**A Proton Medical Accelerator by the SBIR Route - An Example of
Technology Transfer***

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Abstract

Medical facilities for radiation treatment of cancer with protons have been established in many laboratories throughout the world. Essentially all of these have been designed as physics facilities, however, because of the requirement for protons up to 250 MeV. Most of the experience in this branch of accelerator technology lies in the national laboratories and a few large universities. A major issue is the transfer of this technology to the commercial sector to provide hospitals with simple, reliable, and relatively inexpensive accelerators for this application. The author has chosen the SBIR route to accomplish this goal. ACCTEK Associates has received grants from the National Cancer Institute for development of the medical accelerator and beam delivery systems. Considerable encouragement and help has been received from Argonne National Laboratory and the Department of Energy. The experiences to date and the pros and cons on this approach to commercializing medical accelerators are described.

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Introduction

The author's interest in proton accelerators for medical applications dates back to some experiments on radiography of human tissue samples with protons at Argonne National Laboratory about 15 years ago (1,2). Recognizing the very low intensity requirements for medical applications, it seemed that 250 MeV synchrotrons suitable for hospitals could be designed and constructed that would be simple, reliable and inexpensive compared to physics machines. Even so they would be somewhat complicated machines, a working model did not exist, and the cost would still be higher than that of most medical instruments. Support was not obtained for the development of such accelerators at Argonne National Laboratory and the initiative was dropped.

In the meantime, cancer treatment on human patients has been carried out for 14 years very successfully utilizing protons from the 160 MeV cyclotron at Harvard, and for a somewhat shorter period of time utilizing helium ions from the 184" cyclotron at Lawrence Berkeley National Laboratory. These successes have stimulated a resurgence of interest in proton therapy among the medical community, leading eventually to the formation of the Proton Therapy Co-Operative Group (PTCOG). This group, consisting of interested physicians, medical physicists, and accelerator physicists has met at least twice a year since 1985.

The problems of developing proton synchrotrons dedicated to radiation therapy and radiography are significant. This is partly because no such accelerator presently exists to demonstrate what appears to be the major advantage over the

physics machines presently in use, namely, raster scanning with varying energy on each pulse to permit 3-D dose contouring. In addition, the cost of such dedicated machines are still uncertain, in the region of a few million dollars, and the experience in their design and construction exists only in the national laboratories and a few large universities. Some form of technology transfer to the commercial sector is clearly required. The author chose the SBIR route to accomplish this research and development toward commercializing proton accelerators for medical applications. ACCTEK Associates was incorporated in late 1984 for this purpose.

Aspects of the SBIR Program of ACCTEK

Three grants have been received by ACCTEK Associates from the National Cancer Institute, two Phase I study grants and one Phase II R & D grant. A proposal for a Phase II grant on the Beam Delivery System has not yet been acted on.

The timing of the grant periods is shown in Figure 1. This illustrates one of the problems confronting a start-up company relying solely on SBIR grants for its support. Fortunately ACCTEK was able to survive the intermittent support because of the cooperation and encouragement of Argonne National Laboratory. During the period of each grant, the author retired from the laboratory (age 63 at the time of the first grant) in order to comply with the SBIR regulations of employment of the Principal Investigator with the recipient company more than 50% of the

time. He continued to work for the Laboratory less than half time during the period of the grant. Between grants, he returned to full time employment with the Laboratory.

Retirement seemed the simplest method to retain medical insurance. In this way the author was able to carry out a great deal of development towards the goal without the very substantial risk normally involved in a start-up company. The development, however, is obviously spread out over a significantly longer time than would otherwise be the case.

One of the practices of the Department of Health and Human Services, of which the National Institutes of Health are a part, is called the Payment Management System. Advance payments on grants are made on a monthly basis on request. Without this policy ACCTEK Associates would have had considerably more difficulty carrying out this program.

Elements of Technology Transfer

The nature of this program is such that it seems impossible to carry it out without assistance from the national laboratories. The accelerator system, while simple compared to physics machines, is still complex and requires expertise in many different areas of accelerator engineering and physics. This expertise exists mainly in the national laboratories. While there is considerable interest in the medical community there is not an existing market for such instruments, and the costs are apt to be a decisive factor in their commercial viability. So

there exists something of a chicken and egg problem: without a prototype the uncertainties are large, but an initial machine requires a substantial financial commitment, unlikely until the concepts are proven and costs are established. Not the least of the uncertainties involves the beam delivery system and methods of treatment to make effective use of the higher precision of dose localization possible with protons.

