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STERILIZATION OF MEDICAL SUPPLIES WITH GAMMA RADIATION

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I. INTRODUCTION

A. STERILIZATION OF VARIOUS TYPES OF MEDICAL SUPPLIES

The application of gamma radiation to the sterilization of medical supplies is believed to be one of the most promising uses of the fission products. There are fewer obstacles to this application than in the radiation sterilization of food. In the case of medical supplies, the problem of "off" flavor (a major problem in food sterilization) is nonexistent. The question of toxicity is only a consideration with certain pharmaceutical products such as antibiotics and vitamins which are taken into the human body orally or intravenously. Bulk medical supplies such as dressings, cotton gauze, cotton swabs, sutures, instruments, and special items such as human "bone-bank" bone can be sterilized on a mass basis as soon as suitable irradiation facilities are put into operation.

For several months lyophilized human bone for the "bone bank" at the University of Michigan Hospital has been sterilized by gamma irradiation in the Fission Products Laboratory. Highly successful bone grafts were first made in dogs.[1] Since then over 30 human patients have received successful grafts of lyophilized human bone sterilized with gamma radiation. Dr. Paul H. DeVries, M. D., Section of Orthopedics, Department of Surgery, University of Michigan Medical School, and his associates state that gamma radiation has already revolutionized their procedures in bone grafting. Laboratory cobalt-60 sources are adequate for processing human bone, aorta, or similar material for use in surgery.

The sterilization with gamma radiation of most of the important antibiotics and a number of other pharmaceuticals without loss of potency has been demonstrated using solutions of these products packaged in glass ampoules.[2] Although these products have great dollar value, they have small volume, and the daily production of any one pharmaceutical manufacturer could be sterilized with a radiation facility not much larger than the radiation "cave" in the Fission Products Laboratory.[3,4]

B. STERILIZATION OF COTTON PRODUCTS AND OTHER BULK MEDICAL SUPPLIES

The greatest volume of medical supplies that are sterilized is found in the cotton, gauze, adhesive bandages, surgical dressings, and other bulky materials used for medical purposes in the home, in the doctor's office, and in the hospital. Every year the American public spends about $100,000,000[5] for these items. This large amount of money is spent with the knowledge that these materials have been sterilized and as a result are free of microorganisms which could possibly initiate the spread of infection. The sterilization measures and protection against subsequent contamination are costly operations performed by the manufacturer in the interests of public health and customer acceptance of his product. The current sterilization practice employs steam under pressure as the sterilizing agent. Although procedures vary somewhat, in the method employed by one large manufacturer a number of pallet loads of these materials are placed in a chamber batchwise and subjected to pressurized steam for a period of time sufficient to kill any microorganisms present. The success of this method is contingent on the ability of the steam to penetrate the cartons and packages of materials to provide enough heat to destroy these organisms.

A new method of sterilization is proposed which consists of the application of a sterilizing dose of gamma radiation to the materials after packaging and prior to shipment to consumer markets. This new method has several distinct advantages and eliminates many of the disadvantages of the present practice of steam sterilization.

C. ADVANTAGES OF GAMMA-RAY STERILIZATION OF BULK MEDICAL SUPPLIES

It is quite natural to consider gamma rays as a sterilizing agent for bulk medical supplies such as surgical dressings when examining the extensive work that is presently being conducted on the pasteurization and sterilization of food using gamma rays. The advantages offered by gamma-ray sterilization can affect economies of operation while still producing a product free of microorganisms.

1. Gamma radiation is extremely penetrating and can pass through several pallet loads of materials producing death for microorganisms in its path.

2. Complete sterilization could be assured in even the most tightly packed containers, thus producing savings in packaging materials.

3. The restriction to certain types of packaging materials would be eliminated; this alone could result in tremendous savings.

4. Manufacturers could exercise a wider choice of packaging-material colors which could give the product a greater psychological sales appeal.

5. Economies could be accrued by elimination of the salvage due to the irreparable damage done to heat-sensitive materials by the steam. Gamma irradiation produces no appreciable temperature rise in the materials.

6. Continuous processing lends itself to more efficient and economical materials-handling methods as compared to the present system of batch operations.

