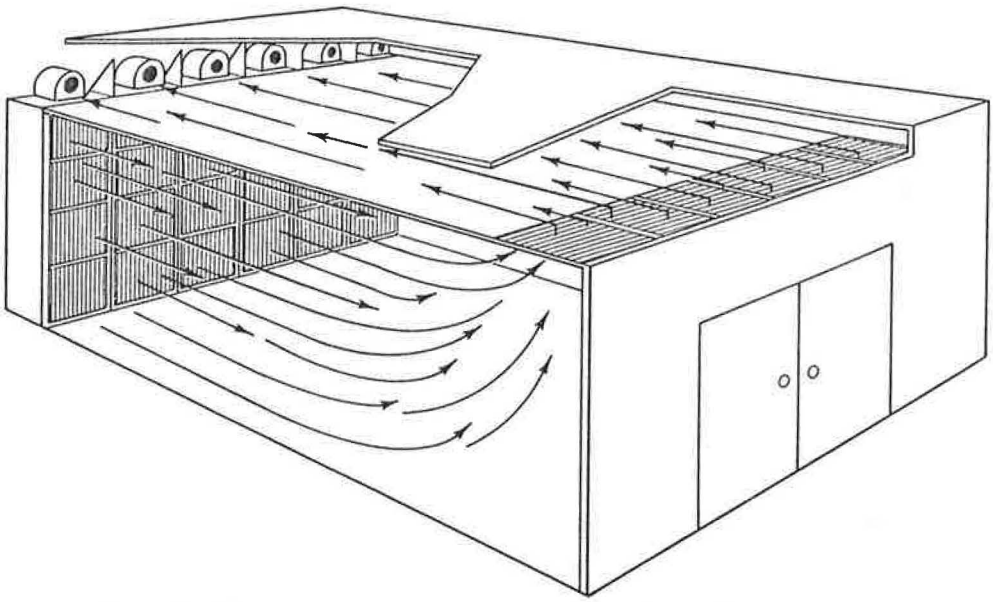

Figure 2. Diagrammatic drawing of experimental crossflow operating room

inches high. The floor area was selected partly on the basis of approximating the size of the typical 20-foot by 20-foot operating room and partly because of the space available for the test facility. The height of the room was fixed by the height of the commercially available laminar-airflow modules. The two interior long walls of the room each had five 2-foot by 3-foot flush-mounted windows for observation and photography. The wall at the downstream end of the room contained a pair of wooden double doors that swung outward.

The test facility, henceforth referred to as the operating room, was constructed within a larger air conditioned room—called the work area—measuring 36 feet by 52 feet by 12-feet high.

Drywall and stud construction was selected for the walls, since it provided the necessary tightness to prevent excessive leakage of air, low cost, durability, and minimum maintenance. The joints in the interior and exterior walls were taped, plastered, and painted to present an easily cleanable wall surface. The floor was covered with vinyl tiles to provide a reasonably nonporous and maintenance-free surface, and a 4-inch cove-floor molding sealed the joint between the walls and the floor on the inside and outside of the room.

The ceiling plenum measured 20 inches by 14 feet, 8 inches in cross section. The upper ceiling was constructed of 2-inch by 12-inch wooden joists, 2 feet on centers. The lower portion of the upper ceiling was covered with drywall whose joints were taped and plastered to prevent excess air leakage and to simplify room pressurization. The lower ceiling was made of 2-foot by 4-foot luminous panels (also with sealed joints) suspended from the upper ceiling on a support system. The sides of the plenum were formed by extending the dry wall of the interior walls to the lower side of the upper ceiling.

In a laminar crossflow room, air is directed from one wall to the opposite wall or, as in this facility, to an adjustable return air grille in the ceiling at the downstream end of the room. This air distribution was achieved by making one entire wall of the room a filter bank in modular form. The pressure drop across the filter bank created the desired uniform airflow into the room. The air was drawn through the room and returned to the suction side of the laminar flow modules through the double ceiling arrangement which served as the return air plenum. The air filtration system was composed of prefilters and the final filters: the prefilter protected the final filters by removing the gross contamination; the final filters were the high efficiency particulate air

type which removed 99.97 percent of all particles 0.3 micron in diameter or larger.

Selection of air moving equipment (the blowers) was based on the system's air resistance at the desired flow rate, the ranges of pressures expected from increased resistance as the filters became dirty, and noise and vibration characteristics. The blowers were to be capable of delivering an average minimum rate of flow through the filters of 90 linear feet per minute with a uniformity of ± 20 feet per minute and of maintaining this flow rate for an increase in pressure of 0.5 inches of water across the filter bank.

The lighting installation in the room was six rows of four fluorescent strip fixtures each attached to the underside of the upper ceiling to eliminate interference with airflow.

Temperature and humidity stability was maintained by introducing, as required, small quantities of conditioned air from the workroom into the return air plenum of the operating room. This air entered seven 6-inch diameter holes in the return air plenum to assure proper mixing of the cool makeup air before it entered the blower-filter modules. Air exhausted from the operating room, other than by leakage or through the open door, passed through an exhaust duct located in the return air plenum and was vented to the outside of the building. A damper in the exhaust duct maintained the desired volumes of air and the static pressure differential between the operating room and the workroom. Since this entire air handling arrangement constituted basically a closed system, the amount of air required to maintain the environmental parameters at acceptable levels was relatively small, generally in the order of 325 cubic feet per minute.

The laminar flow air handling system was built on a modular basis, in which each of the seven modules includes the blower, prefilters and final filters, plenum chamber, and filter shields. These blower-filter modules, when bolted and gasketed together to form the supply air wall, constituted the mechanical portion of a class 100 clean room. Federal Standard No. 209 for this class requires the particle count in the room not to exceed 100 particles per cubic foot of air 0.5 microns and larger.

An air and vacuum manifold, installed near the floor at the center of the east wall, permitted operation of the test equipment used for introducing the experimental contamination, and minimized the need for extra pumps, electrical cords, rubber tubing, and other such items.

Tests for Laminar Flow Rooms

Two requirements are basic to production and maintenance of a clean environment in a laminar flow room: (1) large quantities of air must be introduced into the room through a large surface area of high efficiency particulate air filters. (2) This clean air must then be directed so that the entire room is swept by a single pass of air to remove any contamination generated within the room, without permitting the contamination to move upstream against the flow of air.

Filter Leak Tests

Marsh et al. (*51*) have made clear that providing large quantities of supply air to a laminar flow clean room through a bank of high-efficiency particulate air filters is not always simple. The filter bank must be constructed so that none of the supply air bypasses the filter through leaks in the filter frames, joints between filters, or pinholes in the filter itself. Quality of the filter and installation are important, since it creates a pressure differential of between three-tenths and 1 inch of water, which is adequate to force significant quantities of unfiltered air through any tiny leaks around or in the bank of filters.

To meet the obvious need for a simple filter leak test, Marsh et al. (*51*) developed a reliable and inexpensive "go, no-go" procedure, consisting of generation of smoke on the upstream side of the filter and detection of the quantities of smoke passing through and around the filter with a light-scattering photometer. Using a controlled amount of smoke and a known sensitivity for the detector establishes an acceptable leak criterion. A Sinclair-Phoenix Dust and Smoke Photometer (Model JM 1000) measures the mass concentration of particulate matter in the test environment by means of forward-scattering of light from the particles drawn through the dark-field illumination cham-

ber. A full range concentration is recorded on a single scale by logarithmic amplification of the photocurrent from the photomultiplier tube, which is illuminated by the forward scattered light.

Smoke was provided by a burning cigarette, which produced a rather uniform concentration of smoke with a preponderance of particles three-tenths of a micron and smaller. Smoke concentration was controlled by adjusting the length of the cigarette burned per unit time in a venturi nozzle by screwing the cigarette either into or out of the airstream. The photometer sensitivity was selected to register zero if the filter contained no leaks. A minimal meter deflection of 10 percent of the full scale—equivalent to a concentration of approximately one million particles per cubic foot of air—was considered a significant leak.

As pointed out by Marsh et al. (*51*), this method is not in any sense a test of filter efficiency. It is, rather, an in-place test for the presence or absence of minute holes or leaks around the filter seals and in the filter media. Any hole that is present will permit relatively large concentrations of cigarette smoke to pass compared with the low amount of penetration of the filter media. For this reason, the sensitivity of the photometer and the concentration of the smoke are not overly critical.

The 28 high efficiency particulate air filters were found to have no significant leaks in the filter media or around the filter gaskets. However, approximately one-half of the filters showed significant leaks around the filter frames—all located at one of the corners, or along the vertical sides, of the frame. This defect was corrected by tightening each filter frame to the filter module gasket. A second test showed no significant leaks in the entire air supply filter wall, demonstrating that the room met the cleanliness requirement of Federal Standard No. 209, class 100, as determined by a Royco particle counter.

Airflow Tests

The uni-directional flow of air within this test facility was demonstrated by smoke patterns in the airstream. With the air supply operating, smoke was produced by holding in the airstream a cotton-tipped swab that had been dipped in titanium tetrachloride. Smoke was introduced at several heights in the room, at various distances downstream of the supply wall, and at several locations across the room. Particular attention was given to determining any areas of reverse airflow or considerable turbulence.

Velocity and uniformity of air movement were measured by a heated thermocouple anemometer placed at several representative locations throughout the entire cross section of the room. Maximum and minimum airflows were measured, and average air velocity was calculated.

The airflow tests indicated that the airflow patterns were uni-directional and, in the empty room with doors closed, there were no areas of reverse airflow except for a minimal amount within 18 inches of the wall near the floor at the downstream end of the room.

Airflow Characteristics

In the course of determining the airflow characteristics of this operating room, it became apparent that two separate sets of conditions had to be studied. Under condition 1, which encompassed the airflow parameters as initially installed, the module blowers operated at 850 rpm with a 3-inch pulley on the motor shaft. It was soon obvious, as will be shown shortly, that this condition did not produce sufficient air velocity to meet the laminar airflow requirements of Federal Standard 209. Condition 2—a result of this finding—calls for 4-inch pulleys on the motors, which allows the blowers to rotate at their maximum capacity of 1,150 rpm. Although the airflow characteristics for condition 1 were determined completely before the modifications were made for condition 2, they are reported together so that their similarities and differences may be more readily identified.

The first determination of airflow patterns was along the longitudinal centerline of the room. A cotton-tipped swab, dipped in titanium tetrachloride was placed 7 inches in front of the center filter module and 36 inches above the floor. As the width of the return air grille was varied, the elevation of

Table 1. Airflow patterns along centerline of laminar crossflow room with various widths of the return air grille

Return grille width	Elevation of smoke pattern (inches) at distance downstream from filter wall (feet)												Remarks (percentage open)
	Condition 1						Condition 2						
	0 ft.	4 ft.	8 ft.	12 ft.	16 ft.	18 ft.	0 ft.	4 ft.	8 ft.	12 ft.	16 ft.	18 ft.	
72 in.	36 in.	38 in.	43 in.	59 in.	98 in.	98 in.	36 in.	37 in.	44 in.	52 in.	98 in.	98 in.	100
48 in.	36 in.	38 in.	41 in.	51 in.	71 in.	98 in.	36 in.	37 in.	42 in.	48 in.	72 in.	98 in.	100
24 in.	36 in.	38 in.	41 in.	48 in.	65 in.	76 in.	36 in.	37 in.	42 in.	48 in.	62 in.	72 in.	100
24 in.	36 in.	38 in.	43 in.	48 in.	63 in.	71 in.	36 in.	37 in.	42 in.	48 in.	62 in.	73 in.	50
20 in.	36 in.	38 in.	42 in.	47 in.	61 in.	69 in.	....	....	....	....	....	....	50
18 in.	36 in.	38 in.	41 in.	46 in.	56 in.	65 in.	36 in.	37 in.	42 in.	47 in.	61 in.	73 in.	50
16 in.	36 in.	38 in.	42 in.	47 in.	56 in.	65 in.	....	....	....	....	....	....	50
14 in.	36 in.	38 in.	42 in.	46 in.	53 in.	62 in.	36 in.	37 in.	42 in.	47 in.	60 in.	68 in.	50
11 in.	36 in.	38 in.	42 in.	46 in.	54 in.	64 in.	....	....	....	....	....	....	50

the tracer smoke was measured at distances of 4, 8, 12, 16, and 18 feet downstream from the filter wall (table 1). The return air grille width was varied by either removing or replacing the ceiling panels. Under the "remarks" column, the 50 percent notation refers to perforated panels whose open area was 50 percent of the total panel area.

The measurements in table 1 strongly indicate that within the velocity range (approximately 60 to 85 linear feet per minute as discussed subsequently) there is no measurable difference in the airflow patterns. Under both conditions 1 and 2 a gradual tailing up of the airflow patterns is to be noted as the air travels the length of the room. All measurements in table 1 were made at 85°F. and 40 percent relative humidity.

On the basis of what was observed in table 1 all other portions of this study, except where specifically noted, were conducted with the 14-inch, 50 percent open-return, air-grille width.

Under both conditions, the point source of smoke diffused as it traveled through the room, with no measurable difference in the amount of diffusion. At the source, the horizontal and vertical dimensions of the smoke stream were one-half inch by 1 inch respectively. This point diffused to 4 inches by 6 inches, 8 feet downstream, and to 12 inches by 18 inches, 16 feet downstream. As the airflow patterns were being measured, the source of smoke was moved downstream to the last previously measured elevation, whenever the vertical dimension of the smoke plume exceeded 6 inches, thus permitting a more accurate measurement to be made of the elevation. The point source of smoke located in a downstream position followed the identical pattern of the same source upstream, but in a less diffused manner.

All airflow pattern measurements presented here may be considered to be accurate to plus or minus 2 inches. This range is attributable to the diffusion of the smoke plume even in 4-foot increments and to the mild turbulence within this uni-directional flow of air.

Table 1 presented the airflow patterns at an elevation approximating the height of an operating table and the wound site. Table 2

Table 2. Tabulation of airflow patterns along center line of the laminar crossflow room for eight vertical points at the center filter module

Conditions 1 and 2

Point	Elevation of smoke pattern (inches) at distance downstream (feet)					
	0 ft.	4 ft.	8 ft.	12 ft.	16 ft.	18 ft.
1	6 in.	7 in.	10 in.	14 in.	22 in.	28 in.
2	18 in.	20 in.	23 in.	30 in.	39 in.	51 in.
3	30 in.	31 in.	33 in.	35 in.	42 in.	51 in.
4	42 in.	45 in.	51 in.	60 in.	72 in.	79 in.
5	54 in.	55 in.	58 in.	63 in.	72 in.	82 in.
6	66 in.	69 in.	74 in.	77 in.	87 in.	98 in.
7	78 in.	78 in.	80 in.	82 in.	87 in.	94 in.
8	90 in.	93 in.	93 in.	93 in.	95 in.	97 in.

represents the airflow patterns along the centerline of the room at the center filter module for eight vertical points, 7 inches in front of the center filter module. Figure 3 graphically presents part of the tabular data of table 2 (these patterns were determined in the same manner as were the patterns in table 1), with a similar tailing-up effect as in table 1, which, however, becomes more pronounced at the lower elevations and less pronounced nearer the ceiling. This general pattern was observed across the entire width of the room and for both conditions 1 and 2. Again, the temperature was 85°F. and the relative humidity, 40 percent.

