FEASIBILITY OF A LARGE GAMMA
IRRADIATOR AS A HOSPITAL STERILIZATION
FACILITY

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I. INTRODUCTION

This report presents the results of a study undertaken to identify possible applications and the feasibility of a gamma irradiation facility applied to the sterilization requirements of a large hospital. The study was directed specifically to the San Francisco Bay Area because of the interest of the Stanford University Hospital in such an irradiation facility. Stanford University Hospital personnel carried out a parallel study within their own hospital and assisted us in this study by supplying us with detailed information on their operations. This work was sponsored by the U. S. Atomic Energy Commission, Division of Applied Technology (USAEC-DAT).

The work was carried out over a five-month period in late 1972. The scope of the information-gathering phase of this study included an extensive literature search; a survey of eight Bay Area hospitals; a visit to the University of Western Ontario Hospital in London, Ontario, Canada, where a large irradiation facility is under construction; a visit to the Atomic Energy of Canada, Limited, in Ottawa; discussions with various public health officials, pollution control officials, and hospital officials; attendance at a USP Conference on Radiation Sterilization; and attendance at a Hospital Waste Management Seminar at George Washington University.

The most promising applications for a hospital irradiator identified in the information-gathering phase were analyzed in detail to determine the feasibility of such a facility. The analyses included a scope design and cost estimates for construction and operation of a hospital irradiator.

II. SUMMARY AND CONCLUSIONS

As one of the first steps in this study, a survey of eight randomly selected San Francisco Bay Area hospitals was conducted to identify present methods and techniques these hospitals are using with regard to infection control and sterilization practices, unique or special sterilization problems, and the handling and disposal of infectious wastes. The survey was intended to define problems the Bay Area hospitals were experiencing with regard to sterilization that might identify possible applications for gamma-ray sterilization. The scope of the survey was limited to information that could be obtained in a single day of interviews with key personnel at each hospital.

An extensive literature search was carried out over the period of the study to identify potential candidates for gamma sterilization, to compare sterilization methods and to evaluate experience with gamma sterilization. Over 1200 citations were considered; 400 were compiled into a bibliography, and about 50 were directly used to aid this study.

The Hospital Survey and literature search both identified similar candidates. Both indicated that a substitute for ethylene oxide sterilization was desired to reduce the process time and eliminate the hazard of the residual toxic gas. Both indicated that many inhalation therapy items need a better sterilization method and both indicated that infectious wastes are a potential hazard to those handling it and to the public after disposal.

The literature search also revealed that ionizing radiation has unique sterilization applications for homografts and implants, but these are small scale applications that do not require a large irradiator. In general radiation sterilization applications, some damage can occur in irradiated organic materials; but when compared to steam, ethylene oxide, and chemical solution sterilization, irradiation is the most effective and reliable sterilization process.

The internal study at the Stanford University Hospital identified the same primary candidates for irradiation sterilization as our survey and literature search. In addition they emphasized the desirability of

providing a reliable disinfecting treatment for the ninety percent of their linens that are not presently sterilized.

The final list of most promising candidates was as follows:

- Inhalation therapy materials and equipment.
- Most items presently gas sterilized.
- Disinfecting treatment for linens.
- Infectious wastes.

An investigation and analysis of hospital disposal practices for infectious wastes identified needs for better procedures for handling and disposal, but incineration was found to be the most economically attractive and effective method of disposal. In any but very small hospitals, incineration costs will run no more than one to two cents per pound. Irradiation costs under the most favorable conditions of high throughput will not be less than six or seven cents per pound. However, irradiation costs are within reason if incineration is prevented by governmental regulation.

The general conclusion regarding infectious waste was that, for the present at least, there are likely to be only very limited opportunities for irradiation sterilization of infectious hospital wastes. Incineration is the most attractive option. Irradiation will only be viable when the incineration option is not available.

Several hospital irradiator design concepts were defined and evaluated in terms of capability to meet the varied requirements in a hospital and in terms of capital and operating costs. Because of the USAEC-DAT interest in finding uses for the Hanford Waste Management cesium-137 capsules, capabilities and costs were developed in terms of using these capsules for the irradiator source. Cobalt-60 could of course also be used.

This analysis showed that a relatively large stop-dwell type irradiator, operating in a batch-charge-mode could be adapted to operate with reasonable efficiency as a special purpose sterilizer in a large hospital. An irradiator could initially be operated as little as only one shift per day and still have acceptable costs for a development program. Operations could be expanded to two and three shifts per day as programs expanded and the irradiator would operate more efficiently with lower costs as the use increased. Results of the analysis for a Stanford University Hospital irradiator with some example costs are summarized in Table 2.1.

TABLE 2.1. Summary of Conceptual Stanford-University-Hospital-Irradiator Capabilities

Case	Equipments Groups	Irradiator Operation	Source MCi 137Cs	Boxes Per Year	Total Annual Cost	Cost Per Box	Unit Cost
1.	Respiratory Therapy:	One Shift	1.6	2,400	\$ 44,000	\$18.40	\$0.19/item (a)
Non-Sterile Disposables							
Reusables							
Gas Sterilized Items							
2.	Double Above to Include Other Departments	Two Shifts	1.6	4,800	\$ 53,000	\$11.00	\$0.12/item (a)
3.	Add Linen	3 Shifts	1.5	28,000	\$ 84,000	\$ 3.00	\$0.05/item (a)
							\$0.017/1b Linen
4.	Add 1/2 Infectious Waste	3 Shifts	3.0	35,000	\$108,000	\$ 3.00	\$0.05/item (a)
							\$0.015/1b Linen
							\$0.13/1b Waste

a. Non-Sterile Disposables only

One of the most attractive applications is the sterilization of reusable items from the Respiratory Therapy Department that are presently mostly sterilized with ethylene oxide. There is a relatively high volume of these items to process and their use is growing at a substantial rate. It appears possible to process them through an irradiator at costs equivalent to or less than present gas sterilization costs. In addition, significant savings not claimed in the economic analysis might result from reduced inventory requirements because of more rapid turnaround in the irradiation sterilizer. The hazard of toxic effects of the ethylene oxide is also eliminated.

The sterilization of presently nonsterile disposables is an attractive application with unit costs that are equal to or less than present commercial rates. If a real advantage can be demonstrated for radiation sterilization of these items, it is probable that the manufacturers of this equipment would adopt this method and the benefits would be thus rapidly disseminated to all hospitals.

In a broader sense, based on the results of the analysis combined with the knowledge that hospital personnel generally are anxious for better sterilization and improved infection control methods, a large scale development program for a hospital irradiator such as that under consideration at Stanford University Hospital appears to be justified. There are enough potential applications where reasonable unit costs can be foreseen to make the prospects attractive.

To be successful, a development program utilizing a large hospital irradiator will require strong leadership and a high priority and commitment from the hospital administration. It will require ingenuity and cooperation throughout the hospital to fully utilize the facility. Applications should be thought of in terms of production-type applications rather than individual isolated experiments.

Overall, the utilization of a large irradiator in a hospital should not be expected to pay for itself through operating cost savings. It will almost certainly result in increased hospital operating costs. Disinfection of linen, for example, would be a new procedure where no savings could possibly accrue. The primary incentive for a hospital irradiator is

improved infection control. The exact magnitude of potential improvements can only be identified through a large scale development and test program. As with any new development program there is no assurance of success, but the potential for significant gains in terms of improved sterilization and infection control methods is certainly present.

III. LITERATURE SEARCH

SCOPE AND PROCEDURE

The scope of the literature search was to find the recent published literature on methods of sterilization (practices, items, problems, and economics), methods of hospital waste disposal, and the published experience on the use of gamma radiation for sterilization purposes and to identify from this literature potential candidates for gamma radiation sterilization in hospitals. The methods used for compiling the bibliography included several computer searches (national MEDLARS and MEDLINE searches), extensive searching by the Battelle-Northwest library and checks on references contained within the literature itself.

The MEDLARS (National Library of Medicine) computer searches provided the most information for the bibliography. These computer searches were carried out through the University of Washington Medical Library. The Library Staff queried the computer memory bank (at the National Library of Medicine, Bethesda, Maryland) with subject headings based on the basic question given the staff. The subject headings are listed in Index Medicus, the principal source of medical subjects. Searches were made for citations up to 3 years old initially and 9 years finally. The basic subjects sought were: 1) Decontamination, Disinfectants, Sanitation, Sterilization, Antisepsis, and Infection; and 2) These same topics with the word Radiation added. Subtopics included:

Bandages	Industrial Waste	Prosthesis
Bedding & Linen	Latrines	Artificial Organs
Beds	Laundering	Surgical Equipment
Food	Refuse Disposal	Disposable Equipment
Food Irradiation	Sewage	Protective Equipment
Cadaver	Transplantation	Shoes
Clothing	Equipment & Supplies	Cooking & Eating Utensils
		Protective Clothing

Over 1100 citations on the above and related subjects were found. These were screened and compiled in our bibliography, which includes about

15 percent of the MEDLARS citations. Each reference contained an abstract or a list of topics covered in the article, which helped us select titles for review.

A MEDLARS search has some limitations. One of these is the lag in updating its listings. The other is its failure to contain thesis topics (Masters and Doctoral) until thesis authors publish in the open literature. To get the most recent entries, a MEDLINE computer search was used. This search method was identical to the MEDLARS. The output return is more rapid and recent, but has less depth than the MEDLARS.

The Battelle-Northwest library staff found a number of related citations in the Nuclear Science Abstracts and similar sources. Stanford University Hospital personnel, the University Hospital of London, Ontario, and AECL provided others. Some references in the literature itself were added to the final bibliography for completeness.

The bibliography which is included as Appendix B was classified by subject matter to facilitate its use. Each article's title and the abstract, if available, provided the necessary information. Most of the articles could be classified according to the item or groups of items being cleaned, sterilized, or handled in a specific way (e.g., waste handling). These fell into three major groups:

- I. Sterilization and Handling of Infectious Wastes
- II. Sterilization of Reusable Items
- III. Sterilization/Disinfection of One-Use Items.

These were further divided into subgroups (See outline, next page). The remaining references were included in a fourth division, Sterilization Methods and Procedures. Within each subdivision, references were listed alphabetically by author. Those references in the first three divisions dealing with ionizing radiation are grouped at the end of each subdivision.

From this bibliography and other sources, key references were selected to aid this study. These references are listed separately in the Reference Section of this report. These key books, conference proceedings, and articles were primary sources for:

BIBLIOGRAPHY OUTLINE

(References per Section Shown in Parenthesis)

- I. STERILIZATION AND HANDLING OF INFECTIOUS WASTE
 - A. General Waste Handling Information (35)
 - B. Infectious Solid Waste (11)
 - C. Infectious Liquid Waste (6)
 - D. Infectious Biological Waste (1)
- II. STERILIZATION OF REUSABLE ITEMS
 - A. Reusable Bedding and Other Linen (10)
 - B. Reusable Equipment (5)
 - C. Reusable Diagnostic and Therapeutic Equipment and Materials (7)
 - D. Reusable Surgical Equipment (12)
- III. STERILIZATION/DISINFECTION OF ONE-USE ITEMS
 - A. General Radiation Information (2)
 - B. Unsterile Disposables, Dressings, Etc. (22)
 - C. Grafts and Transplants (36)
 - D. Prosthetic Devices (4)
 - E. Pathogen Free Diets (5)
 - F. Pharmaceuticals (18)
 - G. Medical Supplies (26)
 - H. Surgical Supplies (11)
 - I. Blood and Blood Derivatives (3)
 - J. Biological Tissues (3)
- IV. STERILIZATION METHODS AND PROCEDURES
 - A. General Information (18)
 - B. Ethylene Oxide (11)
 - C. Steam Autoclave (1)
 - D. Disinfectants (12)
 - E. Radiation (38)
 - F. Infection Control (68)

- Identifying promising and unique candidates for radiation sterilization.
- Assessing radiation damage to materials and other problems with radiation.
- Comparing infectious waste handling methods.
- Understanding the nosocomial infection problem in hospitals.
- Comparing all methods of sterilization in hospitals.
- Defining gamma facility requirements and costs in hospitals.

Copies of nearly all articles on radiation sterilization applications were obtained. Those references providing good background information and comparative information on competing methods were also acquired. Most of the articles discussing the use of ionizing radiation for sterilizing were part of one of four conference proceedings (References 1-4). Many of the other articles were redundant. Odds are small that the search missed an important application of gamma sterilization. Radiotherapy applications were not considered in this search (e.g., use of irradiation to reduce organ transplant rejection rates by irradiating the organ of the donor and the blood of the recipient).

FINDINGS

The most important findings gained from a review of this literature are as follows:

Effectiveness and Limitations of Gamma Radiation

The effectiveness of any sterilization method probably can be best understood by looking at the "kill" curves of various microorganisms subjected to the sterilizing process. This is the fraction of initially viable microorganisms surviving the process as a function of time or accumulated dose. When this fraction is small enough to ensure a very small probability of any survivors, then the item is "sterile." Figure 3.1 illustrates several radiation kill curves for three classes of microorganisms: typical dust microorganisms, resistant spores, and a very

FIGURE 3.1. Destruction of Microorganisms by Ionizing Radiation

resistant virus. A sterilizing dose of ionizing radiation is generally recognized as 2.5 megarad (Mrad).⁽⁵⁾ This dose is sufficient to kill all but one in a million of the highly resistant spore, *Bacillus Pumilus*. (A megarad is equal to 10^8 ergs of gamma energy absorbed per gram of target material.) The kill curves are usually independent of dose rate, but can be sensitive to temperature or the presence or absence of air, water and other chemicals. (Reference 14, p.66). From these kill curves, some general observations can be made:

1. A dose of 2.5 Mrad does not affect all microorganisms equally.
2. Pre-irradiating conditions must be "very clean" to minimize the probability of survivors.

Figure 3.2 shows examples of kill curves for two microorganisms at elevated temperatures. The fraction of survivors is given versus time at the indicated temperature. The curves are similar to the radiation kill curves in Figure 3.1 and indicate that the certainty of sterility is never 100% with heat either.

Although the certainty of sterility is hard to define for the irradiation process, certain advantages are apparent over other competing methods. These are:

1. Gamma rays can penetrate deeply, thereby attacking microbes impossible to kill by other methods. The product can be pre-packaged in durable packages that are impermeable to microorganisms.
2. The process is virtually foolproof. No other method can give this assurance. This reduces the need for expensive sterility testing.
3. Only a negligible rise in temperature occurs with gamma rays, thus making low temperature sterilization possible.

The question arises as to the overall effectiveness of an irradiator in the hospital environment. The benefits of being able to sterilize more things and to make the hospital environment safer to the patient and employee must be weighed against the cost of an irradiator. First, to quantify the benefits of irradiation, continued research and monitoring is required. The factors involved in hospital-acquired (nosocomial) infections and hospital-acquired employee illness are complex. The literature

FIGURE 3.2. Destruction of Microorganisms by Heat

on nosocomial infections is fairly extensive with much data available nationally. However, each hospital is unique so that the complicating factors must be evaluated individually. The complicating factors involved are the nature and source of the pathogen, the susceptibility of the patient, and the mode of infection transmission. The incidence of nosocomial infections in each institution can be studied as indicators and the impact of a gamma irradiator might be quantified.

An example of a department that could study the impact of a gamma facility is the Inhalation (Respiratory) Therapy Department. The high nosocomial infection rate due to cross infection from the use of inhalation therapy equipment (nebulizers, humidifiers) appears well established (Reference 6, pp. 124-129; Reference 7, p. 77). It is probable that this department could receive much potential benefit from the use of a gamma facility, and the results should be quantifiable. But the research is still needed to monitor large numbers of patients over a period of time before and after a gamma irradiator is used, and research is needed to establish the suitability of gamma irradiation on the equipment itself. The monetary benefits are potentially high. The annual cost of nosocomial wound infections alone in the United States has been estimated at about \$13 billion in 1967 (Reference 7, p. 82). The total cost of nosocomial infections is not known but 10 to 30 percent of all nosocomial infections are respiratory in nature.^(7,8)

Radiation Damage Considerations

The possibility of radiation damage imposes some limitations on sterilization applications. Radiation damage can be manifested in two ways: 1) damage to the material itself where some property of the material is altered and 2) toxicity created by the irradiation process. The latter will be discussed at the end of this section. A single sterilizing dose (2.5 Mrad) rarely damages any material beyond use, with the exception of Teflon and optical glass which darkens. Radiation "resistant" cerium glass is available and Teflon can often be replaced by more gamma-resistant plastics. Since the damaging effects on materials are generally accumulative, repeated sterilizing doses on many materials limit the useful life of the gamma sterilized items. Plastics, elastomers, and other organic materials are the most susceptible and their properties and radiation damage effects are well covered in References 9-14. However, a summary of radiation damage effects is included in the following material.

The physical properties studied before and after irradiation depended on the desired property of the plastics, fiber or elastomer. The end use of the item dictates the seriousness of any damage. For example optical transmittance or electrical resistivity may be the significant property. The physical properties usually of interest for plastics include the elastic modulus, shear strength, tensile strength, percent elongation at a particular load, and notch impact strength; for elastomers, dynamic modulus and resilience, hystereses, permanent set, compression set, deformation load, flexing compression and abrasion loss. The threshold dose for a 25 percent change in any one of these properties is a commonly used datum for reporting. Figures 3.3-3.5 (Reference 12) show the relative radiation resistance of elastomers and plastics in air at 77°F. Incipient to mild change is considered to be less than 25 percent change in any property. From these figures it is apparent that nearly all elastomers will be affected by a dose of 2.5 Mrad except polyurethane rubber. Plastics in general are less susceptible than the elastomers. Teflon can survive 100X more radiation than indicated if surrounded by a fluid (Reference 11, p.4). This is probably due to the exclusion of atmospheric oxygen otherwise present. Glass, metal and ceramics have higher resistance than plastics.

Each plastic must be studied individually using these references as a guide to determine obvious unsuitability. Candidates for irradiation sterilization must be test irradiated to verify suitability, since each plastic might have a unique makeup or plasticizer that would render it unsuitable even though the generic plastic (e.g., polypropylene) is generally suitable. Other variables influence the actual result of irradiation. These include temperature at irradiation, postirradiation temperature and humidity, and presence of oxygen. It should be mentioned that thin films of materials are more susceptible than thick pieces for the same dose in air, because oxygen reacts with short-lived radicals formed during irradiation.⁽¹⁵⁾

Plester⁽¹⁶⁾ compared the suitability of six different sterilizing methods on plastics. He concluded that ethylene oxide and radiation are generally the most suitable all around methods. Only polytetrafluorethylene (PTFE) Teflon was unsuitable in radiation. Other fluorocarbons (polytrifluorochloroethylene for example) were suitable.

FIGURE 3.3. Relative Radiation Stability of Elastomers⁽¹²⁾

FIGURE 3.4. Relative Radiation Stability of Thermosetting Resins⁽¹²⁾

FIGURE 3.5. Relative Radiation Resistance of Thermoplastic Resins (12)

DasGupta^(13,14) points out that white cotton develops a brown tint and loses tensile strength with sterilizing doses. Cotton is a favorite material for surgical linen because it does not develop static charges like other fabrics. The University of Western Ontario, Department of Engineering Science, has released some unpublished data (1972) that shows that linen made of 50/50 and 35/65 cotton/Fortrel (polyester) did not show this radiation weakening after 10 cycles of 2.5 Mrad doses followed by laundering.

The complex nature of radiation damage makes a research program necessary to get actual test data on items to be sterilized in a hospital. This program must have carefully controlled and recorded exposure data (and post-sterilization handling), and recorded observations of the physical properties of all components and the function of the components. Occasional reevaluating might be necessary due to manufacturer changes in parts and components, changes that only the plastic/elastomer manufacturer may be aware of. Suitability testing would have to be an on-going part of an irradiation program in a hospital, just as it is with other methods of sterilization, but with a much greater effort initially.

The other facet of radiation damage is the possible formation of toxic compounds. The toxicity of irradiated materials is of concern when a material is to be implanted in a patient or comes in direct contact with the patient, particularly with mucous membranes. Toxicity measurements of various types have been carried out on irradiated plastics by O'Leary⁽¹⁷⁾ at Ethicon. The only positive toxicity noted was partial hemolysis of blood that had contacted irradiated (2.5 Mrad) linear polyethylene, polypropylene and Teflon. Here antioxidants in the plastics were suspected to be the cause.

A general concern in hospitals is the resterilization with ethylene oxide of polyvinyl chloride previously irradiated. Here it has been suspected that a toxic compound, 2-chloroethanol, results from a reaction of ethylene oxide and hydrochloric acid. The latter is apparently an eventual irradiation degradation product of polyvinyl chloride. O'Leary reported that 2-chloroethanol did form from residual ethylene oxide in the plastic,

but the amount was independent of gamma irradiation. Too, he stated that the toxic properties of 2-chloroethanol are highly exaggerated. His source, the Health Industries Associates' "Toxicity and Irritation Studies of Ethylene Oxide, Ethylene Glycol and Ethylene Chlorohydrin (2-chloroethanol)" states that the toxicity level of 2-chloroethanol is 10,000 ppm (1%) in any substance touching any body surface. It is improbable that this level of 2-chloroethanol would result after ethylene oxide sterilization even if the reaction were enhanced by ionizing radiation. These results should remove the stigma from polyvinyl chloride that has been sterilized by ionizing radiation.

No residual radiation is induced in irradiated materials at the commonly used energies of gamma rays from cobalt-60 or cesium-137.

Candidates for a Hospital Irradiator

The potential candidates for gamma irradiation identified from the literature survey are listed in Table 3.1. Many of these candidates have been successfully sterilized by ionizing radiation commercially or in research programs. Others are candidates because of the apparent need for better methods, or in the case of wastes, no alternate method might be acceptable due to future regulations. Each group of candidates will be discussed in more detail in the order of Table 3.1.

A. Infectious Solid Wastes

These wastes appear as candidates because there is growing concern that present methods of waste handling in hospitals, transporting wastes to landfill and the landfill itself represent clear dangers to hospital employees, sanitation personnel and the general public. A summary study in Washington for Seattle-King County Department of Public Health quoted eleven references expressing concern that nearly all patient-generated hospital wastes are public health hazards.⁽¹⁸⁾ A recent study for the U.S. Environmental Protection Agency⁽¹⁹⁾ concludes that the transfer, storage, processing and disposal of all hospital wastes be carried out in closed systems because they hold the premise that all such waste is contaminated. A study for the London, Ontario Hospital Planning Council⁽²⁰⁾ held that hospital wastes were contaminated, that landfill of such wastes is not desirable

TABLE 3.1. Potential Irradiation Candidates from Literature Survey

A. INFECTIOUS SOLID WASTES

1. Laboratory Wastes Including Pathological Specimens and Disposable Fomites, Tissues, Blood Specimens, Excreta, Cultures, and Animal Wastes.
2. Disposable Fomites, Equipment, and Wastes from Isolation Patient Rooms (Those with Communicable Diseases).
3. Surgery Wastes.

B. INHALATION THERAPY EQUIPMENT AND ANESTHESIA EQUIPMENT

1. Reusable Items Presently Gas Sterilized.
2. Large Equipment Not Adequately Sterilized Now.
3. Disposable Items Not Being Used Sterile Now Due to High Cost.

C. SPECIAL SURGICAL AND MEDICAL INSTRUMENTS AND EQUIPMENT

1. Endoscopes.
2. Special Equipment for Burn Patients (Circular Beds, Etc.).
3. Kidney Dialysis Membranes.
4. Surgical Drills.
5. Metal Implements Requiring Long Shelf Life.
6. Cardiac and Angiographic Catheters.

D. DISPOSABLE ITEMS (COMMERCIALY GAMMA STERILIZED)

1. Surgical Sutures and Scalpel Blades
2. Hypodermic Needles and Syringes.
3. Surgical Dressings, Bandages, Gauze, Cotton Swabs.
4. Rubber Gloves, Plastic and Rubber Catheters, Endotracheal Tubes.
5. Oxygenators (Disposable Type) and Tygon Tubing for Heart Lung Machines.

TABLE 3.1. (contd)

E. PHARMACEUTICALS, BLOOD DERIVATIVES AND FOOD

1. Drug Preparations (Proteins, Steroids, Enzymes, Vitamins Hormones, Alkaloids, Antigens, Antibiotics, Antiocoagulants, Etc.).
2. Parenterals (Glucose Solution, Etc.).
3. Blood Derivatives (Plasma, Fibrinogen, Etc.).
4. Food for Pathogen Free Diets⁽²¹⁾

F. BIOMATERIALS AND IMPLANTS

1. Lyophilized (Freeze Dried), Perforated and Unperforated Bone Grafts, Tendons, Cartilage.
2. Surgical Impression Materials.
3. Prosthetic Devices (Including Prosthetic Heart Valves).
4. Pudenz Valves (For Hydrocephalics' Shunts).
5. Homographic Heart Valves and Other Homografts.

G. MISCELLANEOUS SPECIAL ITEMS

1. Linen.
2. Replaceable Air Filters.
3. Housekeeping Equipment After Cleaning Isolation Areas.
4. Patient-Care Trays and Utensils.

and that gamma radiation was an alternate method, though an expensive one, to onsite incineration of these wastes. With recent severe restrictions on incineration and hauling, many Los Angeles County hospitals will have to find alternatives to incineration and present methods of hauling to sanitary landfill. All of these point to the necessity to consider gamma radiation as an alternate method, particularly if regulations change and leave few other remaining choices.

