CHAPTER III
PRE-LEGISLATION CASES

This chapter describes the pre-legislation cases from 1985 and 1986. It introduces the cases using the "Level II Analysis" described in Chapter I's section on research design. Using information from the 1994 FLC Winner's Document, all of the FLC 1985-86 awards are organized by federal department or agency and topic area. The topics are based on the interview topics defined in Chapter I's section, "Core Elements of the Government Technology Transfer Process." The following topics are included in the introductory section: technology applications, role of the laboratory researchers and other personnel, intellectual property, technology transfer mechanisms, user groups, user benefits/economic impact/outcomes, government gains, and elapsed time. In order to avoid excessive duplication, topics are addressed primarily with illustrative examples rather than a comprehensive survey of all the cases.

Following the Level II analysis of the 1985-86 group, six selected cases are examined in greater detail. Confidence in the results was confirmed by having two laboratory researchers read their cases. They were generally pleased and made some comments and minor corrections. Because of this more extensive examination, examples for the introductory Level II analysis are largely drawn from the cases not selected. After presentation of the six cases, the final section of the chapter groups the key data from the six cases according to the topics.

INTRODUCTION - LEVEL II ANALYSIS, PRE-LEGISLATION AWARDS

Departments/Agencies and Technology Applications

The eight 1985-86 awards were distributed between laboratories of departments and agencies as follows:

- Agriculture (one technology) - a technology to fight insect and weed contamination of water and vegetation.
- Air Force (one technology) - a purchasing system.
- Commerce (two technologies) - a modem-accessible electronic bulletin board used by the National Institute of Standards and Technology (NIST) to advertise technologies and a program to ensure quality in radiation therapy calibrations.
- Energy (two technologies) - a technology that allows tree root control by public works departments and a technology to detect air pollution and fire in buildings.
- NASA (one technology) - advanced materials for use in electronics, aerospace and other industries.

- Navy (one technology) - equipment to classify waterway sediment.

Roles of the Laboratory Researchers and Other Personnel

The eight 1985-86 awards involved 15 researchers, 14 male and one female. The role of these laboratory researchers varied. Some of the researchers developed computers programs. For example, a group of scientists at a military laboratory developed a purchasing product assessment system. Developing this system involved working with federal agencies issuing RFPs, industry users of the purchasing system, and the standards community. Also, commercialization of the system involved working with private software vendors. Another example of program technologies was a group of scientists who created a dial-in electronic information exchange. Creating this exchange involved assembling hardware and software, organizing information, developing a marketing campaign, and designing a support system. Two research teams developed new instruments: one measured river sediment, and the other measured building pollution while also detecting fires. The remaining 1985-86 technology developers worked with peers in outside institutions to evaluate and test the technologies. Several teams went further and sought potential manufacturers for their technologies.

Intellectual Property

From the Level II analysis, only two of the 1985-86 awards appeared to involve patent applications. But interviewing the researchers revealed that other technologies were patented and one of the apparently patented technologies was not patented.

Technology Transfer Mechanisms

The technology transfer mechanisms included licenses, CRADAs, marketing in trade publications, and other communication. As with the patent data, the data on the licenses and CRADAs was incomplete. Few of the awards as described highlighted CRADAs, so it is assumed that CRADAs were not signed as of 1993. The team that developed the purchasing system transferred the technology through hands-on training seminars and follow-up assistance to thousands of government and industry personnel. The team also marketed the system by writing trade journal articles to publicize its availability for commercialization. The electronic bulletin board on national security and computer issues was a transfer mechanism in itself and helped to move laboratory technologies and products into the market effectively. On this dial-in system,

> . . .The menu directs callers to both NIST products and information about security, conferences, new security and computer standards, product evaluation, new and established software, and hardware systems. Participants are able to exchange information on technical topics with each other, and discuss services, vendors, and opportunities for technology applications. Recent topic additions include data management activities and applications, validation services for test devices, and

conformance to security standards.[1]

User Groups

There were many examples of outside users and partners among the 1985-86 awards. The electronic bulletin board provides an example. The 1994 FLC "Winner's Document" noted that more than 10,000 users had access to the system 24 hours a day, seven days a week via modem. Some portions of the bulletin board were available through the Internet at that time. "Laboratories, agencies, and private organizations outside NIST volunteered contributions to the bulletin board, and NIST has expanded the range of information available," according to the document.

User Benefits/Economic Impacts/Outcomes

The 1985-86 technologies had great potential benefits, according to the Winner's Document. For example, the write-up about the electronic bulletin board said, "You can save U.S. businesses millions of dollars a year with information about security systems, computers, new technologies, and sophisticated software." As another example, the purchasing system integrated components and services from a hundred vendors as demonstrated at a 1989 software exposition. Major Fortune 500 companies who adapted and marketed the system's projects commercially documented savings of 33 percent.

Government Gains

Some of the awards indicated both current and future gains for the government. Two of the awards had specific future applications that would benefit the government. The building leak detector technology developed at a DOE laboratory was to be used by NASA to certify the leak integrity of modules built for the proposed space station. The Navy-developed penetrometer technology supported the Navy's emerging initiative to compile oceanographic information on coastal areas.

The purchasing system project had already generated state-of-the-art national standards and integrated current ones. The system met DOD, ANSI (American National Standards Institute), and Open Systems Interconnections standards and was current with more than thirty other standards common to industry.

Elapsed Time

For three of the eight 1985-86 awards, the award was made because of the speed with which the technology was transferred. For example, the Winner's Document contained statements such as, "The researchers told the users what they needed to know in the fastest . .

[1] 1994 FLC "Winners' Document."

.way," and "The program was moved into general use quickly and painlessly . . ."

On the other hand, two of the awards involved long periods of time. For example, one 1986 award was first conceived in the 1970s. In another award, the researcher started working on the technology in the early 1980s, was nominated for the FLC award and listed in the case list in 1985, but was not given an award until 1992.

SELECTED PRE-LEGISLATION CASES

Table C displays basic data for the six awards selected for further research beyond the 1993 data highlighted above. The six cases are presented in the next section. They are:

- penetrometer for seabed classification/measurement,
- advanced thermoplastic polymer material,
- substance tracer technology,
- slow-release, alginate-based herbicide/pesticide,
- controlled-release, chemically-imbedded herbicide/pesticide, and
- quality assurance for radiation therapy dosage measurement.

Case 1 (1985) - Penetrometer for Seabed Classification/Measurement

Role of Laboratory Researchers and Other Personnel

In the early 1980s, Pearl River County, Mississippi, asked what was then called the Marine Geological Laboratory to help them survey the mineral resources in the lower East Pearl River. They were interested in determining whether the mineral deposits at the bottom of the river could help them offset the cost of dredging.

The field survey was performed by a team comprised of personnel from the Navy laboratory, the state of Mississippi's Department of Economic Development, and the Pearl River County Development Association. Mr. Carey Ingram, an oceanographer at the laboratory, served as the lead scientist for the team.

The survey inspired Mr. Ingram to develop a new penetrometer to measure the river bottom. Mr. Ingram actually invented two different penetrometers for the survey. He adapted one from existing equipment. For the other penetrometer, he served as consulting scientist during prototype development by Louisiana State University (LSU) in Baton Rouge, Louisiana. During the prototype development phase, he co-authored a laboratory report on the technology with LSU engineers.[2]

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[2]J. N. Suhayda and C. Ingram, *Field Testing and Evaluation of an Expendable Bottom Penetrometer System for Automatic Sea Bed Classification and Estimate of Sediment Shear Strength*, Prepared for Naval Oceanographic Office, Marine Geological Laboratory Report No. 523, December 1984.

TABLE C

SELECTED PRE-LEGISLATION CASE CHARACTERISTICS

CASE #	YEAR	TECHNOLOGY	AGENCY/ LABORATORY/ LOCATION	LABORATORY RESEARCHER(s)	PARTNER(s)
1	1985	Penetrometer for Seabed Classification/ Measurement	Naval Oceanographic Office (Stennis Space Center, Mississippi)	Mr. Carey Ingram	Dr. Joseph Suhayda (Louisiana State University), Sippican Corporation
2	1986	Advanced Thermoplastic Polymer Material	NASA - Langley Research Center (Hampton, Virginia)	Dr. Terry St. Clair (Technology Transfer: Ms. Rosa Webster)	Hoescht-Celanese Corporation, M&T Chemical, Mr. Milton Evans (High Technology Services, Inc.)
3	1986	Substance Tracer Technology	DOE - Brookhaven National Laboratory (Long Island)	Dr. Russell Dietz	National Association of Home Builders and AIM, Inc., Perfect Sense, Inc., Electric Power Research Institute, Consolidated Edison, Tracer Labs, Vacuum Instruments, John Booker
4	1986	Slow-Release, Alginate-Based Herbicide/Pesticide	Agricultural Research Service - Southern Regional Research Center (New Orleans, Louisiana)	Mr. William Connick	Grace-Sierra, Dr. James Walter (Thermo Trilogy Corporation), Dr. Ramon Georgis (Biosys, Inc.), Mycogen Corporation, EcoSciences Corporation
5	1986	Controlled-Release, Chemically-Imbedded Herbicide/Pesticide Material	DOE - Pacific Northwest National Laboratory (Richland, Washington)	Dr. Peter Van Voris, Dr. Dominic Cataldo, Frederick Burton	Mr. Harry Barnes (Reemay, Inc.), Mr. Rodney Ruskin (Geoflow, Inc.), Mantaline Corporation
6	1985	Radiation Therapy Quality Assurance	DOC - National Institute of Standards and Technology (Gaithersburg, Maryland)	Dr. Robert Loevinger	Dr. Geoffrey Ibbott (American Association of Physicists in Medicine)

The Technology and Applications

Mr. Ingram adapted one of the penetrometers from a soil-testing device used by the Army Corps of Engineers, a “deep-sea towed-side scan sonar.” The sonar was diver-operated so its depth capabilities depended upon the diver’s depth limit. Mr. Ingram based the more sophisticated penetrometer on an “XBT” (Expendable Bathy Thermograph) manufactured by the Sippican Corporation, based in Massachusetts.

The penetrometer collects data from the bottom of a stream or river through a probe. It then analyzes the data, identifying the sediment below the mud line, and develops a depth profile of the river bed. The XBT-based penetrometer included a ballistically-shaped probe and a recorder for measuring water temperature. The probe fell through the water, hit bottom, and then collected information through the recorder. Mr. Ingram modified the XBT to include an accelerometer in place of a temperature measurement tool (or thermistor).

The penetrometer comprises: a wire for the probe wound on a spool (secured with a release pin), a launcher that releases the spool of wire from a canister holding the spool, a transducer recorder, a calibration unit with telephone jack terminals (to change the polarity of the signal going to the computer from analog to digital), and a Zenith Z-100 microcomputer/printer set-up. A miniature accelerometer inside the probe measures deceleration once the probe hits bottom.

The penetrometer probe is released from a ship into the channel. As the probe falls and hits bottom, the Zenith micro-computer classifies the sediment particles (e.g., soft mud, sand, course gravel) based upon calculations related to impact velocity, depth, strength, mass, shape and diameter. This data is combined with boat direction data to determine geological cross-sections in real-time.

The Laboratory

Mr. Ingram is now part of the Special Support Division of the Naval Oceanographic Office. The Naval Oceanographic Office and a “detachment” of the Naval Research Laboratory (NRL) are co-located on the John C. Stennis Space Center site near Bay Saint Louis, Mississippi, on the Gulf of Mexico coast. The NRL is known as the Navy’s “corporate laboratory” and is headquartered in the Washington, D.C. area. The Stennis Space Center is one of nine NASA field centers. The Stennis Center houses not only the NASA field center and Navy offices, but also 21 other federal agencies from the departments of Commerce, Defense, Interior, and others. The research activities conducted by these agencies range from exploration of space and the oceans to promoting environmental quality.

Each agency at Stennis has developed special technical capabilities and facilities. The Naval Oceanographic Office deploys twelve ships and three aircraft to conduct ocean surveys and other data collection for safe and accurate ocean navigation. The office’s operational center provides the Navy's Regional Oceanography Centers with real-time ocean front and eddy information. Among other programs, the Naval office has a pilot program called "Adopt-a-Ship" which introduces young people to oceanographic survey practices. Along with information for ships and aircraft, the Naval office capabilities include a wide array of instrumentation and communications technologies for naval applications like remote sensing. This includes an oceanographic prediction system using a Cray supercomputer to support Navy initiatives. The Navy offices in Mississippi also house various libraries such as: an atmospheric master library containing all the standard models and databases used by the Navy, a library of over 20,000 technical reports on oceanography, and a library on geomagnetic data and analysis for the U.S. Department of Defense.

University Involvement

The Naval Oceanographic Office signed a contract with LSU's Civil Engineering Department for initial prototype design, construction, field testing, and evaluation of the penetrometer. As a result of a meeting with the university developer, Dr. J. N. Suhayda, Sippican Corporation was interested in modifying its commercially available XBT product for additional sales. Dr. Suhayda and the Sippican engineers discussed how the new penetrometer might be commercialized. Dr. Suhayda and Mr. Ingram worked with the county users to discuss potential future survey needs. They also considered other scientific requirements, as well as budgetary limitations. Subsequently, the university proved that the technology worked.

Funding, Financing

The university and corporate contract work on the penetrometer was performed for the Naval Oceanographic Office Special Projects Branch using Navy funds.

Intellectual Property

Two patents were intended to be based on this penetrometer technology: a Diver-Operated Sea Floor Penetrometer and an Expendable Bottom Penetrometer that is operated from a ship at speeds of up to 15 knots. However, Mr. Ingram said the Navy did not want to pursue his patent application.[3] The agency might not have wanted to spend the money required to apply for a patent. Also, if the patent application process does not look like it will yield a return on the investment, the organization may choose not to pursue this route.

The university also did not file for any rights, although intellectual property was discussed. It was not a conscious or deliberate decision; Dr. Suhayda says they just never got around to this.[4] Once the funding ended, the university felt there was no organization to

[3]Interview with Mr. Ingram, September 4, 1996.

[4]Interview with Dr. Suyhayda, September 23, 1996.

authorize it taking a proprietary interest in the technology since there was a classified aspect to the technology.

It was not possible to contact the Sippican Corporation for this case; however, neither Mr. Ingram or Dr. Suhayda indicated that the company had sought to patent the technology.

