MARKET DRIVEN DESIGN OF ACCELERATOR SYSTEMS FOR STERILIZATION OF MEDICAL PRODUCTS

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Abstract

Historically, most scientific accelerator systems are the primary ingredient of a given facility. In commercial applications of accelerators the customers needs are for a systems in which the accelerator is a part of a process. In the case of the sterilization of medical products, the accelerator is part of a process which ensures a sterile dose to FDA standards to a variety of products. The process includes a variety of hardware and specifications for parameters that are unrelated to accelerator technology. In addition, the customers are in general unfamiliar with accelerator technology. This creates the need for a different approach to design including a multidisciplined group of designers as well as the need for the design of equipment that has industrial ruggedness and reliability, so as to be usable by relatively low skill levels. In addition, the systems must be highly cost efficient, because the accelerator technology will be competing with alternative technologies which invariably are less expensive.

This paper describes the design of the TB 10/15 accelerator system which is currently being operated in several locations around the world. The description includes the market needs that were addressed and how the system was designed to meet them.

INTRODUCTION

Sterilization of medical products was identified as a possible application for a scanned beam accelerator.

Societal pressure to check rising health care costs has resulted in demands for less expensive and more flexible methods to sterilize medical devices. This has generated interest in electron beam sterilization because it offers fast turnaround time and high efficiency compared with competing technologies. The combination provides the opportunity for lower sterilization cost. In addition, competing technologies have inherent problems which encourage the accelerator technology.

1. Cobalt 60 has high costs for the source and replacement. There is public pressure to avoid placement of large amounts of highly radioactive material in urban locations.
2. EO (ethyleneoxide) gas is toxic, carcinogenic, and explosive, and is being phased out.

The market for alternative sterilization methods need was recognized and studied to ascertain if a business could be established. The effort involved market surveys, and cost estimates based on various system designs and scenarios. The system design rapidly converged on the parameters of the Titan Scan machine.

One of the major parameters considered was beam power. The power was sized to be able to provide sterilization support on a contract service basis to a regional area of manufacturers within reasonable transport range. If the system were too large, the capital cost could not be justified because the system could not be kept busy. If it were too small, the facility could not handle the product volume and the cost per watt of beam would be too high. We converged on a 15 kW beam power operating point. We designed for 20 kW.

Another major parameter was beam energy. The FDA regulations preclude operation beyond 10 MeV, to avoid activation in some materials. 10 MeV provides a useful range of direct electrons in most medical products. The density of which is .03 - .3 g/cc.

Another parameter was the number of operating energies. In order to maximize reliability, we chose the simplest approach with the fewest components and that is a single operating energy. At that point all the parameters can be optimized for efficiency and reliability.

Another decision was to have the system dedicated to medical products and not multipurpose. The result was the Titan Scan TB 10/15 scanned beam system.

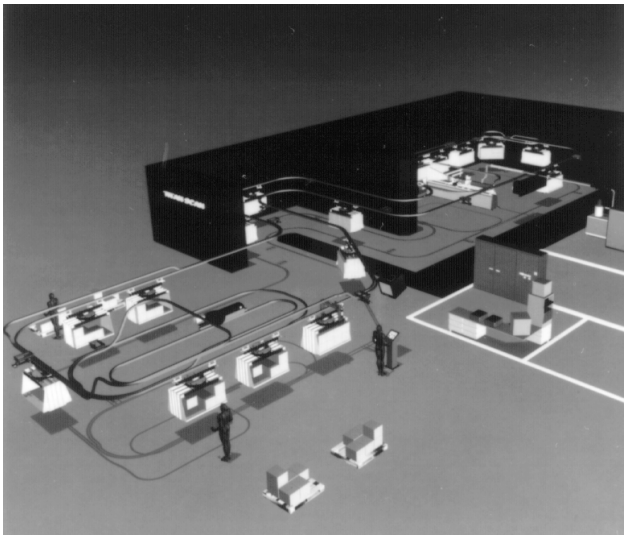

Fig. 1. *Artist sketch of facility.*

FACILITY DESCRIPTION

The Titan Scan TB 10/15 facility is divided into four areas: a processing room, a modulator room, a control room and a product staging area. The processing room is a shielded concrete structure with walls and roof ranging from 2.1 m to about 3.1 m at the thickest point directly in front of the electron beam. The processing room contains a 1.4 m long standing-wave accelerating section, magnetic systems to focus and scan the 10 MeV, 15 kW electron beam, an overhead power and free transport conveyor and the under-beam process table.