D. EFFECTS OF GAMMA IRRADIATION ON BULK MEDICAL SUPPLIES

The question arises as to what effects, other than killing microorganisms, gamma radiation will have on the materials so processed. In experiments[6] conducted at the University of Michigan, studies were made on the radiation dose required to sterilize food wrappers. Using two bacteria, E. coli and B. stearothermophilus, it was found that a dose of 2,000,000 rep was sufficient to effect complete sterilization. No visible damage, such as color change, embrittlement, clouding, etc., was observed in any of the samples of plastic, cloth, or paper irradiated in the course of the work. Also, Seaman[7] has indicated that the dose of radiation necessary to cause damage to cellulose and similar materials far exceeds that required for sterilization. Excessive doses of radiation are known to decrease the tensile strength of cellulose products, but more information is needed on such effects.

In addition to queries on the effects on the physical properties of materials, others are concerned with the possibility of induced radioactivity. Meinke[8] has studied the problem as related to food and has obtained negative results when investigating 24 elements that occur in food. This would indicate that induced activity would not be a problem in the sterilization of surgical dressings.

II. DESIGN OF A GAMMA-IRRADIATION FACILITY TO STERILIZE BULK MEDICAL SUPPLIES

A. SELECTION OF RADIATION SOURCE

Electrical machines such as Van de Graff generators and linear accelerators produce ionizing radiation in the form of high-speed electrons that have been used extensively for research investigations on radiation sterilization. These machines show great promise in the sterilization of small items such as ampoules of pharmaceuticals. The penetration of high-speed electrons is quite limited, and the authors do not believe that high-speed electrons from such machines are suitable for the sterilization of bulk medical supplies, especially when these supplies are handled as is the customary practice on pallets 4 x 4 x 4 feet. Therefore, gamma radiation was chosen as most suitable in the proposed design for such a facility.

If a gamma source were used, the irradiation could take place after the materials had been packaged and just prior to shipment to distributors. This is possible because of the great depth of penetration of the gamma rays. Since the materials would already have been packaged, there would be no danger of possible recontamination before use by the customer. Gamma sources are becoming available as by-products of the atomic energy program and are considered suitable sterilizing agents in this proposed facility. The gamma source specified consists of twenty fuel elements which have been removed from a nuclear reactor. The fuel elements were chosen over the fission products or cesium-137 as gamma sources since they are presently available. Their availability is contingent on the unloading schedule of a reactor and the subsequent chemical processing schedule.

In the operation of a nuclear reactor, fission products and transuranic elements are formed from the uranium contained in the metallic fuel elements. After these materials have accumulated to certain concentrations or because of considerations of damage to the fuel elements, the fuel elements must be processed chemically in order to provide uranium suitable for refabrication into new fuel elements. It is current practice to hold the fuel elements, which have been removed from the reactor, for a period of time sufficient for the intense radioactivity to be degraded and for the neptunium formed to decay to the valuable element plutonium. Except during periods of experimentation, the radioactivity from the fuel elements at present is being dissipated in storage wells using water as a shield. This operation is expensive because of the large inventory costs associated with the fissionable material. If some of these fuel elements were used as a radiation source, part of the cost of the delay period before chemical processing would be defrayed. Thus, it is easily seen that use of the fuel elements as commercial sources of radiation is conveniently and economically adaptable to the present scheme of chemical processing operations.

The requirements in the United States for fuel elements for the irradiation of bulk medical supplies would not be great since there are very few manufacturers in this field large enough to sponsor such an endeavor. Although reactor fuel elements were selected for this use in the United States suitable radiation sources could be fabricated using fission product wastes for use in those parts of the world where fuel elements may not be available.

B. DETERMINATION OF THE OPTIMUM NUMBER OF PASSES

The reactor fuel elements proposed for use in this facility have a very high gamma activity but a very rapid decay rate. It is recommended that each fuel element be used for a period of two months and then replaced with a new fuel element. If the replacement schedules for different fuel elements are staggered, greater uniformity of radiation flux will be possible. However it will probably be necessary to make adjustments in the material flow rate through the facility during the period of operation to compensate for the decay of the fuel elements. The irradiation of a large volume of materials necessitates continuous operation involving the use of a conveyor system to pass the materials into the chamber, past the radiation source, and out of the radiation chamber. Efficient operation requires that the total thickness of materials being conveyed through the chamber should absorb most of the radiation.

