

DESIGN OF A MULTI-PURPOSE ELECTRON BEAM PROCESSING PLANT: CONCEPT vs. ACTUAL

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ABSTRACT

A state of the art electron beam accelerator was designed into a multi-purpose processing plant in Cranbury, New Jersey for use in radiation modification of polymer products and materials and radiation sterilization of medical devices.

This paper gives an overview of facility design, key technical specifications, and plant layout. It includes comments on the start-up, operation, and maintenance of the facility, as well as a comparison of design versus actual performance.

KEYWORDS

Electron beam accelerator; electron beam processing; crosslinking; sterilization; radiation processing; facility design; radiation processing equipment; facility start-up.

INTRODUCTION

Electron beam irradiation is a powerful tool, and the spectrum of commercial applications is exceptionally wide:

- polymer modification, including wire and cable insulations and jackets, heat shrinkable products, crosslinked specialty plastics and molded parts, and poly-tetrafluoroethylene molecular scission; (Cleland, 1980; Bennett, 1977; Bradley, 1984)
- crystal structure modification, such as gemstone enhancement, glass coloring, and semiconductor performance enhancement; (Nassau, 1984; Fuchii and others, 1985)
- radiation sterilization of medical devices; (Gaughran and Goudie, 1974; Bly, 1979; Minbiolo and Davis, 1984; Beck and Morrissey, 1985)

In addition to these well-proven applications, there is a long list of promising development work to further brighten the electron beam processing horizon (Hwang, 1985; Diehl, 1983; Nablo and others, 1985). This is not surprising, given the fundamental nature of electron beam processing.

Nevertheless the actual rate of growth in electron beam processing overall has been less than many industry representatives have been projecting (Business Week, 1977). Certainly one stumbling block to growth has been the high capital cost of the accelerator and its requisite auxiliary equipment. High voltage accelerators, say 1 million electron volts (MeV) and higher, are readily available commercially, but at a cost of a million dollars and higher for a basic installation. And because the cost of a high voltage accelerator system does not scale down much with capacity, the electron beam can be an unaffordable piece of equipment in all but large scale, proven applications.

ORIGINAL PROJECT JUSTIFICATION, CONCEPT, AND APPROVAL

Market Needs

A contract processing center, or "service center", is a logical alternative to the purchase of an accelerator facility in the case of:

Research: Research machines are a luxury. Production machines may have limited beam time available for research and development work, but typically only under the baleful eye of a production manager with a tight budget and tighter schedule. On the other hand, a service center with a progressive orientation can be a responsive incubator for both basic and applied research in electron beam technology, and therefore an important engine in the growth of the industry.

Product Introduction: New commercial applications have uncertainties in terms of market acceptance and growth rate. The front-end, fixed cost hurdle of an accelerator can

slow down or kill a promising business opportunity. A service center has the facilities and the business interest to support the early stages of new product introduction.

Small-to-medium scale production: High fixed costs are difficult to carry in the early stages of product growth. A service center spreads the costs over a number of applications, and still provides economies of scale as volume increases. A service center also eliminates for the user the business risk associated with a single product line and the high investment and sunk costs of a specialized production facility.

The perceived market need in 1983 for a service center was based largely on the success of an existing service center plant within the company in Plainview, New York, which was approaching its capacity on a 24 hour per day basis. Favorable growth trends in each market segment provided the basic justification for the new project. An extensive market study by an outside consulting firm confirmed and quantified the market needs (Booz Allen & Hamilton, 1983).

In particular, the study confirmed the business opportunity in single use medical device sterilization, based on market growth, compounded by a trend toward contract sterilization. The study also confirmed technical and availability advantages compared to alternative technologies, including a new awareness of materials compatibility benefits (less material degradation) compared to gamma irradiation (Sandia National Labs., 1981; Thurrell, 1984). Nevertheless, the business opportunity was necessarily a dual opportunity with the polymer modification market segments given the high capital cost -- and high capacity -- inherent in commercial accelerators.

Project Concept

The first major concept was to design and build a high-capacity, multi-purpose plant with highly-flexible product handling equipment. Provision was made for future adaptation and expansion. (Excluded, however, were: food preservation, handling of contaminated medical devices, hazardous material treatment, and the processing of any material incompatible with a high standard of housekeeping.) This broad market scope of the facility further raised the capital cost and stretched out the payback period for the proposed project, but at the same time it ensured long term success. A key resource was available to support this ambitious concept: the financial resources of the company's parent corporation.