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Power supplies and utilities are located in an adjacent modulator room, which is separated from the processing room by a shield wall so it can be occupied during operation. The control room houses the computers and subsystems that control, monitor and document the sterilization process. An isolated dosimetry lab is located in the control room area. Processed and unprocessed product is separated by a chain-link fence to prevent intermixing.

LINEAR ACCELERATOR (LINAC)

Because the LINAC system is specifically designed to function as part of a medical product sterilization system, it is built with a component safety margin allowing continuous, 24 hour per day operations. The horizontal accelerator axis provides for easy two-sided irradiation of medical products with bulk density in the range from 0.03 to 0.30 grams per cubic centimeter. The beam is scanned into the vertical direction to accommodate packages up to 51 cm in height at the front surface of the carrier.

Figure 2 shows the vertical dose distribution profile on the surface of a 0.1 g/cc uniform density foam phantom from the top to the bottom of a carrier performed with an energy of 10.8 MeV and a repetition rate of 300 pulses per second. Figure 2 results show an average of 15.2 kGy with a coefficient of variation (CV) of 1.54%.

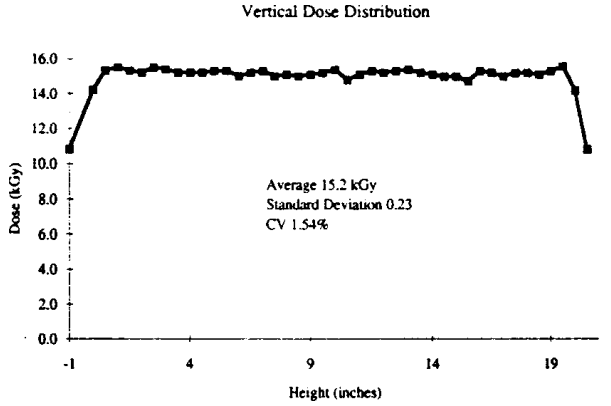

Fig. 2. *Vertical dose distribution (scan width) at the surface of a 0.1 g/cc uniform density foam phantom.*

BEAMLINE

The electron gun is a Pierce geometry triode design with a dispenser cathode and is operated at 25 kV and delivers up to an ampere of peak current. It has a one square cm cathode and is operated with a one liter per second appendage ion pump.

The gun pulser is a floating deck pulser which provides the gun filament and grid bias as well as pulsing the cathode. It has an automatic filament cutback circuit which programs the filament current as a function of rep rate.

A solenoid covers the 1.4 m s-band standing waveguide to insure an acceptable beam shape can capture efficiency. With it we obtain over 300 mA of accelerated beam current. A pair of steering coils are placed under the solenoid for beam positioning.

The output of the waveguide has a fast in-line valve shutter and beam current monitor prior to the scanner.

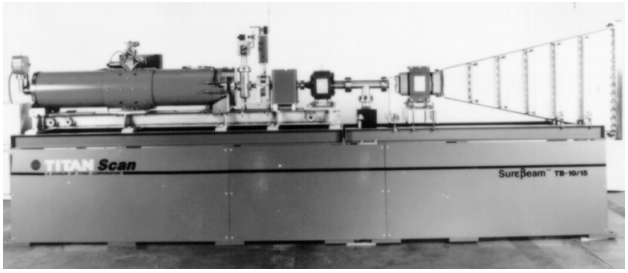

Fig. 3. *Accelerator beamline.*

RF POWER

The RF power source for the TB 10/15 system is a klystron operated at up to 5.0 MW and 40 KW at 2856 MHz. It requires 120 watts of RF drive at full peak power.

An Automated Frequency Control (AFC) system utilizing waveguide Reflected power phase sensing is used to maintain frequency.

MODULATOR

The modulator uses a 14 section Pulse Forming network (PFN) with an operating voltage of 20 kV. End-of-line clippers protect the klystron and thyratron against voltage reversals. The modulator HVPS is shown in Figure 4.