The amount of radiation absorbed naturally depends on the absorption characteristics of the materials being irradiated. To explore this aspect of the problem the absorption coefficients were evaluated for a series of bulk medical materials normally sterilized by steam. These materials included sterilized cotton, cotton swabs, cotton balls, roll bandages, gauze pads, and plastic strips in tin cans. The thickness of materials required to absorb half the gamma radiation (half-value thickness) was measured using gamma radiation from the cobalt-60 source in the radiation "cave" of the Fission Products Laboratory. The average half-value thickness for all the materials except the sterilized cotton and cotton balls was found to be approximately 22 inches, whereas for these materials it was approximately 45 inches. The cobalt-60 used in these measurements emits gamma rays of 1.17 and 1.33 mev. The presence of many different fission products in the fuel elements would cause them to have a spectrum of energies with an average energy of about 0.7 mev. This lower energy would normally result in a lower half-value thickness but due to the phenomenon of multiple scattering, a build-up of the radiation occurs when treating thicknesses of materials as those proposed in this design. In absorption studies on meat,[9] using gamma rays of different energies, this phenomenon was observed. It was therefore decided to use the half-value thicknesses obtained from the cobalt-60 determinations as approximately correct for the lower-energy gammas of the fuel elements corrected for multiple scattering.

In this design it will be assumed that the materials to be irradiated would be loaded on pallets to a thickness of 42 inches. One pass of such an absorber would theoretically result in the absorption of 73 percent of the radiation normal to the surface of the materials. This was calculated from the relation:

$$I = I_0 e^{-\mu x} = I_0 e^{-0.693 \frac{x}{(X\ 1/2)}} , \tag{1}$$

where

I = intensity of radiation passing through thickness x,

I_0 = original intensity of radiation,

μ = broad beam absorption coefficient, inches^{-1},

x = thickness of material, inches, and

$(X\ 1/2)$ = half-value thickness of material, inches.

$$\frac{I}{I_0} = e^{-0.693 \frac{(42)}{(22)}} = e^{-1.3} = 0.27$$

The spacing between the pallet loads as they progress through the chamber will reduce the percent of the radiation absorbed. This is partially offset by the greater total thickness the materials offer to all the radiation not normal to their surface, such as that from the extremities of the source. Consequently, the materials were considered 80 percent efficient as an absorber. Thus each 42-inch pallet was considered to absorb 73 percent x 80 percent or about 58 percent of the radiation flux.

To provide a uniform radiation dosage, the first pass of the conveyor was placed 3 feet from the source. The second pass was farther away but because of the normal attenuation of the radiation with distance, the spacing was kept at a minimum. Knowing the radiation flux and the absorption coefficients of the material, the absorption of the radiation in the first pass was calculated. The radiation flux at the second pass was reduced both by absorption in the previous pass and by the distance to the source. After a number of passes, the radiation would be reduced to the point where it would no longer be economically feasible to add another pass. In this design, because of the width of the pallet and the large amount of absorption in each pass, only two passes on each side of the source were specified.

C. DESCRIPTION OF DESIGN

Figures 1 and 2 show the plan and elevation views, respectively, for the proposed radiation chamber using 20 reactor fuel elements as a source of radiation. As shown, the materials to be sterilized will be conveyed by racks holding three pallet loads on a monorail conveyor system. This particular design arose out of considerations for maximum utilization of the radiation field which emanates in all directions from the radiation source.

Referring to Fig. 1, material handlers will deliver to area A pallet loads of materials from production areas. Here the loaded pallets will be raised by fork lift trucks onto the racks ready for irradiation. The racks will travel on the monorail system through the labyrinthine passage B and into the chamber past barrier wall C. The materials then make two passes, D and E, on one side of the radiation source F and two passes, G and H, on the other side. This arrangement will provide a more uniform radiation dose for the materials by irradiating both sides of the pallet loads. After sufficient dose of radiation is obtained in the chamber, the materials pass around concrete barrier I and out the labyrinthine passageway J to the unloading and removal area K. From area K the sterilized materials could be loaded into railroad cars or sent to accumulation areas to await shipment.

Provided in the chamber is a well L which would be filled with water and would be used to store the radiation source when not in use. It will be necessary for the operator to enter the chamber for such things as routine maintenance, change of radiation source, or recovery of spilled materials from the pallets. The presence of the well will permit this access simply by lowering of the source beneath the protective shield of water. Since there is no residual activity in the chamber after the source is lowered into the water, the operator could perform all necessary duties and leave the chamber without danger.