Technology Transfer Mechanisms

The survey work was performed as technical assistance to Pearl River County. After LSU produced the initial prototype, the Sippican Corporation produced six "holotypes" (or prototype clones) under contract to the Navy.

User Groups

State and local governments often have responsibility for river channel maintenance. This maintenance requires river bottom surveys which are often conducted by drilling holes into the core, an expensive procedure for identifying existing minerals. The penetrometer offers an alternative.

Penetrometer technology could also contribute to Department of Defense requirements for collecting oceanographic data on coastal areas. Another user group is the oil industry, which needs this type of information for offshore oil exploration.

Barriers to Commercialization

Mr. Ingram said that at the time of this case, a patent counted about as much as a publication toward professional advancement. At the time, Navy scientists received $50 to 100 per patent. This amount of money was not much incentive to do technology transfer work, but recently CRADAs have helped to make the process easier, he said.[5]

Other Factors

The Pearl River is a few miles to the west of the Stennis site and separates Mississippi from Louisiana. The surrounding counties and municipalities are very involved with the Stennis Center in a variety of ways; this case is only one example. For example, local elementary and high school students track the endangered sea turtle through a pilot project sponsored by the NASA Teacher Resource Center. The project, called "Close Encounters of the Endangered Kind," uses information provided by the National Marine Fisheries Service at Stennis.

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[5]Interview with Mr. Ingram, September 4, 1996.

User Benefits/Economic Impact/Outcomes

The penetrometer was used to map river bottom cross-sections and to identify existing minerals for Pearl River County. However, the penetrometer technology was never fully developed and transferred to the operational survey community or any other user group. It is possible that the six Sippican Corporation holotypes fulfilled the Navy's need for non-civilian (possibly classified) use at the time.

In the early 1990s, new Navy requirements sparked renewed interest in this area of technology. As a result, the Naval Oceanographic Office joined with the Navy's Civil Engineering Laboratory in Dayton, Ohio, to improve computer calculations for another type of penetrometer, the Acoustic Doppler Penetrometer, developed by Sonatech, Inc. These improvements made this penetrometer technology more cost-effective than the Expendable Bottom Penetrometer, which ended up on the shelf.

International Activity

None.

Government Gains

It is not certain how the Navy used the six instruments delivered by Sippican Corporation under a contract basis.

Elapsed Time

The request for technical assistance came in to Stennis from Pearl River County in 1982. The patent application for the Expendable Bottom Penetrometer was filed with the Navy Patent Counsel in July 1983, which was still considering it and the diver-operated version in early 1985. Mr. Ingram and Dr. Suhayda co-authored the laboratory report in December 1984. The university developed the prototype in 1984, and it was field tested during the summer of 1984. The Sippican Corporation produced the six prototype clones in the latter half of the 1980s. The Expendable Bottom Penetrometer technology has never been fully-developed or mass-produced. As a side note, Mr. Ingram was nominated for the FLC award in 1985. The case is listed as a 1985 case in the FLC Winners' document, but for some reason the award was not made until 1992.

<u>Case 2 (1986) - Advanced Thermoplastic Polymer Material</u>

Role of Laboratory Researchers and Other Personnel

Dr. Terry L. St. Clair is a chemist at the NASA Langley Research Center who creates new materials used in aerospace systems. Dr. St. Clair invented a new type of plastic material, a thermoplastic, and developed a process for producing it. Once Dr. St. Clair was sure the material had reliable properties and could be mass-produced, he began discussing it with manufacturers in order to transfer both the material and the production process. He scheduled a number of workshops, seminars, and lectures for a wide variety of non-aerospace organizations. In addition, he played a role in technology transfer conferences co-sponsored by NASA and the Aerospace Industries Association of America for both Fortune 500 and small companies. During the final development stages, he worked with potential producers and users to refine both the material and the manufacturing process for their purposes.

Technology and Applications

Composite materials are often used in place of metals to decrease weight and add strength. Composites materials are made of fibers (usually carbon fibers) impregnated with a resin or adhesive in a matrix-type format. Most resins limit the composites to applications involving temperatures not exceeding 350 degrees Fahrenheit. The advanced composite materials used by NASA must be able to withstand temperatures as high as 450 to 500 degrees Fahrenheit for up to 10,000 hours. To find a resin that can be used in higher-temperature environments involves long-term experimentation exploring the nature of a new resin as well as methods to process it. The material must also be volative-free during processing and have a high modulus. If all of these objectives are met, NASA makes its new formulations available to commercial sources and suppliers of advanced materials to convert into materials that can be mass-produced on a cost-effective basis.

Dr. St. Clair met all of these objectives by inventing a new polymer, generically called “polyimide sulfone.” It combines the properties of two classes of polymers, polyimides and polysulfones, thus “polyimide sulfone” (or PISO2). One part of the compound, the polysulfones, is easy to process but very soluble. However, when combined with polyimides, the resulting polyimide sulfone resists solvents. The combination, therefore, enables polyimide sulfone be used in applications where solvents such as aviation fluids, adhesives, and other corrosive types of fluids are present. Polyimide sulfone can be used as a matrix-type resin to bind together the fibers reinforcing composite materials. In addition it can be dissolved in solvents and molded like a foam to form products. The resulting composite materials and other products are lightweight and can be used in many types of industrial applications. They are thermally stable when exposed to high temperatures (700 degrees Fahrenheit) for long periods of time. All of this makes PISO2 superior to current plastics used in engineering because the quality and longevity of the ultimate products are improved. It is relatively easy for manufacturers to process because it requires only moderate temperatures and pressures to produce, and therefore it can be produced at a relatively low cost. In addition, during processing, it does not release volatile chemicals so it has low-toxicity.

The Laboratory

The NASA Langley Research Center is one of nine NASA field centers that perform research to advance aeronautics and space flight. Langley, which is located in Hampton, Virginia, employs over 5,000 people and has a budget of around $500 million. The center has unique facilities such as a space simulation complex, a pyrotechnic test facility, a scientific visualization system, a bolt tension monitor, over forty wind tunnels that test speeds as high as Mach 20, and a model-building wind tunnel.

University Involvement

HTS' first SBIR contract was a joint SBIR with Dr. Bruce Norman, a chemical engineering professor at Rensselaer Polytechnic Institute (RPI), who helped to do the development work. RPI is in Troy, New York, where HTS was formerly located.

Funding, Financing

High Technology Services, Inc. (HTS), a small, minority-owned materials testing and consulting firm in Troy, New York, received Phase I and II NASA Small Business Innovation Research (SBIR) contracts to adapt PISO2 to specific applications like specialty coatings for electronic devices and to improve its processing. The company's intention was to eventually mass-produce it for sale to other companies. HTS originally produced the material as a solution called polyamic acid, but it became apparent that they could achieve more processing flexibility if it were available in powder form. So the company set to work to develop a commercial process for producing it in powder form and to identify related applications.

Also, the New York State Energy Research and Development Authority (NYSERDA), a state public-benefit corporation, awarded HTS cost-shared contracts for materials development work. NYSERDA tries not to compete with venture capital groups and banks, so it funds smaller companies that have technologies they are trying to get ready for the market. NYSERDA invests some $17 million each year in R&D projects, at no more than $250,000 per project. Recipient companies repay NYSERDA based on 1.5 percent of sales, until the original investment is returned. NYSERDA contracts can cover equipment purchases, third-party testing, or hiring of new employees, but are not used to pay a company principal's salary.

Intellectual Property

A graduate student from the Massachusetts Institute of Technology helped Dr. St. Clair with scale-up work on the technology at NASA Langley. They filed the invention disclosure together and are listed as co-inventors on the patent. Two patents for the material and the production process were issued in August 1983 and December 1984.

Dr. St. Clair explained that, where there is a graduate student, professor, post-doctoral fellow (such as through the National Research Council), or contractor (such as from Lockheed Martin) working on the technology, that individual can elect to assign his or her rights to the government so that the agency owns the patent in its entirety. Alternatively, the individual can elect to retain his or her portion of the rights (half in this case). The MIT student chose the latter, and MIT filed the patent on behalf of the student.[6] The individual from the university is not required to allow their university, as agent, to receive any portion.

Technology Transfer Mechanisms

Soon after the process was patented, NASA approved manufacturing licenses for Celanese Corporation and M&T Chemical, Inc. These companies produce high-performance plastics, resins, and composite materials. Several years later, HTS also obtained rights through its SBIR contracts and the Bayh-Dole Act. HTS also has licenses for several other NASA patents, but the company's core product line is based on the PISO2 technology. The company was founded in 1983 by its president, Mr. Milton L. Evans, who had worked at General Electric Company for two decades in a variety of positions, including scientific, marketing, and management.

Dr. St. Clair[7] noted that when the federal government grants a technology license, there are many rules surrounding the royalty-sharing arrangements. If there is more than one federal inventor, they share the inventor's portion of the incoming royalties (20 to 25 percent at NASA). NASA gives the inventor(s) all of the up-front money for a license agreement. For example, if $100,000 is provided by a licensee up front, then NASA would give each of four joint inventors $25,000 the first year of the license. If the agreement calls for six percent of gross sales in running royalties, each year NASA would take 75 percent of that total, and then split the remaining 25 percent among the four inventors. By law, an inventor can receive no more than $150,000 per year over and above his or her salary.

Although royalty-sharing arrangements provide incentives for laboratory scientists to work harder at technology transfer, Dr. St. Clair[8] pointed out that various implementation issues need to be examined in coming years. For example, multiple inventors are now often involved in technology transfer activities which may call for mechanisms to resolve potential disputes over royalty-sharing. In this regard, NASA has an "Inventions and Contributions Awards Board" which could address this need at the agency level. He added that it would be important for such a mechanism to appear objective in terms of favoring all the various technology areas.

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[6]Interview with Dr. St. Clair, August 8, 1996.

[7]Ibid.

[8]Interview with Dr. St. Clair, August 8, 1996.

User Groups

The resin industry is a $5 billion-a-year industry. During the 1980s, new types of resins provided significant benefits to the aerospace, transportation, electronics, chemical, and consumer goods industries. It is anticipated that these benefits will continue to accrue through the 1990s as new markets and uses for thermoplastic materials are stimulated.

Polymer resins are an ingredient in composite materials which are used in aircraft structures. Laminating resins are also used in printed circuit boards, because matrix-type resins offer protection from degradation induced both electrically and chemically, as well as through radiation.

Barriers to Commercialization

The barriers HTS has encountered have been mostly financial. It is hard for a small company to bring a complex technology to market. Testing and development work is expensive, as are the raw materials. Mr. Evans[9] notes, however, that NASA has been very cooperative (he has met with NASA Administrator Dan Goldin) in providing the amount they required to get off the ground. NASA provided "a few thousand dollars," according to Mr. Evans,[10] to buy material samples to evaluate its possible use in space applications. The agency is interested in getting them linked with others to license the material and get it commercialized. NASA has also provided HTS with some publicity: an article on PISO2 in NASA's *Spinoff 1992* highlighted HTS as much as the material.[11]

User Benefits/Economic Impact/Outcomes

Celanese License: NASA licensed the technology to Celanese Corporation who intended to manufacture the product because the company did not have any materials in this temperature range like its competitors such as General Electric. After the license was signed, the company assigned researchers to the project. However, shortly thereafter Hoechst AG, the German parent company, bought out Celanese, and the company's CEO retired. Hoechst Celanese Corporation decided not to pursue this and dropped the research. Dr. St. Clair[12] felt that Hoechst Celanese could have been competitive with General Electric, producing the material at about $1 to $10 per pound, depending upon the ultimate uses. NASA technology transfer had

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[9]Interview with Mr. Evans, September 16, 1996.

[10]Ibid.

[11]James L. Haggerty, *NASA Spinoff 1992*, National Aeronautics and Space Administration, Office of Commercial Programs, Technology Transfer Division, ISBN 0-16-038211-4, 1992, p. 109.

[12]Interview with Dr. St. Clair, August 8, 1996.

incomplete records and Celanese had no record of the license being terminated in writing, however, it is assumed that Celanese abandoned the license.

M&T Chemical License: NASA licensed PISO2 to M&T Chemical, Inc. M&T Chemical, a medium-sized company, had previously bought a small start-up company founded by a former General Electric scientist who had a number of patents on materials in the polyimide family and a marketing partner. Presumably, M&T wanted to round out their portfolio in polyimide materials to make the entire portfolio more valuable commercially. M&T Chemical started prototype work on the technology and began marketing PISO2 as "M&T-4605" in 1985. Subsequently, Elf-Acquitaine took over M&T Chemical after the M&T employee with the related patents had left the company. Elf-Acquitaine sold the PISO2 technology rights to National Starch, and M&T is presently out of this business altogether. National Starch is not actively pursuing commercialization in spite of keeping up with the licensing fees. Since NASA does not currently have any record of other licenses on the PISO2 technology, it is presumed that the license has either expired, or reverted back to NASA, or is inactive.

High Technology Services SBIR: HTS obtained rights to adapt PISO2 for specific applications through Phase I and II NASA SBIR contracts. Originally located in Troy, New York, HTS now does business as High Technology Systems, Inc. outside of Albany, New York. The company produces the material "Techimer 4001" in both powder and solution forms and has introduced it to the marketplace. The material's principal application is as a matrix resin for composite materials. But it has a niche market according to HTS' founder Mr. Evans,[13] because it can be molded into thermoplastic products and if it doesn't work out, it can be melted, re-processed, and re-used.

HTS is currently marketing Techimer 4001 as a high-performance thermoplastic that can be used to make aircraft structural adhesives or coatings that protect interior electronic components from high temperatures and radiation. According to Langley personnel, HTS manufactures and sells the material in small quantities that do not allow them to get the volume up or the price down. For larger volume sales, HTS contracts with a manufacturer to produce Techimer for them on a toll basis. HTS then sells the material for two to five times the cost of producing it, so the cost ends up being too high. Mr. Evans[14] confirmed that although Techimer is still a viable product for them, the response has not been that positive. There have not been major sales partially due to competition by DuPont.

HTS is working to develop an even better process and new customers. For example, they are exploring the material's use in a flame-resistant foam for both aerospace and marine applications. Apparently, it does not burn, drip, or smoke when exposed to a flame. In addition, the material is under evaluation for use by Praxir (formerly Union Carbide) and other fabricators,

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[13]Interview with Mr. Evans, September, 16, 1996.

[14]Ibid.

processors, and end users, which might increase sales. Mr. Evans[15] hopes that, eventually, molded aircraft and automobile parts will be made from the material.