B. Inhalation Therapy Equipment and Anesthesia Equipment

Heat sterilization is injurious to plastics and rubber materials found in both inhalation therapy and anesthesia equipment. Ethylene oxide is a feasible agent to sterilize this equipment, but the long aeration periods required are undesirable.⁽²²⁾ Since much of the reusable equipment requires sterilization,^(7,22) and since cold sterilization is not adequate, a large number of items might be gamma sterilized. Certainly large irregular objects that do not fit in conventional gas sterilizers and are only wiped down with isopropanol are candidates. Ultrasonic nebulizers are frequently contaminated (Reference 6, p. 80). Nonsterile disposable items frequently used by Inhalation Therapy in conjunction with the nebulizers, IPPB machines and other equipment might constitute a body of candidates.

C. Special Surgical and Medical Instruments

These items were selected as candidates because present sterilization methods were not adequate. Endoscopes (Reference 7, p. 125) are difficult to sterilize (apparently steam can damage the scopes and gas cannot penetrate all cavities adequately). Burn patients require special expensive reusable equipment such as circle beds. The awkward size of the equipment and the susceptibility of burn patients to infection might make sterilization/disinfection with gamma irradiation desirable.

The use of gamma radiation was described as the best method of choice in England for sterilizing the cellophane membrane and a polyethylene envelope for Kiil Kidney Dialysis machines.⁽²³⁾ This procedure is for first use only before mounting. Stanford University Hospital resterilized their mounted membranes between uses with gamma radiation (at International Neutronics, Inc., Los Altos) and found this method expensive and that

repeated irradiation eventually destroys them. Most Bay Area hospitals are switching to disposable membranes now, so the presently used Kiil units will be obsolete.

Surgical drills that are air powered have intricate compartments that steam or gas cannot reach. These drills are used in several types of surgical procedures where bone is entered (e.g., mastoidotomy). Discussion with an ear, nose and throat specialist revealed the concern for sterilizing these instruments.⁽²⁴⁾

Metal (or other suitable material) instruments or implements (or trays) that are used only occasionally, where sterility is necessary, lend themselves to pre-sterilization packaging for indefinite shelf life if gamma radiation is used to sterilize them. These conditions are found in hospital emergency rooms and specialty departments. Presently, steam sterilized items must be routinely resterilized every 30 days if not used. The volume of items in this category is not large, but the advantage of gamma sterilization here is apparent.

Many catheters that require resterilizing are suitable candidates. Angiographic catheters made out of nylon, polyethylene or polyurethane have been successfully gamma sterilized in excess of 2.5 Mrad in Australia.⁽²⁵⁾ After sterilization, they were subjected to mechanical tests and passed each one. Ethylene oxide was not considered safe and soaking in cold solutions was not effective. Expensive cardiac catheters appear to qualify for the same reasons. Because of the large variation in catheter types and materials around the world and the high turnaround rate in the evolution of these, no general conclusion can be made about the suitability of using gamma irradiation or the magnitude of the sterilization volume.

D. Disposable Items

Many disposable items are commercially sterilized by ionizing radiation. The trend to more items being sterilized commercially will probably continue. A hospital irradiator is not likely to be able to compete economically for sterilizing nonsterile disposables, unless a facility

exists that is not utilized 24 hours/day, and some other source of income or benefit exists that will pay for the facility. The United Kingdom, Denmark and the United States have large commercial irradiators. The items listed in the outline represent major groups of items they sterilize. The Wantage Research Laboratory in England (Reference 1, p. 40) provides a wide range of sterilization services for hospitals. An irradiator in a large hospital could expect to perform such services for themselves and other hospitals.

Disposable oxygenators for heart-lung machines are being sterilized successfully at Risø, Denmark, using linear accelerators (Reference 3, p. 265), and Tygon tubing for heart-lung machines is being sterilized in England (Reference 3, p. 285). These latter two applications might be done as well in a hospital based facility in this country. The authors of the above articles feel that sterilization by ionizing radiation is the best method.

E. Pharmaceuticals, Blood Derivatives and Food

Extensive reviews on the suitability of ionizing radiation to sterilize pharmaceuticals are in References 1, 2, 3 and 26. It is beyond the scope of this effort to summarize the results of many studies on drugs and drug preparations. Suitability results are generally promising, but the U.S. Food and Drug Administration has made the application in hospitals extremely difficult. Stating the FDA position, Mr. David Link⁽²⁷⁾ indicated that drug producers must get FDA approval based on firm evidence that no toxic or deleterious substances are produced. The expense and time required, if this rule applies to hospital preparations, rule out this application.

Blood derivatives constitute an exciting group of potential candidates for radiation sterilization. The need for safe derivatives is high. Viral hepatitis (both infectious and serum) is a constant danger to recipients of whole blood or blood components. The disease has no known cure and is often fatal. Detecting the presence of the disease in donors is far from effective, and it is present in about 2 percent of the population (Hospital Survey). Blood derivatives are made from pooled blood, making the danger

even greater. Radiation might be an answer, but much research is needed to understand the disease itself as well as to understand the effectiveness and suitability of radiation.

Some effort at sterilizing blood components by radiation has been carried out. Whole blood is not yet suitable. Hemolysis (loss of hemoglobin from red cells) occurs at doses far below sterilizing doses (Reference 2, p. 112). Bovine blood showed 25 percent hemolysis (25 percent destruction of red cells) at 50,000 rad (0.05 Mrad) (Reference 30). This is not acceptable. Blood components, thrombin and prothrombin, lose up to 40 percent activity at 3.7 Mrad (Reference 2, p. 111), while stable plasma protein, albumin, and antilymphocyte globulin at unspecified doses were virtually unchanged (Reference 2, p. 112). Antoni et al. (Reference 3, p. 107) reported that some loss in various activities (e.g. clotting time) occur in irradiated plasma (0.5-5 Mrad), but none were completely inactivated. Gergely et al. (Reference 3, p. 115) reported that a "sterilizing dose of gamma rays does not destroy the antibody active sites of Immunoglobulin G molecules." The English abstract of Martinenez de Alva et al. (Reference 3, p. 125), Mexico, contained the following:

"The object of the present study, which should be regarded as a preliminary report, is to present the results obtained by sterilizing, by means of gamma rays (^{60}Co , 1.33 6 MeV) at doses of 2, 2.5 and 3 Mrad, a substance which, like plasma, contains highly labile proteins easily able to undergo structural changes under irradiation. Pure fibrinogen, pure gamma globulin, and albumin of human origin were subjected to the same doses; the results were very satisfactory, in that no appreciable change could be demonstrated as regards the structure, solubility or chemical characteristics of the substances concerned. It was shown by means of simple coagulation tests that some of the proteins involved in this mechanism, such as prothrombin, the Power-Stuart factor and the Hageman factor, were practically unchanged. All the plasma samples and the various proteins were previously lyophilized to give a maximum moisture content of 0.034%, in order to avoid ionizing the water content into oxygenated water, which would modify and oxidize the proteins. It was shown that lyophilized plasmas initially contaminated with different strains and viruses remained sterile with doses as low as 2 Mrad. Finally, it was shown that this method is simple and practical, since sterilization can be checked in the final packaging."

Although these results seem encouraging, the question of using radiation to get hepatitis free blood components is not answered. The sterilizing dose here is difficult to define for several reasons:

1. The virus cannot be isolated.
2. The disease is apparently caused by a toxic viral antigen, not the virus itself. The effect of radiation on the antigen is not established.
3. Research on humans can only be done with patients whose need of the blood derivatives is greater than the risk of infection. This will necessitate statistical analysis of data before and after a radiation program began.

Irradiated blood derivatives will probably not be made on a production basis in a hospital. Pharmaceutical companies will probably control the major volume of such blood products. Whole plasma would be the most likely hospital candidate, but even that would probably be done on an emergency basis only. A hospital with an irradiator might contract services to a county or other central blood bank. However, these applications are highly speculative at this time.

Food irradiation for pathogen-free diets is being successfully accomplished in England, ⁽⁴⁾ but again the FDA has not sanctioned it in the U.S. The experience in England indicated that gamma sterilized food containing less than 15 percent fat was far more palatable than heat sterilized food.

F. Biomaterials and Implants

In this group of potential candidates lie the most unique applications for radiation sterilization. Here ionizing radiation is often clearly the best or only way to sterilize. The only discouraging aspect of these applications is the low volume.

Radiation sterilization of bone-bank bone and cartilage seems to be an accepted practice today. A long paper given by Paul H. DeVries, et al. ⁽²⁸⁾ in 1958 was concluded by:

"Radioactive cobalt has been proved to be an effective means of sterilizing bone transplants. When combined with a freeze-drying process, radiation sterilization utilizing radioactive cobalt has proved an effective method of maintaining a bone-bank.

It has been found that irradiated bone transplants function satisfactorily both experimentally and clinically.

In 104 surgical procedures in which irradiated homogeneous-bone transplants were used, five postoperative wound infections occurred. The irradiated bone transplants were not felt to be the source of these infections.

The encouraging over-all clinical results in 104 operative procedures prompt continued use of irradiated homogeneous-bone transplants." (4 Mrad used.)

Irradiating bone and cartilage also reduces the antigenicity (rejection reaction) of the implants (Ostrowski, et al., Warsaw, Reference 3, p. 139).

"To summarize, it seems that radiosterilization of tissues for clinical purposes, apart from its practical advantages, offers the additional advantage of diminishing tissue antigenicity, which may be important when the tissue, for instance human cartilage, is not subjected to any other preserving procedure." (3.3 ± 0.5 Mrad used.)

Chemical and physical changes in bone appear with 2-4 Mrad doses (Reference 1, p. 15 and p. 71), but clinically the transplants work. C. A. L. Barret, M. D., was quoted in Reference 1, p. 114.

"For example, some have used doses well above 2 000 000 rad, some have decalcified the bone prior to or after irradiation and some have freeze-dried the bone prior to irradiation. I will not argue the point that irradiation does not change the bone--it does. Our point was, and still is, that the change does not seem to be sufficiently great to prejudice adversely the clinical outcome of grafting or implantation, when cases (recipients) are selected with some care."

Barret's experience was with children only having elective surgery.

Surgical impression materials might be a candidate, although ethylene oxide sterilization appears to be satisfactory (high temperature methods are not satisfactory).⁽²⁹⁾ Plastic and irreversible hydrocolloidal materials are used for molds in the following procedures: cranioplasty, tympanoplasty (middle ear reconstruction), oculoplasty, therapeutic contact lens fitting, skin grafting, splinting, fitting cleft palate prostheses and others. No reference to gamma sterilization of these materials was evident in the literature.

Any prosthetic device might be a candidate for radiation sterilization. Many of the presently used devices are metal. Plastics and ceramics are also used occasionally. Since new prosthetic devices are rapidly being developed and their composition can only be speculatively defined at this time, the role of radiation is not certain. An organ replacement such as an artificial heart might be sufficiently sophisticated and complex to necessitate gamma sterilization. Present day metal hip replacements are adequately handled by autoclaving. The only experience with radiation sterilization was with arterial valves and artificial arteries (Reference 1, p. 40 and Reference 12, p. 289). The latter reference (M. F. Alladine and J. R. P. Gibbins, London) pointed out that Starr-Edwards heart valves were successfully sterilized at 2.5 MRADS. The method was "simple, cheap and effective." Little change in the PTFE Teflon occurred and prepackaging allowed for adequate inventory for size selection during surgery. (This experience with Teflon appears to contradict other experience, see p. 3.9). Another candidate, although not a true prosthetic, is the brain to peritonium shunt used for treating hydrocephalic children. The Pudenz-Mayer shunt was irradiated successfully (Reference 1, p. 40). Although these and future uses of gamma irradiation look promising, the volume of prosthetic devices can only justify a small irradiator.

Tissue implants given by a donor to a recipient, classified as homografts, look like promising candidates. These might include heart valves, blood vessels, dura mater (major lining of the brain), retinas and corneas, skin, nerves and bone (discussed previously). Blood vessels had been radiation sterilized, but with new substitute materials available now, the need is no longer existent (Reference 2, p. 114). The most promising application is the sterilization of aortic valves. Gibbons and Alladine in London claim success with 10 patients (Reference 3, p. 181):

"A gamma irradiated graft, sterilized at 3 Mrad, can be used instantly and unlike a freeze-dried graft does not require a period of 30 minutes whilst the valve is reconstituted at the operating table. The surgeon can operate in the knowledge that the valve is sterile and it does not require to be placed in antibiotic solutions before being sewn into the host's aorta. We have no pathological evidence of the fate of these grafts in the host, but examination of patients in whom they have been inserted does not suggest, at the present time, any deterioration in function."

A quote taken from Reference 2, p. 116 relates even more clinical success:

"We have used your irradiated valves in nearly one hundred patients with severe aortic valve disease. We have been completely satisfied with them and believe it is the method of choice in the preservation of this material."

Malm, et al., in New York,⁽³³⁾ prefer irradiation homografts to Starr-Edwards valves and summarized their clinical success:

1. "Clinical results with the use of irradiated aortic homograft valves in 50 patients are reported. These valves have functioned satisfactorily up to 20 months. Anticoagulants have not been used and there have been no peripheral arterial emboli. The incidence of aortic-diastolic murmurs is 23%, but there is only one case of significant aortic insufficiency.
2. Irradiation by high energy electron beam is an effective method of aortic valve sterilization for clinical use. This modality coupled with storage by freezing caused no demonstrable change in the tensile strength of the homograft structure.
3. Preservation of graft tensile strength and geometry, proper selection of graft size, and a precise technique for valve implantation are important in obtaining a satisfactory hemodynamic result."

Judging from these quotes and another source (Reference 1, p. 41), homograft heart valves are best preserved by irradiation. These constitute another unique use of irradiation.

G. Miscellaneous Special Items

Many objects used in the hospital might be candidates for gamma irradiation to improve the hospital environment from the contamination standpoint. Any items reused can be considered contaminated unless sterilized. Special items that might receive decontaminating or sterilizing doses that pose as potential environmental hazards are linen, housekeeping equipment, air filters and patient care trays and utensils. These items were not discussed in the literature as specific items that need to be decontaminated, but these were identified as potential candidates from general reading and experience with hospital procedures. A typical decontaminating dose for these items if they cannot be practically sterilized would be 0.5 Mrad. Such a dose would have a survival fraction of 1/1000 of 99% of all dust microorganisms (see Figure 3.1).

IV. HOSPITAL SURVEY

A survey of San Francisco Bay Area hospitals was conducted to determine the present methods and techniques these hospitals are using with regard to infection control and sterilization practices, unique or special sterilization problems, and the handling and disposal of infectious wastes. The survey was intended to define problems the Bay Area hospitals were experiencing with regard to sterilization that might lead to identifying possible applications for gamma-ray sterilization. The scope of the survey was limited to information that could be obtained in a single day of interviews at each hospital.

SELECTION OF HOSPITALS TO BE SURVEYED

The San Francisco Bay Area consists of six counties; namely, Marin, Contra Costa, San Mateo, Alameda, Santa Clara, and San Francisco. In compiling a list of candidate hospitals for the survey, the following criteria were used:

- Only short-term general acute care medical/surgical facilities were included.
- Speciality hospitals, such as ear, nose and throat, narcotics, psychiatric, etc., were excluded.
- Veterans hospitals, military hospitals, and children's hospitals were excluded.
- Long-term care facilities were excluded.
- The selection of hospital size (number of beds) was determined by random sampling.

The total number of hospitals in the six counties is approximately 105 (containing some 26,741 licensed beds) of which 75 fit the above criteria. The 105 hospitals are listed by county in Table 4.1 with the 75 hospitals (15,867 beds) eligible for the survey identified by an asterisk.

The 75 hospitals were listed in sequential order and a random number table used to select ten hospitals for the survey. Since we were looking for problem areas in infection control that might be sensitive topics in

TABLE 4.1. List of Bay Area Hospitals by County. (a)
(Hospitals meeting survey criteria
are indicated by an asterisk.)

<u>Name</u>	<u>City</u>	<u>County</u>	<u>Size</u>
Hamilton Air Force Base Hosp.	Hamilton A.F.B.	Marin	35
Center Medical Hospital	Kentfield	Marin	99
Novato General Hospital	*Novato	Marin	51
Ross General Hospital	*Ross	Marin	219
Chas. Neumiller Mem. Hosp.	San Quentin (Prison)	Marin	134
Kaiser Foundation Hospital	*San Rafael	Marin	68
Marin General Hospital	*San Rafael	Marin	242
Delta Memorial Hospital	*Antioch	Contra Costa	53
Concord Comm. Hospital	*Concord	Contra Costa	189
Contra Costa County Med. Serv.	*Martinez	Contra Costa	363
Martinez Community Hospital	*Martinez	Contra Costa	48
Veterans Admin. Hospital	Martinez	Contra Costa	482
Doctors Hospital of Pinole	*Pinole	Contra Costa	133
Pittsburg Community Hospital	*Pittsburgh	Contra Costa	78
Kaiser Foundation Hospital	*Richmond	Contra Costa	54
Richmond Hospital	*Richmond	Contra Costa	99
Brookside Hospital	*San Pablo	Contra Costa	242
John Muir Mem. Hospital	*Walnut Creek	Contra Costa	155
Kaiser Foundation Hospital	*Walnut Creek	Contra Costa	201
Belmont Hills Neu.-Psy. Center	Belmont	San Mateo	30
Twin Pines Hospital	Belmont	San Mateo	75
Peninsula Hospital & M.C.	*Burlingame	San Mateo	360
Mary's Help Hospital	*Daly City	San Mateo	261
Canyon Hospital	Redwood City	San Mateo	120
Hassler Hospital	Redwood City	San Mateo	227
Kaiser Foundation Hospital	*Redwood City	San Mateo	130
Harold Chope Community Hosp.	*San Mateo	San Mateo	193
Sequoia Hospital District	*Redwood City	San Mateo	439
Woodside Acres Hospital	Redwood City	San Mateo	24

a. "The AHA Guide to the Health Care Field, 1971," American Hospital Association.

<u>Name</u>	<u>City</u>	<u>County</u>	<u>Size</u>
Church of St. Matt. Mill's	*San Mateo	San Mateo	355
Kaiser Foundation Hospital	*S. San Francisco	San Mateo	39
Alameda Hospital	*Alameda	Alameda	162
Albany Hospital	*Albany	Alameda	39
Alta Bates Community Hosp.	*Berkeley	Alameda	209
Cowell Memorial Hospital	*Berkeley	Alameda	88
Herrick Memorial Hospital	*Berkeley	Alameda	227
Eden Hospital	*Castro Valley	Alameda	243
Laurel Grove Hospital	*Castro Valley	Alameda	78
Washington Hospital	*Fremont	Alameda	156
Kaiser Foundation Hospital	*Hayward	Alameda	123
Levine Hospital of Hayward	*Hayward	Alameda	90
St. Rose Hospital	*Hayward	Alameda	187
Valley Memorial Hospital	*Livermore	Alameda	108
Veterans Admin. Hospital	Livermore	Alameda	346
Fairmont Hospital	Oakland	Alameda	504
Highland General Hospital	*Oakland	Alameda	339
Brookdale General Hospital	*Oakland	Alameda	70
Children's Hos. Med. Cen.	Oakland	Alameda	142
Civic Center Hospital	*Oakland	Alameda	112
Gladman Memorial Hosp.	Oakland	Alameda	70
Kaiser Foundation Hospital	*Oakland	Alameda	241
Naval Hospital	Oakland	Alameda	775
Oakland Hospital	*Oakland	Alameda	90
Peralta Hospital	*Oakland	Alameda	204
Providence Hospital	*Oakland	Alameda	244
Sal. Army Booth Mem. Hosp.	Oakland	Alameda	47
S. Merritt Hospital	*Oakland	Alameda	326
Doctors Hosp. of San Leandro	*San Leandro	Alameda	136
Estudillo Hospital	San Leandro	Alameda	6
Gilmore Hospital	San Leandro	Alameda	16
Memorial Hosp. of San Leandro	*San Leandro	Alameda	120

<u>Name</u>	<u>City</u>	<u>County</u>	<u>Size</u>
Campbell Community Hospital	*Campbell	Santa Clara	48
Wheeler Hospital	*Gilroy	Santa Clara	46
Community Hosp. Los Gatos	*Los Gatos	Santa Clara	174
West Valley Hospital	*Los Gatos	Santa Clara	95
El Camino Hospital	*Mountain View	Santa Clara	408
Stanford Child. Conval. Hosp.	Palo Alto	Santa Clara	32
Veterans Admin. Hospital	Palo Alto	Santa Clara	1,384
Agnews State Hospital	San Jose	Santa Clara	2,828
Alexian Brothers Hospital	*San Jose	Santa Clara	126
Gd. Samaritan Hosp.-S. Clara Valley	*San Jose	Santa Clara	259
O'Connor Hospital	*San Jose	Santa Clara	269
Park Alameda Hospital	*San Jose	Santa Clara	131
Oaks & the Redwoods	*San Jose	Santa Clara	491
S. Clara Valley Med. Center	*San Jose	Santa Clara	496
St. Vincent Pav. of O'Conner	*San Jose	Santa Clara	80
Kaiser Foundation Hospital	*Santa Clara	Santa Clara	235
Stanford University Hospital	*Palo Alto	Santa Clara	612
Callison Memorial Hospital	*San Francisco	San Francisco	83
Childrens Hospital of S.F.	San Francisco	San Francisco	345
Chinese Hospital	*San Francisco	San Francisco	60
Franklin Hospital	*San Francisco	San Francisco	259
French Hospital	*San Francisco	San Francisco	208
Garden Hospital	San Francisco	San Francisco	132
Golden Gate Comm. Hosp.	*San Francisco	San Francisco	75
Hahnemann Hospital	*San Francisco	San Francisco	76
Harkness Hospital & Med. Center	*San Francisco	San Francisco	450
Kaiser Foundation Hospital	*San Francisco	San Francisco	293
Laguna Honda Hospital	San Francisco	San Francisco	1,531
Langley Porter Neu.-Psy. Insti.	San Francisco	San Francisco	97
Letterman General Hospital	San Francisco	San Francisco	590
Mount Zion Hosp. & Med. Center	*San Francisco	San Francisco	452

<u>Name</u>	<u>City</u>	<u>County</u>	<u>Size</u>
Presbyterian Hosp.-Pac. Med. Cen.*	San Francisco	San Francisco	242
S.F. Eye & Ear Hospital	San Francisco	San Francisco	35
S.F. General Hospital	*San Francisco	San Francisco	822
Shriners Hosp. for Crippled Children	San Francisco	San Francisco	50
St. Francis Memorial Hospital	*San Francisco	San Francisco	334
St. Joseph's Hospital	*San Francisco	San Francisco	215
St. Luke's Hospital	*San Francisco	San Francisco	248
St. Mary's Hosp. & Med. Cen.	*San Francisco	San Francisco	417
U.S. Pub. Health Serv. Hosp.	San Francisco	San Francisco	366
Unity Hosp.	*San Francisco	San Francisco	46
University of Calif. Hospitals	*San Francisco	San Francisco	553
Veterans Administration	San Francisco	San Francisco	352

some hospitals, we felt that we might obtain more open discussions of the problems if we promised anonymity to the hospitals being interviewed. In arranging for the interviews, we indicated that we would not identify individual hospitals in our report without their permission. For this reason the hospitals selected for interviews are not identified by name here.

Table 4.2 shows that the ten hospitals provided a reasonably representative sample relative to size and geographical dispersion.

Due to inability to arrange a mutually agreeable time, only eight of the ten hospitals were actually interviewed. Upon completing the interviews and reviewing the results for the eight hospitals and considering the limitations of time and funding for the study and the generally qualitative nature of the information obtained, it was decided that further followup efforts to obtain interviews with the other two hospitals were not justified. There was felt to be little likelihood of developing significant additional information.

SCOPE OF THE SURVEY

The scope of the survey was designed to obtain information regarding procedures and problems relating to sterilization practices and treatment of infectious hospital waste and to identify candidate applications for gamma sterilization.

TABLE 4.2. Characteristics of Selected Hospitals

<u>Location by County</u>	<u>Less Than 100 Beds</u>	<u>100-300 Beds</u>	<u>Over 300</u>	<u>Total</u>
Marin		1		1
Santa Clara		1		1
Contra Costa	1			1
San Mateo			2	2
Alameda	1	2		3
San Francisco	<u>—</u>	<u>—</u>	<u>2</u>	<u>2</u>
Total	2	4	4	10
<u>Size Distribution by Percent</u>				
All Hospitals	31	48	21	100
Ten Selected Hospitals	20	40	40	100
Eight Actual Interviews	25	50	25	100

The interviews covered the following topics:

- Sterilization Practices
 - Equipment and Location
 - Utilization
 - Specific Items Sterilized and Quantities
 - Problem Areas
- Cleaning and Sanitation Practices
 - Surgical Cleaning
 - Patient Room Cleaning
 - Discharge Room Cleaning
 - Daily Routine Isolation Room Cleaning
 - Discharge Isolation Cleaning
- Waste Disposal Practices
 - Laboratory and Pathological Waste
 - Other Infectious Waste
 - Hospital Trash and Non-infectious Material

- Practices Regarding Reusables and Disposables
 - Description and Quantities
 - Sterilization Methods
 - Shelf-Life and Inventory
- Linen Handling Practices
 - Surgical Linen
 - Patient Linen
 - Isolation Linen
- Infection Control Practices
 - Available Statistics on Nosocomial Infections
 - Method and Type of Surveillance
 - Problems Unique to Hospital
 - Isolation Technique
- Infection Dangers to Hospital Employees
 - Special Protection Procedures
 - Need for Better Methods

To collect this information, interviews were held at each hospital with the hospital pathologist, a representative from the Infection Control Committee, the director of nursing, the central services supervisor, housekeeping department supervisor, plant maintenance supervisor, operating room supervisor, and the hospital's industrial engineer to the extent that such positions had been established.