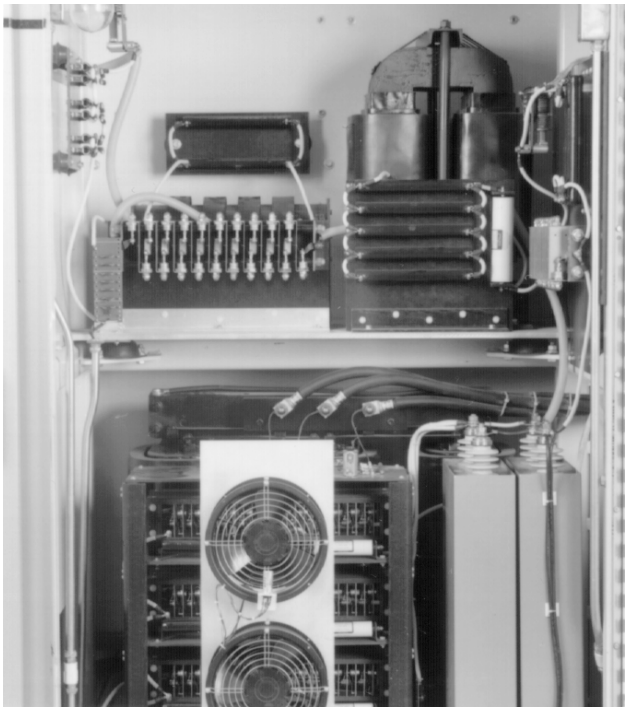

Fig. 4. *Modulator High Voltage Power Supply*

CONTROLS

The system is remotely controlled from the control room. The information and control system uses a graphic based interface with a distributed architecture containing industrial PLC's and a PC control system network. The system provides real-time monitoring and control of process variables and on-line error detection and recovery.

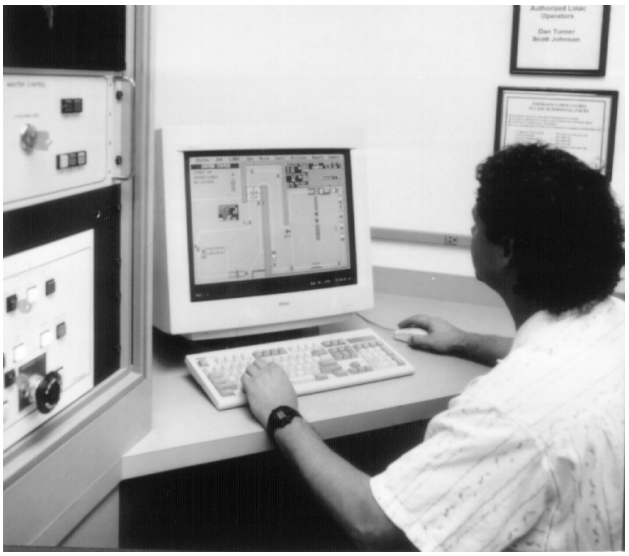

Fig. 5. *Operator's station in the control room.*

Local controls for system adjustment along with power supplies are in a rack near the modulator.

Fig. 6. *Local controls and power supply rack. The PLC also resides in this rack.*

OPERATING DATA

The existing TB 10/15's are in daily operating routinely running 24 hours a day with a 4 hour per week maintenance shift. The operating parameters are as follows:

RF Power	5 MW peak
Beam Current	300 mA
Energy	10.0 MeV
Pulse Width	16.2 μs
Rep Rate	310
Beam Power	15 kW

Medical products from a variety of medical product manufacturers are being processed daily.

MATERIAL HANDLING SYSTEM

The material handling system employs a power and free conveyor to transport carriers between the product staging area and the process room. In the common entrance labyrinth, the inbound and outbound conveyor paths are stacked one above the other. In the process room, the 99 cm long carriers are transferred to an independent servo-controlled process conveyor table that provides and maintains a spacing of less than 2.54 cm between carriers as they are transported through the beam. The tight spacing of the carriers in front of the beam contributes positively to the beam utilization efficiency.

The process conveyor servo-motor maintains carrier speed within 0.5% of the set point and assures a highly uniform and reproducible horizontal dose distribution within the product. Figure 7 shows the horizontal dose distribution measured in polyethylene foam at the midline of the carrier.