Each horizontal pass of the conveyor would be driven by sprockets connected by a common shaft or a chain drive to keep them moving at the same rate. If arcs were provided at the end of each pass, the spacing required between the individual racks and the successive passes would be more than could

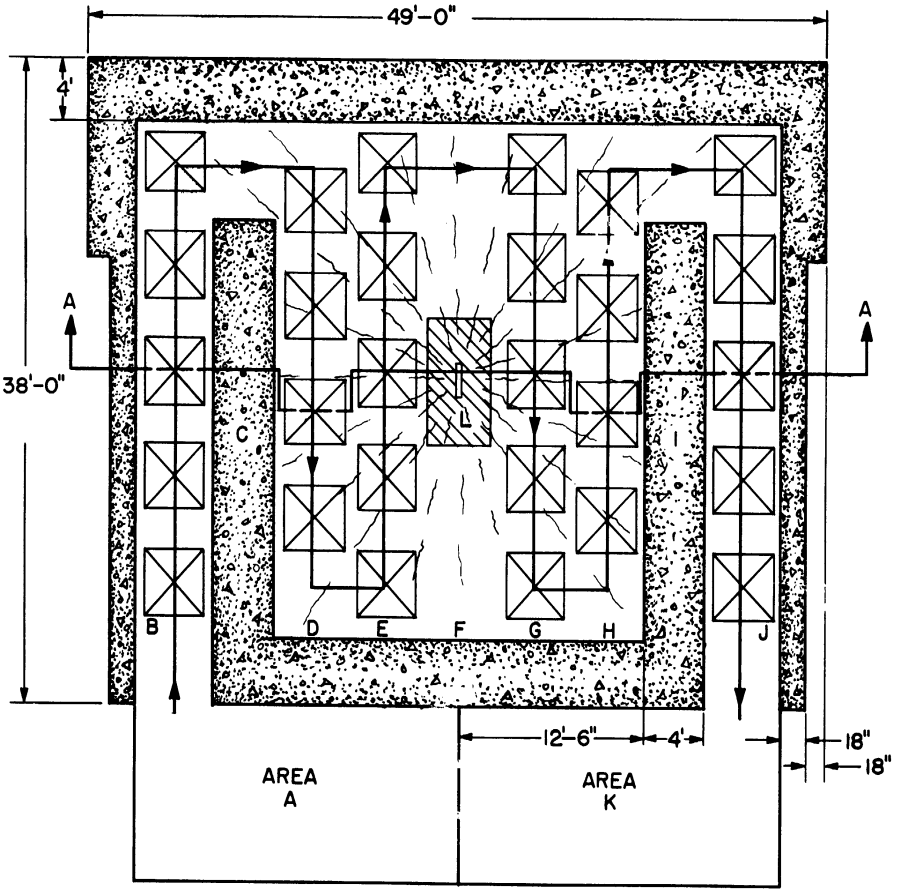

Fig. 1. Plan View of Irradiation Facility

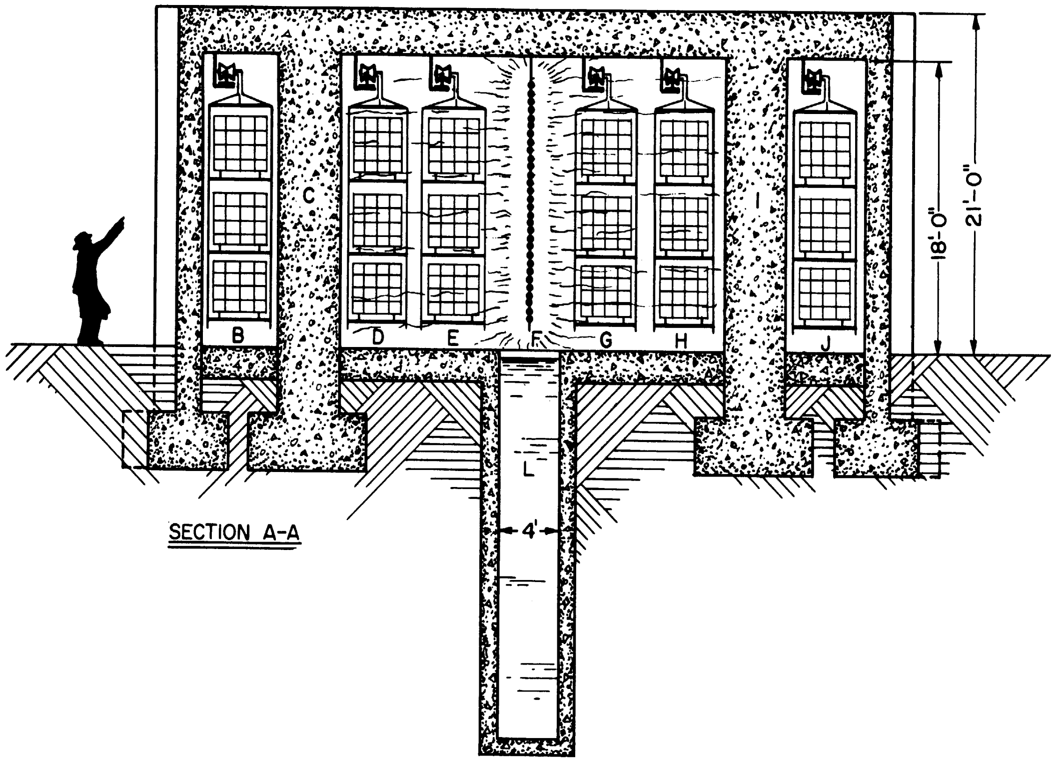

Fig. 2. Elevation View of Irradiation Facility

be tolerated. The most efficient operation would naturally have minimum spacing between each rack to maximize the amount of absorption per pass and the minimum distance between successive passes to reduce the attenuation due to distance. This may be accomplished by installing an oscillating transfer mechanism at the end of each pass for lifting the racks as they reach the end of the pass from one monorail and placing it on the next monorail where it would be conveyed past the source as previously. The transfer mechanism would have to be synchronized with the driving mechanism of the passes to insure smooth transfer of the racks. Guides would be used to maintain the racks in a vertical position while traveling along each pass and from one pass to another to prevent spillage. The spacing between each pass and between adjacent racks was set at 2 feet.

D. SOURCE DISTRIBUTION AND RADIATION DOSE

The decision was made to specify 20 reactor fuel elements as the source of radiation after considering the radiation flux available from one fuel element and the amount of radiation required to affect complete sterilization. The dose of radiation selected as a sterilizing dose was 4,000,000 rep which is greater than the amount generally considered as necessary for sterilization. The productive capacity for the radiation chamber is a function of this required dose and also a function of the radiation field provided by the source.