One general problem encountered in collecting and compiling this information was the lack of quantitative information maintained by hospitals. This was particularly true in certain areas such as waste handling, infection control activities, and central services activities. There is no established need to record quantities or types of infectious waste material in hospitals, hence little quantitative information is available. It was apparent after completing the interviews, that collection of detailed quantitative statistics on any aspect of the survey would require a much more intensive effort over an extended period and for some activities would probably require actual on-site observations by non-hospital personnel.

In the case of infection control, the Joint Commission on Accreditation has applied pressure on hospitals to establish infection control committees, to create the position of infection control nurse, and maintain certain statistical records associated with hospital acquired infections. However, we found that this effort was generally in its infancy. In the larger hospitals an infection control nurse position did exist, and the individual holding this position was occupied on a full-time basis in infection control type work such as surveillance and reporting.

SURVEY RESULTS

The findings of the survey are summarized in the following paragraphs and a more detailed record of the survey results can be found in the Appendix in Tables A-1 through A-8. To provide a more complete picture there is some repetition in the discussion of results where some items such as linens and inhalation therapy equipment are discussed under more than one category.

Sterilization Practices

The most common sterilization method is steam autoclaving. All hospitals had some steam autoclaving equipment and generally this was assigned to Central Services. However, in all hospitals, surgery had the capability for flash sterilizing surgical instruments. Some hospitals had only a small cannister type gas autoclave and one hospital had no gas autoclaving capability. The larger hospitals tended to disperse their sterilization equipment to other departments in addition to Central Services. Cold sterilization techniques (e.g., soaking in Cidex) are used for some items.

The frequency of sterilization is directly dependent upon the size of the hospital and the occupancy. Generally the sterilization is done on the day shift with only a skeleton crew in Central Services on the night shift. Steam autoclaves require 30 minutes to 2 hours per cycle while gas autoclaves require 5 hours or more and up to 12-72 hours including aeration time.

The largest sterilization requirements are generally for steam autoclaving of trays and packs for surgery. Some hospitals utilize

gas sterilization for inhalation therapy equipment and some utilize cold sterilization procedures for these items.

The problem areas most often mentioned regarding sterilization practices included:

- Aeration of gas sterilized items and the time required for this aeration is a handicap.
- Determination of complete removal of gas, especially for inhalation therapy equipment, is a difficult and serious problem.
- Inhalation therapy equipment is believed to be a source of infection.
- Infected specimens are a hazard to the pathologists. Hepatitis and TB are particular concerns.
- Instruments and equipment items frequently mentioned as sources of sterilization difficulty included fiber optics (such as cystoscopes, bronchoscopes and laryngoscopes), urology instruments, catheters, and kidney dialysis equipment.
- In regard to gas sterilization procedures, gas (ethylene oxide) is presenting operating bottlenecks to some hospitals due to the long aeration times required. One medium-sized hospital had no aerator. Several hospitals had small cannister type gas autoclaves only. A frequent complaint voiced by the operating room supervisor was the need to have a larger inventory of instruments due to the lengthy cycle time required to gas sterilize instruments. The small hospitals did not use gas sterilization but instead used cold sterilization techniques to meet their needs for materials that cannot be steam sterilized.

Cleaning and Sanitation Practices

In the surgery department most of the hospitals surveyed use surgical nurses to clean the operating room between operations. A porter or an orderly generally mops floors between cases. The operating room is cleaned between cases and at night in most of the hospitals. Ophine, Matar, Elimstaph No. 2, soap and water, and alcohol (isopropyl) are the cleaning agents generally used.

Patient rooms are cleaned by the Housekeeping Department in most hospitals. Cleaning agents used include Osil, Lab No. 1, 728, Staphine, Ophine 15, Skleen, LPH, and Vesphine. Generally, housekeeping maids do the routine cleaning and men do the floors. Staphine is used to clean bedside utensils. Some hospitals clean bedside utensils on the nursing unit while others send them to Central Services to be sterilized. Trash is picked up from patient rooms at least once per day.

The Housekeeping Department also performs discharge cleaning. In some of the hospitals, Nursing personnel stripped the bed before Housekeeping does the cleaning. In most of the hospitals, Housekeeping makes the bed following discharge cleaning. Cleaning agents used include Osil, soap and water, Sano-six, Staphine, etc. Recine is used for carpet cleaning.

For routine daily isolation room cleaning, Housekeeping gowns up and follows definite written procedures such as double bagging all trash. Cleaning agents include isopropanol, LPH, and Wescadine (iodine solution). Most of the larger hospitals used a color card system to identify different types of isolation patients.

Three of the hospitals surveyed fog isolation rooms after the patient is discharged. Housekeeping Department does discharge cleaning of isolation patient rooms. Mop heads are destroyed after isolation cleaning in some of the hospitals. Equipment used in cleaning rooms is washed and disinfected following its use.

Waste Disposal Practices

The majority of hospitals surveyed burn (incinerate) their pathological wastes. Pathological specimens that are not to be kept are incinerated. Those that are kept are stored in formalin. The majority of the hospitals autoclave their bacteriology culture plates, petri dishes, and glassware before discarding. Autopsies vary from none to 250 per year based on size of hospital. Most of the hospitals estimated that less than 10% of pathological tissue specimens are pathogenic. Disposable petri dishes and glassware quantities vary in direct proportion to size of hospitals, from a few hundred per month to several thousand.

All of the hospitals had definite written procedures or policies on the handling of isolation patient waste. In most of the hospitals it is double bagged with the color of the bag indicating it contains isolation waste. One large hospital put bagged isolation waste into regular solid waste (trash) system. One hospital gas autoclaved their isolation waste, but this was a very minor amount as they only had one or two isolation patients per month.

Most of the hospitals incinerated their surgical wastes.

Three of the eight hospitals incinerate their combustible waste. The other five hospitals have all of their waste hauled away. However some of these incinerate their needles and syringes. Two of the five use a compactor to compact trash before it is hauled away. The amount of hospital waste varies and appears to fall in the range of 10 to 20 pounds per patient per day depending on size of hospital. One hospital has twice "passed" the BAAPCD* inspections. Another hospital is burning in compliance with BAAPCD requirements which are that the smoke plume show less than No. 1 Ringleman (more than 80% light transmission) and less than 25 ppm of hydrocarbons.

Practices Regarding Reusables and Disposables

The practices regarding use of disposables are summarized by equipment classification in the following paragraphs.

Bedside Utensils: Majority of hospitals are using reusable bedside utensils which are sterilized by steam or boiling water sterilizers either in Central Services or on nursing units.

Packs, Sets, and Trays: Of the hospitals surveyed, they are equally divided between reusable and disposable trays and packs. The reusable packs and trays are steam autoclaved.

Surgical Linen: Five of the hospitals are using predominantly reusable linen drapes and packs. Three are using disposable items. The reusable surgical linen is steam autoclaved.

Regular Linen: All of the hospitals are using reusable linens. Many are using disposable chucks. Laundry may be done in-house or by a commercial laundry.

* Bay Area Air Pollution Control District

Surgical Gowns: Three of the hospitals are using disposable surgical gowns. Reusable gowns are steam autoclaved.

Patient Treatment Items: Increasing amounts of patient items are disposable. These include things such as thermometers, catheters, syringes, needles, IV tubing, gloves, dressings, suction sets, etc. Reusable items are steam autoclaved except for rubber items which are gas autoclaved. Inventory is generally three times the amount in use.

Dietary Trays, Dishes, Etc.: All hospitals surveyed use disposable dietary dishes for isolation patients.

Inhalation Therapy Equipment: Mostly reusable. Much of the inhalation therapy equipment is either gas autoclaved or cold sterilized. Such equipment if gas autoclaved is then out of use some 12-72 hours. Some of the inhalation therapy equipment is cold sterilized using a chemical detergent along with Cidex.

Linen Handling Practices

For surgical linen requirements, three of the hospitals used predominantly disposable linen including disposable surgical drapes. Five of the hospitals used predominantly reusable surgical linen which was steam autoclaved prior to use.

Regarding general patient-care linen, the volume of linen varies from hospital to hospital and may run as high as 17-20 pounds per patient day. All of the hospitals use reusable linen for general patient care although the disposable linen has been tried out. Four of the hospitals do their laundry in-house, three send it out to a commercial laundry, and one sends it to a shared-service facility.

All hospitals had definite policies and procedures regarding the handling of isolation linen. Most of the hospitals double bag the isolation linen. The inner bag is water soluble and dissolves. The outer bag is usually a plastic bag which is discarded or is a washable laundry bag.

Infection Control Practices

The hospitals surveyed reported very few nosocomial infections. Larger hospitals which have an infection control nurse maintain and report statistics by type of infection and incidence. Staph infections mainly occur from orthopedic cases.

More sophisticated reporting systems include reporting systems include reporting infections by pathogen and by site of the infection. One hospital reported a 3 to 5 percent nosocomial infection rate (based on percent of discharges).

Infection surveillance is done mainly through nursing services and suspicious wound drainages. In larger hospitals having an infection control nurse, this person audits patient charts to determine source and cause of infections. Bacteriological reports and informal reports from nurses are also used.

Most hospitals have quality control surveillance culturing programs which consist of culturing the various areas of the hospital on a routine basis. Some hospitals are getting away from the routine basis and doing it on request and where they think the probability of infections occurring are the greatest (culture on a problem oriented basis).

Nebulizers and other inhalation therapy equipment are believed to be a source of infection. Hospitals which handle a large volume of infectious patients such as TB patients have to exert more caution. Older facilities tend to be a problem as they are more difficult to clean properly.

Laboratory personnel follow special procedures when working with known infectious specimens or samples. Contaminated Lab dishes are autoclaved usually before being discarded. Most pathologists wear gloves when performing an autopsy.

Most of the hospitals had established written policies regarding gowning and entering isolation patient rooms.

Infection Dangers to Hospital Employees

Some hospitals suspect that hepatitis has been contracted from blood samples as the result of mouth pipetting. Approximately two percent of all blood samples can transmit hepatitis. As a result, some hospitals treat all samples as potentially dangerous. Gloves and gowns worn by technicians and disposal pipettes are used in some cases. In one hospital lab technicians who puncture themselves are given gamma globulin and serology tests for 6 weeks.

Some of the larger hospitals state that about one in 20 of the pathological specimens are hazardous. There is disagreement among pathologists but some believe that a certain level of risk is unavoidable to preserve pathogens for culturing. Pathologists are most concerned about hepatitis. Some pathologists expressed the opinion that it might be feasible to sterilize blood samples by radiation prior to examination. The possibility of contracting infections from frozen section machines and autopsy tables was cited a concern by some pathologists.

CONCLUSIONS FROM SURVEY

The survey revealed that hospital personnel are not completely satisfied with the present methods of sterilization. Some articles are not effectively sterilized using steam, gas, or chemical sterilization due to their material composition, construction, size, weight, volume, and the required turnaround time. The use of some other sterilization technique such as gamma sterilization would be welcomed; however, some of the same constraints would limit gamma sterilization application also. A number of possible applications for gamma sterilization were identified where more positive sterilization could be obtained. However, when considering all factors such as cost, timeliness, size, weight, effectiveness, material damage, etc., it was not clear that gamma sterilization could be utilized more effectively than conventional methods.

One of the obvious difficulties in applying gamma sterilization to the identified candidates is the wide range of equipment sizes, shapes, densities, and quantities in the items suggested. Gamma radiation would be most efficient and effective if it could be applied to a large quantity of similar or identical items. The possibility of treating the candidates identified in the survey in a hospital irradiator is examined in more depth in Section VII.

Potential candidates for gamma sterilization identified primarily on the basis that available methods are not entirely satisfactory for one reason or another can be classified as follows:

- Infectious Solid Wastes
- Inhalation Therapy and Anesthesia Equipment

- Certain Surgical/Medical Instruments that cannot be steam autoclaved and require long gas autoclaving
- Prosthetics
- Unique and miscellaneous items.

These potential applications are discussed separately in the following paragraphs.

Infectious Solid Wastes

Infectious hospital solid waste appeared to be a particularly good candidate for gamma sterilization. There is great concern regarding problems related to disposal of infectious waste from hospitals. Using gamma sterilization, hospital infectious solid wastes could be sterilized in the sealed collection bags before being compacted and hauled away to disposal sites or to municipal incinerators.

The following list illustrates the variety of items which are included in infectious waste discards from hospitals.

Soiled dressings; sponges; waste ampules; needles and syringes; disposable drapes; sanitary napkins; disposable blood lancets; disposable catheters and colostomy bags; disposable enema units; disposable diapers and underpads; disposable gloves; levine tubes; catheters; drainage sets; contaminated glassware, including pipettes, petri dishes, specimen containers, and specimen slides; paper goods containing nasal and sputum discharges, etc.

Disposable or single-use articles have contributed substantially to the problem of developing efficient and safe methods for handling and disposing of these materials. The above list does not include items classified as pathological waste such as body tissue, organs, bones, and amputated limbs. Pathological wastes include materials of medical, surgical, autopsy, and laboratory origin. These wastes result from patient care activities such as diagnostic procedures and treatment and also from laboratories, animal rooms, and first aid rooms. Although there is disagreement among pathologists, some expressed the opinion that most pathological specimens could be sterilized before examination as a means of protecting laboratory personnel. This category includes

blood specimens from known contagious cases such as hepatitis and TB, and specimens of urine, feces, sputum, and sera. Surgically excised pathological tissues and limbs could be sterilized, even cadavers, when there is reason to believe an infection hazard is present. Used culture dishes from a hospital's bacteriology department are also candidates.

One of the problems associated with sterilization of infectious wastes is the lack of strict enforcement of waste handling and disposal procedures in some of the hospitals. The majority of hospitals had written isolation procedures, but it was apparent that practices did not always follow procedures. The sorting of nonburnable waste from burnable waste was often a problem. In one hospital pathological wastes (normal placentas) were being compacted with the hospital's regular trash and waste material. Thus in order to insure sterilization of infectious wastes it may be necessary to sterilize a great deal of noninfectious waste also. This problem has been recognized in a number of studies related to disposal of infectious hospital wastes.

Methods for treating and disposing of infectious wastes are discussed in more detail in Section VI.

Inhalation Therapy and Anesthesia Equipment

Reusable respirator equipment and inhalation therapy equipment emerged as prime candidates for gamma sterilization. Included in this category are such equipment as masks, mouthpieces, mainlines, medication nebulizers, exhalation valves, water reservoirs, connectors, humidifiers, puritan nebulizers, ultrasonic nebulizers, endotracheal tubes, suction catheters, and pulmonator bags. This equipment is highly suspect as a cause of infections in a hospital because it comes in direct contact with the upper respiratory tract. The upper respiratory tract is invariably contaminated with microorganisms present in respiratory secretions.

There is a general consensus that it is important to develop a sterilization process which can effectively produce the sterility desired for inhalation therapy equipment both economically and in a timely manner. More specifically, rubber articles including tubing, endotracheal tubes, pharyngeal airways, corrugated breathing tubes, face pieces, etc., might be particularly good candidates for gamma ray sterilization.

Certain Surgical/Medical Instruments That Cannot Be Steam Autoclaved and Require Long Gas Autoclaving

From interviews with operating room (surgical) personnel, certain instruments were suggested as candidates for gamma sterilization. These instruments are currently being gas sterilized in most hospitals. The largest group identified were the fiber optic instruments including the endoscope, bronchoscope, cystoscope, etc. Oxygenators for cardiac bypass operations that include various valves, flowmeters, and tygon-type tubing appeared to be promising candidates. Certain components from kidney dialysis machines might also be gamma sterilized.

Steam sterilization is not effective in sterilizing these instruments because of the construction of the device. The fibre optic instruments might be amenable to gamma sterilization if cerium stabilized glass were used for the lenses. Other items such as pacemaker and defibrillator leads and plastic and metal components of heart-lung machines were also suggested for gamma sterilization. Some surgical equipment not sterilized at the present includes battery boxes, pacemakers, diathermy units, cautery boxes, drip stands, various meters, and drainage units.

While these items could no doubt be gamma sterilized, it would appear to be extremely difficult to design a facility that would operate at reasonable cost and process this variety of items. Each item also would require a careful analysis and test program to establish its ability to withstand repeated sterilization cycles.

Prosthetics

Certain prosthetic devices such as heart valves and hip pins were suggested by hospital personnel as potential gamma sterilization candidates. It appears that prosthetic devices made of metal, acrylic or plastic, and cranioplastin are materials that could be sterilized effectively.

Unique and Other Miscellaneous Uses

One of the more unique and intriguing suggested applications was that of organ and tissue transplants. It appeared that this area holds

promise for gamma sterilization. Human tissue should be sterile for grafting or transplant operations and radiation might be uniquely suited for this application. However, the quantities are small and a very small facility could handle this application.

Other miscellaneous suggested uses include sterilization of materials undergoing microbiological research pasteurization of diet items, sterilization of infant incubators, and sterilization radiation of pharmaceuticals and antibiotics which are prepared in-house.

It was also suggested that infection control could be improved significantly by giving some materials and equipment a disinfecting treatment at a much lower dose level than would be required for a thorough sterilization. Items in this category included linen, bedding and housekeeping equipment.

V. STERILIZATION OF HOSPITAL EQUIPMENT AND SUPPLIES

With the present trend towards increased use of presterile disposable supplies and equipment in hospitals, hospital-based sterilization of supplies will probably decrease in the future. Even so, with the total use volume of equipment and supplies steadily increasing, the long-range result of this trend is that hospitals will probably always require in-house sterilization capabilities. The reuse of certain high cost equipment items and the need for some in-house sterilization capability for infection control, as well as convenience, insure the presence of hospital sterilizers.

Steam remains the principal sterilization method in hospitals. Ethylene oxide gas sterilization is used on items requiring sterility that cannot tolerate the high temperatures (250 °F) of steam and/or moisture. Hospitals not having gas sterilizers often rely on chemical solutions for sterilizing (cold sterilization). Chemicals are also used to disinfect (reduce bacteria count) objects too awkward to be gassed. Dry heat and boiling water are used very little and are not discussed here. A brief description of each method follows:

STEAM^(34,37)

Items to be sterilized are washed, rinsed, dried (linen is laundered) and packaged before sterilization. Packaging is usually a double layer of steam-permeable textile or paper. Each package is taped shut. Items are usually batch loaded in either of two types of steam chambers:

1. A downward displacement chamber where steam displaces the air by gravity flow. The articles are considered sterile in 20 minutes at 250 °F. (Actual times required depend on parcel size.)
2. A high vacuum chamber where the air is evacuated before steam is added. A shorter sterilization time of 10 minutes at 276 °F is used. The latter is less likely to have residual cold air pockets and thus more likely to insure sterility.

Perkins⁽³⁷⁾ claims that saturated steam sterilization has the following advantages and disadvantages:

Advantages:

1. Quick heating and quick penetration of textile packaging
2. Destroys the most resistant spores rapidly
3. Easy process control
4. No toxic residue remains
5. Cheapest method.

Disadvantages:

1. Incomplete air removal can prevent sterilization
2. Superheated steam, if accidentally used, does not have the microbicidal strength of saturated steam
3. Unsuitable for anhydrous oils, greases and powders.

Other materials that are not suitable include wool, latex, tubing and delicate instruments. Another disadvantage of steam is that the packaging materials, to be steam permeable, limit the shelf life of the sterilized pack or tray to 30 days, the time it might take for microbes to penetrate the wrapping.

Even with these disadvantages, the main advantages of speed, low cost and effectiveness place steam in an attractive position for hospital sterilization. For as low as \$4,000, small flash units can be obtained. The investment can range up to several hundred thousand dollars for large automated systems. Table 5.2 at the end of this section summarizes the merits and disadvantages discussed above.

ETHYLENE OXIDE GAS^(34,37)

Ethylene oxide ($\text{CH}_2\overset{\text{O}}{\text{CH}_2}$) is an effective sterilizing agent at temperatures as low as 130 °F. This makes it the usual choice for materials that cannot withstand steam autoclaving. These are wood, leather, wool, latex rubber, natural sponges, delicate and electrical instruments, and catheters

and tubing that steam cannot penetrate. Ethylene oxide has excellent penetration qualities on the organic materials listed above and allows these items to be prepackaged in ≤ 4 mil polyethylene before sterilization, and thus the sterile item has a reasonable shelf life. Hazards of the gas itself are its explosive nature in air and its toxicity. The explosive character is minimized by using an inert carrier gas such as carbon dioxide or a Freon[®]. Aeration of the objects before use is necessary to reduce the toxicity hazard, and this increases processing time significantly. Special aerators can be used to reduce aeration time, but these add to the cost. Aerators usually use fresh air circulation at 120 °F.⁽³⁷⁾

Another disadvantage of ethylene oxide gas is the need for strict humidity control. The microbicidal effectiveness is reduced if the relative humidity does not lie within 30 to 50 percent. The batch process begins with a vacuum applied to the chamber (-26 inches Hg), then gas at 130 °F (12 percent ethylene oxide and 88 percent Freon[®]) is added until a pressure of 8 psig is attained (720 mg ethylene oxide/liter). Then steam is added to correct the humidity and the temperature maintained for 1-3/4 hours. After this period the chamber is evacuated and filled with filtered air. The total cycle time is 2-1/2 hours. The aeration process then begins. This can require from 4 to 72 hours. If the relative humidity was not in the 30 to 50 percent range, the batch could not be considered sterile and the cycle must be repeated.

The toxicity of residual ethylene oxide is of concern. The gas can dissolve in certain plastics, elastomers and leather. Residual gas in concentrations greater than 2000 ppm (0.2 percent) caused vesicular lesions on the skin of human volunteers (Reference 37, p. 517). Lipton et al.⁽³⁸⁾ report cases of tracheal stenosis (constriction of the trachea) from tracheostomy tubes (PVC) sterilized with ethylene oxide. Extensive hemolysis occurred in the blood of heart-lung machine patients (Reference 37, p. 517) when the blood passed through ethylene oxide sterilized plastic tubing. This clinical evidence indicates that degassing is extremely important for safe use.

The effectiveness of ethylene oxide is demonstrated in Figure 5.1. Here the difficult to kill spore *B. subtilis* shows the usual linear log (fraction remaining) versus time as did the microbes in steam and radiation in Figures 3.1 and 3.2.

FIGURE 5.1. Microbe Survival Behavior During Chemical Disinfection

Table 5.2 at the end of this section also summarizes the major advantages and disadvantages of gas sterilization. Capital investment for a unit is the same order of magnitude as a similar sized steam unit. Operating costs are higher due to the cost of gas and the extra labor to handle the added aeration step.

CHEMICAL SOLUTIONS

These are used as a substitute for ethylene oxide and for disinfection procedures where sterility is not desired or is not possible to attain. The choice of chemical agent must be made to destroy the most important pathogen. Tubercle bacilli and spores are often the most difficult. Most vegetative bacilli are easily killed by nearly all disinfectants. The effectiveness of some common disinfectants are shown in Table 5.1.

TABLE 5.1.⁽³⁴⁾

<u>Agent</u>	<u>Effectiveness Against</u>	
	<u>Tubercle Bacilli</u>	<u>Spores</u>
70-90% Alcohol (Ethanol, Isopropanol)	Very Good	No Effect
Formaldehyde	Good	Fair
Glutaraldehyde	Good	Good
Hexachlorophene	No Effect	No Effect
Phenolics (Cresols, etc.)	Good	Poor
Quaternary Ammonium Cpds (Zephiran [®])	No Effect	No Effect

Maintaining sterility with prepackaging is very difficult with these cold solutions, and no generalization on time required for sterilization can be made. For some strains of bacteria, many hours are required and for certain others, no effective kill can be attained at all. Figure 5.1 shows a typical kill curve. Anthrax spores are only killed very slowly with the strong disinfectant, phenol.

GAMMA RADIATION

Sterilization by ionizing radiation has some clear advantages over the three previously discussed methods. A high energy electron beam is the

fastest method, but its relatively poor penetration restricts its application, so little more will be said about this type of ionizing radiation. Gamma radiation such as the gamma rays from cobalt-60 or cesium-137 is the process of interest here.

The primary advantages of gamma radiation are:

- It is the most universally effective method.
- The process is the most reliable.
- Reliability reduces the amount of sterility testing and quality control needed.
- It is suitable for a large number of materials.
- No significant temperature rise occurs during irradiation.
- Shelf life of prepackaged gamma sterilized items is indefinite.

The effectiveness of gamma radiation is due the great depth to which rays can penetrate and deliver a sterilizing dose with a high certainty time after time. The reliability of the process is due to the absolute certainty of the radiation source to produce gamma radiation of a known energy and power. Its suitability is high for a large number of materials (almost all one-use items). It is the best method (often the only method) for sterilizing many homografts and implants.

The primary disadvantages of gamma irradiation are:

- It is probably the highest cost method due to capital investment.
- It has a large space requirement.
- It is relatively slow.
- It can cause accumulative damage to certain organic materials with repeated sterilizing doses. Plastics generally discolor.