The "dual" market requirement, medical sterilization and polymer modification, was met with a concept for a dual-layout facility. The final design actually divides the plant into two separate operations: one which exceeds the toughest GMP (good manufacturing practices) standards of the U. S. FDA (Food and Drug Administration) for medical device sterilization, and another that facilitates efficient processing of a wide variety of current and projected specialty product/polymer modification applications.

The third major concept for the project was to apply the Plainview plant technical and operations experience, not only in the facility design stage, but also throughout the project. Experienced people are important (1) from the early stages of the project for proper scope definition and design; (2) during the engineering and construction phase for project management as well as for reasons of special detail design, quality/inspection, and plant familiarity; and (3) throughout the project for sales, marketing, and technical development. The long lead time required for engineering, construction, start-up, and revenue growth was a recognized hurdle to a successful project. Thus the practical application of this concept, given the people-intensive nature of the project, was to share the experienced personnel resources between the two plants.

Approval

The internal approval of the capital expense for the project was obtained following the usual routine of market analysis, cash flow analysis, and risk analysis. A satisfactory return on investment for the project was obtained on the basis of a long term perspective, given the length of the project schedule and the ramp of business revenues projected over a period of years. There was indirect justification based on the fact that the accelerator was being purchased from a sister division at an attractive transfer price, and so there were also corporate dividends in building a state-of-the-art showplace for the accelerator.

PLANT DESIGN: KEY FEATURES, TECHNICAL SPECIFICATIONS, AND LAYOUT

Versatility and throughput were the prime performance yardsticks for every phase of the equipment design and specification. The facility was to be able to handle any product, current or anticipated, so that it would be a true showcase for irradiation and an incubator for the coming generation of electron beam applications.

Accelerator

A 4.5 MeV, 150 kilowatt accelerator with state-of-the-art microprocessor process control was chosen for its combination of high throughput and maximum penetration as well as its proven performance over several years of service in other facilities (deWilton, 1985). The process controller offers a high degree of quality assurance due to its ability to monitor all key accelera-

tor performance parameters every 100 milliseconds, providing hard copy records of equipment performance and diagnostic help in maintenance and repairs.

TABLE 1 Electron Accelerator Specification

Electron Beam Power	150 KW
Maximum Accelerator Voltage	4.5 MeV
Voltage Range	2.5 - 4.5 MeV
Voltage Stability	$\pm 2\%$ of Maximum
Maximum Electron Beam Current, 4.5 MeV	34 mA
Maximum Electron Beam Current, 3.0 MeV	50 mA
Minimum Electron Beam Current, over entire Voltage Range	1 mA
Electron Beam Current Range	0 to 100% of Maximum
Electron Beam Current Stability	± 0.35 mA
Electron Beam Ramp Speed	0.8 mA/second
Length of Scan	68 inches (fully variable)
Scan Frequency	Variable up to 200 Hz
Maximum Scan Angle	37.5°
Maximum Beam Current at Reduced Scan Length	1.4 mA/inch
Surface Dose Uniformity over Maximum Length of Scan	$\pm 3\%$ at 49 inches from window

A vertical, in-line orientation was chosen for the accelerator, which is believed to be the most reliable orientation for a 4.5 MeV machine. An overhead crane was designed into the building to facilitate accelerator maintenance, as was a powered, height-adjustable maintenance platform in the upper level vessel room. This platform can conform to the diameter of the vessel or alternatively the diameter of the exposed beam tube.

Various options were included in the initial accelerator purchase order, consistent with the overall concept for the facility:

- | | |
|---------------------------------|-----------------------------------------|
| 1. Six-foot scan system | 8. Wire/cable/tubing processing package |
| 2. Safety system | 9. Output line printer |
| 3. Radiation monitoring system | 10. Input card reader |
| 4. Degaussing system | 11. Remote pedestal beam control (2) |
| 5. Double loaded general optics | 12. Product speed meter on console |
| 6. Beam current monitor | 13. Calendar/clock on console |
| 7. Beam locating aperture | 14. Sterilization processing package |

Another option considered was a 90° rotation bearing for the scan horn. While this would have further increased plant flexibility, it was not a cost-effective feature.

Product Handling Systems

After considering many alternatives, a tow line cart conveyor system was chosen with large twenty square foot trays. The system is equipped with computer controls, and it offers the exciting feature of total interface with the accelerator controls to provide fully automatic processing with every cart in the system monitored for proper irradiation. A small reject spur was added to automatically quarantine any improperly processed cart. By inputting the proper processing conditions in advance, the only labor involvement necessary is to load and unload product, this minimizing the potential for human error and maximizing throughput by having the computer efficiently control the conveyor operation.