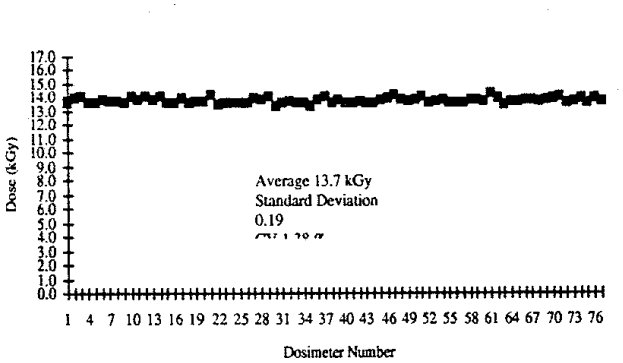

Fig. 7. *Horizontal surface dose profile at the carrier midline.*

A fail-safe 180° rotation mechanism located in the process room assures that each carrier receives uniform two sided irradiation. The concept of horizontal beam processing eliminates the need for cartons to be manually flipped and the associated concern with product shifting.

PROCESS INTERRUPTS

If an event occurs triggering a shutdown of the LINAC while product is being processed, the entire system is shut down. During this shutdown interval, as the beam is turned off, the process conveyor requires additional time to reach a complete stop. It is during this interval that a potential variation in the dose delivered to the product can occur. Process integrity must be maintained at all times even during a process interrupt. To compensate for the potential decrease in dose at the point of the process interrupt, the start-up sequence is such that the beam turns on prior to start-up of the process conveyor. This results in additional beam pulses delivered to the product, compensating for the pulses lost during the shutdown interval. This restart sequence produces a positive transition dose

similar to the transit dose associated with process interrupts in a typical gamma processing facility.

During the facility commissioning and validation, simulated process interrupt tests were conducted and their effects on the absorbed dose were measured. All measurements were made in a phantom product of polyethylene foam of 0.1 g/cc density.

Figure 8 shows the effect of a process interrupt on the absorbed dose at process conveyor speed of 1.2 meters per minute. Figure 8 depicts three process interrupts on the same carrier. All three process interrupts reflect the same small transit dose as one would see in a typical gamma facility interrupt. The dose was measured in the direction of carrier travel on the front face (0 cm) of the phantom, ¼ deep (18.4 cm) into the phantom and on the center line (36.8 cm).

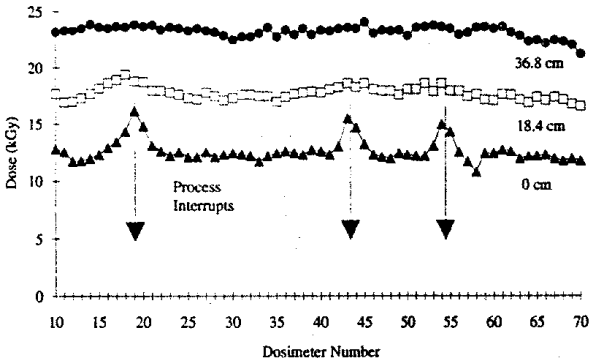

Fig. 8. *Effect of a series of three process interruptions at various product depths at a conveyor speed of 1.2 meters per minute.*

It is interesting to note that the effect of the process interrupt diminishes with depth into the phantom to the point where it is not observable on the center line. This behavior is the result of side scatter and diffusion of electrons in the interior of the phantom.

Using the same phantom material of 0.1 g/cc density foam as used on the interrupt tests, calculations of net beam efficiency were shown to be 56%.

PROCESS PERFORMANCE

Monitoring of process repeatability from carrier to carrier is demonstrated in Figure 9 which depicts a thirty carrier dose map run on cases of petri dish product performed in July, 1993. The reported results are those of dosimeters placed in the standard reference monitoring position on the front of the product cases. The results demonstrate repeatability with a 0.6 kGy standard deviation and an overall coefficient of variation (CV) of 4.1%.

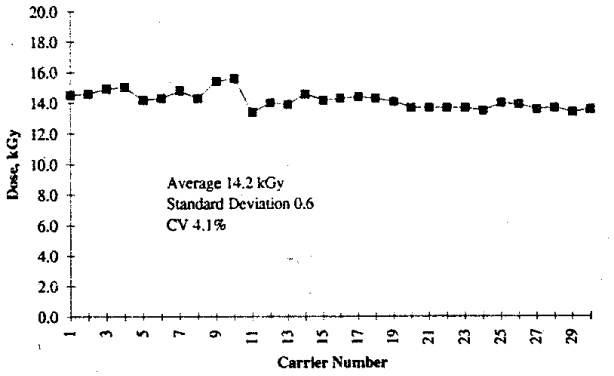

Fig. 9. *Results of thirty carrier measurement on a single process run measured at the reference monitoring position on the product box.*

Process reproducibility is demonstrated in Figure 10 which is an average of the dose results over a series of twelve process runs conducted over twenty days in August 1994 on the same petri dish product. Again, the standard monitoring position has been measured and the results are displayed which show a standard deviation of 0.39 kGy and a CV of 0.3%.