The radiation field will, of course, vary with the geometry of the source. If the fuel elements were arranged side by side with no distance separating them, the radiation field would vary in all directions and would appear as if emanating from a plaque source of uniform concentration. This type of source was previously found to be inefficient.[10] A more efficient design would be to distribute the activity of the source in such a way as to provide a uniform radiation field in one direction. In the case of the fuel elements, the activity may be distributed by spacing of the fuel elements. Since the materials were to be transported on racks through the chamber on a monorail in a number of horizontal passes, it was decided to establish a uniform radiation field in the vertical direction. This would mean that although the materials traveled in a varying radiation field in the horizontal direction, the uniform vertical field would insure that the materials on the top pallet would receive the same dose as those materials located on the bottom pallet.

The uniform vertical field could be accomplished by aligning the long axis of the fuel elements in a direction parallel to the direction of the four passes. In addition, the elements would be arranged with vertical spacings as shown in Fig. 3. The smaller pitch of the fuel elements near the floor and ceiling is used to produce a more uniform radiation field at the extremities of the source.

The optimum spacing of the fuel elements was determined by trial and error by calculating the dose rate in air at certain positions and then plotting the dose rate versus vertical distances for a definite horizontal distance from the source to ascertain the effect of a particular spacing scheme.

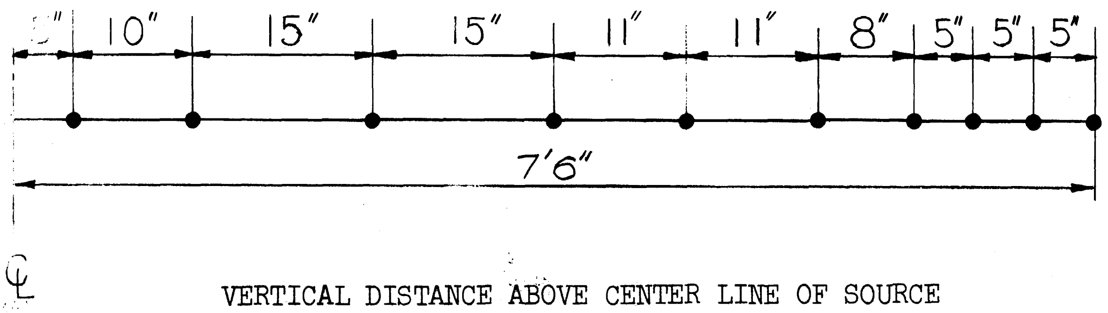

Fig. 3. Elevation View Showing Spacing of One Half of Fuel Elements for Irradiation Facility.