International Activity

HTS has supplied samples to European countries, including Germany, France, and the United Kingdom, but nothing has developed. Firms in China and Japan are also interested in the material.

Government Gains

According to Dr. St. Clair,[16] it's possible that NASA may revisit the PISO2 material as a candidate for renewed industrial marketing efforts resulting in more widespread commercial availability for ultimate government applications (along with the possibility of increasing related R&D funding).

Dr. St. Clair pointed out that there is a positive factor regarding royalties being disbursed to the relevant laboratory (rather than being returned to the U.S. Treasury, generally). The laboratory (or NASA field center, as in this case) might decide, for example, to provide a portion to inventors working in non-patentable technology or technologies related to the agency's mission such as space exploration that may not be commercializable or income-oriented.

Economic Development, Technical Assistance

Mr. Evans recently attended a NASA-sponsored mentor/protégé workshop in Springfield, Virginia, where HTS was introduced to Lockheed Martin. The two firms have since been in contact to examine how Lockheed Martin might use PISO2 in a defense or aerospace application. The New York State Energy Research and Development Authority also invited HTS to NYSERDA-sponsored programs.

Elapsed Time

As noted, the material and the process were jointly patented by NASA and MIT in 1983 and 1984. In 1985, soon after the process was patented, NASA approved the first manufacturing license. In 1990, HTS was awarded the NASA Phase I SBIR contract. HTS's Phase II SBIR contract was finished in 1992.

[15]Ibid.

[16]Interview with Dr. St. Clair, August 8, 1996.

Case 3 (1986) - Substance Tracer Technology

Role of the Researcher and Other Laboratory Personnel

Dr. Russell N. Dietz at Brookhaven National Laboratory (BNL) won an award from the FLC for his perfluorocarbon tracer technology. He now heads the Tracer Technology Center in the laboratory's Department of Applied Science, Environmental Chemistry Division. The Tracer Technology Center has a staff of about five laboratory scientists. Like other DOE laboratories, Brookhaven has its share of visiting researchers. In the case of the tracer technology, other personnel who were involved in various aspects of its testing or development included: a visiting scientist from Israel, a student collaborator, and a physics teacher from a local high school.

Since the early 1980s, Dr. Dietz and collaborators have promoted the technology in a number of publications. They published articles in scientific and technical journals including air pollution and microbiology journals. Their papers appeared in the proceedings of trade organizations such as the American Society for Testing and Materials. They published papers for BNL and government agencies (i.e., the National Oceanographic and Atmospheric Administration). They wrote and presented at seminars sponsored by the Electric Power Research Institute. They also published test and demonstration reports. An innovative approach they have incorporated is the use of a videotape on the technology's applications.

In order to determine other applications for utilities, in 1994, Dr. Dietz conducted a demonstration sponsored by Long Island Lighting Company (LILCO) on the use of the tracer technology to provide on-line measurement of air inleakage into its power stations, as well as underground pipelines and underwater cables. Another LILCO demonstration certified the leak tightness and developed an acceptable protocol for testing its oil-fired gas turbine systems. Similar demonstration projects were also performed with Union Electric in St. Louis and Boston Edison.

Technology and Applications

The technology works via an injector or other type of apparatus releasing a very small amount of a perfluorocarbon "tracer" into the atmosphere or underground cable pipes. The tracer acts as a simulated pollutant and "tags" the surrounding substance, such as the air and/or underground fluid. One or more tiny sampling devices are used to follow the tracer and track its course over time. The level of sensitivity of the sampling devices is so high that only very small amounts of tracer are used, so the technology is environmentally safe. There are five per fluorocarbon tracers that are routinely used. The data collected by the sampling devices is analyzed at the laboratory and used to create models of ventilation flow, heating leaks, air impurities, or other systems it is tracing.

These devices are left in place for anywhere from a week to a month. They can be placed on street lights for outdoor monitoring purposes. Outside, the sampling devices can measure the movement of air pollution of all types, even the fallout from a nuclear disaster. In a house or building, they would be placed every 500 feet or so. In the case of underground cables, a "sniffer" is used to test the air over the pavement since the tracer will permeate the soil and enter the atmosphere through cracks in the pavement.

The two major application areas for this technology are leakages in the air and underground. There are a variety of specific usages in each area. The following sections will divide up the discussions of the technologies by these two areas plus a miscellaneous category.

Ventilation Analysis: The original application for this technology was measuring building ventilation and air leaks. Many R&D-type institutions, both public and private, need to know this information about buildings and homes in order to normalize indoor air quality. For example, designing and implementing an isolation room or operating room for a hospital requires ventilation challenges because the spread of contaminants must be guarded against while maintaining a comfortable environment. The technology could be used to certify the performance of heating, ventilating, and air conditioning (HVAC) systems.

Underground Leak Detection: Another application area researched by Dr. Dietz early-on involved the electric power industry. The tracer technology has been used, for example, to pinpoint leaks in underground power transmission cables so that fewer excavations are needed per leak site. It has also been used to detect leakage of air into condensers for power station systems. In addition, the technology has applications for natural gas and fuel oil utilities and industries, because it has the potential to identify leaks in underground tanks and pipes, or to study petroleum reservoirs.

Measuring the tracer concentration for petroleum reservoirs around the world works like building ventilation. Fluids are injected into the injection wells to push the petroleum up to the production wells. When the injection fluid is tagged with tracers, it helps them to understand timing to reach production wells and other engineering characteristics. In the past, producers used radioactive tracers; in 1986, they started using perfluorocarbons for tracers.

In addition to these original applications, there are a number of applications for this technology with "potentially large markets . . .The potential for new applications and markets is significant," according to Dr. Dietz.[17]

The technology can be used to detect fire. Tests have been performed demonstrating the capability of the tracer technology to detect and locate thermal overheating of electrical components in a system. The tracer is mixed with insulating paints and other materials to form insulating coatings around electrical wiring and components. When the system is monitored, if

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[17] R. N. Dietz, *Commercial Applications of Perfluorcarbon Tracer (PFT) Technology*, Presented at the Department of Commerce Environmental Conference, "Protecting the Environment: New Technologies -- New Markets," Reston, Virginia, September 5-6, 1991, BNL 46265, June 1991, revised September 1991.

the temperature increases, this overheating causes the tracer vapor to be emitted. Sampling devices placed throughout the system not only detect the overheating, but also localize the problem to a specific section of wiring.

Other application areas include explosives detection, environmental monitoring, disaster emergency management, and instrumentation sales. The brochure for the laboratory's Tracer Technology Center explicitly states that the center is seeking private partners interested in proprietary agreements related to the food packaging industry (for screening the seal integrity of food packaging), semiconductor component leaks, and equipment leak certification. Dr. Dietz emphasized, "The opportunity exists for establishing commercial services based on the technology."[18] Also, opportunities exist related to sales of the instruments used for doing the analyses. In particular, the paper noted that there was a need for several instruments to be commercially prototyped and manufactured according to specific end-user requirements.

The Laboratory

Brookhaven National Laboratory is a government-owned, contractor-operated DOE laboratory. Until 1997, BNL was operated by Associated Universities, Inc., a non-profit research management organization sponsored by nine universities: Columbia, Cornell, Harvard, Johns Hopkins, MIT, Princeton, Pennsylvania, Rochester and Yale. BNL's original mission focused on the peaceful aspects of nuclear science such as nuclear medicine. It has since broadened to include other aspects of high-energy physics and energy conversion and storage. BNL now includes oceanography, atmospheric and environmental sciences, and other multidisciplinary frontiers of science.

Since the end of World War II, BNL has been located at the former site of Camp Upton in the center of Long Island in Upton, New York. BNL has an annual operating budget of almost $300 million and a staff of about 3,500. The laboratory has large, complex research facilities (called the "big machines") such as reactors, accelerators, and superconductors. They will allow scientists to observe phenomena that have not occurred since the Big Bang. The laboratory has worked to make its facilities accessible to university and industry scientists through cost-shared cooperative research programs based upon proposals for use. It has earned a reputation beyond the scope of most individual institutions for making its unique facilities available. For example, fourteen major corporations including Dupont, Kodak, Exxon, IBM, and Mobil, have an ongoing presence at the synchrotron radiator, which is the world's largest synchrotron. Basic research may be performed at any of the laboratory's designated user facilities, subject to availability of that facility. Even proprietary research may be performed at the laboratory, as long as BNL and the outside user enter into a formal Proprietary User's Agreement. In such a case, the user would pay full cost recovery to BNL for machine time and any related technical services provided by the laboratory. Also, the user has the option to take title to any inventions resulting from work at the facility and to consider all data generated at the facility as proprietary.

[18]Ibid.

University Involvement

Universities often do air-quality studies for builders and installation manufacturers in response to EPA requirements. BNL is sometimes requested to assist in those studies.

Funding, Financing

The Tracer Technology Center at BNL makes roughly $75,000 to 100,000 per year for its services, doing business with about fifteen to twenty customers each year. The cost of each service is based upon a BNL pricing structure depending partly upon internal cost requirements, just as is the case with the other BNL-provided technical services and facilities. There are probably only three or four other laboratories in the world that have similar capabilities. For example, BNL built an analytical capability for the Japanese government, and the Netherlands copied the technology. So, there is a demand for the service, albeit not enough to justify offering it commercially.

Each project is performed under a separate contract issued at the time of the activity, with the user issuing a purchase order for the service. However, the early projects done with the electric utilities were considered R&D projects to demonstrate the feasibility of the concept. The Consolidated Edison of New York (Con Ed) tests were conducted under a DOE contract with the Electric Power Research Institute (EPRI): they were paid for by Con Ed, EPRI, and Empire State Electric Energy Research Corporation (ESEERCO). Con Ed is a private utility that has 25 percent of the underground cables in the United States. EPRI is an R&D consortium of member companies. ESEERCO is a non-profit R&D corporation in New York, a conglomerate of electric utilities in New York. The procedures used in each case vary, depending upon the application area. For example, for the building ventilation, BNL provides a kit containing the measurement device to the customer who places it on-site. After the device has collected data on-site for an appropriate amount of time, the kit is returned to BNL. The analysis is forwarded to the customer when completed. For the utility work through EPRI, Underground Systems, Inc. tags the feeders; then, the laboratory personnel drive around with the laboratory equipment and locate the leak.

Intellectual Property

Dr. Dietz said laboratory researchers tended to publish rather than patent in past years. Along these lines, the early applications for this technology were not patented. In recent years, however, Associated Universities, Inc. (AUI), the laboratory's contracting operator, developed a more active program of establishing AUI ownership, through patenting, of BNL technologies.

The tracer technique for locating underground line leaks is a proprietary, knowledge-based system that belongs to EPRI. A patent was never filed in this area or any other area except for a patent for an early warning pre-fire detection system (using tracers) issued to AUI in 1993. This is an extremely sensitive system to detect potential fires before they ignite. Dr. Dietz and

Gunnar I. Senum are listed as the inventors.

Technology Transfer Mechanisms

Ventilation Analysis: Dr. Dietz built a complete tracer analytical system for the NAHB Research Foundation so that organization could provide the ventilation/leak detection service commercially for building analysis. In doing this, he further developed the technology so that it would be easier to use and more economical. Initially, the National Association of Home Builders' (NAHB) Research Foundation in Rockville, Maryland, was interested in making this technology available as a service to the NAHB constituents. NAHB works with home manufacturers, building material suppliers, commercial building owners, owners' associations, and utility companies. The intention was to provide a nationwide monitoring service to home owners that assessed the air leakage of homes and building materials. NAHB would provide customers with a statement certifying the level of need for weatherization to reduce energy consumption in old homes or certify the energy efficiency of new homes. The tracer technology was transferred to the NAHB Research Foundation through an exclusive licensing agreement between BNL and a private company, AIM, Inc., in Washington, D.C. BNL helped to set up this company so that they could perform the service for NAHB. AIM's analysis laboratory was set up at NAHB; it was necessary to have the equipment in order to be able to perform the tests.

For a related application, Dr. Dietz developed and tested various ways to evaluate the performance of hospital isolation room ventilation systems. He worked in partnership with Stony Brook University Medical Center and a company called Perfect Sense, Inc., of the city of Islandia on Long Island. The company is in the ventilation business, and their main line of work is making sensors and system controls that respond to pollution.

DOE headquarters put in place a CRADA providing funds for BNL to participate with the company. The company sponsored its own time working on the CRADA, which is standard procedure. Bob Vandella, the company's president, was hoping the instruments could be implemented on-line to warn the hospital of ventilation problems in, for example, isolation rooms, operating rooms, emergency rooms, intensive and critical care units, and HIV and tuberculosis wards.

Underground Leak Detection: Dr. Dietz conducted several tests of the electric utility application of the technology in conjunction with Con Ed, EPRI, and ESEERCO. Tests were conducted in 1988, 1990, and 1992 on both simulated and real leaks of dielectric fluid within subsurface pipes. A companion project was carried out with Cablec Utility Cable Company to determine whether the tracer technology works on their pipes.

The demonstrations of the tracer technology in pinpointing the Con Ed leaks were successful because they showed that the technology was more precise than conventional methods. The demonstration project with Cablec Utility Cable Company also successfully verified that the tracer technology worked on their pipes. As a result, EPRI is promoting this service to companies that are members of the EPRI consortia. Underground Systems, Inc. has a license with EPRI to provide the underground cable testing commercially. The company developed a special injection system used to introduce the tracer into a pipe. This is a case of commercialization of both the instrumentation and the service.

Although the underground line leak work was quite successful, BNL found it was not as easy to quantify and accurately pinpoint a leak in the other utility areas, so BNL is not promoting related application areas.

The Tracer Research Corporation, an established commercial laboratory in Arizona for detecting leaks from underground storage tanks, had its own instruments and procedures that did not involve this tracer technology. Communication between Dr. Dietz and the company led to Tracer performing some tests with BNL to see if they wanted to begin using the tracer technology. In one of these research projects, a tracer was used to tag underground storage tanks in seven cities in Massachusetts (Hanover, Concord, Lexington, Peabody, Milton, Revere, and Freetown) and the results were compared to conventional warning signals for determining the integrity of underground tanks. The tracer was more accurate (100 percent) in detecting leaks.