Commercial users of gamma irradiation claim that the process competes economically (14 percent higher than gas) with ethylene oxide at high volume use. (Martin Stein, Radiation Services Inc., Dover, New Jersey, Reference 27). The convenience of packaging and boxing prior to sterilization, the certainty of sterility and the wide range of materials suitable and the fact that sterilization costs are only a small part of the

total cost of an item make gamma radiation the method of choice. But it cannot be emphasized enough that only in the high volume case can an irradiator be considered economically competitive.

The advantages of radiation make it an attractive candidate for application in a large hospital. The potential role of gamma sterilization in the Stanford University Hospital is examined in Section 7 while the possibilities of using a gamma irradiator for sterilizing infectious hospital wastes is examined in Section 6.

TABLE 5.2. Comparison of Sterilizing Methods

Property	Steam Autoclave	Ethylene Oxide	Chemical Solution(Cold) Sterilization and Disinfection	Gamma Radiation
Effectiveness	Excellent with well trained personnel.	Excellent, can penetrate organic materials. However, humidity control is essential. Some bacilli survive in dry state.	Generally not effective for thorough sterilization. Last resort method only.	Probably most universally effective method due to penetration and kill certainty. Dose requirements for some pathogens is variable.
Speed	Fast, 20-60 minute processing.	Slow, 4-72 hrs needed (aeration lengthens cycle).	Slow	Relatively slow (several hours) when source is used effectively.
Cost	Low Cost. \$4000 to \$9000 for small office or flash unit up to \$30-40,000 for medium size and \$100,000 or more for large bulk sterilizer.	Equipment cost same magnitude as steam but higher operating costs.	Very low cost. Labor is primary cost.	High cost. Probably is the highest cost method due to capital investment. Competes with gas at high volume use. Probably not less than \$100,000 for any kind of bulk capacity.
Shelf Life	30 days. Steam permeable cloth wrap can be penetrated by bacteria.	30+ days. Can be prepackaged in paper of <4 mil polyethylene.	No prepackaging possible. Contamination likely.	Indefinite. Best method for prepackaging.
Materials Suitable	Metal, glass, linen, okay. Cannot process wood, wool, latex, delicate instruments, tubing.	Nearly all materials are suitable. Some metals (magnesium, zinc, tin) form glutinous gel with moist gas.	Materials suitable are almost universal. Equipment suitable is limited. Alcohol neutralizes hexachlorophene, cotton and soap neutralize quaternary ammonium cpds.	Suitable for many materials except certain plastics, fibers, glass; living cells (blood) are unsuitable.
Principal Advantages	Low cost. Small size units can be located where need is. Effective sterilization when properly used. Fast.	Penetrating ability for complex shapes and ability to sterilize heat sensitive materials.	Flexibility of use is greatest advantage. Can be used anywhere on almost any type of exterior surface.	Most reliable process. Sterility testing requirements are minimal.
Principal Disadvantages	Requires continuous sterility testing. Short shelf life. Cannot be used for heat sensitive materials.	Explosive in air. Residual gas can irritate tissues. Long aeration time required. Humidity control necessary.	Not reliably effective. High labor requirement. Interior surfaces inaccessible.	High cost and limited flexibility. Large space requirement.

VI. INFECTIOUS WASTE TREATMENT

Both the literature and our survey of Bay Area hospitals suggested that sterilization of infectious hospital solid wastes might be an appropriate application for a gamma irradiator. This section of the report examines the general problem of disposing of infectious waste and the feasibility of utilizing an irradiator to give this waste a sterilizing treatment.

The treatment and disposal of infectious waste is a growing problem for hospitals. The basic problem of solid waste disposal is more difficult for hospitals than for the community at large because of the hazard of transmitting infectious disease. Furthermore, the per capita waste generation in hospitals is high and has been increasing rapidly in recent years.

Although hospital personnel and public health officials are aware and concerned about the problem, the general public does not as yet appear to be either very much aware or very much concerned about the problem. Our conclusion, reached after observing some current practices and reading of others, is that this problem does warrant serious public concern. A 1971 study⁽²⁰⁾ conducted for the London, Ontario Hospital Planning Council pointed out the profusion of articles relating to hospital waste management but observed that, "The majority of these waste management studies have been concerned only with the movement of waste within the hospital itself. In almost all cases, the actual disposal has been neglected."

DEFINITION OF INFECTIOUS WASTE

The first difficulty encountered when exploring the problems and hazards of infectious waste disposal is the lack of a broadly accepted definition of "infectious waste." In a strict sense the definition and identification of "infectious waste" would appear to be relatively straight forward. The difficulty arises in assuring the separation and segregation of infectious waste from other general wastes. A comment

from a University of Minnesota study⁽⁴⁰⁾ helps to illustrate complexities of waste handling and the problem of segregating an infectious component:

"The complexity of the waste handling operation, even in a relatively small hospital, became obvious. The wastes are handled by patients, doctors, nurses, housekeeping maids, janitors, laundry workers, visitors, technicians, orderlies and aides. They are stored in wastebaskets, GI cans, laundry hampers, carts, buckets, and on the floor. Some are wrapped and some are loose. Some wastes are wet, some bloody, some heavily contaminated, some fairly clean. Some wastes are stored in the patients' rooms, some in utility areas, some at the bottom of chutes and some in incinerator rooms. The wastes traverse the hospital in every horizontal direction and vertically. Some are moved by gravity and some by elevator. The personnel handling wastes have nearly unlimited access to all areas of the hospital. Above all, perhaps, is the phenomenon of continuous generation of waste throughout a 24-hour period and sporadic collection of the waste at fixed intervals during the day shift."

The University of Minnesota study also observed that even though more than 85% of some 105 hospitals they surveyed used bags (mostly plastic but also paper and waterproof paper) to contain collected solid wastes, "Numerous examples were seen of the bags occasionally not being used, of bags not being closed, of disposable bags being used again, of bags breaking or leaking,--and of other inadequacies." Thus the probability of contaminating non-infectious waste with infectious waste appears high.

The London, Ontario Hospital Planning Council's study⁽²⁰⁾ on disposal of infectious hospital waste developed a definition of infectious waste that recognized the difficulty of segregating infectious wastes and defines these wastes "not by the wastes themselves, but by source areas." Their definition:

"All solid substances which cannot be resterilized or reused, originating within or brought into patient care, laboratory or autopsy areas."

Liquid and food wastes were excluded but recognized as infection hazards and suggested for further study.

Others have reached similar conclusions as illustrated by these quotes:

"... everything that touches a patient is a potential public health hazard." (41)

"Early in the study we concluded that there is no practical way of segregating contaminated and uncontaminated waste in a hospital and that, with few exceptions, contaminated and uncontaminated wastes are co-mingled together either on purpose or accidentally so that by the time these materials reach the back-door of the hospital for disposal...there is no distinction.... Therefore, everything...from a hospital floor must be considered to be contaminated and should be classified as waste." (42)

A recently released study of seven Los Angeles hospitals by ESCO/GREENLEAF for the Environmental Protection Agency, ⁽¹⁹⁾ likewise concluded:

"..., in practice, due to the complexities of the waste handling systems and the prevailing intermix of "clean" and "dirty" areas generating wastes, segregation of waste materials throughout the system must rely heavily on the human element of judgment in the classification and distinction of these types of materials. Observations further supported by opinions of hospital and health department representatives indicate that reliability in this method of segregation cannot practically nor economically be achieved."

A definition of contaminated waste (infectious) based on source or point of origin as in the London, Ontario study was also adopted by this ESCO/GREENLEAF study.

"All solid wastes generated from the use of clean materials and used in connection with patient care through clinical services, medical support services and certain non-medical services (including food service, soiled linens, etc.) will be considered as contaminated wastes. Biological and infectious wastes generated as a result of patient treatment, operating and autopsy procedures, and laboratory research activities will, of course, also fall within this classification..."

This definition goes even further than the London, Ontario study in that it also includes food service and soiled linens associated with patient care.

As a result of a crisis in disposal procedures for Los Angeles area hospitals brought about by governmental restrictions on transportation and incineration of infectious waste, the Hospital Council of Southern

California appointed a solid waste disposal committee who developed a much narrower definition of infectious waste.⁽⁴³⁾ Their definition, also based on defining the areas in which infectious waste would be found, was essentially as follows:

- Significant laboratory wastes, including pathologic specimens and disposable fomites attendant thereto. Pathologic specimens shall include all tissues, specimens of blood elements, excreta, and secretions obtained from patients. Fomites shall include any substance that may harbor or transmit pathogenic organisms.
- Surgical operating room pathologic specimens and disposable fomites attendant thereto.
- Similar disposable materials from outpatient areas and emergency departments.
- Equipment, instruments, utensils, and fomites of a disposable nature from the rooms of patients with suspected or diagnosed communicable diseases,* which by the nature of the diseases are required by public health agencies to be isolated.

Because of the limitation in this definition regarding patient care wastes to patients with suspected or diagnosed communicable diseases, the quantities of infectious waste under this definition are much smaller, about 4 percent of disposable solid wastes compared to about 40 percent under the London, Ontario or ESCO/GREENLEAF definitions. After a survey of 32 hospitals the committee concluded that "It is possible to safely separate and collect infectious waste within a hospital. However, this separation does result in increased cost of waste handling." This is essentially the opposite conclusion of the ESCO/GREENLEAF study. It is of interest that both of these studies concerned Los Angeles area hospitals.

These more or less opposite views illustrate rather decisively the lack of consensus regarding a definition of infectious waste. Our conclusion, influenced by our own limited observations during the survey of

* Underlining added.

Bay Area hospitals, is that the more inclusive definitions of the London, Ontario Hospital Planning Council and the ESCO/GREENLEAF study are, for the present conditions, the more realistic definitions.

QUANTITIES OF INFECTIOUS WASTES

Even after the question of a definition is resolved, it is still not easy to develop a quantitative estimate of infectious waste because of the variability in available estimates of total waste generation rates and the lack of definitive data on the sources of the waste in these estimates. There are wide differences in waste generation rates in different hospitals that result from differences in services provided, differences in practices in individual hospitals, and the continuous evolution of health care procedures. Practice regarding use of disposables is no doubt the biggest factor affecting waste generation rates. A confounding factor in some studies of hospital waste generation rates is the practice of including reusable items as a component of the solid waste, for example, soiled linen. In this discussion, the term "solid waste" is intended to mean "disposable solid waste."

Attempts have been made to correlate waste generation rates with hospital size, number of patients, variety of services, number of surgical procedures, and a host of other factors, all of which undoubtedly have a bearing on waste generation rates. The most widely accepted index is a per patient-day basis. This is the index chosen for comparison purposes here. However, it should be recognized that it is inexact and that, in general, large hospitals generate more waste per patient than small hospitals, more services means more waste, etc.

Probably the most exhaustive study on hospital solid waste disposal to date from the standpoint of scope of data collection and depth of statistical analyses on waste generation rates is a University of Minnesota study⁽³⁹⁾ that included an extensive literature review and a nationwide survey of 105 hospitals with on-site measurements of waste quantities (both mass and volume). The tabulated results from their literature review indicated an increase from 6 to 9 lbs/day/patient in

the late 1950's to approximately 12 to 20 lbs/day/patient in the late 1960's. The results of their survey (1967-1969), however, indicated lesser quantities of solid waste, with a range from 5 to 16 lbs/day/patient and an overall average of approximately 9 lbs/day/patient. Infectious waste was not specifically identified in their report but a quite detailed breakdown by source was provided. Applying the London, Ontario definition (or the ESCO/GREENLEAF definition applied to "disposable" infectious waste), the infectious waste portion would run approximately 3.3 lbs/day/patient. The average density of the infectious waste was not defined but would fall mostly in the combustible rubbish category which had a density of 1.6 to 4.3 lbs/cubic foot and averaged 2.9 lbs/cubic foot.

The London, Ontario Hospital Planning Council surveyed⁽²⁰⁾ hospitals in their area and found total solid waste production ranging from 3.5 to 10 lbs/day/patient and infectious waste production ranging from 1.9 to 5.2 lbs/day/patient for six "wholly active treatment hospitals." We calculated a patient-weighted average infectious waste production of 3.8 lbs/day/patient. The average density of the infectious waste was 4.7 lbs/cubic foot.

The ESCO/GREENLEAF study,⁽¹⁹⁾ even though they developed a comprehensive definition of infectious waste, did not identify the infectious waste quantities for the seven Los Angeles hospitals they studied. Total disposable waste ranged from 3.6 to 16.7 lbs/day/patient with a patient-weighted average of 9.8 lbs/day/patient. These quantities are reasonably consistent with the London, Ontario and Minnesota study findings; and judging from the information that was provided on sources of the waste, the infectious waste portion is probably also comparable (around 35 to 40 percent or about 3.5 lbs/day/patient).

The committee appointed by the Hospital Council of Southern California found an average of 10.3 lbs/day/patient of total waste from their survey of 32 hospitals in southern California.⁽⁴³⁾ Also, based on their very limited definition, they found 0.38 lbs/day/patient of infectious waste.

These several estimates are summarized in Table 6.1 and show that where the waste measurements can be compared on a common basis there seems to be reasonably good agreement between different investigators. The reason for the low infectious waste value for the southern California study

TABLE 6.1. Comparisons of Solid Waste and Infectious Solid Waste Quantities Produced by Hospitals

	Disposable Solid Waste, lbs/Day/Patient		Infectious Solid Waste, lbs/Day/Patient		Density of Infectious Waste, lbs/ft ³	
	Range	Avg	Range	Avg	Range	Avg
University of Minnesota ⁽³⁹⁾	5 to 16	9	--	Est 3.3	1.6 to 4.3	2.9
London, Ontario Hospital Planning Council ⁽²⁰⁾	3.5 to 10	--	1.9 to 5.2	3.8	--	4.7
ESCO/GREENLEAF ⁽¹⁹⁾	3.6 to 16.7	9.8	--	Est 3.5	--	--
Hospital Council of Southern California ⁽⁴³⁾	--	10.3	--	0.38	--	--

was previously explained. Based on this comparison a rate of 3 to 4 lbs/day/patient was selected as the best estimate of current infectious solid waste production in hospitals.

METHODS OF DISPOSAL

It is risky to generalize regarding hospital waste disposal methods and particularly so regarding infectious waste disposal methods. There are significant exceptions to every generalization. Most hospitals use a combination of systems. All hospitals provide special procedures for handling and disposal of infectious waste, but as already noted, a consistent identification of infectious waste is not used, and the success in segregating these materials is questionable.

Most often, pathological and surgical wastes and isolation patient wastes are incinerated. This may be done in the hospital's own incinerator or sent to another hospital or to a local mortuary. Food wastes from the kitchen are most often put through a grinder and disposed of down the sewer. Other general refuse may be incinerated on-site with the ashes hauled to landfill or it may be compacted in the hospital's compactor and hauled to a landfill or municipal incinerator. This waste may also be hauled away uncompacted, but the economics generally favor on-site

compacting. Some hospitals use a wet pulping system incorporating a disinfectant followed by discharge to the sanitary sewer or by dewatering and hauling to a landfill. Shredding prior to hauling to a landfill is another option.

The two most common methods for disposing of infectious waste are incineration and compaction followed by hauling to a landfill. Infectious wastes from patient treatment or other sources are usually double-bagged and color-coded (red). These bags of infectious waste are either incinerated with the hospital's pathological waste or compacted in the hospital's compactor along with the non-infectious waste. The following excerpt is of interest:

"...the pressure generated by the compactor on the air in the bag results in a kind of explosion when the bag bursts. The surrounding atmosphere is instantly laden with microorganisms, ...when unbagged or unpacked wastes are subjected to compaction, the air which escapes up the channel (in the side of the plunger designed to allow air escape during compaction) is hardly the sort which will please the hospital microbiologist: microorganisms again are forced into the atmosphere."⁽⁴¹⁾

It seems obvious that it is poor practice to compact any waste that can be classified as infectious.

The Minnesota study⁽³⁹⁾ found that 94 out of 105 hospitals surveyed had one or more incinerators. They did not include data on on-site compaction, but found that the greatest part of the solid waste hauled from almost 90 percent of the hospitals was sent to land disposal sites and most of the rest was hauled to municipal incinerators.

A recent survey⁽¹⁸⁾ of waste disposal practices in 29 hospitals in King County (Seattle), Washington, found that 26 of the 29 incinerate some portion of their pathological and infectious waste either in their own incinerators (16) or at another hospital (four) or a crematory (six). Other methods were also used either separately or in combination with incineration including garbage disposer (nine), autoclave (ten), Formalin (three) and Somat (pulping) (one). Two hospitals had no infectious waste treatment. However, it was also noted that infectious material was found in general refuse storage areas at ten hospitals. Most of these hospitals use plastic bags (27 of 29) and 17 have compactors.

In our own survey of eight S.F. Bay Area hospitals, all incinerated some portion of their pathological wastes, most double-bagged isolation waste in color-coded bags, and most incinerated surgical wastes. Three of the eight incinerate combustible waste, two use compactors and three have their general waste hauled away uncompacted and untreated.

Incineration of all wastes that could be considered infectious is one possible solution to the infectious waste problem. This was, in fact, the recommendation in the London, Ontario study. The principal drawback is concern over air pollution problems. However, a properly operated modern incinerator is said to meet all air pollution standards. Most of the air pollution problems with incineration have been due to improper operation. "It is important that operation be exclusively by experienced, skilled and knowledgeable personnel."⁽³⁹⁾ Incineration was not the first choice in the ESCO/GREENLEAF study, however, they stated:

"The industry is capable of designing incinerators to meet the most stringent standards. ...in view of the severity of air pollution conditions that exist in such areas as the Los Angeles Basin, where progressively restrictions are necessarily being strengthened on air pollution, incineration cannot be recommended. Except in such extreme cases, a properly designed incinerator with qualified operators is the only currently proven method of on-site disposal that could be recommended, whereby materials can be reduced and converted to an innocuous state, microbiologically safe for off-site transfer and disposal."

It is worth noting that destruction of all microorganisms by incineration is no more an absolute method than are other methods (see Section V). Some bacteria can sometimes survive even the most stringent conditions (1700 °F and higher).⁽³⁹⁾

Because of the air pollution conditions in Los Angeles, the ESCO/GREENLEAF recommended method of disposal was pulping or grinding wastes for discharge to the sanitary sewer with on-site sterilization or later sterilization, oxidation, and digestion at an off-site treatment plant.

Gamma sterilization is a possible method of on-site sterilization that could insure a higher degree of sterilization than any other method except possibly incineration. The London, Ontario study considered this option but turned it down in favor of incineration because of unfavorable economics. Gamma irradiation is strictly a sterilization treatment and a separate disposal step, probably compaction and landfill, is still required.

Figures 6.1, 6.2, and 6.3 show some of the alternatives available for hospital waste disposal (by no means all the alternatives), show how these options can be influenced by the definition of infectious waste, and show where gamma sterilization would fit in.

REGULATIONS GOVERNING DISPOSAL

Strict governmental regulations requiring sterilization of infectious wastes before transport or disposal or restricting incineration would enhance the feasibility of a gamma sterilization facility. California has basic standards that require hospitals to either incinerate or to dispose of their infectious wastes in an approved manner. The regulations do not apply when more strict rules are established by local, city, or county governments. The applicable portions of the state and local government regulations in counties surrounding San Francisco Bay are shown in Table 6.2 and 6.3.⁽⁴⁴⁾ These relate to regulations on disposal of infectious waste and human remains. A strict interpretation of sterilization or disinfection might cause problems, but in general the regulations are not very restrictive.

Any hospital incinerators in the Bay Area must conform to regulations of the Bay Area Air Pollution Control District (BAAPCD). The key features of these regulations are:

1. Particulates in effluent must be less than:
0.05 grains/SCF if incinerator burns over 100 tons/day, or
0.15 grains/SCF if incinerator burns less than 100 tons/day
2. Plume must not exceed smoke density of No. 1 on the Ringleman scale (20 percent reduction in light transmission).
3. Hydrocarbon content of effluent must be less than 25 ppm.
4. Each hospital incinerator is inspected yearly, air is sampled and visible emissions are measured. More frequent inspections are made with complaints.

A modern multiple-chamber incinerator with a scrubber is said to easily meet requirements. There is no concern that regulations will become so stringent as to prevent incineration in the foreseeable future.

FIGURE 6.1. Hospital Waste Disposal Options for Most Limited Definitions of Infectious Waste

FIGURE 6.2. Hospital Waste Disposal Options for Intermediate Definition of Infectious Waste

FIGURE 6.3. Hospital Waste Disposal Options for Most General Definitions of Infectious Waste

TABLE 6.2. Infectious Waste Disposal Regulations (Excerpt from Hospital Council of Northern California Survey of State and San Francisco Bay Area Public Health Department Policies regarding disposal of special hospital wastes, September 1972)⁽⁴⁴⁾

State of California - Title 17 of the Administrative Code presently contains the following Public Health Department restrictions applicable to hospitals:

314 Incineration. Infected dressings, surgical dressings, and other similar materials shall be disposed of in an incinerator which will provide complete combustion. Substitute methods of handling waste materials such as treating refuse making it safe for handling in the usual manner, packaging the material and transporting it to a land fill operation, or joint operation of one incinerator for the use of several institutions may be permitted if the method is approved by the local health officer having jurisdiction in the area where the hospital is located and if certification is annually submitted to the Department (of Public Health) by the local health officer that the method is approved by the local health officer and does not jeopardize the public health and safety.

Alameda County - Infectious wastes may be placed in plastic bags with double tie, boxed and sealed with waterproof tape. The boxes must be marked with six inch red "I's" on the five upper sides. The manner of transporting these boxes from the hospital to the disposal site must have the concurrence of the Health Officer. Also, infectious and general wastes may be ground to slurry and disposed of through the sewage system.

Berkeley City - No policy beyond that of the State.

Contra Costa County - Infectious wastes may be placed in wetproof or plastic bags and placed in general wastes. Wastes other than fetal and human remains may be disposed of through the sanitary sewer system after first being disinfected or autoclaved.

Marin County - Infectious wastes may be placed in general wastes after first being sterilized. Also, infectious and general wastes may be ground to slurry and disposed of through the sewage system.

Napa County - Infectious wastes may be placed in wetproof or plastic bags and placed in general wastes. Wastes other than fetal and human remains may be disposed of through the sanitary sewer system after first being disinfected or autoclaved.

San Francisco City and County - Infectious wastes may be bagged and placed in general wastes after first being decontaminated. Also infectious wastes, if decontaminated, may be ground to slurry and disposed of through the sewage system.

San Mateo County - Infectious wastes may be placed in general wastes after first being sterilized. Also, infectious wastes may be ground to slurry and disposed of through the sewage system.

Santa Clara County - Infectious wastes shall only be incinerated.

Solano County - Infectious wastes should be decontaminated, if possible, and placed in clearly marked, leak-proof plastic containers, and then placed in general wastes. Infectious wastes should not be ground to a slurry and disposed of through the local sewage system.

Sonoma County - When authorized in writing by the Public Health Officer, infectious wastes may be double-bagged with a red plastic bag on the exterior and placed in general wastes. Grinding of garbage or infectious wastes is prohibited from introduction into the public sewer by the Uniform Plumbing Code.

TABLE 6.3. Regulations on Disposal of Fetal Remains and Human Remains
(Excerpt from Hospital Council of Northern California Survey
of State and San Francisco Bay Area Public Health Department
Policies regarding disposal of special hospital wastes,
September 1972)

State of California - The California Health and Safety Code restricts the methods by which fetal remains and human tissue may be disposed of through the following provisions:

7054.3 Notwithstanding any other provision of law, a recognizable dead human fetus of less than 20 weeks uterogestation not disposed of by interment shall be disposed of by incineration.

7054.4 Notwithstanding any other provision of law, recognizable anatomical parts, human tissue, or anatomical human remains following conclusion of scientific use shall be disposed of by interment or incineration.

Alameda County - No policy beyond that of the State.

Berkeley City - No policy beyond that of the State.

Contra Costa County - Remains shall not be disposed of through the sewer.

Marin County - Remains should be placed in plastic bags prior to being transported to disposal site.

Napa County - Remains shall not be disposed of through the sewer.

San Francisco City and County - Remains should be placed in leak-proof containers prior to being transported to disposal site, and the remains shall not be transported in patient vehicles.

San Mateo County - Remains should be placed in plastic bags prior to being transported to disposal site. If remains are infected, disinfection should be accomplished.

Santa Clara County - No policy beyond that of the State.

Solano County - Remains should be placed in plastic bags prior to being transported to disposal site.

Sonoma County - No policy beyond that of the State.

DISPOSAL COST COMPARISONS

Representative costs have been developed to provide comparisons between incineration, compaction and hauling to a landfill, and gamma sterilization. These costs are susceptible to large variations due to local conditions and individual hospital preferences. The purpose here is to provide perspective and determine if irradiation has a place in hospital waste disposal systems. For this purpose, it is not necessary to define exact costs for an optimum system.

As far as we could determine, most hospitals do not consider a cost of money interest charge in depreciating their capital assets. To keep our cost comparisons on the same basis as a hospital would use, we have used only a straight line 10-year depreciation charge in these cost comparisons. However, we believe a more realistic basis would provide a cost-of-money charge of at least 8 percent per year. This would increase capital charges from 10 to 15 percent per year.