The procedure for calculation of the dose rate in air was quite extensive because of the irregular spacings of the 20 different components of the source contributing to the flux at any arbitrary point. The total flux at a point is a scalar sum of the contributions from each of the fuel elements. The calculations were simplified by assuming that at a sufficient distance from the fuel elements the source may be considered as being comprised of 20 line segments. The dose rate contribution of one of the fuel elements is given by:

$$I_1 = \alpha(H_a + H_b) \quad , \tag{2}$$

where

α = concentration coefficient for each fuel element.

The calculation of the radiation flux at any point in a given plane parallel to the face of the group of source rods will be demonstrated. The values of H_a and H_b for one fuel element are obtained at any point p from the general equations:

$$H_a = \int_0^{\ell_1} \frac{dx}{x^2 + y^2 + d^2} = \frac{1}{\sqrt{y^2 + d^2}} \tan^{-1} \frac{x}{\sqrt{y^2 + d^2}} \Bigg]_0^{\ell_1} \tag{3}$$

$$H_b = \int_0^{\ell_2} \frac{dx}{x^2 + y^2 + d^2} = \frac{1}{\sqrt{y^2 + d^2}} \tan^{-1} \frac{x}{\sqrt{y^2 + d^2}} \Bigg]_0^{\ell_2} \tag{4}$$

where all distances are in inches and

x = length along the horizontal axis of the 24-inch (assumed) fuel element,

y = horizontal distance from plane of source rods to parallel plane containing point p,

d = vertical distance from point p to the fuel element, and

ℓ_1 and ℓ_2 = lengths along the axis of the fuel elements between the base of a perpendicular from point p and the extremities of the fuel element.

For a particular solution, consider, for example, a plane located 3 feet from the face of the source rods and a point p located in this plane 2 inches above the horizontal center line and 6 inches to the left of the vertical center line as shown in Fig. 4. For convenience, Fig. 4 shows only the fuel elements on either side of point p and the two elements at the extremities of the source holder. In this example the distance d_{10} from point p to fuel element No. 10 was determined from Fig. 3 and the contribution of fuel element No. 10 would be:

$$I = \alpha_{10}(H_{a10} + H_{b10}) \quad , \tag{5}$$

$$H_{a10} = \int_0^6 \frac{dx}{x^2 + (36)^2 + (3)^2} = \frac{1}{\sqrt{(36)^2 + (3)^2}} \tan^{-1} \frac{x}{\sqrt{(36)^2 + (3)^2}}\Bigg]_0^6 \text{, and} \tag{6}$$

$$H_{b10} = \int_0^{18} \frac{dx}{x^2 + (36)^2 + (3)^2} = \frac{1}{\sqrt{(36)^2 + (3)^2}} \tan^{-1} \frac{x}{\sqrt{(36)^2 + (3)^2}}\Bigg]_0^{18} . \tag{7}$$

The contribution to the flux at point p of the other fuel elements is determined by insertion of the proper vertical spacing d into these equations and subsequent multiplication by the concentration coefficient α. Following this procedure for each fuel element the total flux at the point p would be

$$I = I_1 + I_2 + I_3 \text{ ------ } I_{20} \quad . \tag{8}$$

The concentration coefficients, which depend on specific activities and other properties of the fuel elements, were not known. However, a value of the dose rate opposite one fuel element and 3 feet from it was estimated to be approximately 10^6 roentgens per hour.

Since the concentration coefficient for each fuel element would be approximately the same, the function H was integrated and plotted as a function of distance from a fuel element. The values of the function were first normalized to 1 $(10)^6$ roentgens per hour at 3 feet where the value of the dose rate had been estimated. The immediate problem was then reduced to summing the ordinates of the function H at the distances of the 20 fuel elements from the point at which the dose rate was desired. With the spacings as shown in Fig. 3, the values of the radiation intensity were calculated for the points opposite the center line of the sources and 2, 4, and 6 feet above the center line. The dose rate calculations on the center line were made for horizontal distances of 3, 5, 8, and 12 feet from the source. The results of these calculations are depicted in Fig. 5. As Fig. 5 indicates, the radiation field resulting from the distribution indicated in Fig. 3 provides a very uniform radiation field in the vertical direction. As the source is symmetric with respect to the center line, the uniform field would extend over the entire height of the racks transporting the pallets.