Other Applications: A new spinoff of this technology is being explored which would "tag" explosives related to clandestine bombs in airports. For this application, BNL loaned one of their devices to Vacuum Instrument Corporation on Long Island, New York. The company is working on developing its own commercial prototype sniffer. It is called COPS, for continuously-operating perfluorocarbon sniffer. This system can be used to pinpoint tagged fluids in less than ten seconds. Vacuum Instruments is a company that provides leak detection services for commercially manufactured components such as air conditioner condensers and heat exchangers, automobile engines, etc. They were interested in seeing if the BNL technology would work better and/or more cost-effectively than their existing technique.

Pre-fire detection is not being actively pursued at the present time. Dr. Dietz and his colleagues have not found an angle for promoting a viable commercial product, although the concept works well. The laboratory's marketing materials state that licenses on this patent are available on an exclusive or nonexclusive basis, and that the "competitive advantage" is such that a system is "commercially practical." Obviously, AUI has also developed an active licensing program for making its technologies readily available for commercialization. In fact, in a BNL Office of Technology Transfer brochure, the tracer technology was listed as the third example, although 62 technologies are listed as available from a list that is updated as of mid-1996.

User Groups

BNL provides the tracer technology service for customers in the United States, Canada, and occasionally overseas. In addition to all of the projects and users highlighted in this case (utilities, hospitals, petroleum companies, etc.), laboratory service users include small R&D laboratories, utilities, air-quality agencies performing studies, and universities. For example, BNL recently performed the building ventilation service on 1,500 homes for a customer in the Netherlands. The petroleum reservoir work has been done for U.S.-based companies, only.

Barriers to Commercialization

The tracer technology-type services, in the various applications noted, continue to be offered commercially in a small way through Stieff R&D, Perfect Sense, and John Booker. Generally, each of the companies that has entered this area has found that the market does not offer enough of a return on investment for the technology to serve as the main service or product line for a stand-alone commercial entity. Each service provider has realized only a few thousand dollars worth of revenues in this area, which represents a side venture for each of the companies.

Other Factors

BNL obtains its perfluorocarbon tracers from British Nuclear Fuels, Ltd. at about $150 per kilogram. American companies make perfluorocarbon compounds using various electrochemical processes that don't work as well with the BNL tracer methodology. As far as the equipment BNL must purchase to do this work, the samplers and related components (like the adsorbent material) are manufactured by Gilian Instrument Corporation, Computer Control Corporation, and Bios International all in New Jersey; and, Rohm and Haas Company and Supelco Incorporated in Pennsylvania.

User Benefits/Economic Impact/Outcomes

Ventilation Analysis: The NAHB service was advertised for four years. However, it never materialized as a business opportunity because it did not bring in enough of a return on the investment to support a stand-alone commercial laboratory using just the tracer technology for analyzing ventilation and air leaks. Once it became apparent that the business would not succeed commercially, all three parties (BNL, NAHB, and AIM) discussed the issue to resolve what to do. Although one of the options involved having NAHB continue to promote the service with an additional cost for the value-added, in the end BNL bought back the equipment from the company, and the service is no longer available through NAHB.

The part of AIM that was involved now exists under the name Stieff Research and Development Company, Inc. headed by Lawrence Stieff, vice president of AIM. AIM/Stieff R&D have customers in Sweden, among other locations, so they still make use of BNL's service and Dr. Dietz's scientific and technical support. When BNL bought the equipment back from AIM, Inc., they combined it with the Tracer Technology Center's other analytical systems.

The CRADA work with Perfect Sense, Inc. made it apparent that offering hospitals on-line ventilation testing was not feasible, and that it would be more reasonable to provide the service on an as-needed basis. For one thing, there are no laws or regulations requiring hospitals to do this on an on-going basis, so there is no demand for the service. The company now offers various levels of off-line, independent tests to determine whether air leaks are occurring under continuous operating conditions in specialized hospital rooms. The company's brochure notes that the tracer technology provides the "most cost-effective and accurate testing technology in comparison with alternative methodologies." It also notes that the company's solutions work toward compliance with guidelines issued by the U.S. Centers for Disease Control.

Underground Leak Detection: The estimated cost of each demonstration BNL performed with utilities was $20,000 plus the cost of necessary excavations. A leak usually requires five or more excavations, costing $10,000 to 30,000 each, but with the tracer technology only two excavations are required. Over time, BNL did about twenty "leak hunts" for the utility industry. About sixteen of the twenty electric utility leak hunts have been for Con Ed. Since EPRI is mostly a privately funded consortia, it is not known what kind of revenues are being realized, on the whole, from provision of this service to its members.

With the Tracer Research Corporation joint tests with BNL, although the tracer -- and not their conventional method -- was one hundred percent correct in identifying leaks, the company decided not to use the tracer technology.

Other Applications: Vacuum Instruments Corporation planned to market a tracer instrument and related systems to continue validating and certifying the leak integrity of components of the bomb sniffer. The same technique could be used to certify pressure vessels such as fire extinguishers and other materials used in buildings. However, the instrument uses a radioactive foil that requires licensing by the Nuclear Regulatory Commission to be used for trade, and the company has encountered some difficulty in obtaining that radiation licensing. The company says it still plans to pursue this area, but it is not a high priority.

An example of commercialization of instrmentation, John Booker and Company in Texas collaborated with BNL to build instruments for an Italian customer. A dual trap analyzer, one of the monitoring instruments needed for underground cable testing, was built to customer specification and is available from John Booker. John Booker also provides analysis systems "following the Brookhaven concepts."

International Activity

Dr. Dietz conducted an experiment for the Commission of European Communities that simulated pollutant clouds analogous to the Chernobyl nuclear disaster and the Bopal, India, chemical disaster. Called the European Tracer Experiment (ETEX), two tests were conducted in October and November of 1994. A tracer was released to test and improve the computerized models that predict the atmospheric dispersion of these types of pollutants. This type of activity has significance for global emergency planning and management: in the event of such an emergency, it could result in earlier warnings thereby saving lives. In other international activity, a demonstration project was conducted in England with British Railway.

Government Gains

BNL provides the tracer technology service to other government users. For example, in 1991, the Marshall Space Flight Center in Huntsville, Alabama, demonstrated the tracer technology to determine the leak tightness of future NASA space station modules. At the time, another approach being considered by NASA to determine module tightness was the pressure decay approach. The demonstration showed, however, that the tracer technology would require less time and would be more accurate. So NASA planned to leak-certify the space station modules using the tracer technology.

Another government user was the U.S. Environmental Protection Agency. In 1992, the technology was used for atmospheric tracing to study whether the haze in the Grand Canyon came from the Los Angeles basin or from the Mohave power generating station. The stack was monitored for fifty days, a multimillion dollar effort. The EPA program monitor, Marc Pitchford at the EPA office in Las Vegas, was quoted as saying there was no way EPA could have done this without the BNL technology.[19]

Elapsed Time

As of 1996, the tracer technology had been under development at BNL for over twenty years with many milestones. In 1986 when Dr. Dietz received his award from the FLC, the laboratory had entered into its license agreement with NAHB and AIM, Inc. The service was offered through NAHB (for building ventilation) until about 1990. The very successful underground electric utility tests were conducted from the late 1980s to the early 1990s. The tests to determine other electric utility applications didn't take place until 1994. As noted, the underground leak detection is now still offered as a service to EPRI member companies. The petroleum reservoir work started as the regulations were changing in the mid-1980s. The inter-agency projects with NASA and EPA took place in 1991 and 1992, and the major European project took place in 1994. The explosion detection R&D continues. The instrumentation improvement work and instrumentation sales and services are ongoing.

Case 4 (1986) - Slow-Release, Alginate-Based Herbicide/Pesticide

Role of Laboratory Researchers and Other Personnel

The researcher in this case, Mr. William J. Connick, Jr., is a research chemist in the Commodity Utilization Research Unit of the U.S. Department of Agriculture (USDA) Southern Regional Research Center (SRRC) in New Orleans. His unit specializes in biocontrol formulations to control agricultural pests. While researchers like Mr. Connick deal with chemistry, he has teamed with a variety of scientists at other facilities dealing with the biological sciences. This case shows how and why researchers from the two fields came together to

[19]Interviews with Dr. Dietz, August 16, 1996 and September 16, 1996.

develop a new area of research.

Mr. Connick began his work focusing on chemical applications, but he quickly expanded from chemical pesticide/ herbicide applications to living, biological applications when Dr. Paul C. ("Chuck") Quimby approached him after a conference presentation. Dr. Quimby was a researcher at the USDA Southern Weed Science Laboratory in Stoneville, Mississippi. The Stoneville laboratory focused on safe methods of weed control to reduce losses in crops and increase their production, particularly southern crops. Mr. Connick commented to Dr. Quimby that he didn't know that fungi killed weeds. Thus began a long and fruitful collaboration with the Stoneville researchers including Dr. Quimby, Dr. Harrell Lynn Walker, and Dr. C. Douglas Boyette, a graduate student at the University of Arkansas at the time who is now a senior scientist at the Stoneville laboratory.

Mr. Connick also contacted other researchers based on their articles. He saw an article in USDA's *Agricultural Research* journal by a scientist from the Biological Control of Plant Diseases group at the USDA center in Beltsville, Maryland. Mr. Connick subsequently teamed up with the Beltsville scientists, including Dr. Debra R. Fravel, a plant pathologist at the Soilborne Diseases Laboratory at the Beltsville complex, to formulate an alginate-based fungus to control plant diseases. Through the course of this work, Dr. Jack A. Lewis, Mr. Connick's counterpart at the USDA Beltsville complex, screened hundreds of fungi for different formulations. Similarly, Mr. Connick also worked with the USDA/ARS Aquatic Weed Research Laboratory at Ft. Lauderdale, Florida, which researches the control of aquatic weeds through biological methods, among others.

Mr. Connick authored or co-authored articles on each of the technology's applications areas. The article that "started it all" was a 1982 article in the *Journal of Applied Polymer Science* by Mr. Connick dealing with the slow or controlled release of chemical herbicides.[20] The first article on the biological control of weeds using alginate granules was a landmark paper in his series of papers. It was co-authored with Dr. Walker at Stoneville and published in a 1983 edition of *Weed Science*.[21] Another landmark paper was the first paper on the biocontrol of soil-borne plant disease using alginate granules by Mr. Connick and Dr. Fravel (et al) at the Beltsville center, which appeared in a 1985 edition of *Phytopathology*.[22]

The fundamental importance of some of this early work is illustrated by the extent to which Mr. Connick and colleagues are cited in subsequent work. An overview paper by Mr.

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[20]William J. Connick, Jr., "Controlled Release of the Herbicides 2,4-D and Dichlobenil from Alginate Gels," *Journal of Applied Polymer Science* 27: 3341-3348, 1982.

[21]H. Lynn Walker and William J. Connick, Jr., "Sodium Alginate for Production and Formulation of Mycoherbicides," *Weed Science* 31: 333-338, 1983.

[22]D. R. Fravel, J. J. Marois, R. D. Lumsden, and W. J. Connick, Jr., "Encapsulation of Potential Biocontrol Agents in an Alginate-Clay Matrix," *Phytopathology* 75: 774-777, 1985.

Connick, entitled *Pesticide Formulations: Innovations and Developments,* appeared as a chapter in a 1988 publication based upon an American Chemical Society symposium.[23] In this paper, each of the highlighted applications began with the 1983 Walker/Connick paper on biological control. Although Mr. Connick did not mention it,[24] the paper's literature citation noted that Mr. Connick wrote an early paper on alginate-based herbicides for aquatic weed control as far back as 1979 for the International Symposium on the Controlled-Release of Bioactive Materials.

Because of professional connections made through these papers and conferences, Mr. Connick has worked with scientists in many government agencies, universities, and industry over the years. Mr. Connick was in touch with scientists engaged in insect control research. Professor R. C. Axtell, an expert in mosquito control at the North Carolina State University Department of Entomology in Raleigh, read Mr. Connick's papers and contacted him. This resulted in the preparation of floating alginate granules that disintegrate in water to release a fungus that kills mosquito larvae. The testing of this formulation is described in various papers by Prof. Axtell, most notably an article in the 1987 *Journal of the American Mosquito Control Association*.[25] Similarly, researchers at the University of Idaho Department of Plant, Soil and Entomological Sciences cite Mr. Connick's work numerous times in a 1990 article they wrote for the *Journal of Economic Entomology* about their testing of the alginate technology to control aphids in cereals such as brans.[26]

The professional collaborations eventually lead to company collaborations. The first occurred when the Beltsville group enhanced an existing collaboration with Grace-Sierra Crop Protection Company, based in California, to further develop plant disease application. Collabortions with companies are detailed in the section on Technology Transfer Mechanisms.

Technology and Applications

The technology is a process for incorporating chemical pesticides and herbicides into alginate that has been formed into little granules or beads. Alginate is a natural polymer derived from seaweed. It is used in dental gels for impressions, and in the food industry as a thickening agent for foods like puddings and pie fillings. For this technology, the alginate is used as a matrix or medium, and living things such as weed-killing fungi are incorporated into the alginate

[23]William J. Connick, Jr., "Formulation of Living Biological Control Agents with Alginate," Chapter 19 in *Pesticide Formulations: Innovations and Developments*, Washington, D.C.: American Chemical Society, 1988.

[24]Interviews with Mr. Connick, August 28, 1996 and September 6, 1998.

[25]R. C. Axtell and D. R. Guzman, "Encapsulation of the Mosquito Fungal Pathogen *Lagenidium Giganteum* (Oomycetes:Lagenidiales) in Calcium Alginate, *Journal of the American Mosquito Control Association* 3 (3/ September): 450-459, 1987.

[26]G. R. Knudsen, J. B. Johnson and D. J. Eschen, "Alginate Pellet Formulation of a *Beauveria bassiana* (Fungi: Hyphomycetes) Isolate Pathogenic to Cereal Apids," *Journal of Economic Entomology* 83 (6): 2225-2228, 1990.

granules. When dry, the granules stabilize the fungi. Then, when wet, the fungi sprout on the granule surface and release spores in a sustained way over days or weeks.

Alginate formulations are effective against not only weeds, but also plant and soil diseases, and even insects. The effect is the slow release of a weed/pest killer that is superior to traditional chemical spraying because spraying can have negative side effects. Because the delivery of the biocide is direct, the dosages are lower than those used in spraying. Therefore, an indirect effect of this more targeted weed and pest control is reduced groundwater contamination and surface water pollution.

There are a wide range of uses for this technology. It can be used for groundwater protection, and the control of weeds, insects, and plant diseases. More specifically, the technology has been used to fight crop diseases (greenhouse-type root rot), mosquito larvae, aphids that attack cereals, watermilfoil (a submerged aquatic weed), and aflatoxin (a carcinogenic fungus that contaminates certain kinds of nuts and grain). Most recently, the technology is being used for long-term bioremediation of toxic chemicals in the soil.