Incineration Cost

Acquisition costs for incinerators are subject to wide variations depending on geographical location. Competition, freight costs and local requirements are some of the factors that influence the costs.

We obtained representative estimates from a supplier in the San Francisco Bay Area⁽⁴⁸⁾ for several sizes of two chamber, gas fueled incinerators incorporating venturi scrubbers. The costs are for installation on a concrete pad without any building enclosure which, if required, would add to the cost. Based on six hours per day operation, which appears to be a standard basis, the capital cost relationship shown in Figure 6.4 was developed.

Representative operating costs were based on information in the London, Ontario study and an economic analysis of hospital waste disposal alternatives prepared by Crown-Zellerbach engineers.⁽⁴⁷⁾ An average of costs from these two sources was used and the resulting operating cost is also plotted on Figure 6.4. The costs include allowances for operating labor, maintenance, electricity, residue disposal and insurance.

FIGURE 6.4. Hospital Waste Incinerator Costs

Total incineration costs including depreciation at 10 percent per year are plotted on Figure 6.5 as a function of patient census with pounds of waste per patient per day parameters. For hospitals serving more than 500 patients and waste loads larger than 10 pounds/patient/day, incineration costs are indicated to be less than one cent per pound.

Compaction and Landfill Disposal Costs

In examining costs for refuse hauling to disposal sites, it is quickly apparent that, for large quantities of waste, it is generally advantageous to use a compactor. Costs for hauling are determined on a volume basis. It costs roughly twice as much to have compacted waste hauled away, but a compactor can provide about a 4 or 5 to 1 volume reduction for hospitals wastes; thus, the direct cost is roughly halved. The cost of the compactor itself is easily justified from this savings.

A multitude of compactor designs of various capacities are on the market today. These generally provide a fixed compactor with a detachable container that is hauled away when filled.

Information on capabilities and costs were obtained from two suppliers of compactors.^(48,49) Hauling and disposal costs were obtained from a disposal company serving the San Mateo, Palo Alto area.⁽⁵⁰⁾ Compactor requirements were based on operating only one shift per day at 5 cycles per hour. The theoretical capacity of these compactors is much higher but is not achievable in actual practice. Disposal costs were calculated using the following basis:

Waste density	5 lb/ft ³
Compactor volume reduction	5:1
Operating Cost (maintenance only)	15% of capital/yr
Hauling and Disposal Cost:	
Compacted Wastes	\$4.50/yd ³
Uncompacted Wastes	\$2.10 to 2.80/yd ³
Capital Charges (depreciation only)	10%/yr

The resulting disposal cost is plotted on Figure 6.6 as a function of total waste handled. Figure 6.7 shows the costs as a function of the number of patients served and the amount of waste generated per patient. Figure 6.7 can be directly compared to the incineration costs in Figure 6.5. At low

FIGURE 6.5. Incineration Costs for Hospital Wastes as a Function of Patients Served

FIGURE 6.6. Compacting and Hauling - Disposal Cost for Hospital Wastes as a Function of Total Waste Quantities

FIGURE 6.7. Compacting and Hauling - Disposal for Hospital Wastes as a Function of Patients Served

waste volumes incineration is much more costly than compaction, but at high waste volumes, more than 500 patients generating more than 10/pounds/patient/day, incineration begins to show a small advantage.

Waste Irradiation Costs

Costs for irradiation sterilization of infectious hospital wastes were developed for two sizes of irradiators. The designs were patterned after the large medical products irradiators marketed by Atomic Energy of Canada Limited (AECL). However, they are fueled with Hanford Waste Management (HWM) capsules of cesium-137 rather than cobalt-60 since one of the principal reasons for this study is the USAEC, Division of Applied Technology (DAT) interest in finding applications for the Hanford cesium capsules.

Capital cost estimates for these irradiators were developed for us by the Vitro Engineering Division of Automation Industries, Inc.⁽⁵¹⁾ Their cost estimates are shown in Table 6.4 along with the approximate maximum source strengths. These are continuous-operation stop-dwell type irradiators. The cost estimates are developed based on use of a standard-box size, 20 inches wide x 20 inches deep x 36 inches high, for transporting the waste through the irradiator. Additional details on the capital cost estimates and the irradiator description and capabilities are included in the next section (VII).

TABLE 6.4. Hospital Waste Irradiator Cost Estimates

	<u>Small Irradiator</u>	<u>Large Irradiator</u>
Approximate Maximum Source		
HWM ¹³⁷ Cs	3×10^6 Ci	7×10^6 Ci
Equivalent Co-60	4×10^5 Ci	9×10^5 Ci
Irradiator Cell Cost	\$ 90,000	\$120,000
Equipment Cost	<u>160,000</u>	<u>185,000</u>
Total Capital Cost Excluding Source	\$250,000	\$305,000

Costs for waste irradiation were developed in the London, Ontario study⁽²⁰⁾ based on irradiators fueled with cobalt-60. Since their estimates are at least a year old, we added 10 percent to their capital cost estimate to allow for escalation to a current basis. The results are shown for comparison purposes in Table 6.5. Considering that the Vitro estimate is based on fairly limited design information and has an uncertainty on the order of ± 20 percent accuracy, the agreement between the two estimates is good and leaves little doubt regarding the general magnitude of the cost.

TABLE 6.5. Irradiator Cost Estimates from London, Ontario Study⁽²⁰⁾ Escalated 10 Percent

	<u>Small Irradiator</u>	<u>Large Irradiator</u>
Approximate Maximum Co-60	3.5×10^5 Ci	9×10^5 Ci
Irradiator Cell Cost	\$ 77,000	\$ 77,000
Equipment Cost	<u>125,000</u>	<u>209,000</u>
Total Capital Cost Excluding Source	\$202,000	\$286,000

Another possibly significant cost factor is a building or shelter to house the irradiator and provide space for handling the boxes of waste being processed through the irradiator. Vitro Engineering estimates the cost of constructing a 50 ft x 100 ft prefabricated metal building (Butler type) at \$90,000. However, this was not included in the waste irradiation facility here because it was not clear to us that significant additional floor space would be required for an irradiator over that required for other waste handling options. The irradiator cell itself should not have to be enclosed within another building. The depreciation charges on a \$90,000 building, if it should be needed, would add from 0.25¢/lb at 10,000 lb/day to 2.5¢/lb at 1000 lb/day of waste processing.

The basis for the irradiator operating cost estimates is outlined in the next section. Besides the depreciation charge for the irradiator itself, the two most important costs are operating labor, mainly for handling

the boxes of waste, and the cost of cardboard boxes to contain the waste as it passes through the irradiator. This latter cost, based on information from Boise Cascade Corp.,⁽⁵²⁾ was estimated at \$1.00 per box. The cost for this item in the London, Ontario study was \$0.70 per box for a slightly smaller box (18 x 18 x 36 inches).

The waste irradiation costs based on a single use for the boxes are detailed in Table 6.6 and plotted on Figure 6.8. This shows costs dropping rapidly with increasing throughput up to a throughput of around 5000 pounds per day where they reach 10¢/lb and the cost curve flattens out. These results do not show much difference between costs for the small and large irradiator where their capabilities overlap. The higher cost for the larger facility is compensated by its higher efficiency.

The generally accepted sterilizing dose is 2.5 Mrads. However, there is no certainty that this is the optimum dose for treating infectious wastes. The hazard might be reduced to an acceptable level by a dose of only 1.0 Mrad. Figure 6.8 also includes the cost for a reduced dose of 1.0 Mrads. However, the savings at the lower dose is not as large as one would anticipate. This is largely because the handling costs and the cost of boxes are not affected by the dose requirement.

The surprisingly high cost for the boxes could be reduced by reusing the boxes. This seems a reasonable procedure but there is obviously a limit. At some point damaged boxes will begin to cause failures (jams) in the conveyor system. The boxes are sturdy double-wall corrugated cardboard and should be good for several uses. We have assumed that they could be used four times. This reduces box costs to a more reasonable level and further reuse would not significantly affect total costs. Costs calculated with this assumption are plotted in Figure 6.9 and show a savings of about 2¢/lb.

After irradiation, the waste still requires a method of final disposal. Compaction and landfill have been assumed and the irradiation costs include these costs.

TABLE 6.6. Waste Irradiation Costs
(2.5 Mrad Dose)

	Small Irradiator			Large Irradiator		
Waste Processed, 1b/day	500	1,000	2,500	5,000	5,000	10,000
Source, KCi Cs-137	336	672	1,680	3,360	2,880	5,760
Source Cost, \$	33,600	67,200	168,000	336,000	288,000	576,000
Irradiator Cost, \$	250,000	250,000	250,000	250,000	305,000	305,000
Total Capital, \$	283,600	317,000	418,000	586,000	593,000	881,000
Depreciation	28,400	31,700	41,800	58,600	59,300	88,100
Source Replenishment	770	1,550	3,860	7,720	6,600	13,200
Operating Labor	15,330	17,500	24,100	35,000	35,000	57,000
Maintenance	8,000	8,000	8,000	8,000	9,300	9,300
Utilities	1,000	1,000	1,000	1,000	1,000	1,000
Boxes	5,500	11,000	27,000	55,000	55,000	110,000
Misc. and Contingencies	2,000	3,000	3,000	4,000	4,000	7,000
Total Annual Cost	60,000	73,750	108,760	169,320	170,200	285,600
Unit Cost, ¢/1b	32.87	20.2	11.92	9.28	9.33	7.82
Compacting & Disposal, ¢/1b	2.1	1.2	0.85	0.77	0.77	0.75
Total, ¢/1b	35.0	21.4	12.77	10.05	10.10	8.57

FIGURE 6.8. Irradiation Costs for Sterilizing Infectious Hospital Wastes

FIGURE 6.9. Reduced Irradiation Costs for Sterilizing Infectious Hospital Wastes When Processing Boxes are Reused

The irradiation efficiency could be substantially improved (and costs reduced by as much as 50 percent at the higher throughputs) by shredding or compacting the waste to a higher density prior to irradiation. However, the improved infection control for irradiation would be largely lost as the result of the pathogens dispersed during the shredding or compacting operation.

Waste irradiation costs are shown in Figure 6.10 as a function of hospital size (patient census) and amount of waste generated per patient. At 3.5 lb/patient/day of waste (average infectious waste level), costs drop to 9¢/lb for a 1000 patient hospital and to about 7¢/lb for a very large 2000 patient hospital. Incineration costs for infectious waste only were less than 2¢/lb for these hospital sizes, so it is clear that irradiation is a significantly more costly treatment alternative. However, if incineration were prevented by governmental regulations and if infectious waste sterilization was also mandated, irradiation would not be an unreasonably costly option. At 9¢/lb (1000 patients), the cost of treating and disposing of infectious waste would be only 32¢/patient/day (3.5 lb/patient/day x 9¢/lb) which could probably be absorbed without much difficulty. Even for a 200 patient hospital the cost would be only 84¢/patient/day (3.5 lb/patient/day x 24¢/lb) and could conceivably be accepted, especially when no other reasonable alternative was available.

The general conclusion, however, must be that for the present at least there are likely to be only very limited opportunities for irradiation sterilization of infectious hospital wastes. Incineration is the most attractive option. Irradiation will only be viable when the incineration option is not available.

FIGURE 6.10. Irradiation Costs for Hospital Waste as a Function of Patients Served (Target Boxes Reused)

VII. FEASIBILITY OF A HOSPITAL IRRADIATOR

The feasibility of a hospital irradiator depends primarily on a large volume of relatively high value use that is required to justify the large initial capital investment. The candidate applications for an irradiator identified in both our hospital survey and literature review were in general agreement but very little quantitative data were produced. The concurrent study at Stanford University Hospital⁽⁵³⁾ identified similar candidate applications and also developed quantitative data. This provided a basis for developing unit costs and evaluating the economic feasibility of a hospital irradiator. The results of our initial analyses were quite pessimistic and it was only after the Stanford study identified the sizable quantities of candidate materials for irradiation sterilization that feasibility began to look promising.

The concept of a large gamma irradiation facility for sterilization applications in a hospital is not a new idea. In fact, a large irradiator at the University of Western Ontario in Canada (London, Ontario) is nearing completion and is expected to be operational in early 1973. Dr. James L. Whitby, Professor of Bacteriology and Immunology, is the designated responsible user for this irradiation facility. We visited Dr. Whitby,⁽⁵⁴⁾ toured the facility and discussed at lengths his views on its applications. They do not at present have a well defined program for the facility and Dr. Whitby does not foresee any service applications for the facility. It will be strictly a research facility and, from what we could gather, it will probably have a low utilization.

Dr. Whitby's view is that major large-scale applications will be commercial applications and that hospitals can most appropriately use very small irradiators (on the order of one cubic foot of target space) for sterilization of human tissue for grafting, dura mater, bone grafts, etc. He favors burial or incineration for infectious wastes, believes that irradiation sterilization of general patient care materials (bedding, for example) is a marginal use and did not believe there would be enough

of similar items requiring sterilization to use a large facility on a service basis. His principal interest presently is research on synergistic effects of irradiation with other factors such as heat, humidity, oxygen, etc. on sterilization efficiency.

In the light of Dr. Whitby's rather skeptical view towards large irradiator application in hospitals, we were surprised to find that there does appear to be a case for the feasibility of a hospital irradiator. Using the quantitative data from the Stanford study we have been able to scope the general outline of an irradiation facility that could be utilized to carry out service irradiations on a development basis at reasonable unit costs. To a limited extent we have also explored the possibility of more efficient applications for specific classes of items on a regional basis.

INITIAL APPLICATIONS

The major potential candidates identified from the three sources of information are the following:

From Hospital Survey:

- Inhalation Therapy Materials and Equipment
- Many items presently gas sterilized
- Disinfecting treatment for linens
- Infectious Waste

From Literature Search:

- Inhalation Therapy and Anesthesia Materials and Equipment
- All items presently gas sterilized
- Unique, low volume items such as homografts and prosthetics
- Infectious Waste

From Stanford University Hospital:

- Inhalation Therapy Materials and Equipment
- All items gas sterilized
- Linen

To simplify the design concept for a hospital irradiator we adopted the concept of a standard box to contain all materials being processed through the irradiator. After consideration of the compatibility of several box sizes for the items to be processed, a standard size of 20 in. x 20 in. x 36 in. was adopted. This size is a compromise to accommodate many irregular items and most shipping cartons--and not waste space, to give reasonable dose uniformities, and to be a manageable size. Irradiation quantities will be referred to in terms of these standard boxes in the discussion that follows.

Six basic groups of materials were identified in the Stanford study⁽⁵³⁾ and each of these has been evaluated as an irradiation candidate both alone and in various combinations with the other five. The groups are defined as follows:

- Group 1. Respiratory (Inhalation) Therapy Department Non-Sterile Disposables
- Group 2. Respiratory Therapy Department Disinfected Equipment
- Group 3. Respiratory Therapy Department Gas Sterilized Items
- Group 4. The sum of Items From All Other Departments. (Stanford personnel feel that the volume of this group is approximately equal to the sum of Groups 1, 2 and 3.)
- Group 5. Ninety Percent of Linen Processed
- Group 6. Infectious Waste

The first group consists of 80,000 disposable items used annually that do not arrive at the hospital in sterile condition. Present cost to obtain them sterile is about 20 cents per item or \$16,000 annually. The Respiratory Therapy Department would prefer to use these items in a sterile condition but consider the cost too high. A summary of the items, their annual use rate, shipping carton dimensions, average density in the cartons, number of annual standard boxes and the efficiency of stacking shipping cartons in standard boxes is shown in Table 7.1. The average density of these items based on use rate (total weight divided by total volume) is 0.0747 g/cm^3 . The range in density is $0.036\text{-}0.340 \text{ g/cm}^3$. This range necessitates operating the irradiator in batches of standard boxes containing cartons of similar density. This problem is discussed in more detail later.

TABLE 7.1 Respiratory Therapy Department (Stanford University Hospital)
Volume of Non-sterile Disposables

Item	Carton Dimensions, in.			Cartons/ Year	Cartons/ Std. Box	Std. Boxes/ Year	Box Utilization	Equivalent Full Boxes	Density, g/cm ³
	L	W	H						
Humidifiers	15.5	15.5	15.5	200	2	100	0.5172	51.72	0.036
Nebulizers	15.5	15.5	15.5	200	2	100	0.5172	51.72	0.0720
IPPB Sets	16.	20.	14.	312	2	156	0.6222	97.06	0.0775
Oxygen Masks	10.5	25.	10.	26	1	26	0.1823	4.74	0.0775
Aerosol Masks	13.5	13.	13.	50	2	25	0.3169	7.92	0.1273
Oxygen Tubing	20.	8.5	8.5	78	8	9.75	0.8028	7.83	0.1633
Aerosol Tubing	20.	20.	18.5	312	1	312.	0.5139	160.34	0.0484
Venturi Masks	11.	11.	11.	10	3	3.33	0.2773	0.92	0.0886
Tracheotomy Masks	14.25	9.5	7.5	36	8	4.5	0.5640	2.54	0.0692
Nasal Cannulas	14.	10.	7.5	104	8	13.	0.5833	7.58	0.1522
Nasal Catheters	8.0	5.5	4.75	6	6	1	0.0871	0.09	0.0996
T Tubes or Adaptors	16.25	12.5	6.5	150	5	30	0.4584	13.75	0.0360
Oxygen Canopies	16.25	12.5	6.5	60	5	12	0.4584	5.50	0.340
Tracheotomy Adaptors	10.	8.0	4.0	150	36	4.17	0.8000	3.34	0.1273
						796.75		415.05	

Overall Box Utilization = $\frac{415.05}{796.75} \times 100 = 52.1\%$

Average Density of Equivalent Full Box = 0.0747 g/cm³

The second group consists of all items chemically disinfected by the Respiratory Therapy Department. Many of these items contain expensive electronic, electric and mechanical equipment. They are irregular in size, highly variable in density, and impossible to adequately sterilize between patient uses. A disinfecting dose on the order of 0.5 Mrad appears desirable after cleaning between uses. Table 7.2 contains a list of these items, their size, and number of uses. This group is very small compared to the other five, but it is representative of an important type of hospital equipment. These densities are based on each item's volume as a rectangular parallelepiped. The true density goes as high as 9 g/cm³ (e.g., metallic copper). The annual sterilization volume of all but the last four items (they won't fit in

TABLE 7.2. Disinfected Respiratory Therapy Equipment

Item	Unit Weight	Unit Uses Per Year	Dimensions in.			Density g/cm ³	No./Std. Box	Std. Boxes Year
			L	W	H			
Paramagnetic Analyzers	2	12	6	6	6	0.256	54	0.2
Galvanic Cell Analyzers	2	12	6	6	6	0.256	54	0.2
High Pressure Regulators	2.5	200	6	4.5	4	0.641	120	1.7
Intubation Modules	5.25	120	17.5	21	3	0.132	6	20
Oxygen Controller	9.0	120	11	8	8	0.354	12	10
Portable Cardiac Unit	100	120	18	16	14	0.687	2	60
Cylinder Trucks	30	120	15	6	36	0.256	3	40
Respirator (Bennet PR-2)	25	2080	26	26	54	0.019	(a)	0
Volume Ventilator	320	24	24	48	60	0.128	(a)	0
Oxygen Tent	150	Negligible	24	24	48	0.150	(a)	0
Ultrasonic Nebulizer	18	420	36	36	58	0.0066	(a)	0
								132

a. Will not fit in a standard box 20 in. x 20 in. x 36 in.

a standard box) is 17,858 lb as 645 ft³ fitting in 132 standard boxes. The average density of 0.444 g/cm³. The total weight of all items is 85,098 lb/year. The irregular items that do not fit in standard standing boxes weight 67,240 lb/year.

The third group consists of 18 types of Respiratory Therapy items listed in Table 7.3. These are presently sterilized with ethylene oxide in 100 lb loads (packing density equals 0.064 g/cm³) in a 25 ft³ sterilizer. The Respiratory Therapy Department pays \$10 per load for the cost of the gas. Their present volume is about 500 loads per year and the gas cost for sterilization is about \$5,000. The minimum process time per batch is 12 hours. An irradiator might reduce the cycle time, and thus reduce inventory needs to some degree.

TABLE 7.3 Respiratory Therapy Gas Sterilized Items

Nasal Pharyngeal Airways	Electronic Nebulizers-Mistogen
Endotracheal Tubes	Humidifiers-Reusable
Endotracheal Tube Connectors	Spirometers-Reusable
Head Hoods	Ventilator Masks
Bay Mask Resuscitators	Immersion Heaters
Ventilator Circuits	Nebulizers-Reusable
IPPB Sets	Flowmeters
Respirator (Bennet A.P.)	Flex Tubes
Electronic Nebulizers-DeVilbus	Aerosol Tents

Since the Respiratory Therapy Department is the biggest apparent potential user of an irradiator (not considering linen and waste as candidates), it was studied in more detail than any other department in order to quantify their potential volume of use for an irradiator. Stanford personnel felt that the remaining departments together (again not counting linen and waste) could produce an equivalent volume of candidates. This group of undefined items equivalent to the sum of Groups 1, 2 and 3 is identified as Group 4.

Group 5 consists of ninety percent of the linen cleaned at Stanford. The remaining linen is surgical linen which is adequately sterilized at present by steam. The ninety percent portion amounts to 3,343,000 lbs per year (0.272 g/cm^3) and is a candidate for a disinfecting dose on the order of 0.5 Mrad.

Group 6 consists of the total amount of infectious waste as defined by Stanford. These wastes come from the care of isolation patients (patients with or suspected of having infectious diseases), from teaching and research and from surgery (operating rooms). The waste is assumed to be 5 lbs/ft^3 . The magnitude of the infectious wastes are:

Patient care (infectious portion)	713 lbs/day
Teaching and research	625
Operating rooms	<u>89</u>
	1427 lbs/day (2.7 lbs/patient day)

Presently these wastes are incinerated. They could be conveniently placed directly in the standard boxes, three of the 2.5 ft^3 bags fitting in one box with a minimum of handling and irradiated before disposal.

Table 7.4 summarizes the data for all of these initial six applications discussed. The volume of each group is defined in terms of standard boxes per year. An irradiator can be sized to accommodate any one or all groups at a specified dose. A convenient way to represent the irradiator throughput is to multiply the pound throughput times dose to get Mrad lb/year as in Table 7.4. The throughput figures are related to the number of curies required in the radioactive source. This is an indirect relationship however, because the efficiency of irradiation increases with target density. (The efficiency at a density of 0.25 g/cm^3 is roughly twice the efficiency at density of 0.1 g/cm^3 .)

Although implants at Stanford will not constitute a large group by themselves, the numbers and growth rates are impressive. Table 7.5 shows the implant volume for the past two years. The average growth rate is more than 40 percent over this one-year period. The use of an irradiator for sterilizing many of these items would be possible, but even four implants per day can hardly justify a large facility.

TABLE 7.4. Summary of Data on Initial Equipment Groups that are Candidates at Stanford University Hospital

Group	Volume per year ft ³	Weight per year lb	Density g/cm ³	Efficiency % Box Utilization	Standard Boxes per year	Probable Dose Mrad	Mrad-lb Year
1. Respiratory Therapy Non-sterile Dispos- ables	3,437	16,010	0.0747	52	797	2.5	40,025
2. Respiratory Therapy Dept. Reuseables.							
a. In std. boxes	645	17,858	0.444	59	132	0.5	8,929
b. Irregular items		67,240					33,620
3. Respiratory Therapy Gas Sterilized Items	12,365	49,460	0.064	100	1,472	2.5	123,650
4. Other Departments (Equal to Cases 1+2+3)	(Undefined at this time)			-	-	0.5-2.5	206,224
5. Ninety Percent of Linens Processed	197,000	3,342,800	0.272	100	23,652	0.5	1,671,400
6. Infectious Waste	104,000	521,000	0.08	90	13,870	2.5	1,300,000

TABLE 7.5. Implant Volume at Stanford University Hospital⁽⁵³⁾

Type of Implant	Number of Operations Per Year		
	1971	1972	Increase, %
1. Prosthetic Devices	132	212	+60.6
2. Screws and Pins	108	164	51.9
3. Shunts	124	88	-29
4. Heart Valves	276	356	29.0
5. P E Tubes (Heart)	24	76	216
6. Wires	12	16	33.3
7. Pacemaker	68	128	88.2
8. Bone Grafts	44	108	145
9. Tubes	32	36	12.5
10. Silastic Bands	4	20	400
11. Transplants	24	12	-50
12. Cranioplasty	0	8	∞
13. Heterografts	32	28	-12.5
14. Cartilage Ear Parts	12	32	167
15. Teflon Coverings	0	4	∞
16. Mammoplasty	12	12	0
	904	1300	43.8

LONG TERM PROSPECTS

The initial applications just discussed are estimates of processing volumes available if the Stanford University Hospital were to begin using an irradiator today. The situation at the time they might begin operations (2 to 5 years from now) will be somewhat changed. A measure of this change is the experience in the Respiratory Therapy Department. Their business is increasing 10 percent each year. We assumed that the Respiratory Therapy (RT) Department could initially provide 50 percent of the potential irradiator load excluding waste or linen. Stanford personnel feel that, as time progresses and as other departments familiarize themselves with the irradiator, the Respiratory Therapy items may account for no more than 25 percent of the total processing volume (excluding linen or waste). Thus, there are reasonable prospects for use of an irradiator to grow significantly beyond what can be defined today.