Air velocity measurements were made for both conditions, each under two sets of circumstances: at the center of the room (10 feet from the filter wall) with the 14-inch return air-grille width, and 2 feet from the filter wall under the same conditions. Each entry in tables 3 and 4 indicates the relative position of individual filters; the number at each entry is the average velocity of the air corresponding to that filter at various locations downstream. These measurements—each made at a point in space which corresponded to the center of each individual filter—were considered to be accurate within plus or minus 5 feet per minute. This was due to the varying amounts of turbulence in this airflow caused by the relatively nonlaminar flow characteristics and the interaction of the air passing through a filter with one velocity and the air passing through an adjacent filter with a somewhat different velocity. The measurements were estimated to be an average of the fluctuating values in the instrument being used for the determination.

Table 3. Velocity measurements (fpm) 10 feet from filter wall with a 14 inch return air grille width [1]

a.) Condition 1

62	65	62	68	59	69	62
63	60	55	47	60	67	70
63	73	76	80	74	78	72
68	73	70	70	70	60	80

Average velocity = 67 fpm.

b.) Condition 2

69	70	76	65	68	81	75
72	70	72	70	75	73	67
80	100	90	85	95	91	92
70	70	76	76	80	87	83

Average velocity = 78 fpm.

[1] Each entry represents the average velocity of the air measured at a point downstream corresponding to the center of each filter.

Table 3 indicates the increased average velocity of condition 2 over condition 1 as measured at the center of the room.

Table 4 gives the results of the profiles made 2 feet from the filter wall. Two feet was selected because earlier smoke tests indicated that the extreme turbulence of the air passing through the protective filter screen had disappeared at this point. This table is a reflection, however, of the turbulent effect that the air passing through one filter can have on the air passing through the adjacent one. By the time the air was

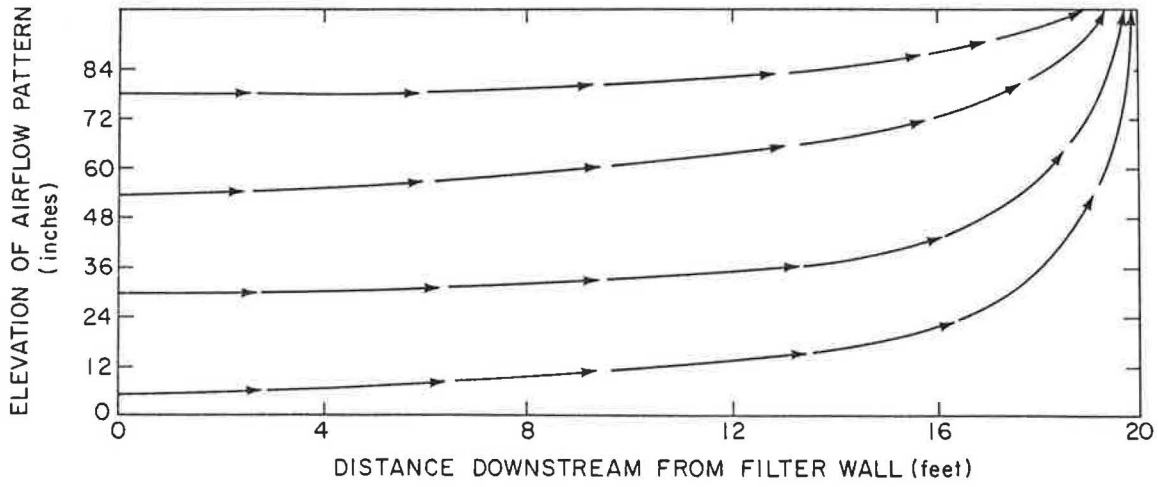

Figure 3. Graph of airflow patterns along centerline of middle filter module of laminar crossflow room

10 feet from the filter wall this influence had been essentially dissipated.

Two observations may be made at this point relative to the variation in the various filter velocities. First, this variation may be attributed at least partially to the "state of the art" of filter manufacturing. Assuming a constant volume of air being supplied to the upstream side of these filters, slight differences in the pressure drop across various filters prevent the same amount of air from passing through each filter. Secondly, there is a tendency for the lower filters to have greater velocities (and hence volumes) than the upper filters, probably because the blowers, introducing air in the downward direction, cause a buildup in the air pressure toward the bottom of each module.

Certain calculations were made in this study that are useful in evaluating airflow characteristics. These calculations and their units were as follows:

1. average velocity (feet per minute)
   $= \frac{\text{sum of velocity readings}}{\text{number of readings}}$
2. cross-sectional area of the room (square feet)
   = width × height
   = $14'-8'' \times 8'-3'' = 121.5$ ft.^{2}
3. volume of the room (cubic feet)
   = width × height × length
   = $14'-8'' \times 8'-3'' \times 20'-0'' = 2{,}430$ ft.^{3}
4. volume of air (cubic feet per minute [cfm])
   = average velocity × cross-sectional area of room
5. ventilation rate (air changes per hour [ch/hr])
   $= \frac{\text{volume of air per minute} \times 60 \text{ minutes per hour}}{\text{volume of the room}}$

The ventilation rate is one of the most important and perhaps least understood parameters of a ventilation system. Chapter 2 discussed the equivalent ventilation rate defined by Blowers and Crew (*2*). This rate was applied to a conventional dilution ventilation system where the rate of bacteria removal by mechanical ventilation in successive short increments of time was expressed as an exponential function. What this stated in essence was that 10 volumes of air, each equal in size to the volume of the room, had to be passed through that room to remove all the bacterial contamination that was in the room initially.

In a laminar flow room, one volume of air passing through the room pushes out ahead of it (like a piston) all the initial room air and its associated airborne contamination. Therefore, theoretically, one air change in a laminar airflow system is as efficient in removing airborne contamination as 10 air changes in a dilution ventilation system.

Referring now only to a laminar flow system, the ventilation rate for a room with a constant filter wall area doubles when the length of the room is decreased by one-half. The significance of the ventilation rate is that it quantifies the rapidity with which airborne contamination is removed from an enclosed space.

Table 5 gives a summary of the airflow characteristics of the laminar flow operating room.

In this discussion on airflow characteristics, the two separate situations of the operating room doors, since they were either opened or closed, were treated together because there was no measurable difference between the two cases for the room in general. The effect of the doors was a localized condition and was not reflected in the air velocities, the ventilation rates, or the overall smoke patterns.

Table 4. Velocity measurements (fpm) 2 feet from filter wall with a 14 inch return air grille width[1]

a.) Condition 1

80	63	65	65	64	58	65
60	60	55	50	70	66	67
80	85	85	90	95	82	82
105	95	83	90	90	70	95

Average velocity = 76 fpm.

b. Condition 2

75	60	79	77	76	66	68
58	67	75	71	82	70	75
105	105	105	98	122	100	110
105	100	100	120	125	95	110

Average velocity = 89 fpm.

[1] Each entry represents the average velocity of the air measured at a point downstream corresponding to the center of each filter.

Wolf et al. (*38*) have pointed out that conventional operating rooms under positive pressure (having more air supplied than exhausted) have unique airflow patterns around an open doorway: a continuous thermally induced flow of cool air into a warm area through the bottom portion of an open door and a continuous thermally induced flow of air out of the warm area through the upper portion of the same door. This laminar flow operating room showed the same pattern: air entered through the lower (cooler) portion of the door opening and exited through the upper (warmer) portion. The air entered the room and traveled toward the filter wall until it was met by the supply air moving downstream in the room. At this point the air that had entered through the open doors changed its direction of flow and joined the supply air. This mixture of air then followed the normal airflow patterns of the room, with some of it leaving through the upper portion of the open door, the remainder being recirculated through the supply filters. Smoke at the center of the door opening fixed the point where the airflow changed direction. Table 6, which records the resulting profile, shows that the primary difference between conditions 1 and 2 and whether one door or two are open is the distance this disturbance extends into the room. The height of this influence does not exceed 36 inches more than 2 feet into the room.

This indraft effect cannot be totally explained by the 6-degree temperature differen-

Table 5. Comparison of airflow characteristics in the laminar crossflow room at 2 feet and 10 feet from the filter wall

Characteristic	Condition 1	Condition 2
a) Two feet from filter wall (14 in. grille)		
1. Average velocity	76 fpm	89 fpm
2. Range of velocities	50 to 105 fpm	50 to 125 fpm
3. Total volume of air	9,150 cfm	10,900 cfm
4. Volume of fresh air	321 cfm	332 cfm
5. Total ventilation rate	226 ch/hr	259 ch/hr
6. Fresh air ventilation rate	8 ch/hr	8 ch/hr
b) Ten feet from filter wall (14 in. grille)		
1. Average velocity	67 fpm	78 fpm
2. Range of velocities	47 to 80 fpm	65 to 100 fpm
3. Total volume of air	8,150 cfm	9,440 cfm
4. Volume of fresh air	321 cfm	332 cfm
5. Total ventilation rate	203 ch/hr	233 ch/hr
6. Fresh air ventilation rate	8 ch/hr	8 ch/hr

Table 6. Extent of reverse flow of air into the laminar crossflow room when the doors are open

Distance of smoke into room measured from door (inches)	Vertical distance of smoke from floor (inches)			
	Condition 1 [1]		Condition 2 [2]	
	One door	Two doors	One door	Two doors
90	0	1	0	0
81	0	4	0	1
72	0	8	1	4
63	0	12	8	7
54	1	15	10	11
45	16	22	17	13
36	26	24	21	18
27	26	30	28	24
18	28	31	33	41
0	34	39	40	50

[1] Condition 1: average velocity of 67 fpm.
[2] Condition 2: average velocity of 78 fpm.

tial across this door. One foot outside the door, at an elevation of 1 foot, the temperature was 77°F.; 1 foot inside the door, at an elevation of 83 inches, it was 83°F. The direction of the airflow due to thermal effects was the same as that reported by Wolf et al. (*38*). The other portion of the explanation for this phenomenon in the laminar flow room probably is that the air, as it is tailing up toward the return air grille, creates a venturi effect which draws outside air into the room in a localized area.

Determinations of the static pressure differentials across various points were made with a water-filled inclined manometer. The manometer readings indicated that the pressure drop across the seven filter modules was a mean of 0.38 inches of water with a range of 0.35 to 0.41; the operating room was under a positive pressure of 0.06 inches of water with respect to the work area (when the doors were closed); and the return air plenum was at the same pressure as the work area, or, under a negative pressure of 0.06 inches of water with respect to the operating room. All these measurements were made under condition 2 with a 14-inch, 50 percent open return air grille.

Chapter 4. Conduct of the Study

Simulated Surgical Cases

As stated in the introduction, the primary objective of this study is to determine empirically the ability of a uni-directional flow of air to prevent airborne contamination contributed by people within the operating room from being transported to and deposited in the critical field at the operating table under a variety of disrupting influences. These influences include stationary and moving obstructions in the flow path of the air, the surgical light and other fixed equipment, the surgeon and his assistants, and other personnel moving about in the vicinity of the operating table. The criterion in evaluating each influence is the amount of actual or simulated biological contamination that reaches the critical sites.

The ultimate value of this study in large measure depended on selecting orientations of people and equipment that represent a variety of surgical procedures. Considerations of time and the opportunities of this investigator personally to observe actual surgical procedures made it necessary to limit this study to two specific procedures: neurological and cardiac. These were selected because, in terms of equipment and people, they represent a severe test of a facility's capabilities, and probably, in terms of the number and positions of people around the table, represent configurations that can be found in a variety of surgical procedures in most hospitals. It was the observation of this investigator (this was confirmed by several practicing surgeons) that most operations performed at either the head or foot of the patient resulted in configurations typified by the neurological case, and most operations performed on the other portions of the body had configurations similar to the cardiac scheme. The names neurological and cardiac as used in this study merely signify the specific configuration of people and equipment in question.

Historically, handedness determined the positioning of people and equipment around the operating table. Thus, for a right-handed surgeon operating above the patient's waist, it is more convenient to have his first assistant either to his left or directly across the table. This arrangement permits the two surgeons to work harmoniously at the wound site, and the first assistant to observe those portions of the wound that may be partially obscured to the surgeon. This arrangement is especially true in open heart surgery. For the same reason, the instrument nurse is positioned where it is most convenient to pass instruments across the table and place them in the surgeon's preferred hand.

The positioning for the right-handed surgeon working below the patient's waist is generally just the opposite to that described

above. The arrangement for the left-handed surgeon would be just the reverse of the right-handed one. The arrangements presented in this study are based on right-handed surgeons working above the patient's waist area.

In neurosurgery, generally, the surgeon and one or two assistants are positioned in close proximity directly at the head of the table. The anesthesiologist, instrument nurse, circulating nurse, and orderlies are positioned in various locations along the length of the table usually near the center. The first two are relatively fixed; the circulating nurse and orderlies move throughout the room as need requires. Figure 4 illustrates the relationships among the surgical team, supporting personnel, associated equipment, and the wound site for a typical neurosurgical procedure.

In a cardiac procedure, the surgeon and one assistant stand at approximately the center of the length of the table and another assistant faces them from a similar position on the other side. The instrument nurse is adjacent to the first assistant near the foot of the table. The anesthesiologist is directly at the head of the patient or slightly away from the table. As in the neurosurgical case, the circulating nurse and orderlies move throughout the room as necessary.