The wire, cable and tubing (W/C/T) market offers attractive growth potential, but also a challenging materials transport problem due to the vast array of potential products ranging from very fine wire and tubing up to large diameter cables. A general purpose system was designed with one meter capstan drums capable of transporting product ranging from 26 gauge wire to 2 inch diameter cable under the beam for multiple pass processing. Three sets of "dancer" tensioning mechanisms as well as a tension operating mode provide high quality, efficient processing of small and intermediate products, and also the power to pull heavy cable through the system at uniform speeds. The driven payoffs and take-ups have the capacity to handle up to 72 inch diameter reels.

A second system with 19 inch capstan drums capable of running up to 3000 feet per minute was added later in the project to provide cost competitive processing of high volumes of small diameter, low dose wire. This system, with the pay-off and take-up located on the vault mezzanine, minimizes the path length to and from the beam for reduced product stress at high speeds. It is designed to process up to 1/4 inch diameter product on 36 inch reels.

Another promising target market required handling polymer pellets in bulk form, and a pneumatic pellet handling system was specified to process several thousand pounds per hour in tandem with the cart conveyor. The system is designed to permit easy access throughout for thorough cleaning between runs to facilitate handling different products without cross contamination.

Consistent with the original concept, the facility is also designed to handle future applications. Vault penetrations are included to allow for processing of sheet (up to eight feet wide), liquids, and rigid extrusions which require entrance and exit portals on opposite sides of the vault. An abundance of spare utility hook-ups are also available for future product handling equipment and vault fixturing.

Plant Layout

The 36,000 square foot processing and warehouse facility is designed with a natural flow of product from receiving, through the vault, and on to the shipping docks. The site was chosen and laid out with the flexibility to expand the building to two times and three times the original size on the 6.7 acre lot. The Cranbury, New Jersey location was chosen primarily for its excellent transportation access and its close proximity to a high density of medical device manufacturers and plastics processors, but also with an eye toward the rapid growth of high technology companies in the Princeton, N. J. area.

The facility is comprised of five distinct areas: accelerator/concrete shielding; cart processing; wire, cable, and tubing processing; warehouse; and office.

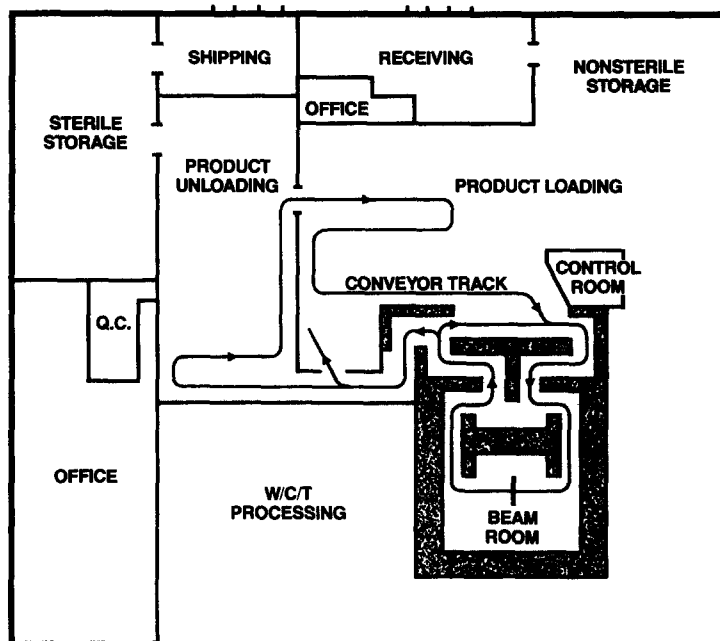


Figure 1 - Plant Layout

The concrete shielding serves both to protect the personnel and to support the accelerator and its related equipment. It is made from poured concrete (except for an access area of stacked block) and contains numerous utility accesses including electrical, air, and water services. The irradiation beam room itself is exceptionally large to allow the installation of multiple under-beam fixtures that can slide back and forth under the beam for quick changeovers of product types.