The aflatoxin applications also appear to have been initiated by Mr. Connick and other researchers at SRRC. Alflatoxin is a carcinogen produced by certain fungi that infect cottonseed, peanuts, tree nuts, and corn kernels. For this application, the alginate formula is used bio-competitively, whereby non-toxic strains of a toxin-producing fungus (*Aspergillus flavus*) are applied in large quantities so that the "good" fungi colonize and prevent the harmful fungi from gaining a toe-hold by "out-competing" them. An article on this was written by the New Orleans researchers in a 1995 edition of *Biocontrol Science and Technology*.[27]

The Laboratory

The SRRC in New Orleans is one of four major research centers for the USDA Agricultural Research Service (ARS) which is headquartered at the Beltsville, Maryland, Agricultural Research Center. The ARS is USDA's in-house research arm. For over fifty years, the New Orleans center has specialized in research on agricultural commodities produced in the southern part of the country, such as cotton, peanuts, and rice. This includes textiles, yarns, fibers, and chemical finishes for textiles. Examples of developments that have come from the SRRC include flame retardant treatments for cotton fabrics, frozen orange juice concentrate, "smart fabrics" that change with weather conditions, and stronger and more vibrant naturally-colored cottons. In addition to the four major ARS centers, there are a hundred ARS laboratories nation-wide.

[27]D. J. Daigle and P. J. Cotty, "Formulating Atoxigenic *Aspergillus flavus* for Field Release," *Biocontrol Science and Technology* 5: 175-184, 1995.

University Involvement

In the university research arena, a vast amount of work has spun off from this technology worldwide since Mr. Connick's early work in this area. For example, University of Arkansas researchers have published papers on their studies on use of the alginate technology for various applications like weed control (in a 1988 edition of *Plant Disease*[28]) and fighting destructive soybean nematodes (in a 1995 supplement to the *Journal of Nematology*[29]). Similarly, cooperative research between the ARS New Orleans center and Tulane University resulted in a paper co-authored with a professor and researchers in the university's Department of Cell and Molecular Biology[30] and ultimately the filing of a patent application for bioremediation applications of the technology. Mr. Connick said the technology had wonderful success as a model research system for many types of projects because it was easy to implement; it was reliable, because the micro-organisms and concepts could be tested in the laboratory; and it was easy to tell whether an organism worked or not.

Although all of this evolved from the research that began at SRRC in New Orleans, not much of the related university research is being done in formal collaboration with the ARS facilities in New Orleans, or any of the USDA laboratories. For one thing, much of the university interest in the technology has been for research purposes rather than for licensing and commercialization.

Funding, Financing

Mr. Connick did not mention any special USDA funding. His research and technology transfer activities were performed under SRRC's research budget.

In the product development stages, Biosys, Inc. supported a number of individual university researchers both in the United States and overseas to perform field research developing efficacy data. This was usually done on a consulting basis without necessarily involving the universities, institutionally. Overall, the products were tested by a number of growers, distributors, and USDA Extension Service entomologists.

The only other support worthy of note was that various companies (eg., the Thiele Kaolin Company of Georgia) provided materials such as the clay used in the USDA/ARS alginate studies. A clay called kaolin is commonly used as a filler in the alginate formulations.

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[28]G. J. Weidemann and G. E. Templeton, "Efficacy and Soil Persistence of *Fusarium solani* f. Sp. *cucurbitae* for Control of Texas Gourd (*Cucurbita texana*)," *Plant Disease* 72 (1): 36-38, 1988.

[29]D. G. Kim and R. D. Riggs, "Efficacy of the Nematophagous Fungus ARF18 in Alginate-clay Pellet Formulations Against *Heterodera glycines*," *Journal of Nematology* 27 (45): 602-608, 1993.

[30]J. W. Bennett, A. J. Turner, A. K. Loomis, and W. J. Connick, Jr., "Comparison of Alginate and "Pesta" for Formulation of *Phanerochaete Chrysosporium*," *Biotechnology Techniques* 10 (1/ January): 7-12, 1996.

Intellectual Property

USDA's current portfolio of patents numbers over 800 for the four major ARS centers along with its system of a hundred laboratories. This system is served by seven patent advisers and five technology transfer coordinators located throughout the country. More than 200 licenses have been issued by ARS' central Office of Technology Transfer (which happens to be located at ARS headquarters in Beltsville). USDA licensees have included companies, individuals, researcher foundations and/or universities, and technology management groups. When a USDA patent is licensed, the inventor can share in royalties "to a small extent."[31]

The alginate technology was patented in the 1980s and 1990s. The first patent on the use of alginates with chemical herbicides was issued to USDA in 1983 ("Controlled release of bioactive materials using alginate gel beads"). Mr. Connick is listed as the inventor. Another related patent was issued in 1986 on incorporating living organisms into alginate for biological control.

The first two patents on the use of the alginate technology for the biological control of soil-borne plant diseases were issued to USDA in 1987 ("Preparation of pellets containing fungi and nutrient for control of soilborne plant pathogens"). The inventors on both patents are Mr. Connick and Dr. Lewis and Dr. George C. Papavizas of the USDA/ARS center at Beltsville.

The first two patents on the use of the alginate technology for biological control of weeds were issued to USDA in 1988 ("Method for the preparation of mycoherbicide-containing pellets"). Mr. Connick and Dr. Walker and Dr. Quimby of the ARS Stoneville laboratory are registered as the inventors. Both of the two sets of 1987 and 1988 patents have the same title and text, but different filing dates and patent numbers. These are what is known as patent "dividends," the later patent involving different applications. In this case, for example, one patent would be for killing weeds and the other for killing insects.

In addition, a joint patent application was filed early in 1996 by USDA/ARS and Tulane University in New Orleans with Mr. Connick listed as a co-inventor. The patent, which is still pending, is in the area of bioremediation of toxic chemicals in soil. Growing from alginate granules, the fungi metabolize the toxic chemicals over time to render the chemicals harmless.

Mr. Connick had some comments about USDA's eagerness toward CRADAs and the effect of this on inventor's intellectual property rights and returns.

[31]Interviews with Mr. Connick, August 28, 1996 and September 6, 1998.

Technology Transfer Mechanisms

The early technology transfer mechanisms in this case were a number of research papers and presentations at national meetings like those of the American Chemical Society and the Controlled-Release Society. As the USDA publications state, ARS has an aggressive technology transfer program and actively pursues relationships with companies. Out of all the government's R&D establishment, USDA was the first government entity to sign a CRADA under the 1986 Federal Technology Transfer Act in July 1987. As of mid-1990, USDA had entered into more than 500 CRADAs with over 100 companies, associations, universities, and other agencies. The technology transfer mechanisms used with each company partner are as follows:

Grace-Sierra Crop Protection Company: Because of U.S. Environmental Protection Agency (EPA) regulations in the early 1980s, W.R. Grace and Company felt that American growers would not be able to compete internationally, and so the company sold its water-soluble horticultural products and related business to a greenhouse company. Soon after this, W.R. Grace merged with Sierra Chemical to form Grace-Sierra Horticultural Products, which produced and sold fertilizers and weed-killing herbicides.

In the 1980s, cooperative research funding provided the only effective way for Grace-Sierra to collaborate economically with the government in a way that protected patents. A Grace-Sierra contact said the problem was that until recently USDA researchers "lived off publications" because that is how they were professionally graded; as a result, back in the 1980s, it was very difficult for collaborating company partners to obtain patents for technologies. Since CRADAs were not possible in the early to mid-1980s, Grace-Sierra successfully proposed cooperative research funding from USDA/ARS to work on biological herbicides as alternatives to chemicals.

At some point, Grace-Sierra Horticultural Products became Grace-Sierra Crop Protection Company. The cooperative work between Grace-Sierra and USDA/ARS - Beltsville evolved into several CRADAs in the late 1980s and early 1990s, and Grace-Sierra was granted a license on the preparation of alginate beads with a biocontrol fungus agents for controlling plant disease. The CRADAs, however, were not all with Grace-Sierra, as the technology passed from company to company in the midst of numerous company ownership changes.

Biosys, Inc.: Another company, Biosys, Inc., a biological pest-control company headquartered in Palo Alto, California, based a product on the alginate technology. The product did not directly infringe the patent, so it did not warrant going through the licensing process, but the early USDA research in this area laid the groundwork to enable the product. Biosys obtained information about the technology through Mr. Connick's papers. Ramon Georgis of Biosys called Mr. Connick to ask if he could visit him at the New Orleans center; they were interested in the fact that the process was being applied to living organisms, as opposed to inorganic chemical substances.

Mycogen Corporation: An exclusive license was granted to Mycogen Corporation of San Diego, California, on all the related patent applications involving biocontrol of weeds. Dr. Walker was instrumental in transferring the alginate technology that he and Mr. Connick invented to Mycogen. In fact, Dr. Walker left government service and went to work for Mycogen in Ruston, Louisiana, for several years.

EcoScience Corporation: Scientists at the University of Florida's Center for Aquatic Plants were looking for better ways to control aquatic watermilfoil. As with regular weeds, the traditional control methods, which offer only temporary relief, involve chemical herbicide treatments and/or expensive mechanical cutting. The researchers were seeking biological control alternatives that would not harm the other plant life and living things in the environment. They tested an experimental product that was developed by EcoScience Corporation of Massachusetts. EcoScience had used procedures described in the 1983 paper by Dr. Walker and Mr. Connick to develop the product. EcoScience has a 20,000 square foot research/administrative headquarters facility in Worcester, Massachusetts, and a manufacturing facility in Amherst, Massachusetts. Mr. Connick's contacts were with the company researchers who developed the product, Dr. James Stack, based in Orlando, and Dr. David Miller in New Jersey, as opposed to the university researchers who were testing it.[32]

Mr. Connick continues to test, evaluate, and refine the technology for new uses. The group at SRRC in New Orleans continues to work on the original chemical applications of this technology, in particular, experimenting with changing the release rates. Their research has become focused on reducing pesticides and herbicides leaching into groundwater in order to reduce groundwater pollution. Two SRRC scientists published a paper on this in 1995 in the *Journal of Environmental Science Health.*[33]

User Groups

Since there are a number of uses for the technology, there are also a number of potential user groups. Users for this technology would include farmers: professional greenhouses; nurseries; landscape firms; homeowners; and anyone involved in plant and crop diseases, weed control, or insect infestation. It is particularly useful to users for which chemical spraying is not an option. With the growing level of interest being placed on protecting the environment and worker safety, products derived from plants and biological organisms offer a viable alternative to increasingly unacceptable chemical herbicides and pesticides. Biological controls are specific only to their host plant or pest; in addition, they have minimal toxicity and are highly effective.

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[32]Uma Verma and R. Charudattan, "Host Range of *Mycoleptodiscus terrestris*, a Microbial Herbicide Candidate for Eurasian Watermilfoil, *Myriophyllum spicatum*," *Biological Control* 3: 271-280, 1993.

[33]Richard M. Johnson and Armand B. Pepperman, "Mobility of Atrazine from Alginate Controlled Release Formulations," *Journal of Environmental Health Sciences* 30 (1): 27-47, 1995.

Barriers to Commercialization

In the commercial arena, there are cost issues associated with scaled-up manufacturing of the technology in all of the application areas because the alginate is expensive. So, a user may end up choosing a less expensive method of control. Dr. Georgis[34] reports that scale-up to the 80,000-liter level was a problem on the Biosys products, but the problems were eventually solved.

Another problem is that the product shelf life often doesn't exceed several months, depending upon the product and whether it is in liquid or granule form. As a result of this limited shelf life, introduction of the product overseas has been limited. Nevertheless, Biosys has applied for patents on the formulation in Japan, Australia, Canada, and the European Patent Office.

Other Factors

Mr. Connick emphasized several times that he gets a great deal of personal satisfaction from the impact being made by his technology, not just in this country but worldwide.[35] He said he is amazed at the way the original technology has evolved and branched off into new areas, even without his knowing it. With incremental technology transfer, such as this, it seems easy to lose track of what is happening with the various aspects of the technology and its applications. This is illustrated by a perception on Mr. Connick's part that there were not any alginate-related formulations on the market at the present time even though Biosys and others were marketing related products. Also, it is possible for various scientists to inaccurately gain or lose credit for "cooperative" work by others.

User Benefits/Economic Impact/Outcomes

Since Mr. Connick's original laboratory discovery, a chain of events has led to commercial activity, all of which is helping to maintain the competitiveness of American agriculture in the global market.

Grace-Sierra Crop Protection Company: Grace-Sierra came out with an off-the-shelf product called GlioGard™ Biological/ Microbial Fungicide, the first product to biologically control plant disease through a fungus. GlioGard was introduced regionally in the early 1990s through test markets. It was marketed as an alginate granule preparation that was effective in controlling "damping-off" diseases in greenhouse plants. The active ingredient was *Gliocladium virens*, a naturally occurring non-toxic soil fungus that was antagonistic to harmful plant fungi, thereby controlling what was known as root rot or "damping-off" disease. It was for use in

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[34]Interview with Dr. Georgis, August 28, 1996 and fax communication from him, September 23, 1996.

[35]Interviews with Mr. Connick, August 28, 1996, and September 6, 1996.

greenhouse ("non-terrestrial") growing conditions or for nursery production of plants eventually to be transplanted as field crops. The product had a reasonable shelf life and was easy to handle; it was incorporated into the soil by hand or using a tiller at the rate of a 25-pound bucket to 25 cubic yards of soil. When the product was added to the soil, moisture was absorbed by the GlioGard granules; this re-hydrated and activated the beneficial micro-organisms the granules contained. In the test marketing, GlioGard received a 90 percent acceptance rating, which was very favorable feedback. GlioGard was on the market about two years, and Grace-Sierra sold "thousands and thousands" of pounds.[36] Although it took three years to gain EPA approval, the Grace-Sierra product became the first bio-fungicide product registered by the EPA.