Also playing a significant role in heart surgery is the technician operating the heart-lung machine. Many of the largest medical research centers, including Federal installations and university hospitals, use

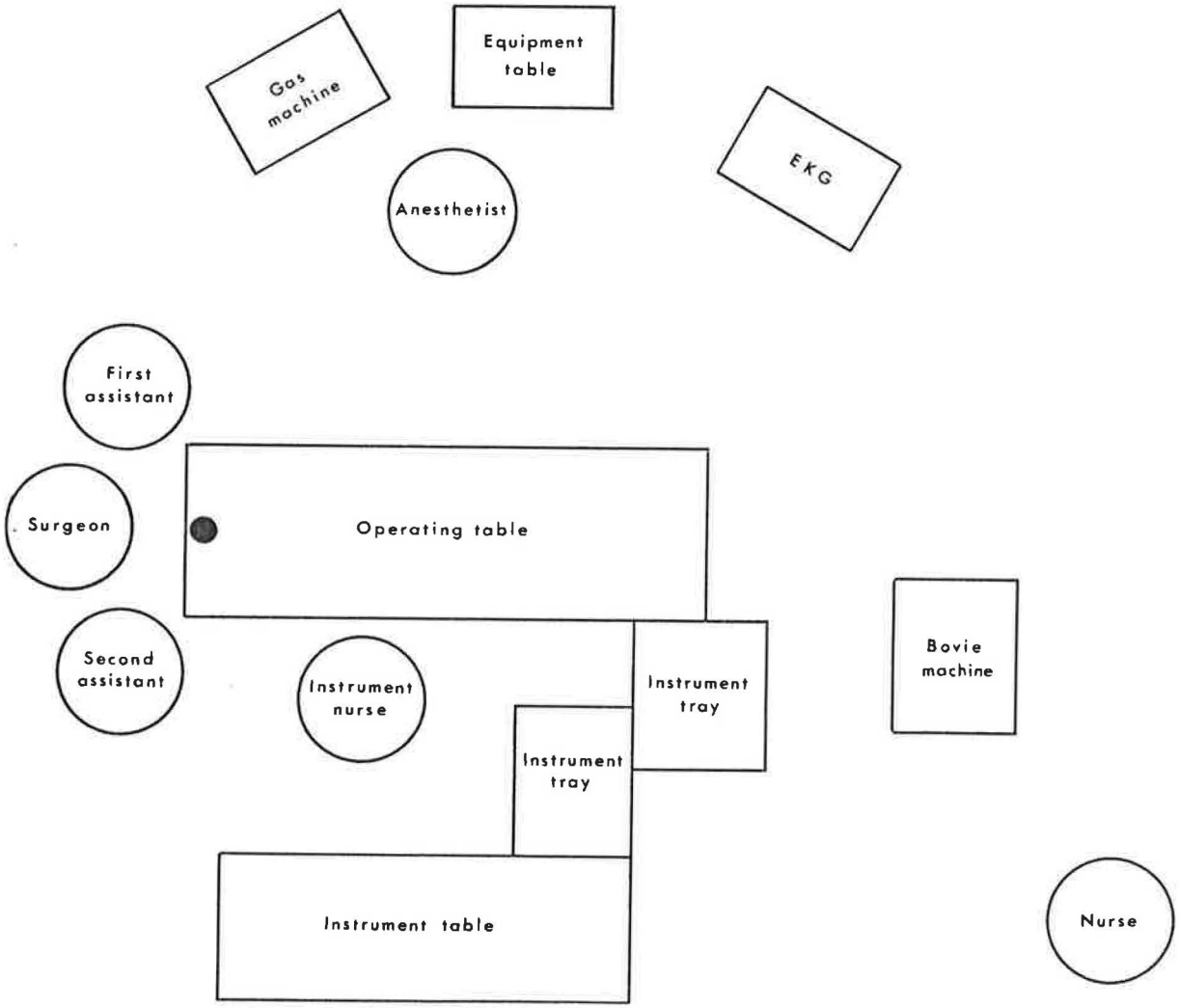

Figure 4. Schematic drawing of typical location of personnel and equipment in neurosurgery

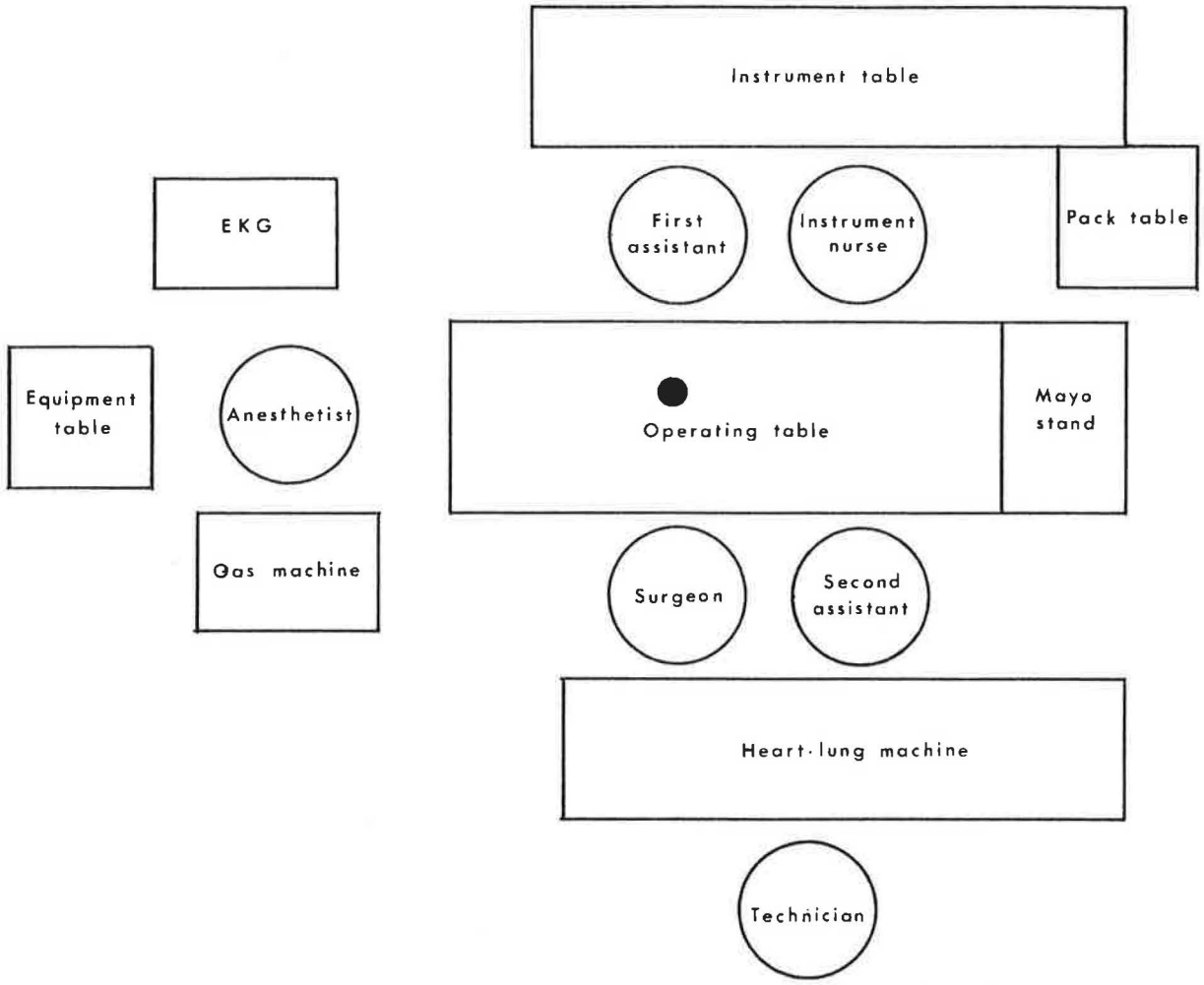

Figure 5. Schematic drawing of typical location of personnel and equipment in cardiac surgery

this machine regularly. It is generally near the foot of the table, but removed 5 or 6 feet to allow room for people moving around the table. Figure 5 indicates the relative position of people and equipment for a typical cardiac surgical procedure.

For this study, the assumption has been made that orderlies and nurses are located in a fixed position representing a place where they would typically stand and at the same time could potentially introduce the most contamination into the wound area. This configuration of people is the worst condition.

There are differences between these two procedures that reflect the preferences of the institution or the surgeon in charge. The preferences may be in the position of the instrument table, the use of a canopy over the table, the use of a working instrument table or Mayo stand placed over the foot or abdomen of the patient to hold the most frequently used instruments, the extent of the draping used on the patient, the use of draping to provide physical barriers between the surgeon and the anesthesiologist, and the position of the operating room lights.

In this study it was possible to include only those preferences which seemed common to a majority of hospitals; these were selected after conferring with several surgeons, an anesthesiologist, and other surgically oriented people.

The operating room furniture and equipment were made to scale from measurements of actual pieces. Most important was the duplication of the shape that the piece of equipment offered to the flow of air. For example,

while the real operating table has a pedestal base it actually is a rectangularly shaped obstruction to the airstream once all the usual draping has been applied. This reasoning was applied to the remainder of the equipment. The measurements of each piece of furniture used in this study is shown in the table.

Description	*Width (inches)*	*Length (inches)*	*Height (inches)*
Operating table	24	72	34
Anesthesia equipment cart	17	21	43
Electrocardiogram machine	15	24	39
Gas machine	16	20	33
Bovie machine	16	24	41
Back instrument table	24	60	46
Instrument table	18	25	60
Large Mayo stand	20	25	53
Small Mayo stand	13	19	38
Pack table	24	36	34
Heart-lung machine	18	60	25
Lamp (23" diameter)	----	----	14

The portion of this study involving the disrupting influences of people and equipment in the airstream is based upon the relationships shown in figures 4 and 5. These two configurations were held constant for the entire experiment, but were "rotated" as described below for various experimental runs.

Each orientation for cardiac and neurosurgery was assigned a designation based on four points of the compass: north-south (NS), south-north (SN), east-west (EW), and west-east (WE). In every case the first point is the direction in which the surgeon is facing. As shown in figures 4 and 5, the neurosurgery configuration is in the NS position and cardiac is in the WE position. All the orientations in this study are shown in figures 6 and 7.

The "people" referred to as taking part in the experimental sampling program were mannequins attired in operating room garments and placed in typical positions. Closely representing the size and shape of the human body, the mannequins permitted greater flexibility during the sampling program, and

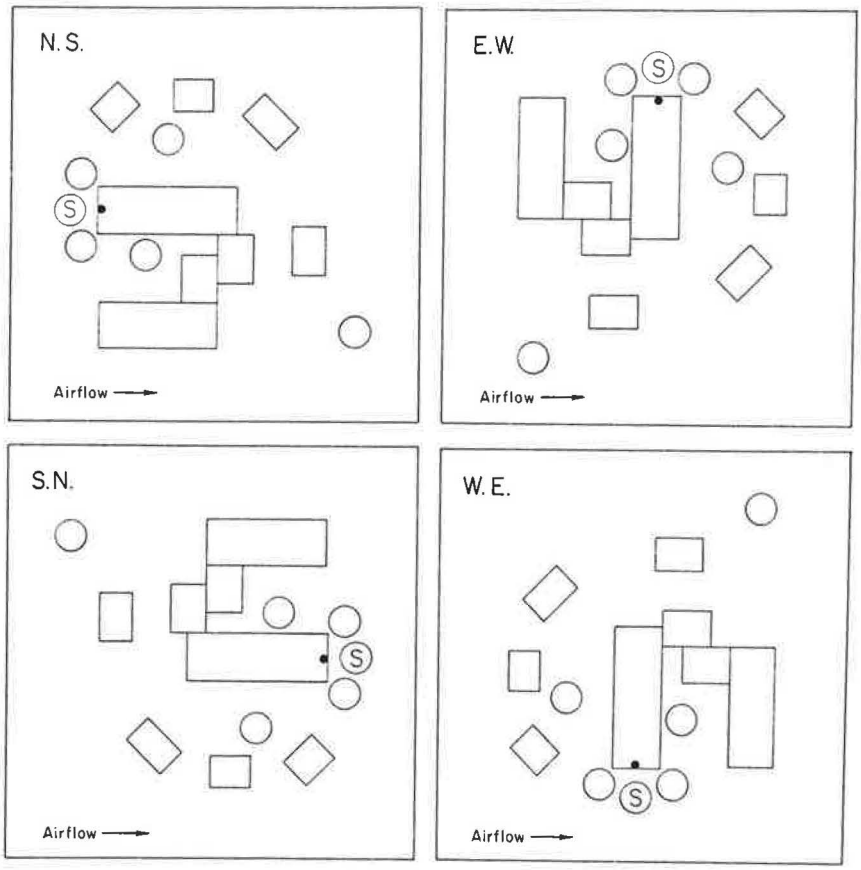

Figure 6. Neurosurgery orientations with respect to direction of airflow

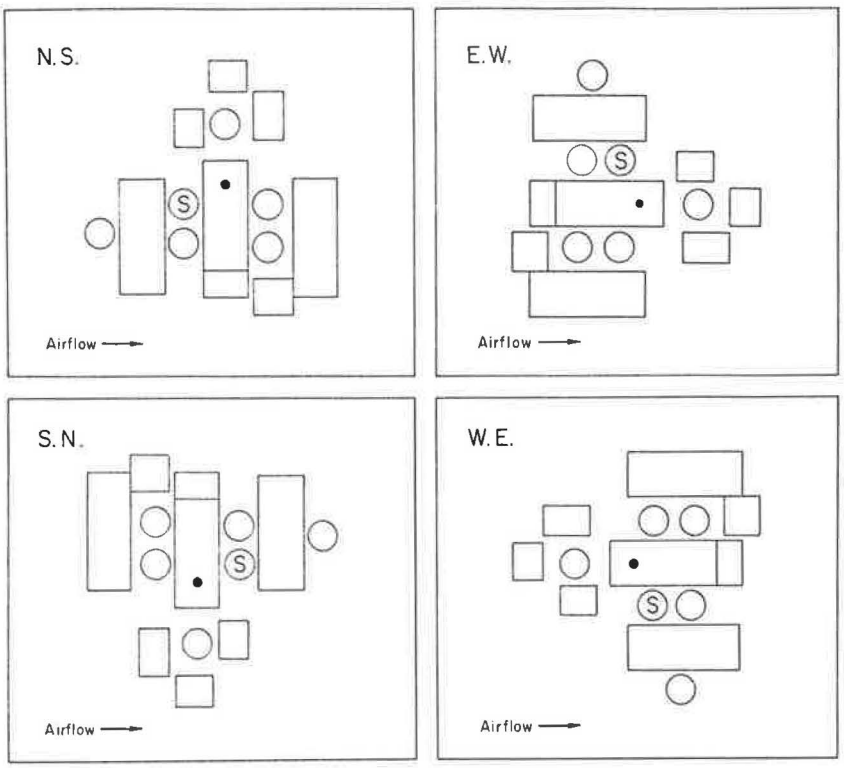

Figure 7. Cardiac surgery orientations with respect to direction of airflow

assumed the identical posture between sampling runs, thus eliminating another variable. Figure 8 is a view of the mannequin surgical team in a cardiac surgery orientation looking toward the filter wall. The aerosol generators shown here are discussed later in this section. Figure 9 illustrates the cardiac surgical team with a view toward the downstream end of the room and the return air grille. Note the uni-directional airflow patterns as shown by the trail of smoke.