The potential users of an irradiator are not limited to the Stanford University Hospital. Within a 15-mile radius of Stanford, there are 6100 hospitalized patients (including 500 at Stanford). Table 7.6 shows the number of patients in each hospital in that 15-mile radius. The 5600 patients outside Stanford will be generating needs on the order of 10 times the requirements within the Stanford University Hospital. It is certainly conceivable that utilization of a Stanford facility up to the limit of its capacity would evolve for applications proven out in their test programs. Sharing puts an irradiator at Stanford in a quite different perspective than an isolated irradiator.

While there are good prospects for uses to increase significantly over those that can be defined today, it should also be recognized that some developments may tend to reduce processing volumes. The principal factors seen here are:

1. Some items identified as candidates today will be found unsuitable for irradiation treatment.
2. Once the desirability of irradiation sterilizing items in Group 1 (non-sterile disposables) is established, the manufacturers may adopt irradiation sterilization and would possibly be able to do it more cheaply and efficiently than a hospital.

HOSPITAL IRRADIATOR CONCEPT

A variety of irradiator concepts have been operated for various purposes but the type generally used for large scale applications is a stop-dwell type in which rows of target boxes are indexed intermittently along both sides of a vertical-plane source plaque. The source plaque is simply a rack in which long capsules of source material are mounted. When not in use the source plaque is submerged in a pool of water to shield the source and allow access to the irradiator cell. For shielding during operation the cell walls are constructed of four to five-foot-thick concrete.

Operation can be either continuous-feed or batch-charge, but in either case a target box will spend equal time in all positions around the plaque to reduce nonuniformity to the minimum. Target box size selection requires trade-offs

TABLE 7.6. Bay Area Hospitals Within a 15-Mile Radius of Stanford University

Hospital	Location	No. of ^(a) Beds	Average ^(a) Occupancy, %	Average ^(a) No. of Patient Days
1. El Camino	Mountain View	435	73	318
2. Oaks & The Redwoods	San Jose	535	74	396
3. Santa Clara Med. Center	San Jose	490	59	289
4. Alexian Brothers	San Jose	126	71	89
5. Good Sam. Hosp. of Santa Clara	San Jose	259	75	194
6. Peninsula Hosp. & Med. Center	Burlingame	387	80	310
7. O'Connor Hospital	San Jose	350	69	242
8. Sequoia Hospital District	Redwood City	439	64	281
9. Park Alameda Hospital	San Jose	110	36	40
10. Mills Memorial Hospital	San Mateo	342	75	257
11. Kaiser Foundation Hospital	Santa Clara	247	79	195
12. Kaiser Foundation Hospital	Redwood City	112	75	84
13. Harold Chope Community	San Mateo	193	63	122
14. Stanford University Hospital	Palo Alto	612	80	490
15. Twin Pines Hospital	Belmont	75	72	54
16. Veterans Administration	Palo Alto	1384	76	1052
17. Canyon Hospital ^(b)	Redwood City	120	61	73
18. Hassler Hospital ^(b)	Redwood City	227	74	168
19. Woodside Aeres Hospital ^(b)	Redwood City	24	42	10
20. Agnews State Hospital ^(b)	San Jose	2828	51	1442
				6106

a. "The AHA Guide to the Health Care Field, 1971," American Hospital Association

b. Long Term or Speciality Care Type Hospital

between thickness for maximum economy and thinness for minimum dose nonuniformity. This type of irradiator is most simply designed and efficiently operated if only a single product or target box is employed. A design to accommodate more than one box size in the same batch would become particularly complex and costly.

Designing an irradiator to meet the varied requirements anticipated in a hospital irradiator is a complex problem that requires design compromises to satisfy competing requirements. We have scoped the outlines of irradiator concepts that can meet the various requirements but it is quite probable that a more intensive design effort would identify methods for significant improvements in efficiency.

To establish the type and size of an irradiator that would best fit the needs of a large hospital, a number of criteria were established. These were as follows:

1. The facility should utilize Hanford cesium-137 capsules as the source.
2. The irradiator should have maximum flexibility in use. The irradiator must be able to accept items of different size and density. It must be able to deliver varied doses. Being able to operate in either batch or continuous modes would be desirable.
3. It must not give unreasonably high dose uniformity ratios (maximum dose/minimum dose).
4. A reasonable efficiency is desired. Wasting gamma energy both while operating and down is expensive.

The characteristics of the Hanford cesium capsule are shown in Table 7.7. The capsule is large and thick walled and self-absorption is high (50 percent) relative to cobalt-60 sources which lose only about 10 percent to self-absorption. Cesium-137 does not emit as much gamma energy per curie as cobalt-60. This combined with the high self-absorption results in cesium requirements about 7.6 times that for cobalt on a curie basis. However, the emitted gamma photons are, for practical

TABLE 7.7. Hanford Cs-137 Source Characteristics⁽⁵⁵⁾

ISOTOPE	Cs-137
Length, inches	20.775
O.D., inches	2.625
Total Stainless Steel Cladding Thickness, inches	0.204
Isotope Weight, ^(a) gm/source	2520
Specific Activity, Ci ¹³⁷ Cs/g	23.8
Total Activity, Ci ¹³⁷ Cs/source	60,000
Self Absorption, ^(b) %	0.495
Emitted Gamma Energy, ^(c) %	0.505
Emitted Gamma Energy Intensity, ^(c) Watts/ft ²	135

a. As CsCl

b. When assembled as a large plaque

c. From one side of a large plaque

purposes, just as efficient as the cobalt photons. Cesium costs about one-fifth as much per curie as cobalt and decays at a rate of only 2.3 percent per year compared to 12.5 percent per year for cobalt. Over a period of time the costs for cesium or cobalt sources are comparable.

The concept of a standard box size to accommodate the various items to be irradiated has already been mentioned. For some items these boxes will be only 50 to 60 percent full but no other practical alternative was apparent.

To move the boxes around the source plaque, we employed the system used in the AECL large medical products irradiators.⁽⁵⁶⁾ This involves moving the boxes on roller conveyors by means of a series of pneumatic pushers for horizontal movement and elevators for vertical transfer from one level to another. Movement is intermittent and sequential and is controlled by a master timer. Variable speed control is necessary to accommodate different density materials and to provide for varying the radiation dose.

Four basic design concepts were defined to fill the many possible needs of a hospital irradiator. These were:

Design A: Batch charge, 7 boxes/batch

Two pass,* one level,* four box positions per pass

1.5 MCi ^{137}Cs maximum source

Design B: Continuous feed, 16 box inventory

Four pass, one level, four box positions per pass

1.5 MCi ^{137}Cs maximum source

Design C: Batch charge, 14 boxes/batch

Two pass, two level, eight box positions per pass

3.0 MCi ^{137}Cs maximum source

Design D: Continuous feed, 31 box inventory

Four pass, two level, eight box positions per pass

3.0 MCi ^{137}Cs maximum source.

Each of these designs has a particular advantage. These will be discussed in more detail in the following paragraphs. The irradiator could be upgraded in capacity and efficiency by adding equipment to change from A to B or A to C etc. The primary advantages of Design A are its simplicity and low capacity, if batch sizes are necessarily small. Design B is only considered to be operated in a continuous-feed fashion since batch-charge operation would require a complicated transport system to keep the boxes in sequence. Design C is indicated as a batch-charge operating system but could also be operated continuously with the addition of a conveyor system to bring boxes in and out of the irradiator. Design D is only practical for continuous-feed operation because too much use time would be lost in loading and unloading in a batch mode. Any of these systems could be expanded to larger capacities by increasing the number of boxes per pass and increasing the source size as long as the irradiator cell is large enough. Figure 7.1 shows a plan view schematic and the box movement sequence for Design A.

* One pass is defined as one row of boxes on one side of the plaque. The number of levels denotes the number of box layers. In a two level system, the levels are traveling in opposite directions.

FIGURE 7.1. Irradiator Design A

The first variables of interest are the capacity of each irradiator design as a function target density. To examine these and other parameters we used the method of Rizzo⁽⁵⁷⁾ and the data of Galanter.⁽⁵⁸⁾ Figure 7.2 shows the maximum continuous throughput rate of each irradiator design. For purposes of these calculations, each pass is filled with boxes. The resident inventory of each irradiator is 8 boxes in A, 16 in B, 16 in C and 32 in D. Because each successive design more efficiently captures the gamma energy emitted, Design A has the lowest throughput rate per curie and B, C and D are successively higher. Throughput capacity here is based on a minimum dose of 2.5 Mrad.

The efficiency is the ratio of the gamma energy absorbed by the target at the minimum dose divided by the total gamma energy produced by radioactive decay. Any overdose (dose uniformities greater than one) is considered as wasted energy. The source utilization efficiency is directly related to the capacity per curie. Figure 7.3 shows the efficiency of the four conceptual designs, irradiator D being nearly twice as efficient as A.

The next parameter of concern is the dose uniformity. It is the ratio of the maximum dose received anywhere in the box or batch to the minimum dose received anywhere in the box or batch. Since the dose requirement is the same as the minimum dose, the dose uniformity ratio is a measure of overdose to some particular point in the system of boxes. All other points, except the minimum dose point, are overdosed to some degree between the minimum and maximum. In the stop-dwell designs A through D, the maximum

FIGURE 7.2. Continuous-Feed-Operation Capacity for Conceptual Hospital Irradiator at 2.5 Mrad Using Standard Boxes (20 in. x 20 in. x 36 in.)

FIGURE 7.3. Source Utilization Efficiency for Conceptual Hospital Irradiator Using Standard Boxes (20 in. x 20 in. x 36 in.)

dose in each box is always at the center of the faces parallel to the plaque. The minimum box dose is at the center of the top and bottom box faces for Designs A and B, (single level) and is at the center of each box for Designs C and D (two level). Figure 7.4 shows the dose uniformity versus target density for the four conceptual Designs A, B, C and D. Three observations from Figure 7.4 are important.

- Higher density materials markedly increase the dose uniformity ratios (greater non-uniformity).
- Increasing the number of passes from two to four affects the dose uniformity ratio very little.
- Increasing the number of levels from one to two reduces the dose uniformity ratio significantly.

Other factors influence dose uniformity. Figure 7.4 showed the uniformity ratios for boxes of the same density being processed in the irradiator. If the boxes are of mixed densities, then over or underdosing can occur in a box if it is of lower or higher density, respectively, than the box for which the stop-dwell speed is set. To get an idea of the degree that over/underdosing occurs, Figure 7.5 was constructed for Designs A and C. The curves for both designs fortuitously coincide. Similar curves for Designs B and D could be constructed, but such curves would have to be qualified by the degree and pattern of the density non-uniformity, since the passes nearest the plaque shield the outside passes in an unknown manner. (However, Figure 7.5 can be used as a good first approximation for density variation effects in Designs B and D.) Correlations similar to this will be necessary to establish speeds for each batch which will depend on the average density and range of densities in the target boxes. Large density variations or varied dose requirements in the boxes in a continuous run could produce many operating difficulties unless a good deal of over/underdosing can be tolerated. Therefore, the most flexible way to run an irradiator with varied dose requirements and/or densities is to operate in a batch-charge mode.

FIGURE 7.4. Dose Uniformity Ratio for Conceptual Hospital Irradiator for Uniform Target Density Using Standard Boxes (20 in. x 20 in. x 36 in.)

FIGURE 7.5. Effect of Nonuniform Target Density on Dose Uniformity for Conceptual Hospital Irradiator

Batch-charge operation is probably the best way to run a hospital irradiator for most of the material groups discussed previously. Designs A and C are good candidates. Only when large volumes of waste or linen are to be irradiated does continuous operation pay off. In these cases, avoiding time loss for shutdown, startup, batch loading and unloading increases the capacity of the irradiator substantially.

To develop a basis for estimating capacities in the batch-charge-mode of operation, we assigned estimated time increments to each required activity in the batch-charge operation. These are summarized in Table 7.8. The down time allowance for each irradiation batch was estimated at 1.1 hours for A and 1.6 hours for C. Based on these down time estimates and the continuous operation capacity curves in Figure 7.2, the maximum capacity of the A and C designs in the batch-charge-mode per 8-hour shift were calculated. These results are shown in Figure 7.6. A batch does not have to be completed in one shift, but fractional batches completed in a shift mean that the batch is not completed until the next shift or the next day in the case of a one-shift operation.

The next step in the analysis was to determine the minimum source requirements for batch-charge operation to process the quantities in each equipment or material group (Table 7.4). These requirements were determined for operating only one 8-hour shift 5 days/week, two 8-hour shifts 5 days/week, and 24 hours/day 7 days/week. The minimum source requirements were obtained by calculating the required effective continuous processing rate, after allowing for down time, and calculating source size by taking the ratio relative to the processing rate from Figure 7.2 for a 1 M Ci source. (A correction factor of 8/7 times the values from Figure 7.2 is also required to correct for the vacant box position that allows the indexing movement around the source.) Table 7.9 shows these minimum source requirements for processing the quantities in each equipment group (described in Table 7.4) using irradiator concepts A and C.

By combining these minimum source requirements for the individual groups, the source required for processing any combination of groups in the same irradiator can be determined. However, the source requirement

TABLE 7.8. Estimated Down Time for Batch-Charge Operation of Irradiator

	<u>Irradiator Down Time, Min.</u>
1. Load boxes to be irradiated onto carts, four per cart. (This can be done during irradiation. Enough carts must be available for two batches, those with the new batch and those to receive the finished batch).	0
2. Case A, 7 boxes/batch	
a. Wheel cart in/out of cell during unloading	10
b. Unload rack onto cart (unloading)	7
c. Wheel cart in/out of cell during loading. 5 Min. ea. x 2 =	10
d. Load each box onto rack (1 Min./box)	7
e. Startup irradiator and raise source from pool	5
f. Return source to pool and shut down irradiator	5
g. Maintenance and contingency allowance	<u>20</u>
	64 Min. (1.1 Hr)
3. Case C, 14 boxes/batch	
a. Wheel carts in/out during unloading	20
b. Load carts from rack	14
c. Wheel cart in/out during loading 5 Min. x 4 =	20
d. Load each box onto rack	14
e. Startup irradiator and raise source from pool	5
f. Return source to pool and shutdown irradiator	5
g. Maintenance and contingency allowance	<u>20</u>
	98 Min. (1.6 Hr)
4. Distribute Irradiated Boxes (time not allocated to irradiator down time)	0

FIGURE 7.6. Batch-Charge-Operation Capacity for Conceptual Hospital Irradiator at 2.5 Mrad Using Standard Boxes (20 in. x 20 in. x 36 in.)

TABLE 7.9. Minimum Cs-137 Source Requirements to Batch Irradiate
Each Material Group in Design Concepts A and C

Group Number	1 8-hr Shift, 5 Days/wk			2 8-hr Shifts, 5 Days/wk			3 8-hr Shifts 7 Days/wk		
	<u>Boxes</u> <u>Shift</u>	<u>MCi</u> <u>Required</u>		<u>Boxes</u> <u>Shift</u>	<u>MCi</u> <u>Required</u>		<u>Boxes</u> <u>Shift</u>	<u>MCi</u> <u>Required</u>	
1	3.065	0.48 0.31	A C	1.53	0.24 0.15	A C	0.73	0.11 0.07	A C
2	0.507	0.024 0.015	A C	0.254	0.0117 0.0074	A C	0.121	0.0057 0.0035	
3	5.66	0.93 0.60	A C	2.83	0.445 0.29	A C	1.35	0.205 0.140	A C
4	9.23	1.425 0.922	A C	4.61	0.692 0.446	A C	2.20	0.319 0.213	A C
5	91.0	- -		45.5	- 3.29		21.7	- 0.775	
6	26.7	- -		13.3	- -		6.35	- 0.68	

for a combination of groups is not a simple sum of the component group source requirements. An adjustment for total down time is required. In any period of successive batch-charge irradiations, the irradiator will be idle during unloading and loading. It is necessary to define the fraction of this down time for each equipment group at each particular shift-mode of operation (i.e., one-shift, two-shifts or three-shifts per day). If, for example, group "i" has a down time for changing batches of one hour out of four hours of operation when operating one-shift per day, then the fraction of down time, A_i , equals 0.25. At two shifts per day, the same daily production could be achieved by completing a batch in eight hours. The fraction of down time is then one hour out of eight or 0.125 and the source required is only 3/7 of the one-shift source. This fraction of available operating time, A_i , that is consumed as down time for group "i" does not change when two or more groups are processed in the same irradiator operating in the same batch mode. Thus the down time fractions are additive and the net available operating time fraction can be determined by difference. Thus also, the total source requirements can be corrected for actual net available irradiation time as follows.

If we define the minimum source requirement for batch-charge operation of the irradiator for group "i" alone in the specified shift mode and specified irradiator (Table 7.9) as Z_i , then for any combination of "n" groups using the same shift mode, and same irradiator, the minimum source requirement is computed using the relationship:

$$\begin{array}{l} \text{Curies Required to} \\ \text{Irradiate n Groups} \\ \text{Batchwise} \end{array} = \frac{\sum_{i=1}^n (1-A_i)Z_i}{1 - \sum_{i=1}^n A_i}$$

Any combination that makes the denominator zero or negative is impossible to operate in that shift mode, regardless of the plaque strength, because down time is equal to or greater than available time. The other limitation on capacity is the maximum source strength previously defined. The above equation was used to compute the source requirements for four combinations of groups compared in the economic analysis. These are discussed in more detail after the costs of facilities A through D are established.

ECONOMIC ANALYSIS

In addition to the cost estimates for the irradiators discussed in the infectious waste section of this report, capital cost estimates were also obtained for the batch-type irradiators just described.⁽⁵¹⁾ These estimates are shown in Table 7.10. The design D is identical to the small infectious-waste irradiator. No advantage for Design B was identified and it was dropped from consideration here.

TABLE 7.10 Hospital Irradiator Cost Estimates

	<u>Design A</u>	<u>Design C</u>	<u>Design D</u>
Maximum Source, HWM ¹³⁷ Cs	1.5 MCi	3.0 MCi	3.0 MCi
Operating Mode	Batch-Charge	Batch-Charge	Continuous-Feed
Irradiator Cell Cost	\$ 90,000	\$ 90,000	\$ 90,000
Equipment Cost	<u>\$ 70,000</u>	<u>\$ 90,000</u>	<u>\$160,000</u>
Total Capital Cost Excluding Source ----	\$160,000	\$180,000	\$250,000

These cost estimates include all direct construction costs, indirect costs including contractor overhead and profit, architect-engineer and field engineering costs. They have an uncertainty on the order of ± 20 percent and could vary at least ± 10 percent just on the basis of design costs, depending on the availability of suitable off-the-shelf designs.

The estimates are based on current construction costs. Construction costs are presently increasing at about a 7 percent per year rate so it should be anticipated that the construction cost at a future date may be significantly greater than these estimates.

The irradiator cell has 15 ft x 15 ft inside dimensions and the walls and ceiling are four-foot thick normal concrete. A cobalt source would require five-foot walls and cell costs would be about 15 percent higher.

Operating costs were based on the following assumptions:

- Operating labor

(a) Two hours per shift or six hours per day, whichever is smaller, for routine operational activities, checking instruments, record keeping etc.

(b) Labor associated with loading and unloading the irradiator and box handling:

1.1 hours per 7 box batch for concept "A", or

1.6 hours per 14 box batch for concept "C", or

four minutes handling time per box for concept "D" (continuous).

(c) Labor cost was estimated at \$6/hr including benefits and administrative overhead costs.

- Maintenance costs

Based on 2 percent per year of equipment cost for each shift operated or 5 percent per year for 24-hour operation.

- Utilities

Based on \$300 per year per shift or \$1000 per year for 24-hour operation.

- Boxes

Based on \$1.00 per box with boxes used an average of four times before discarding.

- Miscellaneous and contingencies

An allowance of \$1000 per year for each shift per day.

- Source Cost

Based on HWM cesium capsules at 10¢/Ci. The initial source is depreciated at 10 percent per year and replenishments are 2.3 percent of initial source cost per year.

- Facility Depreciation

Based on 10 percent per year.

Based on these assumptions and estimates the operating cost relationships shown in Table 7.11 were developed.

Four cases were defined for using the batch irradiators to sterilize various combinations of the items in the six Stanford equipment groups as

TABLE 7.11 Irradiator Operating Cost Equations

Description	Operating Schedule	Annual Cost, \$
Irradiator "A"	One shift, 5-day/wk	$21,820 + 0.0123 \times Ci^{137}Cs + 1.19 \times \text{Boxes/yr}$
Batch Charge	Two shifts, 5-day/wk	$27,740 + 0.0123 \times Ci^{137}Cs + 1.19 \times \text{Boxes/yr}$
1.5 MCi ¹³⁷ Cs Max.	Three shifts, 7-day/wk	$36,740 + 0.0123 \times Ci^{137}Cs + 1.19 \times \text{Boxes/yr}$
Irradiator "C"	One shift, 5-day/wk	$24,220 + 0.0123 \times Ci^{137}Cs + 0.93 \times \text{Boxes/yr}$
Batch Charge	Two shifts, 5-day/wk	$30,440 + 0.0123 \times Ci^{137}Cs + 0.93 \times \text{Boxes/yr}$
3.0 MCi ¹³⁷ Cs Max.	Three shifts, 7-day/wk	$39,140 + 0.0123 \times Ci^{137}Cs + 0.93 \times \text{Boxes/yr}$
Irradiator "D"	One shift, 5-day/wk	$32,600 + 0.0123 \times Ci^{137}Cs + 0.65 \times \text{Boxes/yr}$
Continuous Feed	Two shifts, 5-day/wk	$40,240 + 0.0123 \times Ci^{137}Cs + 0.65 \times \text{Boxes/yr}$
3.0 MCi ¹³⁷ Cs Max.	Three shifts, 7-day/wk	$50,140 + 0.0123 \times Ci^{137}Cs + 0.65 \times \text{Boxes/yr}$

shown in Table 7.4. These four cases are intended to (a) illustrate the flexibility of the batch systems for handling the hospital requirements, (b) show how the use of such a facility could be expanded as development programs expand and (c) give an indication of unit costs for sterilization. Source requirements, facility utilization factors, and operating costs were calculated by the procedures previously described. Fixed costs are pro-rated on the basis of fractional use by each equipment group in each case. Results of these calculations are shown in Table 7.12.

Case 1 includes items in groups 1, 2 and 3. These can all be processed in one shift (5-day week) in Design A. Unit costs for Group 1 items average 19¢ each, which is the approximate gas sterilization cost. Group 2 items average \$1.26 per item and Group 3 averages 57¢ per pound. (The number of items in Group 3 was not available). The average cost could be reduced about 10 percent by operating two shifts rather than one shift where, although fixed costs increase, the source requirement is halved and a net savings results.

Case 2 includes the Case 1 group plus Group 4. Here a two-shift operation in Design A is required. The unit cost of Group 1 items is reduced to 12¢ each with proportionate reductions in costs for Groups 2 and 3. A slight savings is indicated for three-shift operation. The same items could be processed in Design C in one shift per day but at a 10 percent higher cost. A 10 percent savings is indicated for Design C over Design A at two shifts per day

TABLE 7.12. Feasible Batch-Charge Operating Modes, Product Combinations and Unit Costs for Stanford University Hospital Development-Irradiation Facility

Case Number	Equipment Groups	Irradiator Concept (a)	Source Allocation, MCi Cs-137	Process Volume Standard Boxes Per Year	Fraction of Irradiator Use	Process Time Per Batch Hours (b)	Annual Costs, \$				Average Cost Per Standard Box, \$	Average Unit Cost
							Fixed	Source	Variable	Total		
1	1	A/1 (0.82)	0.55	797	0.336	6.3	7,332	6,765	948	15,045	18.88	\$0.19/Item
	2		0.029	132	0.017	2.7	371	358	157	886	6.71	\$1.26/Item
	3		1.01	1,472	0.647	6.3	14,117	12,423	1,751	28,291	19.65	\$0.57/lb
	(1+2+3)		1.59	2,401	1.00	---	21,820	19,546	2,856	44,222	18.41	---
	(1+2+3)	A/2 (0.92)	0.723	2,401			27,740	8,893	2,856	39,489	16.45	---
2	1	A/2 (0.84)	0.28	797	0.175	6.4	4,854	3,444	948	9,246	11.60	\$0.12/Item
	2		0.014	132	0.008	2.8	222	172	157	551	4.17	\$0.78/Item
	3		0.50	1,472	0.318	6.4	8,821	6,150	1,751	16,722	11.36	\$0.33/lb
	4		0.76	2,401	0.499	---	13,892	9,348	2,856	26,046	10.95	---
	(1+2+3+4)		1.55	4,800	1.00		27,739	19,114	5,712	52,565	10.95	---
	(1+2+3+4)	A/3 (0.92)	0.673	4,800			36,740	8,278	5,712	50,730	10.57	---
	(1+2+3+4)	C/1 (0.75)	2.22	4,800			24,220	27,306	4,464	55,990	11.66	---
3	1	C/3 (0.62)	0.112	797	0.058	8.9	2,270	1,378	741	4,389	5.51	\$0.05/Item
	2		0.006	132	0.003	3.9	117	74	123	314	2.38	\$0.45/Item
	3		0.221	1,472	0.117	8.9	4,579	2,718	1,369	8,666	5.89	\$0.17/lb
	4		0.333	2,401	0.177	---	6,928	4,096	2,233	13,257	5.52	---
	5		0.850	23,652	0.645		25,245	10,455	21,996	57,696	2.44	0.017/lb
	(1+2+3+4+5)		1.52	28,454	1.00		39,140	18,721	26,462	84,322	2.96	---
4	1	C/3 (0.53)	0.131	797	0.037	5.4	1,448	1,611	741	3,800	4.77	\$0.05/Item
	2		0.007	132	0.002	2.8	78	86	123	287	2.17	\$0.41/Item
	3		0.259	1,472	0.074	5.4	2,896	3,186	1,369	7,451	5.06	0.15/lb
	4		0.390	2,400	0.113	---	4,423	4,797	2,233	11,453	4.77	---
	5		0.994	23,652	0.413	2.6	16,165	12,226	21,996	50,387	2.13	0.015/lb
	6 (1/2)		1.167	6,935	0.361	5.4	14,130	14,130	6,450	34,934	5.04	\$0.13/lb
	(1+2+3+4+5+6/2)		2.95	35,388	1.00		39,140	36,260	32,912	108,312	3.06	---

(a) Letter identifies design concept (see P. 7.14).