E. CAPACITY CALCULATIONS

The dose rate was calculated for many arbitrary points throughout the chamber using the fuel element spacings shown in Fig. 3. The dose rates at these points were then plotted to produce the isodose curves shown in Fig. 6. These isodose curves denote the levels of the radiation flux in air and must be corrected for the absorption which takes place when the chamber is in operation.

The materials located at the center of any pallet will receive the minimum dose of radiation. The materials on the side of the pallet closest to the radiation source will receive a higher dose due to less shielding and nearness to the source. Since the pallets do not reverse in their travel past the source, the edge closest to the source on the right side becomes the farthest away on the left side of the chamber. This compensates somewhat for the high dose received on one side of the source. Figure 7 is a plot of the dose rate corrected for absorption as a function of distance traveled in the irradiation chamber for materials located at three different positions on a pallet. Curve A shows the radiation field traversed by the materials on the edge of the pallet nearest to the source; curve B, the central portion; and curve C, the materials on the pallet farthest from the source. The area under the curves represents the dose received by the materials located at these positions as they travel through the chamber. The curves have been drawn for only one half a traverse since the path of travel is symmetrical for both sides of the chamber. The total dose received by materials located at the center portion of the pallet would be twice the area under curve B while for the materials on the outer edge, the total dose would be the sum of areas under the curves A and C.

Twice the area under the curve B was determined to be equal to 11 x 10^7 rep-feet per hour. This value was then divided into the dose required for

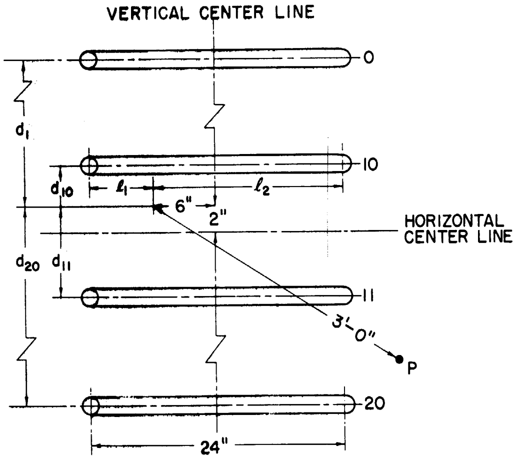

Fig. 4. Dimensions for Example Calculation of Radiation Field

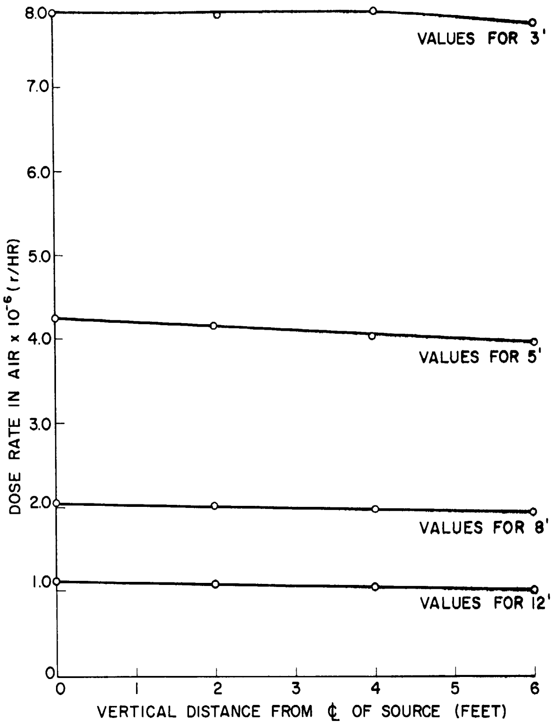

Fig. 5. Radiation Flux Versus Vertical Distance for Selectively Spaced Fuel Elements