The first requirement is an entrepreneur, such as the author, with the requisite interest and experience necessarily gained at a major institution. He has to be willing to dedicate many years of his career to the development of the commercial viability of the use of protons for medical applications. This effort must extend much beyond the production of the suitable accelerator. To fulfill the substantial potential of proton therapy requires development of delivery techniques such as raster scanning, improvements in diagnostics, monitoring, verification, treatment planning, and every other aspect involved in treatment. The effort is certain to be a continuing evolution over an extended period of time, but the end result appears most worthwhile.

Having made the decision to undertake this effort by the SBIR route it was very important in the design phase of this program to have as consultants a number of experienced accelerator engineers and physicists from Argonne National Laboratory. The value was significantly out of proportion to the relatively small amount of time any one of the consultants spent

on the program. The overall status of the conceptual design is presented in another paper at this conference (3).

The present R & D phase on the medical accelerator involves building prototype magnets and vacuum systems, doing H⁻ source development specifically for the medical accelerator, assembling them into an operating beam line at 300 KeV, and carrying out a series of experiments related to the author's concept of the medical accelerator. For this purpose it seemed most advantageous to carry the work on at Argonne National Laboratory. Not only was adequate space available with the necessary power and water, etc., but a very large amount of idle equipment exists (even if out-of-date by present standards) which would be useful for this program. In addition engineering help in writing specifications, and technician help in assembly and installation were available on an as-needed basis. Such an arrangement would allow a great deal more flexibility in the program.

A Work-For-Others agreement (4) was drawn up between the University of Chicago (operator of Argonne) and ACCTEK Associates and approved by DOE and NCI. One problem was the length of time it took to get all the necessary approvals, even though there was encouragement with no negative reaction at every step of the process. This caused a delay in the beginning of the project which ACCTEK is now trying to overcome.

Another positive element of technology transfer from the laboratory to ACCTEK on this project has been the part time employment by ACCTEK of one laboratory employee with special

expertise who was underutilized at the laboratory, and employment, again part time, of two retired technicians with 25 years of accelerator experience. In this way ACCTEK had an experienced staff to carry out this development effort.

In all of this ACCTEK has received positive encouragement from Argonne's Office of Technology Transfer and laboratory management.

Concluding Remarks

A great deal of technology is developed in the national laboratories and some of this has a significant commercial utility. DOE recognizes that it is in the national interest to try to transfer this technology to the commercial sector and several innovative programs, such as modification of the patent laws, have been initiated to assist this process. Each of the laboratories has an Office of Technology Transfer, and Argonne, with the University of Chicago, has established the ARCH Corporation to identify and license selected Argonne developments. The inventor or developer is involved in these arrangements.

The SBIR program offers another potentially productive means of technology transfer to industry since the developer is directly involved. While not all engineers and scientists who develop useful concepts or equipment are motivated to become entrepreneurs, when one is so motivated he should be strongly encouraged because this is a most effective technology transfer mechanism.

The situation described in this paper may be somewhat unique, both in the size and cost of the product and in the options that were open to the author. Some of these options would not be available to a much younger man in a national laboratory. Retirement would not be an option so that medical insurance would be a major issue. Likewise life insurance and disability insurance, which are lost as a part time employee, would be serious issues. Insurance policies can be purchased by a small company, but at a significantly higher cost than that of the laboratory group policies. In addition, the young entrepreneur likely has little experience in this area, and the time required to make such administrative arrangements is a significant penalty.

Government agencies, such as DOE, could encourage younger would-be entrepreneurs by changing existing personnel policies, or laws if necessary, to make a special category for SBIR grantees. Policies on retirement, medical insurance, life and disability insurance could be modified. The numbers of people in this group are not so large that it would be much of a perturbation on the existing structure and the almost prohibitive risk to a young man could be substantially reduced.

Laboratories might also offer, at cost, administrative services to the young entrepreneur while he is working on an SBIR grant. The administrative chores of a young company are often greatly underestimated, represent a significant drain on the time of the entrepreneur, and are likely an area with which the scientist/engineer is unfamiliar.

Probably more important is the impact on the career choices a young entrepreneur has to make. As a part time employee he will be less valuable to the laboratory so promotions, more responsible assignments, and salary increases are jeopardized. In choosing to commercialize a product he has committed himself to this direction for his career. However it is just this commitment to take a new development into the commercial sector that is one of the most effective forms of technology transfer. Without such a commitment the probability of failure would be much higher. So this risk seems a necessary and proper one for an entrepreneur to make to support the goals of the SBIR program.

References

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- (4) Contract No. 31-109-ENG38-85824

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Figure caption -

Figure 1. SBIR grant activity of ACCTEK Associates

PMA — Proton Medical Accelerator

BDS — Beam Delivery System