Selection of Sampling Technique

The basis for meeting the objectives of this study have been discussed in chapter 2. As pointed out by Kethley et al. (*24*), personnel in the operating room do liberate airborne bacterial particulates, including such organisms as *Staphylococcus aureus,* and streptococci, which have been implicated beyond a reasonable doubt in postoperative infections. Other studies have demonstrated a large range in the size of particles shed by human beings: large particles, 50–100 microns, represent a fallout problem and can be responsible for contamination of the wound; small particles, 1–5 microns, represent an inhalation and respiratory transfer problem and can be readily borne by currents of air. These facts, then, make the study of ventilation effectiveness in an operating room a study of the distribution of airborne contamination.

Since airflow patterns in any room are extremely complex, a standard set of measurements was needed to obtain comparable data in a manageable and useful form from various locations in the test facility. Lidwell and Williams (*27*), Kethley et al. (*24*), Bond and Michaelsen (*52*), and others have demonstrated that tracer substances under rigidly controlled laboratory conditions are an effective indicator of the movement and distribution of airborne contamination. The criteria appropriate for selecting a tracer aerosol and the characteristics of the ideal tracer substance are given below:

1. The substance should be capable of being readily aerosolized in varying known levels of concentration.

2. The substance should be nonpathogenic and nonhazardous to all personnel and ani-

mals in contact with any concentration of the aerosol.

3. It should persist in a uniform physical state during any experimental run.

4. It should decay rapidly enough to prevent any influence on subsequent experimental runs.

5. It should simulate all of the biological properties of pathogens found in the particular environment except for pathogenicity.

6. It should have a particle size distribution representative of the aerosols found in the environment under study.

7. It must be capable of being produced in concentrations sufficiently high to facilitate quantitative measurement.

8. It must be consistent in all respects in order that reproducible results can be obtained on a day-to-day basis throughout the experiment.

9. It should be readily and uniquely recognized as a contaminent distinctly different from all other contaminants in the specific area being studied.

It is apparent that no tracer substance can meet all these criteria simultaneously. A search of the unclassified literature reveals that criteria five and six are beyond the present "state of the art," particularly as it relates to the hospital environment. This situation is attributable not to a lack of technical knowledge about the production and analysis of aerosols, but rather to the limits imposed by the sparsity of definitive and quantitative information about the microflora of the hospital environment.

In aerosol tracer work the investigator is faced with three independent factors each of which contains two conditions thereby creating two to the third power, or eight alternatives. Specifically, the tracer being used may consist of either viable or nonviable particles, the condition of the tracer may be either wet or dry, and the aerosol can be created by either a mechanical or human generator. These alternatives are given in the following table.

	Tracer	*Condition*	*Generator*
1.	Viable	wet	mechanical
2.	Viable	wet	human
3.	Viable	dry	mechanical
4.	Viable	dry	human
5.	Nonviable	wet	mechanical
6.	Nonviable	wet	human
7.	Nonviable	dry	mechanical
8.	Nonviable	dry	human

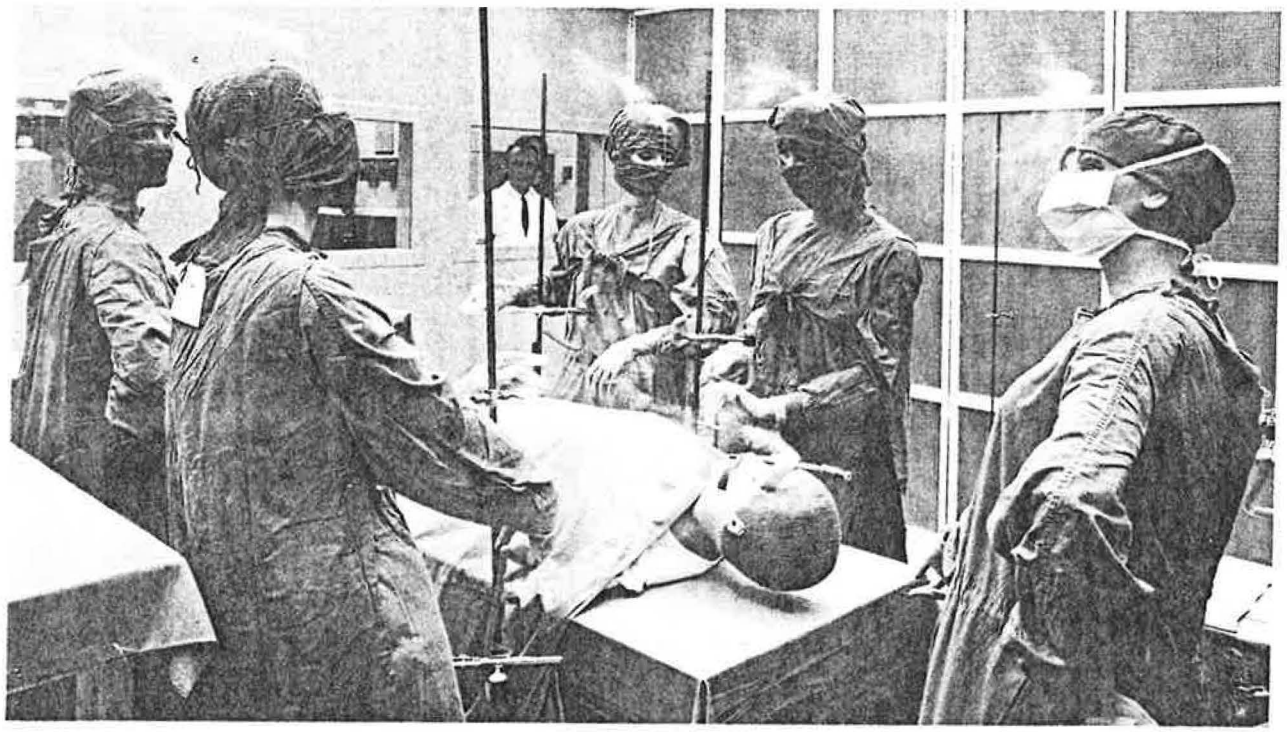

Figure 8. View of mannequin surgical team for cardiac surgery looking toward filter wall

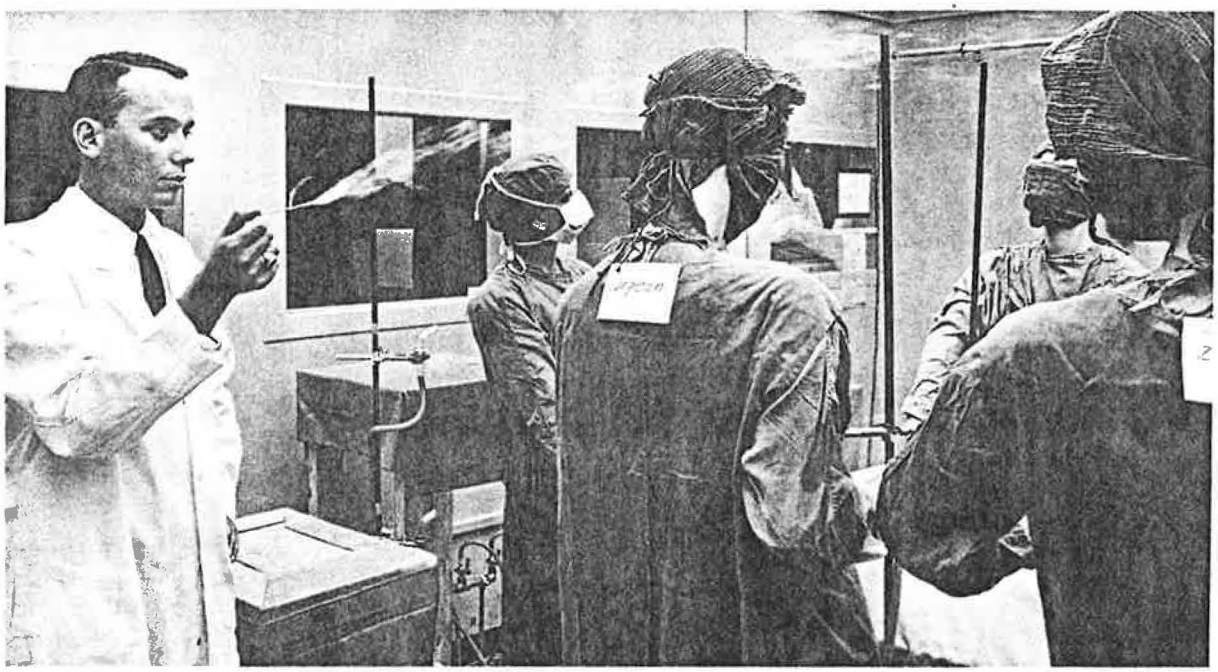

Figure 9. View of mannequin surgical team for cardiac surgery looking toward downstream end of the room

Judicious selection of the various combinations of these three variables involved recognition of the limitations of each selection. For example, the nonviable tracers, such as uranine dye, sodium chloride, polystyrene spheres, or zinc cadmium sulfate spheres, can be generated inexpensively and in a controlled size distribution. They are influenced by environmental factors, such as temperature and humidity, but are not subject to the biological variables of die-off, viability, and durability. Simulated organisms can duplicate the size and density but not necessarily the living aspects of microorganisms and, therefore, may bear little resemblance to the behavior of actual organisms under the same environmental influences.

Wolf et al. (*45*) relate that biological particles may exist as single organisms or in clumps of several bacteria. The organism may be attached to a dust particle or float along in the air surrounded by a film of dried material. Vegetative cells usually do not survive under adverse environmental conditions of temperature and humidity.

The merits of "wet" versus "dry" aerosols relate, in part, to the use of viable or nonviable aerosols. Wet aerosols are not difficult to produce and may be regulated as to particle size, reproducibility, and concentration. On the other hand, the viability of vegetative cells in a wet aerosol is difficult to maintain. Vegetative cells, such as *Serratia marcescens, Staphylococcus aureus,* and *Sarcina lutea,* survive at different levels of air temperature and humidity. In a small, laboratory scale environment, these organisms can be used successfully in an aerosol when the environmental parameters can be carefully maintained. However, in the typical environment of fluctuating air temperatures and humidities, wet aerosols may not be a reliable scale of measurement.

The term mechanical aerosol generator refers to an inanimate device that expels solid or liquid particles into the air from a reservoir by air pressure or other similar atomizing method. Most mechanical generators disseminate their aerosol from a small tube or opening and may therefore be considered as point source generators. Typical generators are discussed by Decker et al. (*16*).

Human beings liberate contamination, either their own natural microflora or artificially seeded organisms, by natural body motions. Human beings by virtue of many points on the body that can shed contamination may be considered as area sources.

In this study, the term "human generator" refers to a combination of the human and mechanical. It embodies the generation of the aerosol from a mechanical generator to take advantage of the uniformity and reproducibility of the aerosol inherent in this type of device and the mannequin to disperse the point source to simulate the area source of human generators. The method of doing this is discussed in detail in a following section.

Kethley and Cown (*53*), make it clear that the standard biological air sampling techniques used for conventional or dilution ventilation are not ideally suited to a laminar flow room. In the dilution ventilation system, the airborne contamination is rather uniformly dispersed throughout the room before it is removed. In laminar flow, the airborne contamination is carried by the airstream directly out of the room with very little lateral mixing or dispersion. As a result, a sampling location directly adjacent to a contaminated streamline may show no contamination, and the term "representative sample" here becomes meaningless. Of concern, then, are the contamination levels at the critical site and not adjacent to it. To measure the total level of airborne contamination in a laminar flow room, the entire volume of air would have to be examined as it exits from the room. This is technically impossible with present sampling equipment.

This study attempted to measure quantitatively the total level of airborne contamination in the room by placing a seven-point air sampling manifold at the downstream end of the room directly under the return air grille, where all the air was converging to leave the room. While it is recognized that adjacent streamlines may or may not be contaminated, this manifold did have the advantage of sampling the air simultaneously at several points, thus at least lessening the contaminated streamline effect. With these limitations in mind, the sampling program was carried out in two separate phases:

Phase 1: An aerosol of uranine dye was generated simultaneously at several locations in the operating room with DeVilbiss No. 40 nebulizers. The airborne concentration of the aerosol was collected on Millipore filters and that proportion of the aerosol that settled at critical sites was collected on microscope slides coated with silicone grease. The relative concentration of dye in both samples was measured photofluorometrically. This portion of the work represented the aerosol conditions of the nonviable, wet, human alternative. Its purpose was to measure the effect of the obstructions in the airstream and either to confirm or to disprove the importance of other configurations of people and equipment previously thought by the investigator to be of little consequence.

Uranine dye, a disodium salt of fluorescein, has been used effectively as a tracer in air pollution work (*9*). Colleagues of this author have had considerable experience with this technique in aerosol tracer analysis. This aerosol can be easily generated in a size range of 1 to 15 microns, may be readily detected in small concentrations, is nontoxic in the concentrations and time periods normally used, and is low in cost.

Phase 2: A wet suspension of *Sarcina lutea* was aerosolized from a DeVilbiss No. 40 nebulizer at several locations in the operating room. The airborne portion of the aerosol was sampled with Andersen sieve and Reyniers air samplers and that portion at the critical sites measured by fallout plates. Standard biological incubation and enumeration techniques were used to measure the concentration. This represented the viable, wet, human alternative. This portion of the sampling program most closely represented the operating room environment during an actual surgical procedure.

The selection of *Sarcina lutea* as a biological tracer organism was based on a number of considerations related to the previous discussion of an "ideal" tracer. This organism —found in the normal human skin flora of both adults and children—has no record of involvement in a pathogenic condition. Under certain environmental conditions, it has a reasonably rapid die-off rate. Easily handled in the laboratory, since it has a distinctive colony morphology, this organism is 1 to 2 microns in size and grows readily on blood

agar and trypticase soy agar. This particle size is typical of the micrococci and staphylococci which constitute a majority of the microflora of human skin.

Experimental Contamination

Nonbiological Contamination

Phase 1 of the sampling program, as discussed earlier, involved the aerosolization of a nonbiological tracer substance (uranine dye) as a suitable substitute for actual biological contamination shed by people during surgery. Discussed below are the details of preparing the uranine solution, generating the aerosol, and collecting and analyzing the sample.

A 1 percent uranine solution was prepared by weighing 10 grams of uranine dye on an analytical balance and diluting it up to 1 liter with distilled water in a volumetric flask. Ten cubic centimeters were then transferred into each of the DeVilbiss nebulizers with a pipette, air was passed through each nebulizer at the critical flow rate for 10 minutes, and the aerosol was introduced directly into the test environment.