Just as the product received EPA approval, W.R. Grace sold Grace-Sierra to O.M. Scotts Company. During the course of the research between USDA/ARS and Grace-Sierra, there were questions about each fungus they screened and each alginate/fungus formulation they tested. The issues were related to economics (e.g., development costs) and how to scale up from pilot plant to mass production. In fact, upon scaling up the manufacturing of GlioGard, the O.M. Scotts Company ran into problems preparing the alginate beads. At higher levels of production, they became more labor-intensive to produce, and more quality control was required. Plus, the alginate/clay mixture was expensive. So the overall costs were higher. Scotts embarked upon a six-month crash course and changed the formulation. In the end, they re-engineered a portion of Mr. Connick's original technology to make it work (but making it different enough, according to Mr. Connick,[37] that it didn't infringe upon the patent). In any case, according to the company research, Dr. James ("Jim") Walter,[38] the alginate bead preparation contained the fundamental active fungal ingredient that could be traced back to the original work at both the Beltsville and New Orleans USDA/ARS sites.

The change in formulation subsequently required some minor adjustments to EPA's regulatory requirements. After all that, O.M. Scotts Company let the product rights revert back to W.R. Grace and Company. At that point, the product name was changed to SoilGard™ 12G Microbial Fungicide. It was manufactured through the Grace Company's Biopesticides Division. The company decided to distribute it on its own rather than through distributors.

In the summer of 1996, W.R. Grace "changed hands" and sold off several of its products, including SoilGard, as well as the intellectual property rights and related personnel, to Thermo-Electron's Thermo Trilogy Corporation. Apparently, Grace-Sierra recently notified the laboratory that it would not be renewing its license for the next year, although the annual renewal fee had been paid every year until then. Presumably, Thermo Trilogy will need to re-negotiate the technology license with the laboratory. Thermo Trilogy is currently a relatively small private

[36] Interview with Dr. Walter, September 12, 1996.

[37] Interviews with Mr. Connick, August 28, 1996 and September 6, 1996.

[38] Interview with Dr. Walter, September 12, 1996.

company that may go public next year.

Dr. Walter is now director of research and development at Thermo Trilogy. He has worked for each of the succession of companies involved with the technology through USDA/ARS - Beltsville beginning with the Grace Company. Mr. Walter[39] says the base technology has survived despite changes in ownerships, distributors, and formulations, and the resulting product is still on the market and is successful.

Biosys, Inc.: Biosys took the alginate formulation technology and first adapted it for use on window screens, not as granules or beads. The screens were used to trap beneficial nematodes, which are naturally occurring worm-like organisms that seek out and kill insects that damage plant roots. The beneficial nematodes are distinguished from destructive parasitic threadworm-like nematodes that destroy about $100 billion in crops, such as beets, worldwide each year. Mr. Connick learned about the Biosys product from a 1995 American Chemical Society publication containing a chapter on the nematode formulation by Dr. Georgis, D.B. Dunlop and P.S. Grewal of Biosys.[40] The nematodes were combined with alginate technology to create a product called BioSafe.[R] BioSafe controlled soil-based insects in their early post-egg stages -- as larvae and grubs -- as opposed to the adults above ground that feed on leaves.

Being a natural product, BioSafe was exempt from EPA registration. Biosys signed a marketing and distribution agreement with Ortho's Consumer Products Division of Chevron Chemical Company located in San Ramon, California. BioSafe was marketed toward "natural gardeners" for use in vegetable gardens, around fruit trees, with ornamental plants, and in flower beds. It killed flies, beetles, and a type of gnat, but did not harm beneficial insects such as ladybugs or earthworms. It had a five-month shelf life and was on the market until 1995 for a total of about six years. It was available commercially in two sizes: BioSafe[R] 20, treating 480 square feet, and BioSafe[R] 100, treating 2,400 square feet.

Dr. Georgis[41] said BioSafe was a popular product because it was both safe and effective. It was also discovered that it killed housepet fleas, as well. However, when Ortho sold its retail line to Monsanto, they subsequently canceled seventy percent of their products, including BioSafe.

Meanwhile, Biosys signed a two-year CRADA with another ARS laboratory, the USDA Subtropical Agricultural Research Laboratory at Weslaco, Texas, after the laboratory discovered a new species of insect-killing nematodes in 1990. This ARS laboratory, which is six miles from Mexico by the Rio Grande, conducts crop and fruit insect research, and biological pest control

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[39]Interview with Dr. Walter, September 12, 1996.

[40]R. Georgis, D. B. Dunlop, and P. S. Grewal, "Formulation of Entomopathogenic Nematodes," Chapter 13 in *Biorational Pest Control Agents*, Washington, D.C.: American Chemical Society, 1995.

[41]Interview with Dr. Georgis, August 28, 1996, and fax communication from him, September 23, 1996.

research. The CRADA was revised when another species was discovered, and Biosys is now a co-licensee of the technology.

Dr. Georgis of Biosys insisted that this technology was related to the original work by Mr. Connick.[42] Mr. Connick was uncertain how closely related their work was to his original work, and he was careful to point out that he was not involved in the Biosys work.[43] Biosys' CRADA involved at least nine company researchers -- including formulation scientists and field development scientists -- in addition to the ARS scientist, Dr. Jimmy R. Raulston and his group.[44] According to Dr. Georgis, an excellent relationship was put into place (and still exists) between Biosys and the ARS researchers. The Biosys portion of the nematode-related research was completely funded by the company. The research evolved into a new line of Biosys products, three of which are now on the market in both granule and liquid formulations: Vector[R] MC for controlling mole crickets in turf grass or Bermuda grass; Lesco[TM] Vector[R] MC, for insect control; and BioVector[R] 355 for controlling citrus weevils. The two Vector products are marketed by Lesco, Inc. of Rocky River, Ohio, while the BioVector product is marketed and distributed by Biosys.

Although there have been company location moves and name changes, all three products have been very successful. Based upon introduction of the first two products, Biosys' market share increased from 27 to 84 percent in the citrus market (compared to the company's previous product). The third product is doing well in only its first year of introduction. In 1995, 20,000 acres of Florida citrus groves were treated with BioVector 355, and it is expected that this figure will more than double in 1996.[45] Early trials of Vector MC were conducted at one of the world's largest golf clubs in Savannah, Georgia, which previously had spent up to $100,000 per year on cricket control. These BioSafe products are less expensive than chemical pesticides and do not need to be applied as often. For example, the granule version of BioVector is sold in 25-pound drums, each of which will treat twenty to thirty acres of citrus groves (or somewhat less coverage if used in nurseries) at about $20 per acre. The liquid version is sold in a similarly-priced 2.5-gallon jug that must be used within two days. Furthermore, these products can be mixed in with fertilizers during "fertigation," or mixed with registered pesticides. However, seasonal applications must be carefully timed during the year, and it is important that watering occur after each treatment.

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[42]Interview with Dr. Georgis, August 28, 1996, and fax communication from him, September 23, 1996.

[43]Interviews with Mr. Connick, August 28, 1996, and September 6, 1996.

[44]Dr. Raulston recently received a 1996 FLC Award of Excellence "for discovery, development, and commercialization of the Riobravis nematode for control of soil-inhabiting insect pests of major economic importance."

[45]Interview with Dr. Georgis, August 28, 1996, and fax communication from him, September 23, 1996.

USDA/ARS has filed a patent application on discovery of the new nematode. Biosys has developed proprietary knowledge on its formulation and production, and a related patent application is in process. Biosys buys the nematodes from Archer-Daniels Midland, which grows a new batch every thirty days since they are time-sensitive.

EcoScience Corporation: EcoScience, which raised over $80 million in equity capital and public stock offerings in 1992, experimented with a product called Aqua-Fyte™, a bio-herbicide to control watermilfoil in environmentally sensitive lakes and waterways. A company annual report stated that extensive laboratory and field testing was a key part of EcoScience's product development activities. The company received an Experimental Use Permit from the EPA for large-scale trials of the product. The experiments involved laboratory comparisons of treated waterweeds and untreated controls. They also provided the product to the University of Florida researchers for use in their tests of watermilfoil control products. Mr. Connick[46] believes the product was used for experimental purposes only, and that the company doesn't produce it any more.

Mycogen Corporation: Mycogen Corporation maintained its license for a number of years; however, they exercised the right to terminate it about 1993. Apparently, the company decided not to continue in that direction. No products made it to the marketplace.

International Activity

The International Atomic Energy Agency Laboratories, an international consortium based in Austria, that includes the International Atomic Energy Agency, is researching applications for this technology. The Agrochemicals Unit of this laboratory did a search of laboratory research, and their work cited Mr. Connick. They wrote an early paper on the use of alginates for chemical pesticides and have done several papers since then on the use of alginates with herbicides (e.g., 1994 edition of *Pesticide Sciences*[47]), all citing Mr. Connick's research.

Other overseas researchers have also published studies based upon Mr. Connick's work. For example, a 1992 article by scientists at the Institute for Chemical Research in Belgium cites Mr. Connick.[48] A 1993 article by Chinese researchers at Beijing Agricultural University also cites him.[49]

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[46]Interviews with Mr. Connick, August 28, 1996, and September 6, 1996.

[47]Jianying Gan, Manzoor Hussain and Nasir M. Rathor, "Behaviour of an Alginate-Kaolin Based Controlled-Release Formulation of the Herbicide Thiobencarb in Simulated Ecosystems," *Pesticide Sciences* 42: 265-272, 1994.

[48]Debongnie Ph. and Pussemier L., "Encapsulation de Carbofuran ou D'Aldicarbe Dans des Billes D'Alginate: Liberation Retardee, en Solution et sur Colonne de Sol," *Med. Fac. Landbouww. Univ. Gent*, 1992.

[49]Qi Mengwen, Wang Fujan and Wang Huaguo, "Study on Release Dynamics of C-Labelled Herbicides from Controlled-Release Formulation into Water," *Acta Agriculturae Nucleatae Sinica* 8 (4): 240-246, 1994.

Government Gains

Mr. Connick's pending joint patent with Tulane for bioremediation relates to applications that could be used to clean up toxic wastes at military sites, explosive sites, chemical dump sites, and old refineries. It could also be used in Superfund environmental clean-up activities.

Elapsed Time

In 1978, Mr. Connick developed the chemical pesticide applications at his Center in New Orleans and the first patent was granted in 1983. In 1981, he began working on the weed-killing applications with the Stoneville laboratory. He published his first article in 1983, and was issued a patent in 1988. About 1984, he teamed up with the center in Beltsville to begin work on plant diseases and ultimately teamed with Grace-Sierra Company. The first publication with the Beltsville group was in 1985, and a related patent was granted in 1987. The time frame for the commercial activity was as follows:

- The first Grace-Sierra product, which was under development for a number of years, hit the market in 1991.

- The Biosys nematode products from its CRADA with ARS-Weslaco took three to four years from basic research to market introduction. The scale-up of formulation and production to the 80,000-liter level took six months and four or five people. Upon development of the finished product, the marketing effort lasted eight months.

- The EcoScience/University of Florida experiments took place in 1992 and were described in a 1993 article in *Biological Control* by two university researchers.

<u>Case 5 (1986) - Controlled-Release, Chemically-Imbedded Herbicide/Pesticide Material</u>

Role of Laboratory Researchers and Other Personnel

The researchers for this case were Dr. Peter Van Voris, a biologist and senior program manager of the Earth and Environmental Sciences Center at the Pacific Northwest National Laboratory (PNNL); Dr. Dominic A. Cataldo, a plant physiologist; and the now-retired Dr. Frederick G. Burton, a biophysicist. These DOE researchers, with widely varying backgrounds at PNNL, came together to conceive of a new technology for controlling underground root growth where plant roots were unwanted. The researchers' serendipitous convergence into this technology area was the result of a wisecrack at a bridge game related to the idea of putting plants on birth control! At the time, Dr. Burton was doing research at DOE funded by the World Health Organization on a slow-release contraceptive device. Dr. Van Voris' team was made up of a variety of backgrounds, including soil scientists, computers modelers, etc.

The Technology and Applications

The technology is a controlled-release root barrier that incorporates a chemical herbicide into a plastic or rubber material that slowly releases root inhibitor over time. When applied this way, the herbicide is not harmful to plant or animal life. Outside of its “zone,” vegetation can flourish naturally, so it doesn’t harm the environment. Also, the material is safe for children to be around, and it avoids the need to spray chemicals.

Because the technology was originally applied to radioactive sites to control root growth, it needed to release a steady dose of the herbicide over a hundred years. It also needed to control roots without killing the plants, and it needed to be non-soluble so it wouldn’t be washed away. The trick was finding the right herbicide along with a material to which it could be attached such as a polymer or other synthetic rubber that would hold it in place over an extended period of time.

The PNNL group of researchers experimented with a number of herbicides that would control roots, including phosphoric acid, but they all involved cost and risk factors and high maintenance. Eventually, they found a commercially available herbicide called Treflan[R], produced by DowElanco, containing the active ingredient trifluralin. Trifluralin is not systemic, meaning it is not absorbed by the upper leaves of plants or trees, nor will it harm nearby landscaping, birds, mammals, or insects. Also, the concentrations required in order to inhibit root growth are low. It is biodegradable, meaning it decomposes in soil. If it were to be applied directly to soil rather than molded into plastic or a geotextile fabric, it would rapidly decompose. In addition, it is not very water soluble compared to other herbicides. It doesn’t leach in water, and it is non-toxic. So, overall, it was an economical and ecologically sound choice for this technology. Treflan, which was already registered with the EPA, gained EPA approval in April 1990 specifically for use in landscaping and food crop applications.

Three major commercial applications resulted from this barrier: (1) protection for underground plastic watering pipes; (2) a fabric used under sidewalks roads and other structures; and (3) herbicide sewer gaskets. There are a number of other applications still being developed such as controlling insects and rodents.

For the commercial products being produced, the trifluralin active ingredient is shaped into small pellets and bonded onto another material, then slowly released in controlled uniform doses over time. In order to target the technology to particular applications, the researchers varied the herbicide’s concentration and tested it against the roots of a group of control plants. They also experimented with several different types of candidate carrying materials that appeared to protect the herbicide from degradation. And, they varied the thickness of the various carrier materials. The technology could, thus, assume varying shapes and sizes. An “accelerated-diffusion” apparatus was used to test the long-term effectiveness of the pellets combined with other materials, since the carrier material needed to be relatively strong, yet inexpensive to process.

For two of the commercial products, the Treflan was fused into plastic pipes and fittings molded in the factory. For one of the products, the sewer gasket, the PNNL researchers actually designed, constructed, and tested the prototype themselves. In order to develop a prototype for the irrigation pipe application, they worked with Mr. Rodney Ruskin of Agrifim International.