The flow of the conveyor system for cart processing is laid out for flexibility in dosing product, for separation of processed from unprocessed product, and for achieving the high throughput capabilities of a powerful, microprocessor-controlled accelerator. An inner loop allows for multipass processing with ready access for turning product between passes. The outer loop allows material handling access to keep up with the high flow of product. An extended track in the unprocessed area allows for advanced staging of carts, also ensuring uninterrupted flow. A key aspect of the track layout is the separation of nonsterile from sterile products. The

facility as designed exceeds all GMP requirements for product segregation with physical barriers to prevent mixing of processed and unprocessed product in the receiving/shipping area, the warehouse, or the processing area.

W/C/T processing is also physically separated from cart work/sterilization to emphasize the special needs of processing for both markets. Key layout features for W/C/T processing include separate operational controls on location, plenty of "in-process" space to feed the accelerator, an underbeam fixture which easily slides back and forth under the beam, and dual capstan capabilities: one set for short runs and for product over 1/4 inch diameter, and the other for long runs of low dose product under 1/4 inch diameter.

Warehouse and office space were purposefully kept at a minimum. An electron beam processing operation is based on high throughput. Product should not linger in the warehouse awaiting either processing or shipping, so the available floor space for storage is comfortable but not excessive. The Quality Assurance and Dosimetry laboratory is strategically located between the production floor and the records in the office, highlighting the emphasis placed on meeting customer requirements during processing.

PROJECT IMPLEMENTATION: ENGINEERING, CONSTRUCTION, AND START-UP

The focus of the project on the front end was, of course, the overall facility design and the specification of the key equipment. On the tail end of the project, the focus was on achieving design performance from the facility and its equipment. These two phases were bridged by a most challenging intermediate phase: Project Implementation.

Project Schedule

Following internal approval, final bids were obtained for engineering and construction. The procedure for obtaining local zoning approval was initiated based on preliminary drawings and specifications. Here the approach was to explain clearly the nature of the technology to local community leaders and to introduce company management personnel to them. This advance groundwork turned out to be useful when the inevitable snags arose during the zoning approval process. Note that three years prior a blase' attempt to obtain zoning in an area 50 miles away was turned down due to an emotional reaction from an uninformed public. Zoning approval was obtained in the case of the Cranbury Plant, although the process, including the appeal period, took considerably more time than anticipated.

Final project engineering continued during the zoning phase but construction could not be started until final zoning approval. Delays in the construction start date produced changes in vendors and also interfered with the pre-planned sequencing of the project. The late start of the project also delayed some concrete work into the winter months, further delaying the overall project. On the positive side, however, a single contractor had been selected for both engineering and construction, and his commitment and experience helped overcome a number of the problems that come up in any construction project of this magnitude. The advantage of having the existing staff of Plainview personnel was important: their time could be divided between support of the existing service center and technical input required for the new facility.

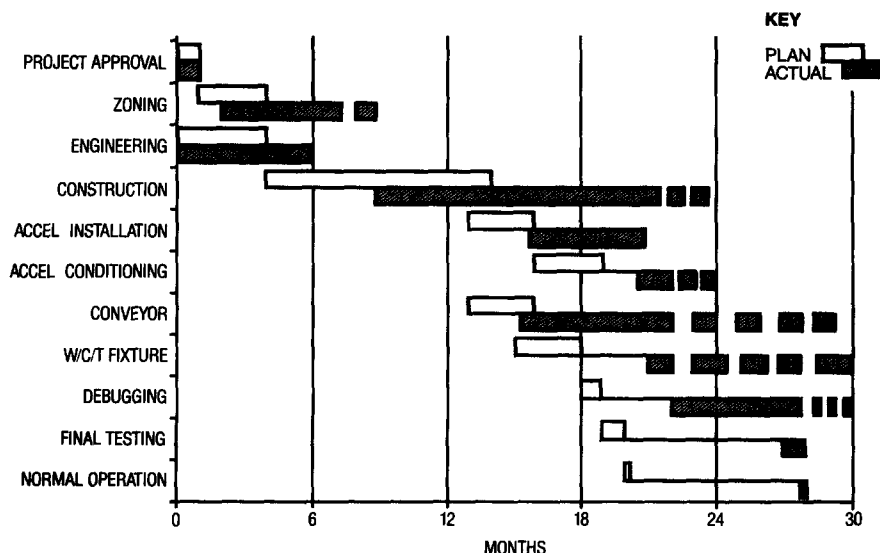


Figure 2 - Project Schedule

The overall length of the project was a disappointment. It was extremely difficult or impossible to overlay critical schedule components on both the front end and the tail end of the schedule. On the front end, the problems were typical of many projects: the basic tasks of preliminary engineering, zoning, land acquisition, detailed engineering, and start of construction each took longer than expected, and they were accomplished more in series than parallel. The actual sequence of the items was somewhat convoluted.