The DeVilbiss nebulizer operated on the principle of a limiting orifice. Providing the ratio of the pressure at the downstream end of the orifice (test environment in this case) to the pressure at the upstream side of the orifice (the supply air pressure) was less than 0.53, the volume and size of the aerosol produced remained constant. A pressure regulator on the supply air manifold was used to maintain the pressure at 10 psi gauge.

The bulk of the literature on determination of this nonviable particle size has been in inhalation aerosol therapy. Dautrebande (*54*) and Herring (*55*) have made numerous references to studies involving the particle size determination of the aerosol produced by the DeVilbiss No. 40 nebulizer. All these studies reported essentially the same results: the mean particle size of the aerosol produced with a DeVilbiss No. 40 nebulizer is 6.2 microns and the range is 1.6 to 14.8 microns as determined with the electron microscope. This particle size range and its mean are suitable for the experimental aerosol in this type of study [Greene et al. (*11*) and Noble et al. (*18*)].

Five microscope slides for each experimental run—prepared in the workroom—were placed on a paper towel, numbered, and coated with silicone grease up to the frosted portion of the glass. Four of the five slides were taken into the test facility and placed at the following locations: the wound site, center of the back instrument table, the instrument table, and in front of the center filter module, 30 inches off the floor. The slide in front of the filter was turned to face the incoming air and served as the background slide. The fifth slide remained in the workroom and was used as the blank. At the end of each experimental run all five slides were collected in a large petri dish.

To remove the uranine dye, each microscope slide was drip washed into a 50-cc. beaker with a total of 20 cc. of distilled water. Microscopic examination of slides, after being washed in this manner, showed a complete absence of the dye. Each cuvette was rinsed twice with the sample solution, then filled, wiped with a tissue to remove moisture and fingerprints, placed in the fluorometer (Photomultiplier Microphotometer, American Instrument Company, Inc., Silver Spring, Md.) and the relative fluorescent intensity or percentage of light transmission read. A new cuvette, previously washed in a nitric acid solution, was used for each sample.

Each of seven Millipore filters was placed in a filter holder. The holders were then affixed to a 0.06 cfm critical orifice and attached to the air sampling manifold on 2-foot centers. The total volume of air sampled for each experimental run was 4.2 cu. ft.

The analysis of the filters was handled in the same manner as the surface samples except that each filter was placed directly into a 50-cc. beaker containing 20 cc. of distilled water. Each filter was vigorously agitated with a clean glass rod to assist in removing the uranine dye before the next filter was placed in the beaker; previous filters from the same run were not removed. The photometer was calibrated to zero for each sampling

Table 7. Coordinates of the four orientations of personnel and equipment in neurosurgery

Obstruction	Coordinates: X and Y (in feet)							
	North-south		South-north		East-west		West-east	
Operating table	9.00,	7.50	9.00,	7.50	9.00,	7.50	9.00,	7.50
Surgeon	4.50,	7.50	13.50,	7.50	9.00,	12.00	9.00,	3.00
1st assistant	5.25,	9.00	12.75,	6.00	10.50,	11.25	7.50,	3.75
2nd assistant	5.25,	6.00	12.75,	9.00	7.50,	11.25	10.50,	3.75
Anesthesiologist	9.00,	10.50	9.00,	4.50	12.00,	7.50	6.00,	7.50
Instrument nurse	8.00,	5.25	10.00,	9.75	6.75,	8.50	11.25,	6.50
Back instrument table	8.50,	2.50	9.50,	12.50	4.00,	8.00	14.00,	7.00
Instrument table No. 1	12.25,	5.25	5.75,	9.75	6.75,	4.25	11.25,	10.75
Instrument table No. 2	10.50,	4.50	7.50,	10.50	6.00,	6.00	12.00,	9.00
EKG machine	13.25,	11.25	4.75,	3.75	12.75,	3.25	5.25,	11.75
Equipment table	10.00,	12.25	8.00,	2.75	13.75,	6.50	4.25,	8.50
Gas machine	6.75,	11.25	11.25,	3.75	12.75,	9.75	5.25,	5.25
Bovie machine	15.00,	5.75	3.00,	9.25	7.25,	1.50	10.75,	13.50

Table 8. Coordinates of the four orientations of personnel and equipment in cardiac surgery

Obstruction	Coordinates: X and Y (in feet)							
	North-south		South-north		East-west		West-east	
Operating table	9.00,	7.50	9.00,	7.50	9.00,	7.50	9.00,	7.50
Surgeon	7.00,	8.50	11.00,	6.50	10.00,	9.50	8.00,	5.50
1st assistant	10.75,	9.00	7.25,	6.00	10.50,	5.75	7.50,	9.25
2nd assistant	7.50,	6.75	10.50,	8.25	8.25,	9.00	9.75,	6.00
Anesthesiologist	9.00,	12.25	9.00,	2.75	13.75,	7.50	4.25,	7.50
Instrument nurse	11.00,	6.00	7.00,	9.00	7.50,	5.50	10.50,	9.50
Back instrument table	12.75,	6.75	5.25,	8.25	8.25,	3.75	9.75,	11.25
EKG machine	12.50,	12.75	5.50,	2.25	14.25,	4.00	3.75,	11.00
Equipment table	9.00,	14.25	9.00,	0.75	15.75,	7.50	2.25,	7.50
Gas machine	7.00,	12.25	11.00,	2.75	13.75,	9.50	4.25,	5.50
Heart-lung	5.50,	6.00	12.50,	9.00	7.50,	11.00	10.50,	4.00
Mayo stand	9.00,	5.25	9.00,	9.75	6.75,	7.50	11.25,	7.50
Basin stand	11.00,	3.75	7.00,	11.25	5.25,	5.50	12.75,	9.50

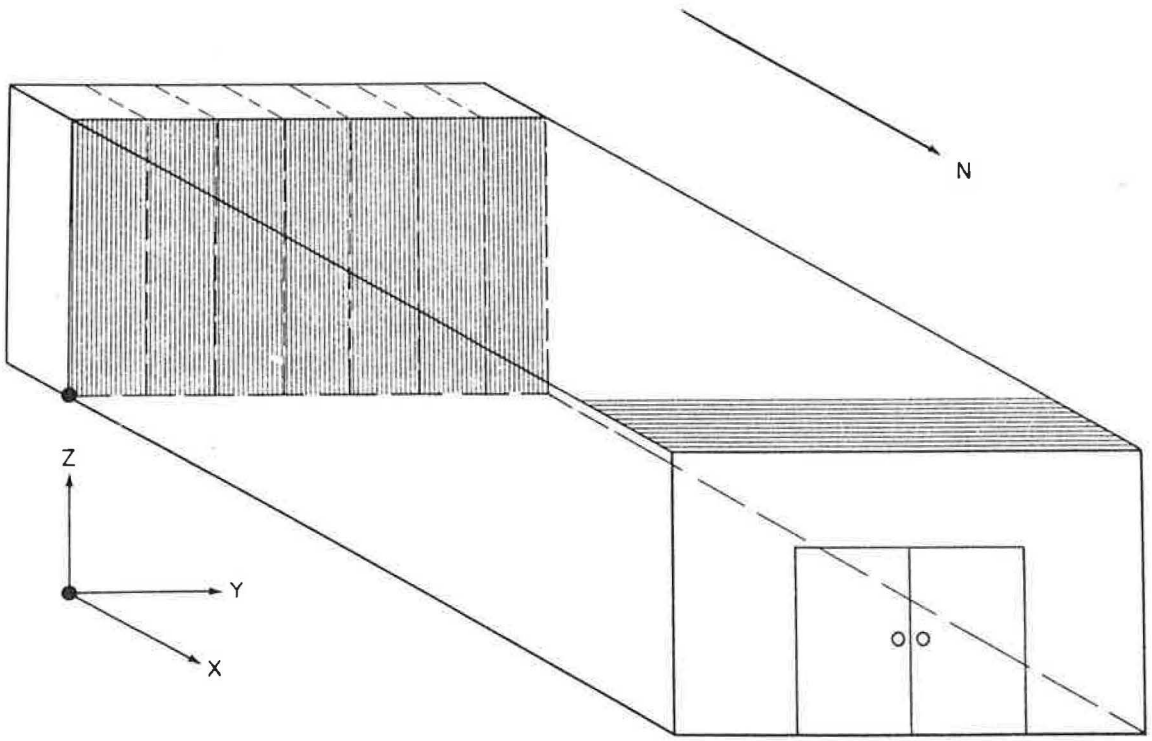

Figure 10. Coordinate system for the experimental laminar crossflow operating room

period. Since zero reading indicated no fluorescence, the greater the reading on the instrument the greater the amount of uranine in the sample and the greater the amount of contamination at the sampling point.

Biological Contamination

Once a decision had been made to use the *Sarcina* species as the biological tracer organism it became necessary first to obtain a pure culture of various strains and then qualitatively to learn the die-off characteristics of each strain under operating room conditions. After selecting four strains of *Sarcina,* nine pairs of sterile petri plates were placed under a protective plastic bag, and a trypticase soy broth culture of the first strain was sprayed over the uncovered plates. This procedure was repeated with other sets of plates for each of the other three strains. One plate of each pair was then held at room temperature and the other incubated at 37°C. Each successive day, beginning with the first, one plate at room temperature and one at 37°C. for each species were overlaid with trypticase soy agar, incubated at 37°C. for 48 hours, and examined. This procedure was repeated with distilled water instead of the trypticase soy agar.

These tests showed there was no appreciable decrease in the viable count with any of the strains over the 9-day period when the trypticase soy agar broth was used. With distilled water, one strain did show a significant decrease in viable count within a few days, suggesting that a culture of this one strain of *Sarcina lutea* could be prepared, maintained, and aerosolized as the experimental contamination. At the same time, one could expect a reasonably rapid die-off rate of viable aerosol after an experimental run.

Location of Contamination

The specific location of the aerosol generators determined, at least in part, the accuracy with which this experimental contamination simulated the real microbiological contamination generated during an actual surgical procedure. The coordinate system used to locate a point in space is illustrated in figure 10.

The origin of each coordinate is in the southeast corner of the room at floor level. The X coordinate indicates the distance downstream from the filter wall, the Y coordinate the horizontal dimension across the width of the room, and the Z coordinate the height above the floor.

Expressed in this (X, Y, Z) coordinate system the center point of this room, which measures 20.0 feet (X) 14.8 feet (Y) and 8.2 feet (Z), would be 10.0 feet, 7.4 feet, and 4.1 feet. This coordinate system and scale of measurement were selected for ease in the collection and reporting of the information. A grid in the X and Y directions was laid out on the floor of the room to facilitate the location of all obstructions. The exact location of the center of each obstruction under each configuration is given in tables 7 and 8.

In a laminar flow room, with its uni-directional airflow characteristics, the precise coordinates (X, Y, Z) of the point where contamination is liberated become an important consideration. A source located at point (0, 7.5, 5.0) will introduce contamination that travels through the room in the X direction, but the Y and Z coordinates will remain approximately the same until an obstruction in the path of the airflow is encountered. In this study it was logical to assume that primary interest was in those specific areas of the human body which contribute most to the amount of airborne contamination. In the operating room this means the head and perineal area of surgical, nursing, and other personnel.

For each member of the surgical team, two generators were placed on a pole—one at an elevation corresponding to the perineal area, the other to the area of the head. The position of the poles and generators with respect to the mannequin and direction of the airflow was selected so that the turbulence of the air passing around the mannequin would transform the point source of contamination into an area source, thus more closely simulating human patterns of contamination. For example, if a mannequin stood facing directly downstream, the gen-

erators were placed downstream of the mannequin but directed toward it. If a mannequin stood facing upstream the generators were placed upstream but pointed toward it, or downstream. A mannequin standing perpendicular to the flow of air had the generators upstream but facing toward it. See figure 8 for the placement of the generators for the cardiac surgery north-south orientation.

Chapter 5. Experimental Results

Uranine Dye Aerosol Results

Tables 9–12, which show the results of the uranine dye aerosol study in the neurosurgery configuration, represent the relative fluorescent intensity of the dye samples at six locations under four different orientations, two door conditions, and two light conditions. Two observations were made for each of the 96 combinations in a completely randomized design. These figures do not represent units of measure, but only the relative amount of fluorescent material collected.

The experimental design sought to study the several variables of interest simultaneously in order to define their interrelations and the nature of the process. Data analysis, then, took the form of an analysis of variance with the following general linear model:

$$X_{ijkl} = u + A_i + B_j + C_k + (AB)_{ij} + (AC)_{ik} + (BC)_{jk} + (ABC)_{ijk} + e_{ijkl}$$

where:

X_{ijkl} = overall response, a random variable

u = mean response

A_i = door effect of the i^{th} condition, $i = 1, 2$
door opened periodically = 1
door closed = 2

B_j = light effect of the j^{th} condition, $j = 1, 2$
light present and on = 1
light removed = 2

C_k = orientation effect of the k^{th} condition, $k = 1, 2, 3, 4$
North-south = 1
South-north = 2
East-west = 3
West-east = 4

$(AB)_{ij}$ = interaction effect of the i^{th} door condition with j^{th} light condition

$(AC)_{ik}$ = interaction effect of the i^{th} door condition with k^{th} orientation

$(BC)_{jk}$ = interaction effect of the j^{th} light condition with the k^{th} orientation

$(ABC)_{ijk}$ = interaction effect of the i^{th} door condition with j^{th} light condition and the k^{th} orientation

e_{ijkl} = the random error

$l = 1, 2$; two observations are made for each cell of the design

The following restrictions are assumed for the fixed effects of the above linear model without loss of generality:

$$0 = \sum_i (A_i) = \sum_i (AB)_{ij} = \sum_i (AC)_{ik} = \sum_i (ABC)_{ijk}$$

$$0 = \sum_j (B_j) = \sum_j (AB)_{ij} = \sum_j (BC)_{jk} = \sum_j (ABC)_{ijk}$$

$$0 = \sum_k (C_k) = \sum_k (AC)_{ik} = \sum_k (BC)_{jk} = \sum_k (ABC)_{ijk}$$

The random errors, e_{ijkl}, are independent and identically distributed as normal variants with mean zero and variance σ^2_e.

It is recognized that included in the overall response of this model are what may be called transport and environmental phenomena. This random variation encompasses variations in temperature, relative humidity, mass, density, dispersion of the aerosol, deposition in the collecting device, die-off, and electrostatic charges.