Integer number identifies shift-mode of operation, i.e. one, two or three shifts per day.

Number in parentheses represents net fraction of available operating time utilized for actual irradiations.

Process time includes down time.

Case 3 includes all of Case 2 plus Group 5 (linen at 0.5 Mrad). Here the minimum facility requirement is Design C at three shifts per day. There is, however, still some excess capacity. The unit cost for Group 1-4 items is cut in half with Group 1, for example, at 5¢ per item.

Case 4 includes all of Case 3 plus one-half of Group 6 (infectious waste). At this point, Design C is filled to capacity. Unit costs are only reduced about 10 percent compared to Case 3. The linen treating cost is only 1.5 to 1.7¢ per pound in Cases 3 and 4 and is a reasonable cost. The waste treatment cost of 13¢ per pound is too high to compete with incineration but might be acceptable for some special category of waste or for a test program to evaluate the effectiveness of this treatment.

Two additional cases were calculated based on using Design D to evaluate the long-term potential for cost reduction if the 6000 patients within the 15-mile radius of Stanford could be served by a more efficient, single purpose continuous feed irradiator. These results are shown in Table 7.13.

TABLE 7.13. Potential Unit Costs for Irradiator Serving Hospitals Within a 15-Mile Radius of Stanford University Hospital (3 MCi Cs-137 Source)

<u>Case Number</u>	<u>Equipment Groups</u>		<u>Boxes/yr Potential</u>	<u>Boxes/yr Capacity Design D</u>	<u>Unit Costs</u>
	<u>Number</u>	<u>Description</u>			
5	1 & 3	RT Disposables and Gas Sterilized Items	26,000	51,000	\$2.37/Box and 2¢/item for Group 1 items
6	5	Linen	272,000	187,000	\$1.12/Box or 0.8¢/lb

Case 5 combines Groups 1 and 3, the respiratory therapy disposables and gas sterilized items from these 6000 patients. Even from all of these hospitals there would be only about half enough material to fill the irradiator capacity. If the irradiator were full, the unit cost would be roughly halved compared to Case 3 or 4. This method of operation cannot be ruled out but does not look particularly promising.

Case 6 considers processing all of the linen from the 6000 patients. Here Design D can process only about 70 percent of the potential load indicating that a somewhat larger irradiator might be more feasible. The unit cost is reduced to 0.8¢ per pound or 50 percent compared to Case 3 or 4. Here then is an application where a large continuous feed irradiator could be used efficiently to improve infection control in a group of hospitals.

An important aspect of feasibility for a hospital irradiator is the dose uniformity that can be anticipated. Table 7.14 shows the estimated average dose-uniformity ratios for each candidate group in each of the six cases just discussed. Dose uniformity ratios much greater than 2:1 are probably marginally acceptable but should be alright for a development program. As the use increases and the more efficient Design C is used, the uniformity ratios drop well below 2:1 for all groups except Group 2. It should be recognized that these are average ratios based on the average density for each group. The actual ratios will be larger if materials of very different densities are processed in the same batch. In general however, dose uniformity ratios appear to fall within acceptable ranges.

TABLE 7.14. Dose Uniformity Ratios for Various Irradiator Concepts and Candidate Groups

<u>Case</u>	<u>Irradiator Concept</u>	<u>Group</u>	<u>Density g/cc</u>	<u>Average Dose Uniformity Ratio</u>
1	A/1	1	0.075	2.23
		2	0.444	3.43
		3	0.064	2.21
2	A/2	1	0.075	2.23
		2	0.444	3.13
		3	0.064	2.21
		4		
3	C/3	1	0.075	1.54
		2	0.444	2.15
		3	0.064	1.54
		4	-	-
		5	0.272	-
4	C/3	1	0.075	1.54
		2	0.444	2.15
		3	0.064	1.54
		4	-	-
		5	0.272	1.76
		6	0.08	1.54
5	D/3	1+3	0.064-0.075	1.45
6	D/3	5	0.272	1.70

CONCLUSIONS

Based on the results of this analysis the following specific conclusions were drawn:

1. A relatively large stop-dwell type irradiator can be adapted to operate with reasonable efficiency as a special purpose sterilizer in a large hospital.
2. The most efficient method of operation for the variety of items likely to be processed is a batch-charge mode.
3. For some special high volume items such as linen, a more efficient continuous irradiator could be operated to serve a large group of hospitals.
4. An irradiator could initially be operated as little as only one shift per day and still have acceptable costs for a development program.
5. Operations could be expanded to two and three shifts per day as programs expanded and the irradiator would operate more efficiently with lower costs as the use increased.
6. In the case of the Stanford University Hospital, respiratory therapy equipment, nonsterile disposables, and reusable items presently gas sterilized would provide a good base load for an irradiator development program.
7. A development program based on a large hospital irradiator would be most productive carrying out full scale production testing aimed at finding optimum dose requirements and efficient operating and material handling techniques. More basic research should be carried out in small facilities.

In a broader sense, based on the results of the analysis combined with the knowledge that hospital personnel generally are anxious for better sterilization and improved infection control methods, a large scale development program for a hospital irradiator such as that under consideration at Stanford University Hospital appears to be justified. There are enough potential applications where reasonable unit costs can be foreseen to make the prospects attractive.

Such a program should be designed on a large enough scale to obtain statistically valid measurements of reductions in nosocomial infection rates. At the same time, operating data can be accumulated on actual handling and processing costs in a hospital. For example, one component of the hospital could be furnished with radiation sterilized linen while another comparable component continued with present methods. Over a period of time improved infection control, if real, should be identifiable. At the same time, the handling and processing would have settled into a routine that could be realistically costed.

To be successful, a development program utilizing a large hospital irradiator will require strong leadership and a high priority and commitment from the hospital administration. It will require ingenuity and cooperation throughout the hospital to fully utilize the facility. Applications should be visualized in terms of production-type applications rather than individual isolated experiments.

Overall, the utilization of a large irradiator in a hospital should not be expected to pay for itself through operating cost savings. It will almost certainly result in increased hospital operating costs. Disinfection of linen, for example, would be a new procedure where no savings could possibly accrue. The primary incentive for a hospital irradiator is improved infection control. The exact magnitude of potential improvements can only be identified through a large scale development and test program. As with any new development program there is no assurance of success, but the potential for significant gains in terms of improved sterilization and infection control methods is certainly present.

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APPENDIX A
HOSPITAL SURVEY RESULTS

TABLE A-1. Hospital Survey Results -- General Hospital Characteristics

	Hospital A	Hospital B	Hospital C	Hospital D	Hospital E	Hospital F	Hospital G	Hospital H
1. Approximate number of beds currently in use	200	40	200	590	440	120	215	90
2. Hospital occupancy	70%	48%	90%	61%	64%	82%	80%	71%
3. Length of patient stay	5.4 days	8-10 days	8 days	8.1 days	7.5 days	4.7 days		5.1 days
4. Number of doctors on medical staff	400	88			250	275	522	96
5. Approximate number of outpatient visits	1,000 per month	No outpatient department	No outpatient service department	9,000 per month	2,500 per month	1,750 per month	1,700 per month	125 Referred outpatient visits per month
6. Services provided	Full Service	No OB: Referred ER* Services	No real ER* business; No OB or Pediatric Surgery	Full Service	Full Service	Full Service with ER* being referred	No obstetrics	Full Service
7. Date Hospital was built	1962	1930	1907	1909	1948	1962	1900	1929
8. Type (Proprietary, District, etc.)	Community Non-profit	Proprietary	Company Hospital	Local Gov't	District Hospital	Non-profit Community Hospital	Non-profit Community Hospital	Non-profit Community Hospital
9. Approximate number of Surgeries per month	500/mo		200/mo	500/mo	600/mo	400/mo	300/mo	125/mo
10. Number of FTE Employees (Full Time Equivalent)	365		500	1,950	800	350	600	180
11. Special Characteristics			75% of patients are male (20% are local)	Hospital has large number of clinics		Obstetrics makes up 40% of workload	Hospital has 62 bed psychiatric unit	

* ER = Emergency Room

TABLE A-2. Hospital Survey Results -- Sterilization Practices

Hospital	Equipment and Location	Utilization	Specific Items Sterilized and Quantities	Problem Areas
Hospital A 200 Beds	Central Services has 3 steam autoclaves and one gas cannister. Central Services autoclaves operating room instruments. It is located next to Surgery. Surgery has a flash steam sterilizer. Inhalation therapy equipment cleaned by Central Services. Linen sterilization done by Central Services	Estimate they process 20 packs a day in Central Services. Hospital felt that such instruments as fiber optic instruments and cystoscopic instruments should be gas autoclaved. One batch per day thru gas autoclave. Anything that is cloth that is autoclaved has a one month shelf life before autoclaving is required again. Inhalation therapy equipment is soaked in Cidex.* 6-8 loads/day in Central Services (250°F, 30 psi)	Gas cannister used mainly for X-ray equipment. Specific items such as pacemakers come in already sterilized from the Vendor. Solutions are autoclaved. Pharmacy makes up some solutions and these are autoclaved. Solutions are done at 230°F for 30 min (500 ml in 1500 ml bottle)	Hospital at present has no aerator. Hospital plans to add a large gas autoclave and aerator. Hospital states big disadvantage of gas autoclave is time which, in effect, means larger inventory of instruments is required. Storage of disposable linen was reported to be a problem. Aerate 12-24 hr (metal) 7 days (plastic)
Hospital B 40 Beds	Central Services has one large steam autoclave and one small steam autoclave. Central Services does bulk of sterilization. The Operating Room nurse utilizes a small gas cannister autoclave. Small autoclave used for flashing surgical instruments.	Gas cannister used once or twice a week. Large autoclave processes 4 loads per day.	Inhalation therapy equipment sent out to be cleaned.	
Hospital C 200 Beds	Surgery steam autoclaves their own instruments and also has a flash sterilizer. Large autoclave located in Central Services. Separate autoclave used by nursing to autoclave bed pans and bedside utensils.	(No information obtained on sterilization cycle.)	Cardiac catheters are gas autoclaved at another hospital. Bedside utensils are steam autoclaved. Surgical inhalation therapy (anesthesiology) equipment is soaked in Cidex. Other inhalation therapy equipment is gas autoclaved. Bacteriology plates of various cultures are sterilized before being discarded. They autoclave sheets and gowns for burn patients.	

* Glutaraldehyde

TABLE A-2. (Contd)

Hospital	Equipment and Location	Utilization	Specific Items Sterilized and Quantities	Problem Areas
Hospital D 590 Beds	<p>Central Services sterilizes surgical trays and packs. Autoclaves also located in many of the clinics of the hospital.</p> <p><u>Central Services Equipment:</u></p> <p>3 large steam autoclaves 1 small steam autoclave 1 dry oven 1 gas autoclave 1 aerator 1 washer/sterilizer</p> <p><u>Other autoclaves in Hospital:</u></p> <p>Emergency Room Surgical Clinic Delivery Obstetrics and Gynecology Clinic Eye Clinic Pathology Flash Sterilizer in Surgery</p>	<p>Steam autoclaves require 30 minutes to 2 hours per cycle. Gas autoclaves require 15 to 24 hours per cycle including aeration time.</p>	<p>Central Services autoclaves surgical packs, trays, OB and nursery linen. Bedside utensils are sanitized at nursing units by nursing aides. Inhalation therapy equipment is gas autoclaved.</p> <p>Handles 25 kidney patients each week. These people must have their blood changed 3 times per week. Shunts are cleaned in the autoclave. Coils are cleaned in formaldehyde.</p>	<p>How does one really know that the gas has been removed from an item that has been gas aerated? Particularly critical for respiratory equipment.</p> <p>For non-sterilizable rubber goods they use a Cidex solution. Staphene solution used for metal wares. How do we know items are really sterile? Items probably are not completely sterilized but are disinfected to some degree.</p> <p>Hospital needs larger inventories if gas sterilization is to be used more extensively.</p> <p>Certain inhalation therapy items are thought to be sources of infection.</p>
Hospital E 440 Beds	<p>Central Services has one large steam autoclave and one small steam autoclave. Central Services has one small gas sterilizer.</p> <p>Boiling water sterilizers on nursing floor. They also have some bedpan wall-type sterilizers.</p> <p>Surgery has a flash steam sterilizer.</p>	<p>1 large steam autoclave to autoclave surgical items. They process 3 to 4 loads per day.</p> <p>1 small steam autoclave in Central Services processes about 4 to 5 loads per day.</p> <p>One batch in gas autoclave takes 5 1/2 hours (long additional aeration time required).</p> <p>Present method of disinfecting bacteriological frozen cultures is to spray with disinfectant after thawing.</p>	<p>Central Services prepares packs for surgery.</p> <p>Oxygen regulators used by inhalation therapy are cold sterilized with Cidex. They use Cidex to clean most of their inhalation therapy equipment.</p> <p>Bacteriological plates are collected in plastic bag and autoclaved before discarded.</p> <p>Emesis basins and bedpans sterilized on nursing floor.</p> <p>All pathological waste is incinerated.</p>	<p>Claimed ethylene oxide must never be used on an irradiated product. (Item is said to give off a toxic gas, particularly poly-vinyl-chloride type plastics.)</p> <p>Some frozen sections can be dangerous, particularly lung nodules which pathologist does not know is infected until frozen section is examined.</p> <p>Hepatitis is another concern.</p> <p>Adequate sterilization of fiber optic equipment is a concern.</p> <p>Equipment suggested for radiation sterilization included:</p> <ol style="list-style-type: none"> 1. Cystoscope 2. Fiber optic lighting equipment 3. Bronchoscopy equipment 4. Laryngoscope

TABLE A-2. (Contd)

Hospital	Equipment and Location	Utilization	Specific Items Sterilized and Quantities	Problem Areas
Hospital F 120 Beds	Hospital has total of 7 steam autoclaves and a gas autoclaves. Central Services has 1 large steam autoclave and 1 small steam autoclave. All surgical linen is sterilized in Central Services. Surgery has a flash steam sterilizer.	Process 5 loads per day in large steam autoclave. Gas autoclave runs 3-5 loads per day. They gas autoclave such things as heart catheters, neurological instruments, instruments for the coronary care unit.	Steam autoclave major surgical packs in Central Services. All surgical linen autoclaved in large steam autoclave. Bedside utensils autoclaved in small steam autoclave. Hospital uses reusable surgical linen and Central Services sterilizes all surgical linen. Approximately 15-17 trays are processed in Central Services and 12 of these are stored in Central Services. Central Services autoclaves inhalation therapy equipment.	Supervisor stated that residual effect noted on linen which has been sterilized in small steam autoclave. Things which cannot be steam sterilized include: 1. Transducers for arterial blood measurements. 2. Bovies (Cauterizing machine used in surgery) 3. Suction Tips 4. Needles 5. Catheters 6. Laprascope 7. Endoscope and bronchoscope items Human tissue for skin grafts, if stored, is stored in an antibiotic solution in a refrigerator.
Hospital G 215 Beds	Central Services has 2 steam autoclaves. They autoclave irrigating solutions for surgery in one. They process packs and trays in other autoclave. Gas cannister is located in inhalation therapy. Hospital utilizes a huge steam autoclave 36" x 42" x 84" which is operated by Maintenance Dept. Four different units of the hospital use the gas autoclave located in inhalation therapy. They are: 1. Medical Intensive Care Unit 2. Hemodialysis Unit 3. Inhalation Therapy Unit 4. Central Services sterilizes fiber optic equipment here. Surgery has a flash steam sterilizer	Approximately 4 loads of packs and trays are processed each day shift. Only one load processed each day in large autoclave operated by Maintenance Dept.	Cysto equipment is cold sterilized. Anesthesiology equipment is gas autoclaved. Gas sterilization used for inhalation therapy equipment. Hospital is establishing an 18 bed Hemodialysis (kidney) Center. They use 2 different pieces of equipment: <u>Acute Patient</u> The tubing and the coil on this equipment is never reused. Every 2 weeks the machine and pump are cleaned with formaldehyde. For acute patients only arterial-venous shunts are used. <u>Chronic Patient</u> The Dow system is used for chronic patients. After each use, machine goes to lab and is cleaned with formaldehyde.	Surgery does gas autoclave some disposable items to save money. They have a problem in getting them aerated.

TABLE A-2. (Contd)

Hospital	Equipment and Location	Utilization	Specific Items Sterilized and Quantities	Problem Areas
Hospital H 90 Beds	<p>Most sterilization done by Central Services. They have one large steam autoclave.</p> <p>Petri dishes are incinerated after use. Glass tubing is autoclaved and then discarded.</p> <p>Surgery has a large steam autoclave as well as a flash sterilizer.</p>	Central Services processes 2 big loads per day in their steam autoclave.	<p>Items which are steam autoclaved by Central Services include dressing packs, reusable gloves, peri pads, bulk dressings, fluffs, disposable trach tubes, ice scoops, etc.</p> <p>Surgery autoclaves their own surgical packs and linens.</p> <p>Anesthesiology equipment is soaked in Elimistap No. 2 (cold sterilization). Following items are cold sterilized:</p> <ol style="list-style-type: none"> 1. Urology instruments 2. Fiber optics 	Hospital states they have no need for a gas autoclave.

TABLE A-3. Hospital Survey Results--Cleaning and Sanitation Practices

Hospital	<u>Surgical Cleaning</u>	<u>Patient Room Cleaning</u>	<u>Discharge Room Cleaning</u>	<u>Daily Routine Isolation Room Cleaning</u>	<u>Discharge Isolation Cleaning</u>
	<ul style="list-style-type: none"> • Who Performs • Procedure • Frequency • Cleaning Agents Used 	<ul style="list-style-type: none"> • Who Performs • Procedure • Frequency • Cleaning Agents Used 	<ul style="list-style-type: none"> • Who Performs • Procedure • Cleaning Agents Used 	<ul style="list-style-type: none"> • Who Performs • Procedure • Cleaning Agents Used 	<ul style="list-style-type: none"> • Who Performs • Procedure Used • Cleaning Agents Used
Hospital A 200 Beds	Maid cleans operating room between operations.	Waste picked up on a continuous basis daily. Regular waste is double bagged in plain color bag. Germicide used for general cleaning is called 728 (brand name).	Housekeeping performs discharge room cleaning. Carpet cleaner is Recine. Housekeeping service is contracted out to "Red Top" a housekeeping management service organization.	Isolation waste is double bagged and bag is color coded (red bag) to identify it.	
Hospital B 40 Beds	Alcohol (isopropyl) used to wipe operating room furniture. Men do the cleaning of floors after surgery. Surgical nurses do the washing of the surgical room furniture.	Osil is the main cleaning agent used in the hospital.	Cleaned by housekeeping using Osil.	Personnel gown up and use alcohol (isopropyl) to clean room.	This hospital always fogs to disinfect after isolation patient is discharged. They use Elimstaph No. 2 to fog.
Hospital C 200 Beds	Matar is used to wash down operating room furniture. Surgical personnel clean surgery with the help of one housekeeping porter.	Housekeeping cleans patient rooms. Cleaning agent used is Lab No. 1.	Bed is washed down with soap and water. Nursing makes up the bed upon patient discharge.	Personnel gown up and use alcohol to clean room.	Alcohol is the cleaning agent used after isolation patient discharged.
Hospital D 590 Beds	Housekeeping does cleaning of operating rooms between operations.	Each nursing unit has a 30 gal can. Can is emptied twice daily. Total of 29 nursing units in hospital. Housekeeping cleans patient floors. Housekeeping cleans bathroom fixtures daily. Staphine and LPH are cleaning agents used.	Nursing cleans the bed frame upon discharge of patient.	Housekeeping gowns up to perform isolation room cleaning.	Hospital does no fogging. Mop heads are destroyed after cleaning an isolation room upon discharge of patient.

Table A-3. (Contd)

	<u>Surgical Cleaning</u>	<u>Patient Room Cleaning</u>	<u>Discharge Room Cleaning</u>	<u>Daily Routine Isolation Room Cleaning</u>	<u>Discharge Isolation Cleaning</u>
	• Who Performs	• Who Performs	• Who Performs	• Who Performs	• Who Performs
	• Procedure	• Procedure	• Procedure	• Procedure	• Procedure
	• Frequency	• Frequency	• Cleaning Agents Used		
<u>Hospital</u>	<u>• Cleaning Agents Used</u>	<u>• Cleaning Agents Used</u>		<u>• Cleaning Agents Used</u>	<u>• Cleaning Agents Used</u>
Hospital E 440 Beds	Floor is cleaned by porter who reports organizationally to Surgery. Surgery furniture washed by the nurses using soap and alcohol.	Skleen and LPH are used on carpets in nursing corridor.	Housekeeping cleans room after patient discharge. Nursing strips bed. Rooms are periodically washed with Sano-six which is a disinfecting agent. Housekeeping makes bed following patient discharge.	LPH is the disinfectant used for isolation cleaning.	Mops used to clean an isolation room after patient has been discharged are discarded. Housekeeping does isolation room cleaning.
Hospital F 120 Beds	Operating room cleaned by surgery personnel after each operation. Floors are mopped and OR furniture is washed. Ophine is used to clean both surgical furniture and floor.	Main cleaning agents are Vesphine and Ophine 15. Trash picked up once per day or as needed from patient's room. Needles, glassware, trash, and linen separated on nursing units.	Discharge cleaning done by maids who clean bedside utensils, the bed, bedframe, and take out soiled linen. Housekeeping porters do the floor work and periodic wall washing.	Housekeeping personnel gown up and clean rooms. Isolation trash is put in a red bag (double bagged).	No fogging. Room thoroughly cleaned and washed down. Equipment used in cleaning room is washed down and cleaned following its use.
Hospital G 215 Beds	Operating room nurses wash down the surgical furniture following each case.	Maid removes trash from patient rooms. Plastic liners are tied and dropped down trash chute. Staphine used to clean bedside utensils. Bedside utensils are sterilized on the nursing unit using either steam sterilization or chemical (cold) sterilization. Carpets are shampooed once a month. All nursing corridors are carpeted.	Housekeeping department does discharge cleaning. Nursing will strip the bed.	Housekeeping personnel gown and do routine cleaning of isolation cases. Hospital uses a card system to identify type of isolation patient.	Hospital has a very highly procedurized set of isolation policies and procedures. Sano-six is the disinfectant used to clean and fog isolation rooms. Rooms are fogged according to infectious disease.
Hospital H 90 Beds	Full time porter is assigned to surgery to clean between cases. Elimstaph No. 2 is the cleaning agent used in surgery.	Housekeeping maids do routine cleaning.	Housekeeping strips bed and does discharge cleaning.	Cleaning agent used to clean isolation rooms is Wescadine (iodine solution).	Housekeeping strips the bed. Room is fogged after isolation patient is discharged using Elimstaph. Everything left in room to be fogged.

TABLE A-4. Hospital Survey Results -- Waste Disposal Practices

Hospital	Lab and Pathology Waste	Other Infectious Waste	Hospital Trash and Non-Infectious Material
	<ul style="list-style-type: none"> • Disposal of Tissues • Bacteriology Cultures • Autopsies • Liquid Waste 	<ul style="list-style-type: none"> • Isolation Waste • Surgical Waste 	<ul style="list-style-type: none"> • Patient and Nursing Trash • Kitchen • General Areas • Problems
Hospital A 200 Beds	Pathological waste is burned in a gas fired incinerator. Housekeeping picks up surgical waste except for amputations. Pathological waste such as bacteriological plates, glassware, tubing, plates, etc. are autoclaved before incineration.	Estimate 4 to 6 isolation bags per day. Specimens and organs removed from body are put in Formalin.	Total hospital waste estimated at 1000 to 4000 pounds per day (5 to 20 lb/pt/day). Hospital incinerates all burnable wastes. Nonburnable items such as glass are picked up by a private carrier. Trash is collected internally using hand pushed cart. All waste is double bagged. Present problem is that waste could remain unburned overnight. 3/4 burnable, 1/4 to Dumpster (500 yards max. trip). Have twice "passed" BAAPCD* inspections. Waste hauled 5 miles.
Hospital B 40 Beds	Pathological waste given to a hospital in Berkeley. Bacteriology plates are put in destruction furnace along with needles and syringes. Bacteriology runs 400 specimens per month. Approximately 2300 to 2400 petri dishes are used. They use approximately 1200 non-disposable glass items.	Marked bags are used for isolation trash and waste material.	Trash collected in metal containers at the the nursing units. Every soiled utility room has a container. Trash is collected from patient rooms twice a day. All trash is stored in 14 cubic yard box which is picked up 3 times per month. Needles and syringes are burned in a destruction furnace. Needles are used at the rate of 1000 a month. Private scavenger company collects trash.
Hospital C 200 Beds	Pathological waste is incinerated. Bacteriology culture plates are autoclaved before discarding. 5 to 10% of pathological tissues are pathogenic. Pathological specimens are kept 3 to 4 weeks.	Isolation waste is incinerated. Waste from isolation rooms are double bagged and taken to incinerator.	All burnable waste is incinerated. Non-burnable items and wet garbage is picked up by a scavenger service and hauled to Mountain View. There is not an exact or distinct separation of burnable and non-burnable items. Their incinerator has a barometric dampner. Trash is collected in large 30 gallon cans. Trash bags are taken to chute. Trash lands in an area close to incinerator.