For another commercial product, pellets or dots of the herbicide were permanently bonded several inches apart onto a geotextile fabric. Geotextiles are the textile-like materials placed over soil to help prevent erosion or serve a variety of engineering and/or landscaping purposes. They are becoming increasingly popular. Dr. Van Voris discovered a geotextile fabric in his local hardware store called Typar[R], manufactured by DuPont. They began testing the herbicide in conjunction with this material after trying several others. They also experimented with and discovered different ways to join the herbicide with the material.[50] PNNL was fortunate to have been working with DuPont, a multi-billion dollar chemical company, before its line of Typar products came on the market.

Tests of the root barrier technology's ability to protect the asphalt shields from the plant roots were conducted at the two DOE Colorado sites. Despite a Nobel laureate and other experts brought in by PNNL management saying the technology wouldn't work,[51] the PNNL research team persisted, and the tests were successful.

The Laboratory

PNNL, formerly Pacific Northwest Laboratory, is a government-owned contractor-operated DOE laboratory in Richland, Washington, operated by Battelle Memorial Institute, the world's largest and oldest contract research organization. Battelle has operated PNNL since its establishment in 1965. It has an annual operating budget of almost $450 million and a staff of 4,000. PNNL is a multi-program laboratory. In this era of non-proliferation, the laboratory's modern mission involves solving broad-based environmental waste problems with one very major exception. PNNL is involved with radioactive waste disposal because it is adjacent to the DOE Hanford Site of fifty-year-old underground storage tanks containing defense nuclear wastes. The Hanford Site has an annual operating budget of over $1.2 trillion and staff of over 11,000. Because of this proximity, PNNL tends to focus on environmental restoration. One of the user facilities available at PNNL is the Hanford National Environmental Research Park. Another focal area for PNNL is global climate change. PNNL has earned a reputation for anticipating future national needs and strategizing and planning programs to meet those needs.

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[50] Later, a DuPont scientist developed a more sophisticated injection-molding process for handling this.

[51] Robert Cassidy, "The Blood, Sweat, and Years of Developing a Product: How Researchers at Battelle's Northwest Lab Waged War to Bring a Seemingly Hopeless Idea to Market," *Research & Development* 31 (3/ September): 58-64, 1989.

The technology was originally developed for the DOE system to protect its radioactive waste disposal sites from root penetration. At DOE's Hanford Site next door to PNNL, patrols ride around the site's 570 square miles to check the tumbleweed for radiation using Geiger counters. Similarly, in addition to many others, there are two DOE radioactive waste disposal sites in Colorado. These sites contain, not bomb remains, but uranium remains, called "tailings," from uranium mining, extraction, and milling conducted in the Grand Junction area. The tailings emit radon, a gas which emanates from the ground. As a result, DOE put an asphalt barrier called "Petromet" on top of the Colorado waste sites. Eventually, ultraviolet light from the sun damaged the asphalt, which cracked, and the radon gas came up through the cracks. So DOE put soil on top of the asphalt to protect it from the sun's ultraviolet light, and they stabilized this soil with plants. However, the plants eventually broke up the asphalt shield below them.

University Involvement

There was no university role in this case.

Funding, Financing

The total cost for bringing the technology to its first stage of development at PNNL was less than $250,000 over a three-year period. Rockwell International, which managed the Hanford Site at the time, contributed $20,000 to the development effort. An additional $600,000 from the Office of Nuclear Energy at DOE headquarters (due to applications at the nuclear waste disposal sites), allowed the work to continue and supported the Colorado tests. However, PNNL's managing operator, Battelle Memorial Institute, said the project didn't have any market potential and stopped supporting it. According to the team, their blessing was needed in order to get DOE money.

Only five percent of Dr. Van Voris' group's time is devoted to long-term controlled-release technologies. There are no sources of funding in the DOE's national laboratory system for this technology area. Therefore, the small amount of funding they receive includes private funds from several companies for long-term product development and public funds from the military for pest control.

The other 95 percent of the PNNL researchers' time is spent working on DOE mission areas and other agencies' problems. This work is not related to the herbicide/pesticide technology. While the weapons laboratories are considered the "big dogs" within the DOE system, PNNL is funded out of the Environmental Restoration and Waste Management (DOE/EM) offices at DOE, and the laboratory must compete for funds with other DOE laboratories doing work in this area. As with its other laboratories, DOE/EM decides the overall budget for PNNL, and hears pitches from the PNNL divisions in order to figure out how to allocate that budget. Dr. Van Voris[52] described this competition as "ruthless" and "cut-throat,"

[52]Interview with Dr. Van Voris, September 19, 1996.

both within PNNL and the overall DOE system. He advocated that the best way to survive in this type of environment was to practice strategic planning to handle both the laboratory level and headquarters level.

Intellectual Property

Back in 1979, the PNNL researchers filed an invention disclosure on this technology to control roots. Since then, there have been seven invention disclosures on various related applications.

The first patent was filed in 1983. However, the U.S. Patent and Trademark Office said that unless testing was actually conducted for a hundred years, the claims in the patent application were unacceptable, so what ended up being patented was the process. By 1989, seven additional patents were pending.

Technology Transfer Mechanisms

After the successful tests of the technology, dozens of firms were contacted as part of a concerted technology transfer outreach effort to find licensors. Also, during the 1980s, the researchers wrote a number of papers and made presentations (e.g., the *Journal of Controlled Release*,[53] *Nuclear Technology*,[54] *Water Engineering and Management*,[55] various Pacific Northwest Laboratory papers[56] and marketing materials), and contributed to books.[57] Later, after the technology was licensed, the irrigation application in particular received a great deal of attention in the printed media. For example, various combinations of PNNL laboratory researchers, Mr. Ruskin, and Agrifim company scientists presented and published in proceedings for the International Micro-Irrigation Congress,[58] American Society of Agricultural Engineers'

[53]F. G. Burton, W. E. Skiens, J. F. Cline, D. A. Cataldo and P. Van Voris, "A Controlled-Release Herbicide Device for Multiple-Year Control of Roots at Waste Burial Sites," *Journal of Controlled Release* 3: 47-54, 1986.

[54]J. F. Cline, D. A. Cataldo, W. E Skiens and F. G. Burton, "Biobarriers Used in Shallow Burial Ground Stabilization," *Nuclear Technology* 58: 150-153, 1982.

[55]P. Van Voris, D. A. Cataldo et al, "Stopping Root Intrusion in Sewer Systems," *Water Engineering and Management* (July): 6-9, 1986.

[56]J. F. Cline, F. G. Burton, D. A. Cataldo, W. E. Skiens and K. A. Gano, *Long-Term Biobarriers to Plant and Animal Intrusions of Uranium Tailings*, Richland, Washington: Pacific Northwest Laboratory, PNL-4340, 1982; see also, D. A. Cataldo and P. Van Voris, "A Study of Product and Environmental Concerns with Irrigation Devices Containing Treflan," Richland, Washington: Battelle Pacific Northwest Laboratories, Laboratory Project ID 23113207292, unpublished.

[57]F. G. Burton, D. A. Cataldo, J. F. Cline and W. E. Skiens, "The Use of Controlled Release Herbicides in Waste Burial Sites," in *Controlled Release Delivery Systems*, T. J. Roseman and S. Z. Mansdorf, editors, New York: Marcel Dekker, Inc., 1983.

[58]P. Van Voris, D. A. Cataldo and R. Ruskin, "Protection of Buried Drip Irrigation Devices from Root

National Irrigation symposiums,[59] International Erosion Control Association conference, American Society for Enology and Viticulture,[60] and others. In addition, there were articles by outside researchers involved in the technology that appeared in publications of the American Water Works Association, Hawaii Water Pollution Control Association, and Pan Pacific Green Industry conference. Trade journal publicity, which is more industry-oriented (while peer-reviewed scientific and technical journals are oriented toward university researchers), appeared in *Agriculture Engineering*,[61] *Irrigation News*, *Grape Growers*, *Nut Growers*, and others.

The technology transfer mechanism used with each partnering company is described below.

Agrifim Irrigation International: Agrifim Irrigation International, Inc., N.V. in California's San Francisco Bay area, obtained an exclusive worldwide license from Battelle to apply the technology to keep roots from invading underground watering and agricultural irrigation pipes. Agrifim sub-licensed its Battelle license exclusively to Geoflow™ Subsurface Irrigation, an Agrifim division.

Geoflow has been manufacturing and installing below-ground drip irrigation products for two decades. These systems are buried six to eight inches below ground, with one to two feet between the drip lines. They have many advantages over traditional above-ground watering systems. For one thing, watering with a drip system usually requires only a few minutes a day every second or third day. This type of irrigation has been used traditionally in agriculture, particularly vineyards. In fact, Geoflow has had a long-term relationship with the U.S. Department of Agriculture's (USDA)/Agricultural Research Service (ARS) Water Management Research Laboratory in Fresno, California. In addition to agriculture, the Geoflow watering products are now being applied to landscaping, sports/commercial turf applications such as football fields, and others.

Intrusion Through Slow-Release Herbicides," *Fourth International Micro-Irrigation Congress, Congress Proceedings, Volume 2, Albury-Wodonga, Australia, October 23-28, 1988*.

[59]R. Ruskin, "Reclained Water and Subsurface Irrigation," Presented at *ASAE International Winter Meeting, December 15-18, 1992*, Paper No. 922578, St. Joseph, Michigan: American Society of Agricultural Engineers, 1992; see also, A. Sanjines and R. Ruskin, "Root Intrusion Protection for Subsurface Drip Emitters," Presented at *ASAE International Summer Meeting, June 23-26, 1991,* Paper No. 912047, St. Joseph, Michigan: American Society of Agricultural Engineers, 1991; and R. Ruskin, D. A. Cataldo and P. Van Voris, "Root Intrusion Protection of Buried Drip Irrigation Devices with Slow Release Herbicides," *Proceedings of the Third National ASAE Irrigation Symposium, Phoenix, Arizona, October 1990*, p. 211-216.

[60]Rodney Ruskin, "Subsurface Drip Irrigation in Vineyards," American Society for Enology and Viticulture, Presentation at the Annual General Meeting, Sacramento, California, June 23-25, 1993.

[61]Rodney Ruskin, "Underground Irrigation," *Agricultural Engineering* (March): 9-11, 1993.

However, one of the main drawbacks to underground systems is the intrusion of roots over time. Geoflow's founder and CEO Rodney Ruskin (originally with Agrifim) worked with the PNNL researchers using their technology to create a product called Rootguard,^{R} which protects underground systems from clogging caused by roots. The Rootguard technology in the plastic hoses prevents root tips from growing close to the water emitters in the hoses. Geoflow specializes in products with Rootguard protection and, in fact, is the only company that guarantees root control. Geoflow products containing Rootguard are engineered to last twenty years and warranted for ten years. If roots intrude within the first five years, Geoflow replaces the product for free; within the second five-year period, they are replaced at a proportional discount.

Reemay, Inc.: For the geotextile-based products, the fabric tested by the laboratory researchers was DuPont's Typar^{R}. In late 1986, DuPont sold its division producing non-woven products and its Typar product line to the privately-owned InterTech Group of North Charleston, South Carolina. A subsidiary of InterTech Group located in Old Hickory, Tennessee, a chemical manufacturer called Reemay, Inc., bought the Typar product line and this technology. Reemay signed an exclusive license with PNNL to manufacture a geotextile fabric containing the herbicide pellets. Mr. Harry Barnes, a Reemay manager,[62] said the technology transfer process from the laboratory went well. The product was designed to protect two to three inches of soil from root penetration for 7 to 125 years. Incorporating the herbicide into a geotextile harbored the herbicide so that it did not quickly seep into groundwater, lakes, or streams.

Mantaline Corporation: To manufacture herbicide sewer gaskets, the Mantaline Corporation of Ohio obtained an exclusive license with PNNL. The company developed and tested a polymer gasket impregnated with the herbicide, which prevented roots in sewer pipes for 25 to 50 years. Mantaline's product was called Root Shield^{TM}.

A fourth license was issued for the application called GrowGuard that involved putting a treated cord into pavement cracks. This application was tested at O'Hare International Airport in Chicago.

User Groups

Users of this technology include farmers, municipalities, facilities maintenance companies, and even homeowners. The technology has the potential to save these users millions of dollars each year in maintenance costs or in reduced water consumption. For example, routing out sewer lines is a $300 million annual cost in the United States. Local government public works departments are using the technology to protect roads, highway joints, sidewalks, and landscaping from roots and weeds. Curbs and gutters ruined by roots cost approximately $15 to $20 a foot to repair, and sidewalks costs $5 per square foot to repair. When these infrastructure costs are added to the cost of landscaping-related labor, it becomes apparent that the cost of

[62]Interview with Mr. Barnes, September 4, 1996.

installing a root control barrier represents a savings in the long run. Other areas where the technology could be applied includes both private and public driveway construction, swimming pools, and tennis courts.

The technology applications are currently being expanded to include insect and rodent control. In fact, the insect applications are currently being researched and tested, although not yet ready for market. For example, roach control is a $500 million market in the United States, and a $1.1 billion market globally. Termite control is a $130 million market in the United States (chemicals only) and a $.5 billion market globally (including labor).

Long-term application areas being targeted include biodegrading telephone poles and railroad ties, and decaying buried power/gas lines. There are twenty million telephone poles and five million railroad ties in the United States. The expected life cycle of each pole is 15 to 20 years. A million of them need to be replaced each year. The technology could be used as a fungicide to keep the poles and railroad ties from rotting. Presently, the labor involved in testing, applying Kreosote treatments, and replacing those ties and poles is a $5 billion global industry. Similarly, underground power lines and wires involve a potentially huge commercial market because tree growth and rodent attacks on buried power and gas lines is a major problem.

Barriers to Commercialization

According to Dr. Van Voris[63] there are some inherent problems that make industry adverse to commercializing controlled-release technologies. First, chemicals produced by DuPont, Dow Chemical, and others are sold by the carloads. With slower-acting controlled-release products, smaller quantities are needed, so the products are sold by the truckload rather than by the carload, and it is difficult to break the mindset toward larger quantities.

Another problem is that industry is interested in resales, so companies are reluctant to sell products that are effective as long as two years. As a compromise, the companies are now developing a material that lasts six months; the amount of the pesticide incorporated into the product is still only one-third of the amount that would be needed in another form of product for a mere three-month time frame.