Stochastic elements were built into this experiment in this fashion: For each repli-

Table 9. Levels of uranine contamination at selected sites under four experimental conditions for neurosurgery north-south orientation[1]

Sample location and runs	Doors open		Doors closed	
	Light	No light	Light	No light
Wound:				
1	2.90	2.10	7.6	2.07
2	.90	.246	.46	.47
Back instrument table:				
1	.058	.111	.074	.069
2	.210	.056	.062	.059
Instrument table:				
1	.51	.61	.60	.75
2	.56	.76	.55	.40
Room exhaust:				
1	17.4	19.8	19.8	24.3
2	19.8	23.1	19.8	22.8
Background:				
1	.056	.117	.061	.070
2	.052	.079	.045	.055
Blank:				
1	.055	.123	.052	.074
2	.056	.046	.050	.056

[1] Reported as relative fluorescent intensity.

Table 10. Levels of uranine contamination at selected sites under four experimental conditions for neurosurgery south-north orientation[1]

Sample location and runs	Doors open		Doors closed	
	Light	No light	Light	No light
Wound:				
1	0.117	0.147	0.102	0.039
2	.219	.060	.051	.085
Back instrument table:				
1	.084	.135	.074	.041
2	.057	.087	.064	.053
Instrument table:				
1	.060	.156	.117	.080
2	.052	.052	.063	.045
Room exhaust:				
1	21.9	22.5	23.1	19.8
2	22.2	22.5	21.9	23.7
Background:				
1	.053	.105	.053	.038
2	.047	.056	.050	.046
Blank:				
1	.102	.099	.043	.132
2	.055	.065	.045	.049

[1] Reported as relative fluorescent intensity.

cation, an orientation was selected by drawing a number (one, two, three, or four representing a given orientation). Once the orientation had been selected, the process was repeated for selecting the order of the experiments.

A separate analysis of variance was done for each location in the experiment (see tables 13–17). It became evident that the level of airborne contamination falling out at each sample location was highly dependent upon the placement of people and equipment relative to the direction of the airflow. In all locations a significant difference at the 5 percent level was noted for orientation.

The positions of the doors in this facility, whether opened periodically or kept closed, and the position of the operating room lamp, either in the room and on, or removed from the room, do not significantly affect the amount of airborne contamination at the wound, back instrument table, instrument

Table 11. Levels of uranine contamination at selected sites under four experimental conditions for neurosurgery east-west orientation[1]

Sample location and runs	Doors open		Doors closed	
	Light	No light	Light	No light
Wound:				
1	0.068	0.102	0.061	0.074
2	.081	.099	.090	.055
Back instrument table:				
1	.059	.068	.045	.073
2	.080	.216	.059	.066
Instrument table:				
1	.060	.055	.105	.080
2	.061	.080	.051	.045
Room exhaust:				
1	12.3	13.5	15.3	13.5
2	12.0	12.3	15.6	12.0
Background:				
1	.048	.055	.048	.048
2	.042	.070	.046	.042
Blank:				
1	.047	.061	.053	.047
2	.045	.056	.051	.050

[1] Reported as relative fluorescent intensity.

Table 12. Levels of uranine contamination at selected sites under four experimental conditions for neurosurgery west-east orientation[1]

Sample location and runs	Doors open		Doors closed	
	Light	No light	Light	No light
Wound:				
1	0.150	0.180	0.213	0.162
2	.47	.41	.48	.39
Back instrument table:				
1	.252	.37	.34	.32
2	.48	.55	.40	.32
Instrument table:				
1	.099	.084	.075	.056
2	.084	.035	.050	.073
Room exhaust:				
1	18.3	22.2	18.0	16.2
2	26.4	24.3	19.5	18.0
Background:				
1	.052	.060	.064	.093
2	.036	.044	.039	.035
Blank:				
1	.102	.056	.064	.045
2	.040	.036	.035	.044

[1] Reported as relative fluorescent intensity.

Table 13. Analysis of variance for wound

Source	d.f.	s.s.	m.s.	F	P
Doors	1	0.5390	0.5390	0.2815	$0.50 < P < .75$
Lights	1	1.6530	1.6530	.8632	$0.25 < P < .50$
Orientation	3	22.6136	7.5379	3.9363	$0.025 < P < .05$[1]
d × l	1	.5385	.5385	.2812	$0.25 < P < .50$
d × o	3	1.9504	.6501	.3395	$0.75 < P < .90$
l × o	3	4.4335	1.4778	.7717	$.50 < P < .75$
d × l × o	3	1.5316	.5105	.2666	$.75 < P < .90$
Error	16	30.6398	1.9150	----------	----------
Total	31	63.8993	----------	----------	----------

[1] Significant at 5 percent level.

table, and the room exhaust. A significant effect for the light position at the 5 percent level is shown, however, at the background sample location. The reason and practical importance of this observation are not clear from the experiment.

The door by orientation (d × o) interaction found at the room exhaust sample location may be explained by noting that the contamination level at the same location in the EW orientation is, on the average, less than the NS, SN, or WE configuration, regardless of the door condition. This situation is a function of the relative position of the source of contamination with respect to the location of any downstream sampling point. The uni-directional airflow characteristics of a laminar flow room permit the contaminated stream line of air either to hit or miss the sampling throat of the collecting device with relatively small lateral movement of the source. This type of sensitivity might account for the apparent significant interaction effect between the doors and orientation at the room exhaust location.

All probabilities (P-values) quoted in tables 13–17 are significance probabilities, *assuming* these are for single inferences. Note, however, that in each table seven inferences are made simultaneously and the quoted probabilities, therefore, are not appropriate to this multiple inference situation. The appropriate P-values for such a situation should be the nominal values quoted divided by seven. For example, if significance is to be claimed at the 5 percent level while performing seven tests simultaneously each separate test, to be conservative, should be performed at a level of $0.05/7 = 0.007$ (approx.) to assure that all seven inferences are simultaneously correct with $\alpha = 0.05$. In this context, the significance nominally indicated in table 13 for "orientation," for "doors" in table 14, for "d × o" interaction in table 16, and for "lights" in table 17 should all be considered as chance occurrence and not truly significant. However, the "orientation" differences indicated by the small P-values in tables 14–16 continue to represent significant differences even in the context of multiple inferences.

Since the analysis of variance, performed separately for each sample location, did not clearly indicate the nature of the discovered

Table 14. Analysis of variance for back instrument table

Source	d.f.	s.s.	m.s.	F	P
Doors	1	0.01777	0.01777	4.0543	$0.05 < P < 0.10$ [1]
Lights	1	.00120	.00120	.2740	$.50 < P < .75$
Orientation	3	.53115	.17705	40.4038	$P < .0005$ [1]
d × l	1	.00578	.00578	1.3186	$.25 < P < .50$
d × o	3	.00133	.00044	.1013	$.95 < P < .975$
l × o	3	.00548	.00183	.4164	$.75 < P < .90$
d × l × o	3	.00914	.00305	.6950	$.50 < P < .75$
Error	16	.07011	.00438	----------	----------
Total	31	.64195	----------	----------	----------

[1] Significant at 5 percent level.

Table 15. Analysis of variance for instrument table

Source	d.f.	s.s.	m.s.	F	P
Doors	1	0.00099	0.00099	0.1828	$0.50 < P < 0.75$
Lights	1	.00218	.00218	.4021	$.50 < P < .75$
Orientation	3	1.62867	.54289	100.2284	$P < .0005$ [1]
d × l	1	.00573	.00573	1.0569	$.25 < P < .50$
d × o	3	.00186	.00062	.1141	$.95 < P < .975$
l × o	3	.00977	.00326	.6011	$.50 < P < .75$
d × l × o	3	.00921	.00307	.5666	$.50 < P < .75$
Error	16	.08666	.00542	----------	----------
Total	31	1.74505	----------	----------	----------

[1] Significant at 5 percent level.

differences, it was desirable to look further into the differences between estimated orientation effects in order to arrive at a confidence statement for the multiple comparisons. The technique used below for estimating mean differences between any two of the k samples is described in Dixon and Massey (*56*).

Table 18 presents the summary of the data for each neurosurgical configuration, including the mean and variance for each sample location under the appropriate orientation. By the method in Dixon and Massey, the 95 percent joint confidence intervals were constructed for differences of pairs of orientation effects at each sample location (table 19). Combining the information in tables 18 and 19 for each sample location revealed which orientation had the least amount of airborne contamination. Each orientation was ranked in this manner in table 20.

While there are differences in contamination levels at various sample locations, such

Table 16. Analysis of variance for room exhaust

Source	d.f.	s.s.	m.s.	F	P
Doors	1	1.6200	1.6200	0.4507	$0.50 < P < 0.75$
Lights	1	1.6200	1.6200	.4507	$.50 < P < .75$
Orientation	3	381.8816	127.2939	35.4147	$P < .0005$ [1]
d × l	1	4.9613	4.9613	1.3803	$.25 < P < .50$
d × o	3	56.3625	18.7875	5.2269	$.01 < P < .025$ [1]
l × o	3	22.3875	7.4625	2.0762	$.10 < P < .25$
d × l × o	3	5.3663	1.7888	.4977	$.75 < P < .90$
Error	16	57.5100	3.5944	----	----
Total	31	531.7088	----	----	----

[1] Significant at 5 percent level.

Table 17. Analysis of variance for background

Source	d.f.	s.s.	m.s.	F	P
Doors	1	0.00060	0.00060	2.0881	$0.10 < P < 0.25$
Lights	1	.00152	.00152	5.2784	$.025 < P < .05$ [1]
Orientation	3	.00132	.00044	1.5206	$.25 < P < .50$
d × l	1	.00100	.00100	3.4628	$.10 < P < .25$
d × o	3	.00105	.00350	1.2186	$.25 < P < .50$
l × o	3	.00045	.00015	.5252	$.50 < P < .75$
d × l × o	3	.00059	.00020	.6849	$.50 < P < .75$
Error	16	.00463	.00029	----	----
Total	31	.0118	----	----	----

[1] Significant at 5 percent level.

Table 18. Summary of eight observations of uranine contamination at four selected sites with four orientations of personnel and equipment for neurosurgery[1]

Orientation	Wound	Back instrument table	Instrument table	Background
North-south:				
Mean	2.09325	0.087375	0.59250	0.06687
Variance	5.87348	.00277	.01428	.00052
South-north:				
Mean	.10250	.06438	.07812	.05600
Variance	.00351	.00142	.00151	.00042
East-west:				
Mean	.07875	.08325	.06712	.04987
Variance	.00030	.00299	.00039	.00008
West-east:				
Mean	.30688	.37899	.06950	.05288
Variance	.02066	.00922	.00044	.00038

[1] Reported as relative fluorescent intensity.

Table 19. Ninety-five percent joint confidence interval for all differences of pairs of orientation effects

Contrast	Wound	Back instrument table	Instrument table	Background
NS vs. SN	0.0068 to 3.9728 [1]	−0.0686 to 0.1146	0.4090 to 0.6198 [1]	−0.0134 to 0.0352
NS vs. EW	.0325 to 3.9965 [1]	− .0865 to .0957	.4200 to .6308 [1]	− .0073 to .0413
NS vs. WE	− .1956 to 3.7684	− .3832 to −.2000 [1]	.4176 to .6284 [1]	− .0103 to .0383
SN vs. EW	−1.9582 to 2.0058	− .1095 to .0727	−.0944 to .1164	− .0182 to .0304
SN vs. WE	−2.1864 to 1.7776	− .4062 to −.2230 [1]	−.0968 to .1140	− .0212 to .0274
EW vs. WE	−2.2101 to 1.7539	− .3873 to −.2041 [1]	−.1078 to .1030	− .0213 to .0273

[1] Contrast significantly different from zero at 95 percent confidence level.

differences are not always significant. At the wound, for example, there are no significant differences among EW, SN and WE, but there is a significant difference between NS and SN and NS and EW. At the back instrument table, the effect of the WE orientation is significantly larger than any of the effects for the other three orientations. At the instrument table, the NS orientation effect is significantly different from the other three effects. As expected, no differences were found for the background values. In terms of the nonsignificant differences observed, EW is less than either SN or WE at the wound, SN is less than EW and NS at the back instrument table, and the smallest contamination level at the instrument table is found with the EW orientation. The best orientation, or that which yields the least amount of airborne contamination at the most sample locations, is the EW, that is, when the orientation is perpendicular to the flow of air and the critical work surfaces (back instrument table) are upstream of all sources of contamination. The reasons for this will be discussed in the next section.

Table 20. Ranking of levels of uranine contamination by orientation and sample location for neurosurgery

Location	Increasing → contamination			
Wound	EW	SN	WE	NS
Back instrument table	SN	EW	NS	WE
Instrument table	EW	WE	SN	NS
Background	EW	WE	SN	NS

The relatively large variance at the wound between sample runs of the neurosurgery NS orientation (see table 18) is due to the investigator's inability to duplicate the positions of the surgical team. Slight differences in the folds of the surgical clothing,

Table 21. Effect on levels of uranine contamination at four selected sites due to the lateral movement of the surgical team for the neurosurgery north-south orientation [1]

Location	Level of uranine contamination					
	Surgical team together			Surgical team apart		
	Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3
Wound	2.10	2.22	1.92	17.1	17.1	17.7
Back instrument table	.174	.075	.082	.099	.074	.120
Instrument table	.60	.67	.61	.69	.56	.75
Background	.216	.079	.061	.120	.082	.079

Person	Coordinates of surgical team together (in feet)		Coordinates of surgical team apart (in feet)	
	X	Y	X	Y
Surgeon	4.50	7.50	4.50	7.50
1st assistant	5.25	9.00	5.25	10.00
2nd assistant	5.25	6.00	5.25	5.00
Anesthesiologist	9.00	10.50	9.00	10.50
Instrument nurse	8.00	5.25	8.00	5.25

[1] Reported as relative fluorescent intensity.

minimum rotation of the mannequin and small inaccuracies in placing the aerosol generators may account for this variance. In addition, this is the only orientation where large contamination sources (the surgeon and his two assistants) are directly between the incoming supply of clean air and the wound. Supplementary experimentation, with all conditions constant except that each assistant surgeon was moved 12 inches from the surgeon, produced approximately an eightfold increase in contamination at the wound, while all other sample locations remained the same (see table 21). The largest proportion of contamination recovered at the wound site came from the lower generator of the surgeon, that is, the perineal area (see table 22).

Table 22. Level of uranine contamination at wound site for neurosurgery north-south orientation for various lateral movements of surgical team under differing conditions of generation[1]

Condition	Trial 1	Trial 2	Trial 3
1. Surgical team together, all generators operating	2.10	2.22	1.92
2. Surgical team apart, all generators operating	17.1	17.1	17.7
3. Surgical team apart:			
a. Only surgeon's generators operating	12.0	10.5	12.6
b. Only surgeon's upper generator operating	2.49	2.70	3.10
c. Only surgeon's lower generator operating	6.50	7.60	8.50

[1] Reported as relative fluorescent intensity.