* Bay Area Air Pollution Control District

TABLE A-4. (Contd)

	<u>Lab and Pathology Waste</u>	<u>Other Infectious Waste</u>	<u>Hospital Trash and Non-Infectious Material</u>
	<ul style="list-style-type: none"> . Disposal of Tissues . Bacteriology Cultures . Autopsies . Liquid Waste 	<ul style="list-style-type: none"> . Isolation Waste . Surgical Waste 	<ul style="list-style-type: none"> . Patient and Nursing Trash . Kitchen . General Areas . Problems
<u>Hospital</u>			
Hospital D 590 Beds	<p><u>Pathology Waste</u> Pathological waste is incinerated. Pathological specimens go in a plastic container to pathology. If specimen is to be kept for any length of time, it is put in 10% solution of Formalin. If specimen is large, it may be put in saline solution. Amputated limbs are sent to morgue where pathologist will examine.</p> <p>Bits of viscera from a body make up most of the waste and most is not infectious. General policy is that all viscera is examined and then put in Formalin. Hospital has written procedures and policies on waste disposal. All solid wastes to be contained at their source.</p> <p><u>Bacteriological Waste</u> Bacteriological waste is placed in old army 5-gallon soup cans. They use disposable petri dishes for cultures. 1000 petri dishes (plastic) 300 tubes are put into a decontamination sterilizer daily. Then into regular waste.</p> <p>250 autopsies per year. 15 to 20 pounds of pathological tissue/autopsy sent to incineration. Surgical tissue kept in Zinkers (2% gluteraldehyde). TB can survive this.</p>	<p>Isolation waste double bagged and incinerated.</p> <p>Isotopic waste is collected in plastic containers and disposed of by University of California which operates pathological laboratory (UC at Berkeley).</p>	<p>The bulk of hospital waste is compacted. Compacted trash hauled away to Mountain View.</p>
Hospital E	<p>Glass and pathological waste is burned. Incinerated items include pathological items, laboratory waste, and some isolation material.</p> <p>Wet garbage is put through grinder and goes down the drain.</p> <p>BACT: 8000 specimens/yr = 75,000 containers (mostly disposable plastic).</p> <p>Containers placed in plastic bag and sent to lab for autoclaving.</p>	<p>All isolation waste is double bagged in a red plastic bag and gas autoclaved. It is then incinerated. (Isolation cases amount to only one or two per month.)</p>	<p>Trash from patient rooms is emptied into 55 gallon drums which have a plastic liner and are mounted on wheels. Contents of drum when emptied will range from 35 to 50 pounds. Hand truck used to collect lined bags from drum. Trash and waste is taken to compactor. All trash is compacted. Compacted waste is picked up by private scavenger company.</p> <p>Compactor box is a 22 cubic yard box. It is emptied when full, about every fifth day.</p>

TABLE A-4. (Contd)

	<u>Lab and Pathology Waste</u>	<u>Other Infectious Waste</u>	<u>Hospital Trash and Non-Infectious Material</u>
<u>Hospital</u>	<ul style="list-style-type: none"> Disposal of Tissues Bacteriology Cultures Autopsies Liquid Waste 	<ul style="list-style-type: none"> Isolation Waste Surgical Waste 	<ul style="list-style-type: none"> Patient Nursing Trash Kitchen General Areas Problems
Hospital F 120 Beds	<p>Pathological waste is burned in an incinerator. Petri dishes are autoclaved and then disposed of via the collection box.</p> <p>400 cultures/mo = 2300 plastic petris 1200 nondisposable glass (both are autoclaved).</p> <p>100 needles/mo</p>	<p>Isolation trash put in a red bag. Isolation waste is double bagged. Operating room waste is put in plastic bags and taken to bin.</p> <p>A grinder is used in autopsy room for blood and fecal matter.</p>	<p>Needles and syringes are burned in the incinerator. Majority of trash and waste is collected and stored in a 14 cubic yard collection box. This city picks it up and hauls it away 2 1/2 miles to a sanitary landfill. Of total trash, 1/3 estimated to come from patient area and 2/3 from service areas.</p> <p>Burning in compliance with BAAPCD (less than 0.15 grains per cubic foot of particulate, less than 1 Ringleman, less than 25 parts per million of hydrocarbons).</p>
Hospital G 215 Beds	<p>Petri dishes are incinerated. Needles are burned. Bacteriology trash is collected two or three times per week.</p> <p>Organs removed during autopsy are put back in body.</p> <p>Laboratory uses incinerator to burn pathological waste.</p> <p>Approximately 900 cultures/mo = 2700 dishes/mo</p>	<p>All isolation waste is picked up by janitor and physically carried down to incinerator. Isolation linen is double bagged.</p> <p>Isolation waste is burned in the incinerator by Maintenance Department.</p>	<p>Hospital utilizes a trash chute. Hospital collects all their trash and waste material in a large 20 cubic yard container. A private carrier hauls it away. They estimate they have 18 loads per month. Glassware is separated on the nursing units and goes to trash box. Contaminated needles are burned. Needles which are not contaminated are broken and go down the chute with the rest of the waste.</p>
Hospital H 90 Beds	<p>Small pathological specimens are ground up. Larger specimens are incinerated. Large amputated limbs are sent to mortuary for burning. Estimate their cultures to be 1000 to 2000 per year. Use (4 petri dishes per culture + 2 tubes). Laboratory in this hospital does have a garbage disposal (grinder). Liquid infectious waste flushes down toilet.</p> <p>6x(1-2000) pieces of bact containers petri → incinerator tubes → Central Services autoclave</p> <p>17,354 clinical lab tests per year</p>	<p>Surgical waste is incinerated. Surgical specimens go to laboratory. Contaminated dressings are bagged and incinerated.</p>	<p>Wet garbage, tin cans, and bottles are put in garbage cans which are picked up and hauled to a sanitary land fill. All combustible material is incinerated. Wet garbage which is picked up usually fills 11-30 gallon cans. These cans are picked up twice each week.</p> <p>Combustible incinerated material was estimated to be 200 pounds per day.</p> <p>Incinerator is not gas fired. The afterburner chamber on the stack is gas fired. They have had several citations.</p>

TABLE A-5. Hospital Survey Results -- Practices Regarding Use of Reusable and Disposable Items

Hospital	Equipment and Volume	Sterilization Methods	Shelf Life and Inventory
Hospital A 200 Beds	Bedside Utensils: Reusable		
	Packs, Sets, & Trays: Predominantly Reusable; 20 packs per day	Steam Sterilized	
	Surgical Linen: Some disposable linen used in surgery	Steam Sterilized	
	Regular Linen: 17.5 pounds per patient day - Commercial Laundry		
	Surgical Gowns: Some disposable surgical gowns		Average life of reusable surgical drape estimated to be 3 months
	Patient Treatment Items: Central Services estimates 70% of volume to be reusable and 30% disposable		
	Dietary Trays, Dishes, Etc: Dishes for isolation patients are paper		
	Inhalation Therapy Equipment: No information obtained	Cold Sterilized by Central Services	Cloth package shelf life is 1 month; All others have shelf life of 3 months
Hospital B 40 Beds	Anesthesiology Equipment: No information obtained		
	Bedside Utensils: Bedpans are reusable. Other bedside utensils are disposable.	Steam Sterilized	
	Packs, Sets & Trays: Majority of trays and packs they use are disposable	Those that are sterilized are steam sterilized	
	Surgical Linen: Reusable		
	Regular Linen: Reusable		
	Surgical Gowns: Gowns are reusable		
	Patient Treatment Items: Majority of items are disposable		
	Dietary Trays, Dishes, Etc.: Dishes for isolation patients are paper		
	Inhalation Therapy Equipment: Sent out to be cleaned (Service is contracted out)		
	Anesthesiology Equipment: No information obtained.		

TABLE A-5. (Contd)

Hospital	Equipment and Volume	Sterilization Methods	Shelf Life and Inventory
Hospital C 200 Beds	Bedside Utensils: Reusable	Bedside utensils are steam autoclaved	
	Packs, Sets, & Trays: Disposable items include catheters, prep sets, needles, and syringes. Most trays and packs are disposable. Instrument sets are reusable.		
	Surgical Linen: Operating Room uses disposable surgical drapes		
	Regular Linen: Reusable		
	Surgical Gowns: Disposable surgical gowns and gloves		
	Patient Treatment Items: Catheters are disposable. Thermometers are reusable.		
	Dietary Trays, Dishes, Etc.: Dishes for isolation patients are paper and are disposable		
	Inhalation Therapy Equipment: Reusable		
	Anesthesiology Equipment: Reusable		
	Bedside Utensils: Basically reusable		
Hospital D 590 Beds	Packs, Sets, & Trays: Hospital uses predominantly reusable	Sanitized on nursing floor	Inventory is 3 times amount in use
	Surgical Linen: Hospital uses reusable surgical drapes	Gas autoclaved	
	Regular Linen: Reusable	Cold sterilized (Cidex)	
	Surgical Gowns: Reusable	Steam autoclaved if necessary by Central Services	
	Patient Treatment Items: See "other"		
	Dietary Trays, Dishes, Etc.: Dietary dishes for isolation patients are disposable		
	Inhalation Therapy Equipment: Daily: 25-40 humidifiers and nebulizers, 10-30 Bird sets, 1-2 units.	Gas 5 hours, aerate 8 hours. (Out of use 36 to 72 hours)	

TABLE A-5. (Contd)

Hospital	Equipment and Volume	Sterilization Methods	Shelf-Life and Inventory
Hospital D (Contd)	Anesthesiology Equipment: No information obtained Other: Hospital uses the following disposable items: syringes, needles dressings, suction catheters, tubings, obstetrics, gloves, IV tubings, catheters, drainage bags, manometers, scalpel blades and handles, and some catheter trays		
Hospital E 440 Beds	Bedside Utensils: Reusable Packs, Sets, & Trays: Packs are reusable Surgical Linen: Reusable Regular Linen: No information obtained Surgical Gowns: Use reusable surgical gowns. Patient Treatment Items: Majority of patient treatment items are disposable. Thermometers are reusable. Hospital makes its own distilled water. Catheters are disposable. Majority of needles and syringes are disposable. Irrigating and saline solutions are purchased. Dietary Trays, Dishes, Etc.: Dishes for isolation patients are disposable. Inhalation Therapy Equipment: Reusable Anesthesiology Equipment: Reusable	Using a boiling water sterilizer. Cleaned on nursing floor by nurses. Packs are steam autoclaved 40 minutes at 250 °F. Steam autoclaved by Surgery Steam autoclaved Thermometers are cold sterilized. Most of this equipment is sterilized using a cold wet process. LPH which is a chemical detergent is used with Cidex. They would use gas on gages and instruments if they felt they were badly contaminated.	
Hospital F 120 Beds	Bedside Utensils: Reusable Packs, Sets, & Trays: Surgical packs are reusable	Steam Sterilized by Central Services after cleaning by Housekeeping. Steam Sterilized. 9 to 10 surgical packs processed in Central Services each day.	Inventory of packs turns over 2 to 3 times per month.

TABLE A-5. (Contd)

Hospital	Equipment and Volume	Sterilization Methods	Shelf-Life and Inventory
Hospital F (contd)	<p>Surgical Linen: Surgical linen is reusable</p> <p>Regular Linen: Done by a shared services facility</p> <p>Surgical Gowns: Most gowns are disposable</p> <p>Patient Treatment Items: Central Services estimates 50% of volume is disposable and 50% reusable. Tubing, syringes, gloves, gowns, IV sets, needles, suction tips, etc. are disposable.</p> <p>Dietary Trays, Dishes, Etc: Dietary dishes for isolation patients are disposable.</p> <p>Inhalation Therapy Equipment: No information obtained.</p> <p>Anesthesiology Equipment: No information obtained.</p>		Everything gas autoclaved is re-autoclaved every 3 months.
Hospital G 215 Beds	<p>Bedside Utensils: Bedside utensils are reusable. Hospital using stainless steel bedpans but recently purchased some plastic ones.</p> <p>Packs, Sets, & Trays: Majority of trays are reusable. Surgical packs are disposable.</p> <p>Surgical Linen: Most of the surgical drapes are disposable.</p> <p>Regular Linen: Reusable</p> <p>Surgical Gowns: Reusable gowns are used</p> <p>Patient Treatment Items: CS estimate that their volume is 50% disposable and 50% reusable. Nursing feels the majority of patient treatment items are disposable.</p>	<p>Staphine used to clean bedside utensils.</p> <p>Reusable packs and trays are steam autoclaved.</p> <p>Linen is laundered in-house.</p>	

TABLE A-5. (Contd)

Hospital	Equipment and Volume	Sterilization Methods	Shelf-Life and Inventory
Hospital G (Contd)	Dietary Trays, Dishes, & Etc: Dishes for isolation patients are disposable.		
	Inhalation Therapy Equipment: Reusable	Most of the inhalation therapy equipment is gas autoclaved.	
	Anesthesiology Equipment: Reusable	Anesthesiology equipment is gas autoclaved.	
	Bedside Utensils: Bedside utensils are reusable.	Sterilized by boiling on nursing floor.	
Hospital H 90 Beds	Packs, Sets, & Trays: Most of the trays are reusable.		
	Surgical Linen: Surgical linen is pre-dominantly reusable.	Surgical linen is autoclaved by Surgery personnel.	
	Regular Linen: Reusable	Regular linen is sent to commercial laundry.	
	Surgical Gowns: Hospital uses reusable surgical and obstetrical drapes.		
	Patient Treatment Items: Many disposable items used.		
	Dietary Trays, Dishes, Etc: Disposable dishes used for isolation patients.		
	Inhalation Therapy Equipment: Inhalation therapy work is contracted out to Allied Pulmonary.		
	Anesthesiology Equipment: No information obtained.		
	Other: Examples of disposable items used by hospital include: needles, syringes, irrigating syringes, suction catheters, levine tubes, Foley catheters, chuck pads, etc.		

Table A-6. Hospital Survey Results -- Linen Handling Practices

Hospital	<u>Surgical Linen</u>	<u>Patient Linen</u>	<u>Isolation Linen</u>
	<ul style="list-style-type: none"> Type and Volume Cleaning and/or Sterilization Procedure 	<ul style="list-style-type: none"> Type and Volume Cleaning and/or Sterilization Procedure 	<ul style="list-style-type: none"> Type and Volume Cleaning and/or Sterilization Procedure
Hospital A 200 Beds	Disposable linen is used in surgery for cysto packs and D & C operations. They use disposable gloves as well as disposable caps and gowns. Some surgeons use disposable gowns.	Total linen usage estimated at 17.5-20 lbs of linen per patient per day. Hospital uses thermal blankets and a bedspread. Hospital tried out disposable linens 3 years ago but had problem with volume. Also incinerator could not handle volume.	Infected linens from isolation rooms are double bagged. All linen sent to a commercial laundry.
Hospital B 40 Beds	Bulk of surgical linen is reusable.	Regular linen is done by a commercial laundry.	Separated from other linen by a marked bag. Commercial laundry does all linen.
Hospital C 200 Beds	Operating room uses disposable surgical drapes. Disposable surgical gowns and gloves are used.	All regular laundry is done in-house. Dirty linen is collected and fed into a laundry chute.	Bagged separately but laundered in hospital's own laundry. Linen from isolation rooms is double bagged. First bag dissolves in water.
Hospital D 590 Beds	Obstetrics, delivery, and nursery linen is autoclaved by Central Services. All linen for surgery, obstetrics, and burn cases is sterilized by Central Services.	Hospital does its own laundry. 20 lbs per day per patient.	Bagged separate from other linen. Done by hospital in-house laundry.
Hospital E 440 Beds	Surgical linen is autoclaved by surgery. Only surgical autoclaving done by Central Services is for items that can be sterilized by gas.	Nursing changes bed and they collect soiled linen. Soiled linen put in large bag and carried from room to room until it is full. Nursing strips bed upon patient discharge. Soiled linen bag is taken to laundry chute when it is full.	Isolation soiled linen is double bagged. Isolation gowns are double bagged.
Hospital F 120 Beds	They are using reusable drapes. Surgical drapes are cleaned by shared services laundry but sterilized by Central Services.	Linen is done by a shared services facility.	Double bagged and sent to shared services laundry.
Hospital G 215 Beds	Surgical packs are predominantly disposable. They do use reusable surgical gowns. Most of the surgical drapes are disposable.	20,000 lbs of linen is processed per week by the hospital's laundry. This includes all reusable surgical linen, drapes, and uniforms.	Isolation linen is double bagged. The first bag is water soluble and dissolves. The second bag is a red plastic bag. The second bag after being emptied is thrown in trash.
Hospital H 90 Beds	Most surgical linen is reusable.	Done by a commercial laundry.	Contaminated linen is put in a single bag which is marked to indicate that it has contaminated linen. All linens sent out to a commercial laundry.

Table A-7. Hospital Survey Results -- Infection Control Practices

INFECTION CONTROL				
<u>Hospitals</u>	<u>Available Statistics on Infection</u>	<u>Method & Type of Surveillance</u>	<u>Problems Unique to Hospital</u>	<u>Isolation Technique</u>
Hospital A 200 Beds	Have not maintained many statistics but plan on reporting statistics regarding attack rate and urinary infection. Hospital reports nosocomial infections are rare. Staph infections mainly from orthopedic cases.	Surveillance is done through nursing services who report infections and suspicious would drainages to Infection Control Committee. Committee is headed by the hospital pathologist. Lab estimates they take 100 cultures per month as part of environmental culture program.	None reported. Nebulizers and other IT equipment is thought to be a source of infection.	Double bag infectious waste from isolation rooms. Pathologists wear gloves when performing an autopsy.
Hospital B 40 Beds	Nine reported infections in 1972. Seven reported infections in 1971. No nosocomial infections.	Surveillance is done through nursing services.	None reported.	Infectious waste is bagged separately. All waste is stored in central 14 cubic yard containers. Standard rule to fog isolated patient's room following discharge.
Hospital C 200 Beds	They keep statistics by: 1. Clean wound 2. Clean contaminated 3. Contaminated 4. Type of infection 5. Acquired in hospital or came in with it They have not had any nosocomial infections. They calculate the number of clean wound infections against the total number of operative procedures performed.	Surveillance generally through nursing services. 1. Report suspicion of infection to nurse supervisor 2. Nurse supervisor informs doctor 3. Doctor takes culture specimen 4. Nurse can take culture specimen They have a routine culture program. Culture or, laundry, kitchen, as well as cardio-pulmonary equipment. 3-5% Nosocomial infection rate.	Hospital has large number of TB patients. They estimate 6 to 7 isolation cases in hospital all the time. Old facility causes problems. More positive cultures due to this.	They gown for autopsies. Gown when going in isolation patient's room.

Table A-7. (Contd)

INFECTION CONTROL				
Hospitals	Available Statistics on Infection	Method & Type of Surveillance	Problems Unique to Hospital	Isolation Technique
Hospital D 590 Beds	<p>Infection Control Nurse maintains many statistics on infections in hospital. She maintained separate statistics on urinary tract infections. Also keeps information on number of infected sites based on number of discharges. They record all hospital infections by type such as:</p> <p>Endometritis Respiratory Tract Urinary Tract Gastro-intestinal IV intracaths Cutdown sites</p> <p>Develop attack rate statistics based on:</p> $\frac{\text{No. of cases specific infection}}{\text{No. persons at risk}} \times 100 = \text{Attack rate}$	<p>Hospital has Infection Control Nurse. This nurse reports to Chairman of Epidemiology Committee who is a MD. Infection Control Nurse makes rounds of entire hospital twice each week. All surveillance done by this nurse. She checks patients charts. Case finding methods used by Infection Control Nurse include:</p> <ol style="list-style-type: none"> 1. Bacteriological reports 2. Ward rounds 3. Informal reports from nursing <p>Hospital has a surveillance culturing policy.</p>	<p>This is the general county hospital. They get numerous accidents, gun shot wounds, drug cases, etc. They have a Trauma Team on duty at all times.</p> <p>Hospital does a lot of kidney dialysis work. Coils to dialysis machine are cleaned in formaldehyde.</p> <p>Quality assurance cultures are done on a problem oriented basis. They do not culture on a routine basis.</p>	<p>Contaminated lab items such as specimens and cultures are autoclaved and then put in garbage carts.</p> <p>All specimens from infected patients are flagged. Special lab procedures are used such as lab techs handling specimens with care.</p> <p>This hospital spells out in procedures what equipment and supplies must be available for isolation procedures.</p>
Hospital E 440 Beds	<p>Hospital has Infection Control Nurse. She follows all diagnoses particularly bacteriological diagnoses.</p> <p>3-5% of Disch. get nosocomial infectious (approximately 35% are urinary tract).</p>	<p>Any infectious matter reported to Infection Control Nurse. Nursing and lab have input to the system. Infection Control Nurse records data and statistics.</p> <p>Hospital has routine culture program. Cultures also taken by request as well as on a routine basis.</p> <p>No routine environmental culturing except: ice machine, I.T. equipment and solutions, pool, autoclaves (fraction positive is very small).</p>	<p>Pathologist stated that irradiated plastic items have caused them problems in their nuclear medicine work. Apparently the plastic breaks down. Colloidal material breaks down giving unusual results.</p>	<p>Hospital deliberately tries to avoid admitting infectious patients. For example, they will not admit a known TB patient. They send infectious patients to county hospital.</p>

Table A-7. (Contd)

INFECTION CONTROL				
Hospitals	Available Statistics on Infection	Method & Type of Surveillance	Problems Unique to Hospital	Isolation Technique
Hospital F 120 Beds	Pathologist estimates that they have 10 to 15 nosocomial infections per year. This includes tracheotomy patients in the intensive care unit.	Cultures run regularly on staph patients. Hospital has routine culture program, which includes autoclaves, surgery, nursing, and isolation rooms. Every autopsy is cultured.	Pathologist did not feel that gas sterilization kills virus. Pathologist feels expensive autopsy knives would lend themselves to irradiation. Steam sterilization ruins them.	
Hospital G 215 Beds	No. of cultures done in August, 1972, were as follows: Blood cultures = 82 Urine cultures = 211 Misc. cultures = 594 Stool. cultures = 18 905 They routinely culture floors, equipment, autoclaves, equipment, etc. They will culture a draining wound even if doctor doesn't request it.	Surveillance is done via Nursing Services.		Isolation procedures taken from Medical College of Virginia where director of nursing took her graduate work.
Hospital H 90 Beds	Perform routine cultures. Culture hospital on a routine basis (quarterly). Culture speciality units much oftener. Surgery cultured monthly.	Nursing is the surveillance source. They report suspicious would drainage to doctors. 1971: 71 post operative infections 30 other (eg. pneumonia) 1375 operations 69 autopsies		They have isolation procedures which include gowning. They estimate that less than 1% of patients are isolation cases.

TABLE A-8. Hospital Survey Results -- Infection Dangers to Hospital Employees

Pathologist	Special Procedures for Handling Blood or Pathological Samples from Known Infection Cases	Number of Pathological Specimens and Autopsies Where Bacteriological Cultures Are Taken	Desirability of Better Methods to Protect Lab Personnel from Infection	Area Where Inadequate Cleanup Exists after Use: Lab; Morgue; Cytology
Hospital A 200 Beds			Serum hepatitis and acute miliary TB (rare but dangerous) are hazards.	Frozen section machine and morgue are contaminated (100 autopsies year) - usually gram negative.
Hospital B 40 Beds				
Hospital C 200 Beds	All specimens are treated as dangerous (approximately 2% of all blood samples can transmit hepatitis.	Not asked. 5-10% of all specimens are pathogenic.	Pathologist in some danger.	
Hospital D 590 Beds	"Handle with Care"	1 in 20	Risk necessary to preserve pathogens for culturing.	Heat sterilize cryostat is satisfactory. Workbench is a source of contamination.
Hospital E 440 Beds	Yes, gloves and smocks worn, disposable pipettes used (incinerated or autoclaved). No eating in lab.	10% of autopsies (160 to 180 per year)	If known infection case, pathologist would like better protection	Frozen section machine is a problem - clean with bedadine, sprayed with disinfectant.
Hospital F 120 Beds	All blood specimens handled as if a hepatitis case.	All autopsies have cultures. 12 out of 4200 pathological specimens were cultured.	Hepatitis is a serious concern.	Autopsy instruments (large knives, etc.) section machine is cold sterilized. Cadavers and autopsy tables could be gamma sterilized.
Hospital G 215 Beds	If technician gets a needle puncture, employee gets gamma globulin and serology tests for 6 weeks.			Attendant uses water plus Staphene to clean morgue. This solution is discarded via drain in morgue.
Hospital H 90 Beds				

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