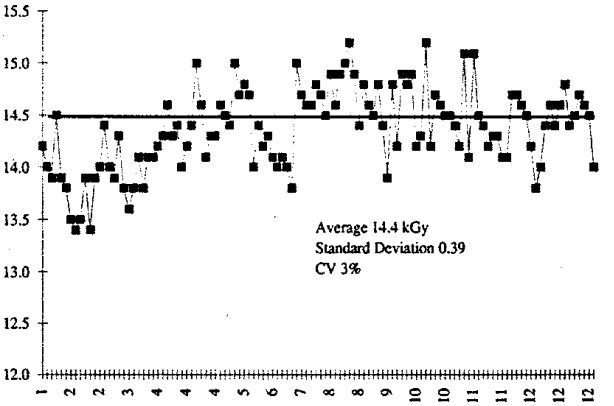

Fig. 10. *Dose results from twelve process runs performed over a 20 day period measured at the reference monitoring position on the product box.*

VALIDATION MAINTENANCE

It is important in medical device sterilization to have demonstrated results which are consistent over time with the original validation of the process.

All of these issues and specifications along with many others were developed and clarified in conjunction with customer's needs as revealed in countless discussions and correspondence.

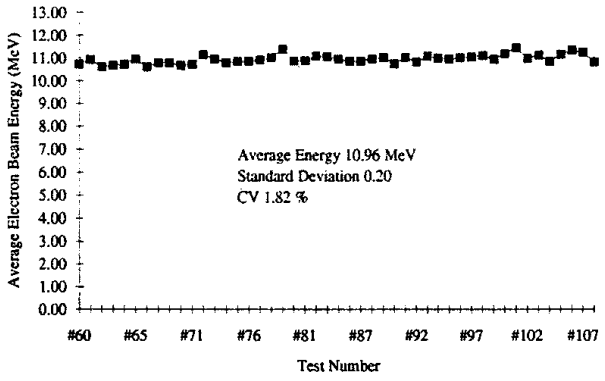

Fig. 11. *Plot of 47 energy determinations from penetration range measurements in aluminum block over an eight month period.*

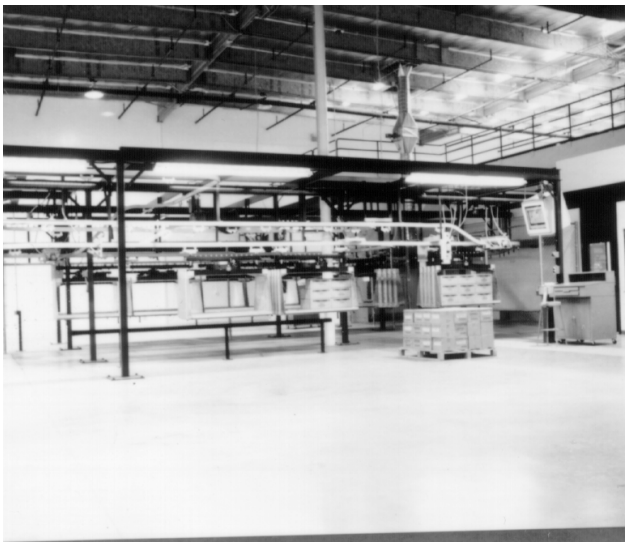

Fig. 12. *Product handling area of a typical system.*

CONCLUSION

The successful application of an rf linac to the sterilization of medical products has been performed by the Titan Corporation. It required careful attention to market requirements, in order to be successful in addition to careful design and implementation of the accelerator system. The parameters that drove the system performance included beam power, energy, surface dose uniformity, process interrupt recovery without product loss, stability of energy surface dose, and depth dose with time, and high reliability. Many critical parameters were not directly accelerator related. Close collaboration of the system design team was required to reach the multidisciplined goals.

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