Late in the project there were similar problems. Nine installation and checkout activities -- involving the vault itself, the accelerator, the conveyor, and other equipment -- all required time in the beam room. These activities were highly interactive, and occurred largely in series rather than in parallel. Expert help was made available for each of the activities, but nevertheless the scheduling of work was confused and inefficient. The expertise of the specialists was often less than what was proclaimed, and in each case the expertise was narrow and lacking in overview.

Largely for the above reasons the installation of accelerator took longer than scheduled; however the "conditioning" of the accelerator, while anticipated to be a lengthy step for a high voltage machine, was accomplished in less than the scheduled time. Special steps could be taken to shorten the accelerator installation and compress the conditioning cycle because of the "internal" nature of the purchase, although there remained the vague balance between an expeditious start up of the accelerator on the one hand and concerns about long term negative effects on its performance on the other hand. The installation and check-out of the product handling systems was even more drawn out, due to many minor mechanical problems as well as interface problems with the accelerator.

In retrospect, the biggest problem with the project schedule was unrealistic expectations, although more intense planning and questioning of the vendors would certainly have helped. The fact that there was a change in the ownership of the company could be a convenient excuse for delays, however that event occurred about the time normal operations began. Caveat emptor with regard to the project schedule: the black art of accelerator installation and start up, and with the added complication of the auxiliary equipment, is not particularly compatible with critical path scheduling.

Start up

The term "start up" in an electron beam accelerator project can be defined in many ways. For this project, accelerator conditioning at low beam was considered part of the project itself. Thus the start up was a phase that focused on testing and debugging the product handling equipment while the accelerator was in normal operation. Much of the start up activity involved the software interface between the accelerator and each successive piece of product handling equipment. This was a rather lengthy process, although reliable commercial operation was possible after the early stages of debugging. Information on the start up of the accelerator and each product handling system is provided under the Equipment Performance heading of the paper. The start up of the facility was uneventful with respect to radiation safety, an accomplishment based on the preparations made by experienced company personnel, including a comprehensive radiation safety program (Faluotico, 1987).

Project Cost

The capital cost of the project came in close to budget, thanks to a generous contingency allowance at the start and a fixed cost contract for the engineering and construction. The indirect expenses of the project exceeded budget due to the elongated schedule. For this project, the primary indirect costs were interest on construction in progress and internal people costs: project management/engineering/start-up plus marketing and technical activities. Figure 3 gives the distribution of the capital costs and also the distribution of indirect expenses, and illustrates the relative costs of the two categories.

EQUIPMENT PERFORMANCE AND ACTUAL PLANT OPERATION

This section highlights the actual performance, reliability, maintenance, and vendor support for the three major equipment systems and of the overall plant.

Equipment Performance

The accelerator performance has been outstanding from a mechanical and electrical standpoint, although a few minor design and component changes were necessary to produce extended runs at full power. On a day to day basis the response, accuracy and precision of the generated beam has been excellent. Downtime has been minimal, in part due to following a strict maintenance schedule, but also due to the advantage of having a full time experienced accelerator technician on the staff. The microprocessor software required revision to adjust to changes made to overcome conveyor system design faults. The controller/microprocessor has operated reliably and has provided many operating advantages with only minimal associated limitations. Vendor support has been very good to date.