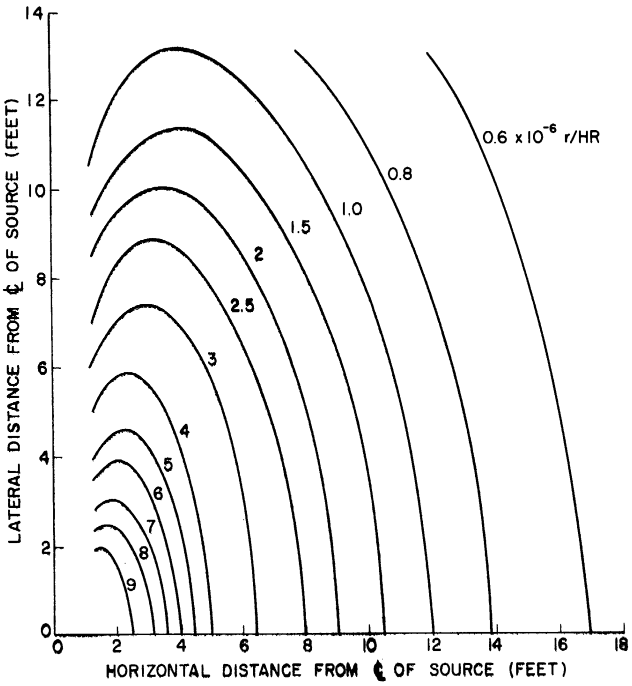

Fig. 6. Isodose Curves in Horizontal Plane Perpendicular to Source at Center Line for One Quadrant of Radiation Chamber

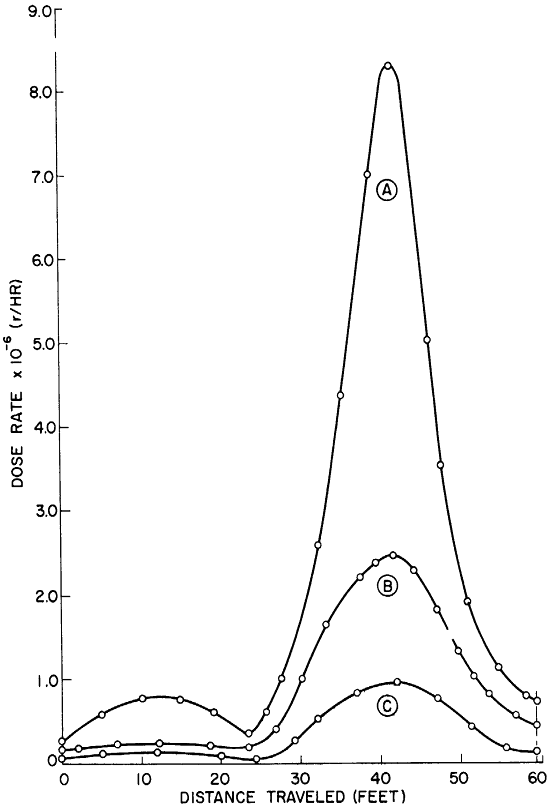

Fig. 7. Dosage Rate as a Function of Distance Along Path of Travel in Radiation Chamber

sterilization and multiplied by the feet of travel to obtain the time required to completely sterilize the materials.

$$\frac{4(10)^6\text{rep}}{11(10)^7\text{rep-feet/hour}} \times 118 \text{ feet} = 4.3 \text{ hours/cycle.}$$

This time was calculated to be 4.3 hours. Since the fuel elements will also be decaying during the time they are in use as gamma sources, a variable speed drive would be needed to alter the conveyor speed as required.

In each cycle there would be 20 racks transporting three pallet loads per rack. The capacity per hour would then be:

$$\frac{20 \text{ racks}}{\text{cycle}} \times \frac{3 \text{ pallets}}{\text{rack}} \times \frac{\text{cycle}}{4.3 \text{ hours}} \cong \frac{15 \text{ pallets}}{\text{hour}} .$$

Thus, in an 8-hour day the radiation facility could handle a normal day's pallet production of 100 to 120 pallets. The radiation chamber could easily handle extraordinary production rates by scheduling two shift operations.

F. OTHER CALCULATIONS (SUMMARIZED)

Shielding calculations were made which indicated that 4'0" of concrete would be required. A cost estimate was prepared which indicated that the radiation chamber could be constructed for $57,900. An estimate of $55,000 per year was made for anticipated operations costs. This cost will depend in a major part on the rental charges for fuel elements. These charges were unknown. Therefore, the estimated cost for the construction of the radiation chamber is considered more reliable than the estimated annual cost for operations.

G. CONCLUSION

The sterilization of medical supplies by gamma irradiation appears promising considering both the limited experimental work and the present feasibility studies. A preliminary design has been presented for the radiation sterilization of bulk medical supplies in pallets 4 x 4 x 4 feet using cooling-reactor fuel elements as a source of radiation. The estimated capacity of 120 pallets per 8-hour day is sufficient to handle the production of a large manufacturing plant, and the estimated cost of operation compares favorably with known costs for steam sterilization.

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