As indicated earlier, both the neurosurgery and cardiac configurations were to be investigated. Since the type of analysis applied to neurosurgery is also applicable to cardiac procedures, door and light positions were deleted for the cardiac procedures, inasmuch as they showed no significant influence on contamination levels in neurosurgery. Although the cardiac analysis was not completed, the results (table 23) reflect the performance of the laminar flow ventilation system with a different configuration of people and equipment.

Overall, the cardiac surgery SN produced the lowest level of airborne contamination at the critical sites. This level is attributable in some measure to the blocking effect of draping and personnel on airflow patterns. The air moving past the first assistant and instrument nurse met the draping at the upstream edge of the table, was deflected upward (the path of least resistance) and over the wound, thus carrying the contami-

Table 23. Summary of levels of uranine contamination at selected sites with four orientations of personnel and equipment for cardiac surgery[1]

Sample location and runs	NS	SN	EW	WE
Wound:				
1	0.77	0.108	0.99	0.56
2	.79	.087	1.44	.63
Mean	.78	.098	1.22	.60
Back instrument table:				
1	.90	.092	.138	.070
2	1.32	.068	.180	.061
Mean	1.11	.080	.159	.066
Mayo stand:				
1	.49	.69	4.1	.49
2	.75	.76	4.5	.90
Mean	.62	.73	4.3	.70
Room exhaust:				
1	22.8	27.0	25.2	28.0
2	27.6	27.0	25.5	28.0
Mean	25.2	27.0	25.4	28.0
Background:				
1	.051	.061	.070	.059
2	.055	.061	.058	.053
Mean	.053	.061	.064	.056
Blank:				
1	.065	.060	.073	.056
2	.077	.064	.065	.059
Mean	.071	.062	.069	.058

[1] Reported as relative fluorescent intensity.

nation downstream without coming in contact with the surgical site.

Most significant in the cardiac study, however, was the discovery of very high concentrations of uranine dye at the Mayo stand in the east-west orientation. This concentration resulted from a venturi effect created by interaction of the air movement and the obstructions close to the Mayo stand. The combination of the instrument nurse, second assistant surgeon, and the operating table drapes caused a severe backflow of air over the Mayo stand, thus localizing the contamination from these two people on the instruments in use.

Microbial Contamination Results

As discussed in chapter 4, the uranine dye aerosol studies sought to identity the major parameters of interest in this work. This was phase 1; phase 2 was undertaken to represent the viable contamination associated with human beings (the surgical team) under typical surgical conditions.

A broth culture of *Sarcina lutea* of a given titer was placed in each nebulizer. An Andersen sieve sampler, Reyniers air sampler, and a fallout plate were placed at each of three locations: wound site, instrument table, and back instrument table. In addition, air samples were placed on the air manifold at the downstream end of the room. All air samplers were operated at a sampling rate of 1 cu. ft. per minute as determined by critical orifices and calibrated flow meters.

The first experiments in phase 2 of this work sought to determine the overall effectiveness of a laminar flow room in removing viable contamination and to discover how much better, if any, the laminar flow facility was than the conventional dilution ventilation system. Two trials were made: in the first, the laminar flow system was on; in the second, it was turned off, but with three small hassock type fans operating to simulate to a degree a dilution-ventilation system. In the "laminar flow off" situation, no fresh air was introduced into the room. Between the "laminar flow on" and "laminar flow off" runs, the ventilating fans were allowed to operate for 30 minutes to remove completely any residual airborne contamination from the previous run.

The first experiment was with the mannequin surgical team in the neurosurgery SN orientation, with only five generators in operation. This orientation was selected because preliminary results of the uranine dye experiments had indicated this was preferable. (Final results proved this incorrect.) The total numbers of organisms collected in

Table 24. Total number of organisms collected in 30 minutes at four sites under two experimental conditions using three sampling techniques with mannequin surgical team for neurosurgery south-north orientation

	Laminar flow on				Laminar flow off			
Sampler	Wound	Instrument table	Back instrument table	Manifold [1]	Wound	Instrument table	Back instrument table	Manifold [1]
Reyniers	1	0	0	4, 15	[2]	[2]	[2]	[2]
Fallout	0	0	0	.....	75	81	92	
Andersen								
1	0	0	0	.....	332	460	548	.....
2	0	0	0	.....	400	516	600	.....
3	0	1	0	.....	648	724	676	.....
4	1	0	0	.....	440	332	448	.....
5	0	1	0	.....	296	176	308	.....
6	0	0	0	.....	3	0	14	.....
Total	1	2	0	.....	2,119	2,208	2,594	.....

[1] Two simultaneous tests at manifold position.

[2] TNTC—too numerous to count.

NOTE: The generators operated for 20 minutes and the samplers for 30 minutes. The total air sampled at the manifold equaled 60 cf. Approximately 30×10^4 cells were generated with a titer of 10^4 cells per ml.

the sample at specific locations (table 24) collected during a total challenge of 25 × 10^4 cells generated during a 20-minute period at a rate of 1.5 ml. of culture per minute and with a titer of 10^4 cells per milliliter. All air samplers were operated for 30 minutes.

The rate of viable organisms generated corresponds to surgical teams using average to poor practices, according to Kethley and Cown (*53*).

In the second experiment, the mannequin surgical team was replaced with the same number of human subjects (in the same positions), who were asked to perform at a level of activity simulating the activity of a regular surgical team. This challenge was accentuated by (1) not providing normal

Table 25. Total number of organisms collected in 30 minutes at four sites under two experimental conditions using three sampling techniques with human surgical team dressed in street clothing for neurosurgery south-north orientation

	Laminar flow on				Laminar flow off			
Sampler	Wound	Instrument table	Back instrument table	Manifold [1]	Wound	Instrument table	Back instrument table	Manifold [1]
Reyniers	15	0	2	26, 32, 2	175	96	148	65, 110, 116
Fallout	0	0	0	.....	8	19	18	.....
Andersen								
1	5	1	3	.....	65	48	53	.....
2	1	1	0	.....	46	45	45	.....
3	0	1	0	.....	30	26	20	.....
4	0	1	0	.....	20	19	21	.....
5	0	6	1	.....	28	32	21	.....
6	0	0	0	.....	1	1	4	.....
Total	6	10	4	.....	190	171	164	.....

[1] Three simultaneous tests at manifold position.

NOTE: All samplers were operated for 30 minutes. The total air sampled at the manifold equaled 90 cf. Two periods of high-level activity were experienced.

Table 26. Total number of organisms collected in 45 minutes at four sites under two experimental conditions using three sampling techniques during four mockup procedures in nonlaminar flow operating room

	Draped				Undraped			
Sampler	Wound	Instrument table	Back instrument table	Exhaust grilles [1]	Wound	Instrument table	Back instrument table	Exhaust grilles
Reyniers	21 [2]	28, 23	26, 39	[1] 32, 43, 24, 38	34, 58	30, 13	25, 32	[2] 33
Fallout	4, 6	3, 5	5, 3	.....	0, 8	2, 0	3, 5	.....
Andersen								
1	10, 26	.....	7, 18	.....	7, 12	.....	12, 13	.....
2	2, 8	.....	1, 9	.....	1, 3	.....	7, 5	.....
3	2, 4	.....	0, 6	.....	0, 0	.....	2, 4	.....
4	5, 7	.....	2, 3	.....	2, 6	.....	0, 2	.....
5	10, 5	.....	3, 2	.....	3, 4	.....	0, 3	.....
6	1, 0	.....	1, 0	.....	1, 0	.....	2, 1	.....
Total	30, 50	.....	14, 38	.....	14, 25	.....	23, 28	.....

[1] Four simultaneous tests at exhaust grilles.

[2] Unsatisfactory sample.

NOTE: Sample time amounted to 45 minutes. The normal air supply to this area contained less than 1 organism per 100 cf. All Andersen samplers operated for 30 minutes.

protective clothing for the team, and (2) asking these people to carry out activities not normally expected of the surgical team. For example, during the 10th- and 20th-minute increments of the 30-minute sampling period, each person performed some type of vigorous activity that violated every normal manner of behavior in an operating room. This included calisthenics, sweeping the floor, shaking one's laboratory coat, and rubbing hands, arms, and hair directly over each of the air samplers. The results of this experiment are given in table 25.

In the "laminar flow on" situation, contamination collected on the Reyniers plates at the wound and back instrument table sample locations was found only during the high activity time increments of the 10th and 20th minute; all other portions of the plates were free of growth. This absence indicates the rapid clean-down capability of the laminar flow room even when subjected to a challenge of this magnitude.

The final portion of this study consisted of a direct comparison between the laminar-flow facility and a well-designed conventional dilution ventilation system. Four mock-up neurosurgical procedures were performed in the conventional room and two animal neurosurgical procedures in the laminar flow room, each by the full complement

Table 27. Total number of organisms collected at four sites under two experimental conditions using three sampling techniques during two surgical procedures in laminar flow operating room

	Draped				Undraped			
Sampler	Wound	Instrument table	Back instrument table	Manifold [1]	Wound	Instrument table	Back instrument table	Manifold [1]
Reyniers	2	1	0	5, 22, 40, 50, 43	3	6	1	20, 23, 62, 59, 72
Fallout	floor = 7	0	0	.....	floor = 1	.....	.....	.....
	cart at door = 1	.....	.....	.....	cart at door = 3	.....	.....	.....
Andersen								
1	.....	1	0	.....	.....	1	0	.....
2	.....	0	0	.....	.....	1	0	.....
3	.....	0	0	.....	.....	0	0	.....
4	.....	0	0	.....	.....	0	0	.....
5	.....	0	0	.....	.....	2	0	.....
6	.....	0	0	.....	.....	0	0	.....
Total	.....	1	0	.....	.....	4	0	.....

[1] Five simultaneous tests at manifold position.

NOTE: Sample time, draped, amounted to 40 minutes; sample time, undraped, amounted to 45 minutes. All Andersen samplers operated for 30 minutes.

Table 28. Summary of numbers of organisms per 100 cubic feet of air for laminar flow and nonlaminar flow operating room

	Laminar flow				Nonlaminar flow			
Sampler	Wound	Instrument table	Back instrument table	Manifold	Wound	Instrument table	Back instrument table	Exhaust grilles
Reyniers	5.9	8.2	1.2	93	84	52	68	76
Andersen	.....	8.3	0	.....	99	.....	86	.....
Overall median in sterile field	.....	4.7				78		

of an actual neurosurgical team. Tables 26 and 27 present the results of this work in terms of total number of organisms recovered at each location during the sampling period. The draped condition refers to the normal use of several layers of draping and the usual surgical dress. The undraped condition refers to the use of only a single drape for the patient and instrument tables and the surgical team attired in scrub suits, booties, caps, masks, and gloves. These two conditions were selected to accentuate the differences anticipated in the levels of viable airborne contamination between the two rooms. The EW orientation was used in the laminar flow room since the uranine dye studies showed this to be the optimal one.

For the procedures in the laminar flow room, the level of airborne microbial contamination for the draped condition ranged from a rate of zero to five organisms per 100 cu. ft. of air at critical sites within the sterile field. The average level of contamination in the air as measured at five points at the exhaust grille was approximately 80 organisms per 100 cu. ft. of air. All levels of airborne contamination were higher for the undraped case, as was expected.

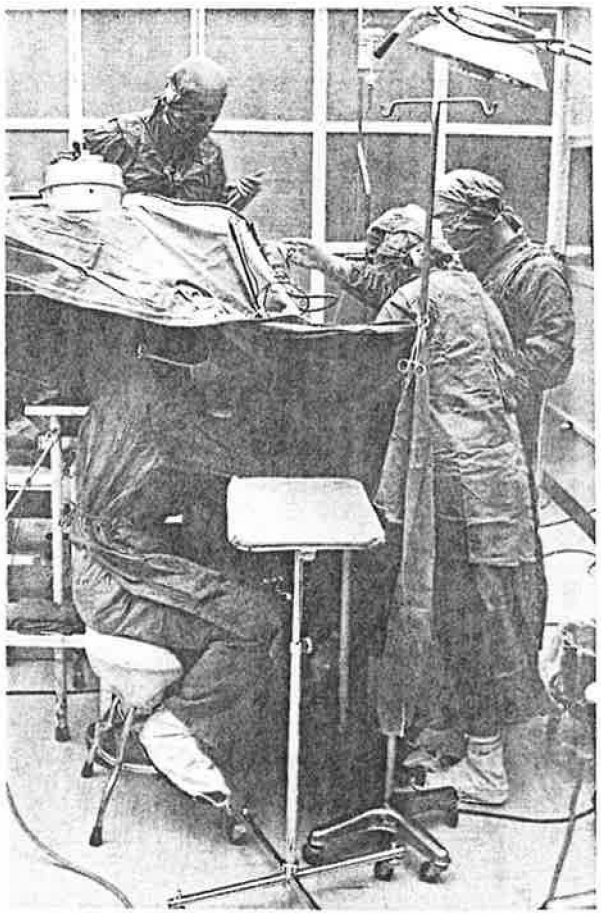

Figure 12. The surgical team and the filter wall in the laminar flow operating room

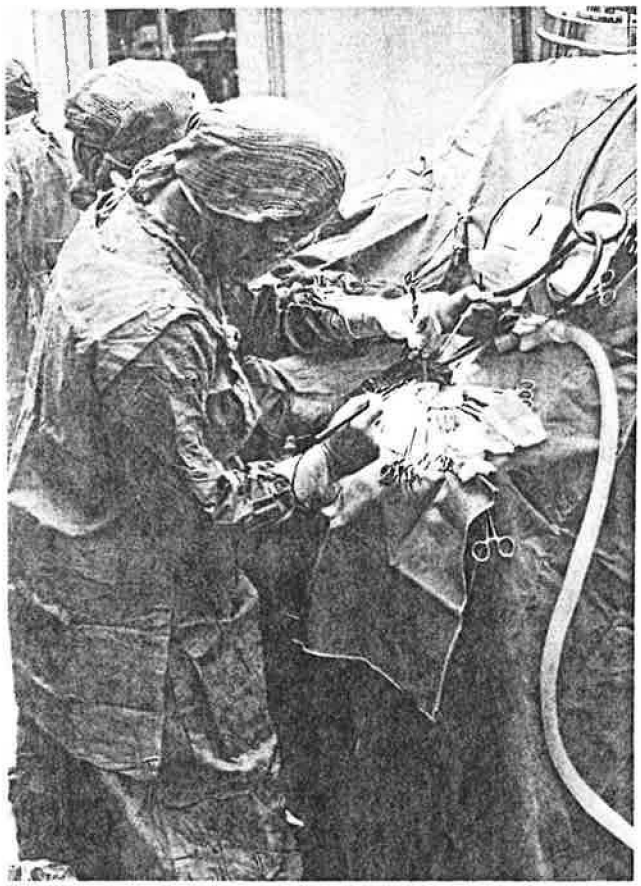

Figure 11. The surgeon and the sterile field in the laminar flow operating room

For the procedures in the conventional, or nonlaminar flow, room the levels of airborne microbial contamination for both the draped and undraped condition averaged approximately 78 organisms per 100 cu. ft. of air at critical sites within the sterile field.