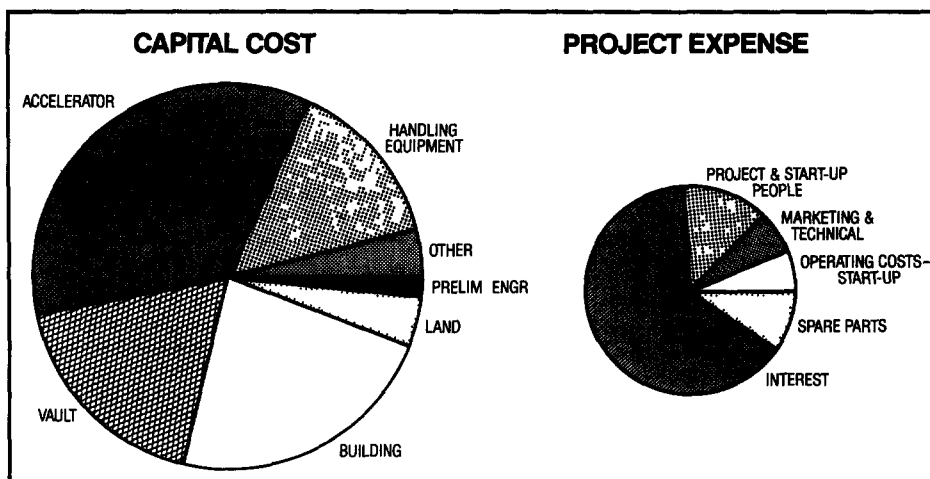


Figure 3 - Project Cost Distribution

The cart conveyor system has undergone significant changes compared to its original design and early operation. The problems with the system as designed were many, but the main problem was ozone corrosion of a cart monitoring station inside the vault. The inability of the vendor to correct it caused the basic operational mode of the entire system to be reworked at a lower throughput. Testing showed that software problems within the system and interface problems with the accelerator controls caused erratic performance in the automatic mode. The manual mode provided the necessary reliability until the problems were solved, but at the cost of additional monitoring. Software problems were subsequently resolved, however nagging minor hardware problems will require frequent maintenance of a degree that was unexpected.

The W/C/T fixture is now performing satisfactorily in the middle range of products. The overwhelming start-up problems were related to lack of operations manuals and otherwise poor vendor support. The company was left to work with the drives subcontractor and knowledgeable customers to untangle the design of the system. Adjustments and additions have been required on the mechanical transport equipment, the drives, and the controls to get the equipment to perform. At present, the performance is satisfactory, the reliability substandard, and the maintenance is more than expected.

It should be pointed out that all of the equipment should have a very long life expectancy. Once debugged, all of the controls are built to provide the high degree of quality assurance needed in a high throughput electron beam facility. This again points out that the high short term costs are paid back over the long term.

Operation

Considering that the start-up is actually a ramp-up, the operation of the facility took the form of continuous progress along the learning curve. The fact that several highly-flexible equipment systems were required for the facility made for a much longer learning curve than either the company or the vendors had anticipated. Much of the first operational phase was spent extensive set-ups and experimentation on short runs of product for the purpose of product qualification. The integration of special customer product handling systems into the operations was also required.

Progress remained difficult until long, repetitive runs were begun with several customers, and the experience base of the workers expanded. Optimization became an operational goal on successive production runs. The key to efficiency was to modify the equipment or its operating mode to meet specific customer needs, rather than to force the product handling systems to deliver their purported design capabilities. This second operational phase was characterized by exciting increases in productivity, solidification of a production team, development of standard operational procedures, and the evolution of an efficient system of quality assurance documentation and paperflow.

The facility is currently operating on a two shift basis, with the shifts uniquely arranged to provide maximum production flexibility as well as process development/maintenance time, on a daily basis. Conveyor processing is predictably efficient and W/C/T production is routine in the middle of the product size spectrum. The range of processing applications is at least as wide as the original project concept. The industrial customers benefit from the enhanced quality and

cleanliness associated with medical device sterilization, and the medical device customers benefit from the company's broadening spectrum of polymer/radiation-response know how (available on a non-proprietary basis).

DESIGN CONCEPT vs. ACTUAL -- CONCLUSIONS

The essential difference between the design concept for the plant and its realization was time: project implementation time and learning curve time. Any electron beam processing plant is considerably more complex than the first-glance view of a piece of standard industrial equipment in a building. And a multi-purpose electron beam processing plant was found to be much more complex than a single purpose plant.

The advantage of having two plants was of great significance in moving along the learning curve. The application of manpower and ten years of processing experience from the Plainview plant to many of the problems/opportunities at the Cranbury plant clearly saved time. The base of knowledge in approaching the qualification of a new product reduced experimentation time significantly. The ability to process product at either facility provided an added dimension of flexibility to the scheduling of equipment trials, so that longer runs could be made without missing turnaround commitments.



Figure 4 - Cranbury Facility

Looking to the future, continued productivity improvements are expected in all current areas of processing, and the challenge of new product applications and configurations is eagerly anticipated. The strength of a service center lies in its processing knowhow as much as in its equipment, and business growth is directly related to its ability to handle new challenges.

Conclusion

A multi-purpose electron beam processing plant makes for a much more complicated and expensive project (and start-up) than a single purpose plant. Nevertheless the concept has proven to be sound both technically and, in the long run, commercially, if only one has the expertise, financial resources, and patience to see the project through a total cycle of three years or more. As Moliere' said: "The trees that are slow to grow bear the best fruit".

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