Table 28 presents a summary of levels of airborne contamination measured at various sites in both rooms. The figures for each room are averaged across the draped and undraped procedures.

Figure 13. The surgical team in the laminar flow operating room as seen from the filter wall looking downstream

Figures 11–13 show typical activities of the surgical team during the procedures in the laminar flow operating room. Figure 11 shows the surgeon performing the operation, figure 12 is a view of the surgical team and the filter wall, and figure 13 depicts the surgical team as seen from the filter wall looking downstream.

Data from the biological portion of this study, and specifically with the use of a human surgical team, have identified several important characteristics of the application of laminar flow to operating rooms.

1. With laminar flow the majority of the fallout plates were negative. This cleanliness can be explained by the large horizontal component of contaminant transport due to the velocity of the air compared to its gravity-induced vertical component. For example, the movement of a bacterium of 2 microns in diameter would be 80 feet per minute in the horizontal direction versus 0.024 feet per minute in the vertical direction (*45*). Therefore, in a room 20 feet long this particle would fall only one-fourteenth of an inch according to Stokes Law. A 20-micron size particle would fall approximately 7 inches or one hundred times farther.

2. The effect of ventilation rates is clearly demonstrated in this work. The conventional dilution system that was studied had a ventilation rate of approximately 10 air changes per hour while the laminar flow room had a rate of approximately 240 changes per hour, or a difference of 24 times. The difference between the levels of contamination at comparable locations within the two rooms was in the same order.

3. Results of the biological sampling in both the laminar and nonlaminar flow room may be reported as total number of organisms or number of organisms per cubic foot of air. However, interpretation of the latter is difficult when it is applied to sampling a laminar flow room. As discussed previously, contamination is transported by the streamlines and removed from the room with minimum dispersion, and an observation made adjacent to a contaminated streamline would probably show no contamination. In a dilution system, however, airborne contamination is dispersed throughout the room before removal. Contamination

found in samples taken throughout the room may be considered representative of the contamination level in the room. Thus, the results of air and surface sampling in a laminar flow situation must be interpreted only in terms of that specific sample location. Extrapolation to conditions in the remainder of the room must be avoided.

Chapter 6. Discussion

Data from this study can be interpreted only within the context of the experimental work. The numerical values reported are to be considered not on an absolute, but on a relative scale. They can, therefore, be compared only with other information resulting from duplication of the experimental format and sampling technique. The limitations imposed by nonhuman and stationary subjects, the task of simulating the mechanisms and patterns of humans shedding contamination, must be taken into consideration.

Despite these limitations, the data and subsequent analysis permit clear interpretations consistent with the objectives set forth at the outset. These can be summarized as follows:

Effect of Orientation

The relative position of the surgical team, the associated equipment, and the critical site with respect to airflow direction was the most significant aspect of the study. Examining first the neurosurgery EW orientation, one was able to see from figure 6 that there were no sources of contamination between the clean supply air and the wound, back instrument table, and instrument table. Contamination from the head of the instrument nurse was carried directly downstream and above the chest of the patient. Contamination from her perineal area was carried vertically until it reached a level slightly above the table and then it, too, was taken downstream. This vertical movement was brought about by the blocking effect of the patient's draping which extends downward nearly to the floor. Contamination from the surgeon and his two assistants was taken directly downstream before moving laterally to the flow of air. Figure 14 illustrates the airflow pattern around the head and face of the surgeon; figure 15 depicts the airflow patterns at the wound site for the neurosurgery EW orientation.

Similarly, the neurosurgery WE orientation provided a free flow of air between the surgeon and the assistants and the wound. However, the gas machine acted as a baffle which modified the uni-directional airflow patterns and actually directed some of the contamination toward, rather than away from, the wound. Both the anesthesiologist and instrument nurse contaminated the back instrument table in this orientation.

Neurosurgery NS was the orientation that placed the surgeon and assistants directly between the clean air supply and the wound. From the standpoint of wound contamination, this was the worst condition as shown in table 20. Table 21 illustrates one of the most significant features and limitations in the application of a laminar flow room: under certain conditions a relatively small change in the position of personnel and equipment can result in a large increase in airborne contamination levels. Since this contamination remained in direct association with its source, it was possible to create a situation potentially hazardous to the surgeon-wound and surgical team-sterile field relationship. These data confirm in a simulated surgical environment the work of Kethley (*57*) and Arnold et al. (*58*) in which this phenomenon was first demonstrated.

Another danger spot was found on the Mayo stand in the cardiac surgery EW orientation. Since this stand was raised slightly over the patient's feet and was usually heavily draped, a serious backflow situation developed which caused the contamination from the instrument nurse and second assistant to be deposited on the instruments.

Although the neurosurgery SN orienta-

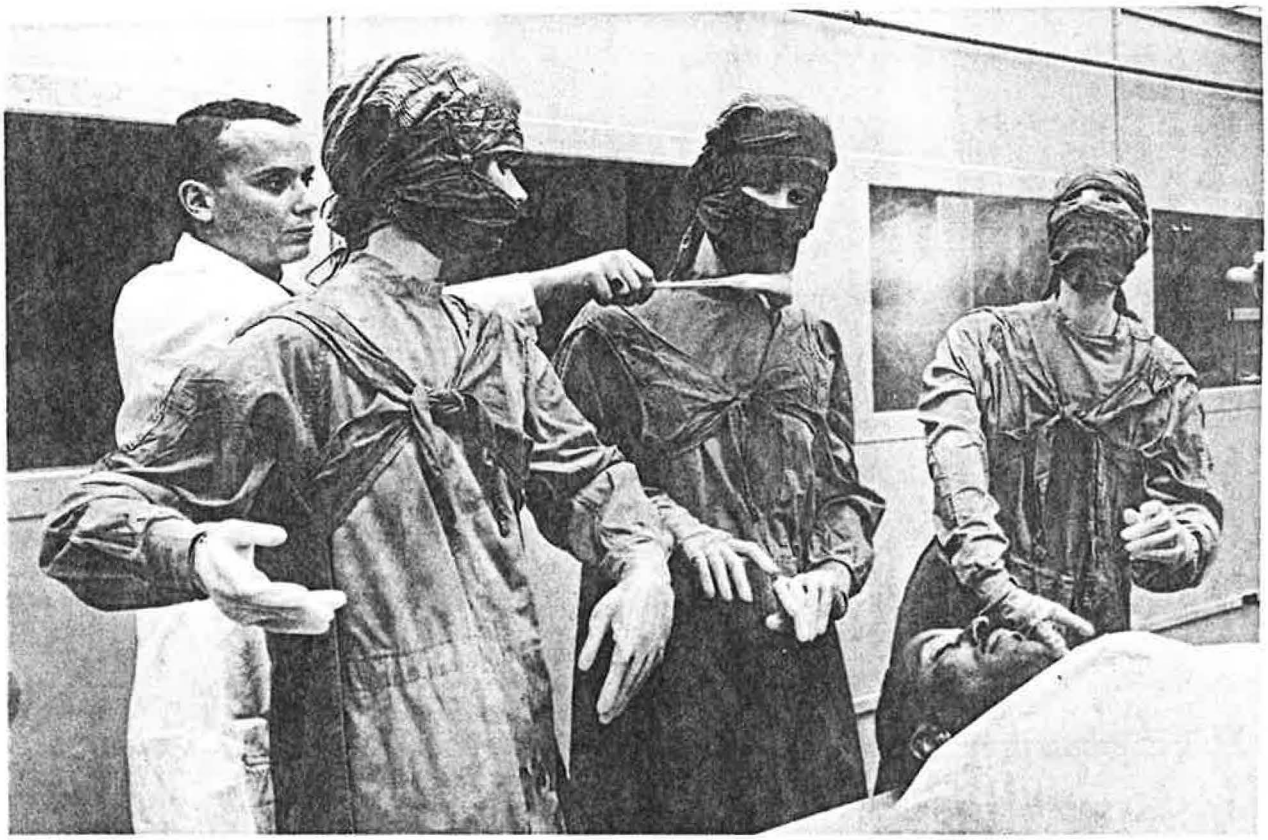

Figure 14. Airflow patterns around head and face of surgeon in neurosurgical east-west orientation

tion was expected to be the ideal situation, since the first pass of clean air was over the critical work sites (instrument table, back instrument table, and wound site) this did not turn out to be true with respect to the wound site. The massive obstruction (surgical team) presented to the airflow just downstream of the wound caused the formation of a pocket of highly turbulent air. As a result, relatively high levels of airborne contamination were concentrated in an area that included the wound site, at least at its outer perimeter.

Position of People

In addition to observations on the effects of surgical team orientation, certain other observations can be made concerning personnel positioning in surgery. A person does not exert any influence on the level of airborne contamination at any critical work site providing he is downstream (except as noted in neurosurgery SN above). A person may also stand or work upstream of a critical site if he is displaced laterally, that is, perpendicular to the flow of air. Other conditions that would further reduce contamination levels when personnel are upstream would be standing sideways to the flow of air, wearing fitted clothing, and keeping other obstructing influences (equipment) to a minimum. For all practical purposes two people can stand approximately 12 inches apart without one affecting the airflow patterns of the other.

Doors and Lights

Airflow patterns around the opened operating room doors have been discussed in chapter 3. These patterns had no significant effect at any of the critical sites in the operating room under any conditions of orientation during these experiments. Therefore, in this laminar flow room the doors serve merely to control traffic and add nothing to the integrity of the clean air.

The small diameter, high intensity surgical lamp offered neither a large obstruction nor added a thermal effect in the airstream. A much larger lamp with a greater power

Figure 15. Airflow patterns at the wound site for neurosurgical east-west orientation

output, such as those used in other types of surgery, would probably have to be studied before one could say categorically that the surgical lamp was of no consequence in a laminar flow operating room.

Additional Work to be Done

During the course of this work several areas outside the scope of this study were identified for further investigation. Some of these areas were studied as they appeared; but others, generally the more involved, were recognized but not fully evaluated. The areas that need further investigation include the following:

1. The noise levels in a laminar airflow room from the motor, fans, and moving air may become too high for comfort in surgeries. From the surgeon's standpoint, there is often a problem of voice communication with his associates, particularly the instrument nurse. From the engineering standpoint, an evaluation of this problem and design of remedial steps must be undertaken before this type of ventilation system will be accepted by the surgical community.

2. There are two possible problems with the use of Andersen and Reyniers air samplers in a laminar flow room: (a) the efficiency of these two samplers and (b) the 1 cu. ft.-per-minute sampling rate may not yield a representative sample of the level of viable airborne contamination under laminar flow conditions. With such low sampling volumes, an accidental contaminant introduced during the loading procedure can represent a significant portion of the total contamination level sampled.

3. Only four orientations of people and equipment were investigated. The question arises, is there some optimum angular orientation in a crossflow room which would yield even lower levels of contamination at the critical worksites?

4. Many of the industrial clean room techniques involving equipment design, clothing, and staging of work operations have potential application to the surgery situation. Equipment which presents a mini-

mum obstruction to the flow of air and form fitting clothing made of the newer types of material so as to minimize the amount of viable material passing from the person to his environment need to be evaluated.

5. Strictly from a biological standpoint the elaborate draping and clothing requirements so popular in the operating room may not be of significant value under conditions of laminar flow. This needs further investigation.

6. Much of a typical physical facility may not really be necessary in the laminar flow situation. To maintain the clean integrity of the room, it is not clear what other door locations, end walls, and side walls contribute. Each portion of the facility should be carefully examined for the role it plays in the overall facility. The engineer may be able to "back off" from the idealized facility used in this study to simplify the remodeling of an existing area to use laminar flow.

Chapter 7. Summary and Conclusions

A study of the application of uni-directional flow of air in a hospital operating room using both qualitative and quantitative measurements was conducted in a mock-up facility. The accomplishments of this work can be summarized as follows:

Determination of Airflow Patterns

Qualitative measurements made with a visible tracer demonstrated the uni-directional airflow characteristics in this facility. In the empty room, the air moved with minimum turbulence and with no backflow at any point between the filter wall and the return air grille. A mean air velocity of 78 linear feet per minute and a ventilation rate of 233 air changes per hour were achieved. These measurements, and subsequent biological sampling, indicated that the large volume of bacteria free air passing through the entire room in a uni-directional manner provided an ultraclean environment. The only sources of viable contamination of concern then were the people occupying and working in the facility.

The use of the ceiling return grille, rather than the more popular return damper wall, neither added to nor detracted from the quality of the air at any of the critical work sites that were investigated.

Determination of Orientation

A quantitative sampling technique employing a salt of sodium fluorescein was developed for determining the direction of the airflow which provided the least amount of contamination at the sampling locations with respect to the relative positions of people, equipment, and critical site. Of the orientations studied, the neurosurgery EW orientation proved to have the lowest overall level of viable airborne contamination at the wound, back instrument table, and instrument table. The SN orientation had the next highest overall level of contamination followed by WE and NS. At the same time, it was found that neither the position of the operating room doors nor the surgical lamp had any significant influence on the level of airborne contamination at the sample locations.

Determination of Biological Quality of Laminar Flow Operating Rooms

For the particular biological sampling technique used in this study, the level of viable airborne contamination at the wound site as given in tables 24–27 ranged from approximately two to five organisms per 100 cu. ft. of air sampled; for the instrument table and back instrument table, zero to three organisms per 100 cu. ft. of air sampled. This number compares to a level of viable airborne contamination in a conventional dilution ventilation operating room of one to 80 organisms per 1 cu. ft. of air.

Sampling during the work involving tables 24 and 25 revealed, first, that any contamination associated with the floor did not extend above the 30-inch elevation level except under the most severe circumstances. Secondly, after the sources of airborne con-

tamination were removed from the room, the air samplers were unable to recover any contamination after 2 minutes due to the rapid clean-down capability of the air-handling system.

Cautions in Laminar Flow Operating Rooms

Laminar flow can be a useful tool to provide a highly sophisticated environmental control area in the surgical field, but it should be used carefully. The work reported in tables 9-12 and table 21 shows that high levels of airborne contamination can occur within the critical work area. Special studies are clearly indicated in each new application of laminar flow.

In conclusion, this study has shown that the laminar flow concept can be of significant value in reducing the level of viable airborne contaminants in the hospital operating room. The laminar flow ventilation system is far superior to present day conventional or dilution ventilation systems in attaining a high level of environmental control. Laminar flow can be used today without altering any of the accepted surgical routines or procedures.

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