In addition, there has not been a consumer demand for certain of the products because there were no existing/competing products. This makes it difficult to create visibility for new products entering the market. An example is the use of the root-controlling fabric under city sidewalks. Although buckled sidewalks pose a potential liability for local governments, there is still not a visible market for the product. And it doesn't help that appointed local officials maintain the attitude that they would be spending money for a product that would outlast them in their jobs.

[63]Interview with Dr. Van Voris, September 19, 1996.

As a result of all these problems, the technology has not resulted in an "instant revolution" as predicted, but rather evolution. Dr. Van Voris[64] said the so-called "green revolution" is just now becoming mainstream, and product spinoffs from this technology are just beginning to emerge. He adds that it is important to look at not just commercial value, but also other intangible benefits such as the fact that the technology has opened the door for other breakthroughs or that it may be reducing the risk of cancer and toxic exposure by children. From these perspectives, the technology's real value won't become apparent for fifteen to twenty years.

From the company perspective, Mr. Barnes of Reemay echoed that "these products are a different animal to market."[65] Reemay, for example, was a chemical and textile firm; but, with introduction of the Biobarrier product, the company is now in the pesticide market at a time when customers are cutting down on the use of chemicals that require expertise about wind and weather conditions. Customers must be convinced that the technology is not going to be harmful. Meanwhile, management saw instant success and didn't see this hidden problem. In addition, these products do not involve traditional marketing issues because the company is having to create the markets for the products. With Biobarrier, the product must be specified into the design of, say, a golf cart path while it is still on the drawing board. The golf course designer needs to be forward-thinking enough to know that a particular tree might ruin the path or the golf cart as it ages. As Mr. Barnes said, "You've got to sell the technology before you can sell the product."[66] To do this, Reemay exhibits at conferences of the Golf Course Superintendents, American Public Works Association, and the Water Department Directors. Reemay is also experiencing marketing problems with the weed control product that it is marketing to landscape designers rather than commercial landscaping firms, because landscaping firms are also in the business of weed control and are considered competition.

Other Factors

Dr. Van Voris' frustration with the DOE system and its lack of support for his team to continue its work on further technology development was apparent from indirectly related comments.[67]

User Benefits/Economic Impact/Outcomes

The FLC Winners' publication said that the product has resulted in millions of dollars of revenue to the product manufacturers. Dr. Van Voris notes that, from the perspective of private

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[64]Interview with Dr. Van Voris, September 19, 1996.

[65]Interview with Mr. Barnes, September 4, 1996.

[66]Ibid.

[67]Until recently, DOE provided funding for specific laboratory technology transfer projects and CRADA work.

industry, $20 to 40 million in sales would be more desirable than the amounts currently being made. Because each of the companies here are privately-held, it is difficult to obtain and report quantifiable data on sales or workforce aspects.

Agrifim Irrigation: In the United States, products of Agrifim's division Geoflow have been installed mostly in California, Texas, and Hawaii. The four main areas for using underground watering systems with Rootguard® are for irrigating agricultural crops, landscape watering, turfgrass treatments, and now irrigation via recycled wastewater. The company lists a total of fifty agricultural sites where Rootguard has been installed, with users ranging from Silverstar Farms in Brush Prairie, Washington, to New York Vineyard in the State of New York. The sites involve crops as varied as alfalfa, asparagus, cantaloupes, citrus, cotton, hops, all types of nuts, prunes, raspberries, ginger, sugar cane, and vineyards of all types.

In the area of landscape watering systems, since the late 1980s, Geoflow has been servicing new markets such as public parks, golf courses, roadside median strips, military bases, shopping centers and storefronts, university campuses, senior citizen centers, rooftop gardens, and so on. The sampling of twenty-eight landscape site installations in the company literature ranges from K-Mart and Taco Bell to the Price Club.

Geoflow has also installed underground systems using Rootguard at turfgrass sites such as football fields and baseball diamonds. The fifteen examples of users provided by the company range from Travis Air Force Base in California to the Water Valley School in Texas.

Until Rootguard came on the market, it was difficult to do underground watering using recycled wastewater (also called "gray" water) from homes and other sources because roots were particularly attracted to this nutrient-rich water. It is now the water policy of several states (eg., Arizona, California, Florida) to convert a certain percentage of wastewater into reclaimed water for watering lawns, agricultural irrigation, and other non-potable applications. Geoflow's line of products in this area are called Wasteflow™. Wasteflow systems have been installed at the Fort Myers, Florida, airport; at two resort developments in Hawaii; at a Brigham Young University site; and in Melbourne, Australia. Although the use of Wasteflow systems reduces the need to build water treatment plants, it appears that these systems are roughly twice as expensive as the Rootguard systems. For example, 1,000 feet of half-inch hose containing Rootguard costs a little over $200, whereas the same item in the Wasteflow line costs about twice as much.

In other new areas, The Toro Company now has a sub-license for the technology from Geoflow Inc. to allow Toro to make and market underground watering systems for back yards and similar recreation areas. Another group has been testing a new product for controlling termites and fire ants at the USDA/ARS center in New Orleans. A foreign patent has been obtained for this application and the company will soon be launching and promoting the product worldwide. In the future, Agrifim plans to focus on aquatic weed applications of the technology. Other applications that haven't been exploited include swimming pools and landfills. Meanwhile, the laboratory is seeking new partners to pursue the sewer gasket application.

Reemay, Inc.: Reemay's line of fabric-like products is called "Biobarrier," a name the company trademarked in 1988. The company's major product is the Biobarrier^R Root Control System, which slowly degrades in the ground. In fact, Reemay won an award in Europe for the product's unique approach to slowly releasing the chemical herbicide. The diverse interest in Reemay's fabric-like product now includes architects, state and local public works departments, construction companies, and sports companies.

However, Reemay's market was not always that diverse. Mr. Barnes[68] said the company spent a great deal of money and effort trying to sell to the nuclear waste market and ultimately did some work with DOE's Hanford Site and its Savannah River Plant. However, Biobarrier "wasn't going anywhere" as a product in this area in spite of the fact that this was the original application area and in spite of the great need for solutions in this area. It appears that this is a case of differing expectations. Reemay thought it would get more help or support from Battelle. The technology was licensed from Battelle with the thought that, as the licensor, Battelle would help them "get their foot in the door" in the area of nuclear applications and other parts of the DOE system. According to Mr. Barnes, the individual operating sites within DOE's Defense Programs are becoming competitive profit centers that contract out many of their activities, similar to the private sector downsizing trend of the 1980s. So when a company such as Reemay licenses from one laboratory within the system, that does not necessarily help in marketing to other sites or laboratories.

In the past two years, the Biobarrier product has branched to applications in municipalities where tree roots are uplifting sidewalk and road pavements. The Reemay fabric is designed to last fifteen years; whereas the expensive and labor-intensive process of pruning roots must be done every one to five years. Public works departments have tried everything from plastic sheeting to lumber to concrete barriers to control root problems. Biobarrier is easier to install, and the result is a decrease in accidents and related liability. Mr. Barnes said Biobarrier "found its home" in this market segment, and has started to move. In fact, Reemay considers that it is at the front end of the curve and the future looks bright for Biobarrier products. There are several factors contributing to this trend. First, more people are taking on leisure activities that require smooth paths (eg., roller-blading, skate-boarding, jogging, bicycling, and walking). Also, because of new state "green laws," more parks and scenic paths are being built and more new trees are being planted. In the past, Mr. Barnes says, if a tree damaged a sidewalk, the tree would be cut down. So, the product is "at the right place, at the right time," word is spreading, and there are now many customers. For example, horticultural experts at Virginia Tech and Radford University advised the city of Bristol, Virginia, to replace trees with five-foot trunks growing in three-foot spaces, and to use the root control product. Other examples include the city of Sanibel, Florida (thirty miles of bicycle paths); the city of Carmichael, California (nine miles of sidewalks in seven parks); the Portland, Oregon, airport (two miles of median strips); and, Sarasota County, Florida (focus on preventing tree damage by mowers, as well as mower damage

[68]Interview with Mr. Barnes, September 4, 1996.

by trees).

In late 1994, Reemay introduced a second product in the Biobarrier line called Biobarrier[R] II Preemergence Weed Control System. This is another fabric-like product that can be custom-contoured around existing landscaping designs by cutting it with a knife. Then the weed killing sheets can be covered with mulch, bark chips, gravel, sand, or soil. Biobarrier II controls weeds for at least a decade. Cutting long-term maintenance costs by using this product requires careful planning during design and construction phases for commercial and industrial landscaping. Users can choose between repeated chemical applications or high landscaping labor costs. Another advantage of Biobarrier II is that it releases the exact amount of herbicide that is biologically required, so landscapers don't have to calculate complicated ratios for diluting chemicals in water.

As a private company, Reemay does not readily divulge its exact product revenues, although Mr. Barnes said that the volume has not been as great as expected. The Reemay license is still in effect, and the company is paying royalties to Battelle. He added that Biobarrier is an expensive product to manufacture. This expense has to be passed on to the company's customers, who must be convinced of the product's value.

Reemay is also trying to create a new market for the protection of underground fiber-optic cable which gets crushed by root growth.

Mantaline: For two years, Mantaline (with Dr. Van Voris' help) sought an exemption from the Federal Insecticide, Fungicide, and Rodenticide Act. In 1987, Mantaline received regulatory approval from the U.S. Environmental Protection Agency to manufacture gaskets incorporating the herbicide. In 1988, Mantaline's President Robert ("Bob") Merian was quoted in a DOE publication as saying, "The possibilities for Root Shield are quite exciting . . .Product reception at city test sites is exceedingly strong . . .we are proceeding at full speed."[69] However, the sewer gasket failed as a commercial product and as a solution to infrastructure problems. It seems that public works officials were not eager to spend money for this product whose benefits would outlast the time frame of their own job. The Mantaline license is now dead.

International Activity

Geoflow proudly advertises that its Rootguard products are manufactured in the United States and, as noted from the examples, sold worldwide, having been installed in several locations in Spain, Canada, Australia, and New Zealand. However, its "made-in-the-USA" label applies only to basic products. Special Rootguard products containing both an herbicide and a bactericide to control water pollution are being produced in Israel, Columbia, India, and South Africa under license.

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[69]Battelle, *Putting Science and Technology to Work: A Casebook of Transferred Technologies,* Prepared for DOE Pacific Northwest Laboratory, PNL-SA-16279, October 1988, p. 4.

Reemay is only marketing in the United States. However, the company is doing full-scale product testing of two products to control termites and cockroaches in Australia. In addition, the cockroach product is being marketed in Japan.

Government Gains

Applications for the technology include fighting insect repellants, a problem being addressed by a variety of federal agencies. For example, the U.S. Department of Defense transfers funds to the U.S. Department of Agriculture and to the Army Corps of Engineers to reduce the amount of pesticides used at military sites. It is now mandated that military bases deploy pesticide strategies. According to Dr. Van Voris, the only way to do this long term is to support infrastructure maintenance by using this technology. Another application being considered is soldiers' uniforms that repel mosquitos and other insects over a long period of time.

Elapsed Time

The technology was conceived in the 1970s. The research geared up in 1978 and the first invention disclosure was filed in 1979. The tests in Colorado were conducted during the early 1980s. The journal articles, paper presentations, and other publications were written by the PNNL researchers primarily in the 1982 to 1986 time frame. At that time, DOE did not have a clear patent/licensing procedure in place for its contractor-operated laboratories, and it took some time to work the technology through the DOE system. The first patent application was filed in 1983. Eventually, the patent rights were released to Battelle, which started negotiating the first license in 1983. The license was eventually granted in 1985 to Mantaline. Mantaline's sewer gasket received regulatory approval two years later. The licenses with Reemay and Agrifim were both signed in 1986. Joint journal articles between the PNNL researchers and Mr. Ruskin of Agrifim were written primarily in the 1988 to 1993 time frame. Reemay's Biobarrier root control product has been commercialized for eight years and on the market for four to five years.

Case 6 (1985) - Radiation Therapy Quality Assurance

Role of Laboratory Researchers and Other Personnel

Dr. Robert Loevinger joined what was then called the National Bureau of Standards (NBS)[70] in 1968 as a radiation specialist in the dosimetry group. He worked in the Ionizing Radiation Division, which is located in the Radiation Physics Building at NBS' Physics Laboratory Gaithersburg, Maryland. He retired twenty years later in 1988, working there on a part-time basis since then. Before joining NBS, Dr. Loevinger was a medical physicist. Today,

[70] The 1989 NIST Authorization Act changed NBS to the National Institute of Standards and Technology (NIST). The 1988 Omnibus Trade and Competitiveness Act established the new Technology Administration (TA) at Department of Commerce headquarters, with the Gaithersburg laboratory reporting to DOC/TA.

virtually all radiation therapies in the United States are traceable for their accuracy to the measurement and calibration programs that were led by Dr. Loevinger at NBS.

In the radiation community, Dr. Loevinger is considered “Mr. Dosimetry.” He has published over a hundred technical papers. His early-1980s article in *Medical Physics* outlined the basis for a new x-ray measurement protocol for calculating cancer patient dosages of radiation therapy.[71] Dr. Loevinger has received numerous other honors. In 1980, for example, he received a Department of Commerce Silver Medal for his work at NBS. In 1982, he was chosen to present an annual memorial lecture by the Health Physics Society. Dr. Loevinger, now retired, is also recognized as an international expert through his participation on influential committees in his field. He was a member of a radiation standards committee for the American National Standards Institute and was on the Medical Internal Radiation Dose Committee for the Society of Nuclear Medicine. Further, he continued working for some time with the Science Council of the American Association of Physicists in Medicine (AAPM), the subject of this case. He was also a permanent consultant for the AAPM Radiation Therapy Committee and a member of two of the committee’s tasks forces.

Dr. Loevinger’s work to establish a national quality assurance system for radiation therapy measurements was accomplished in cooperation with the Radiological Society of North America (RSNA) and the American Association of Physicists in Medicine (AAPM). The Radiological Society includes doctors specializing in radiology and medical physicists who work in conjunction with those radiologists. AAPM was founded in the 1950s and headquartered in College Park, Maryland. AAPM is the only national society in the United States whose major concern is the physics aspect of radiation therapy. Its membership is composed of radiation scientists and technologists from radiation centers in over 1,000 hospitals and clinics in the United States. They serve 1,200 radiation therapy facilities, which treat a total of 600,000 cancer patients each year. RSNA, the older of the two organizations, was the first medical group to require more standardization because of the growing number of persons needing radiation therapy for cancer (as opposed to diagnostic radiation used to x-ray broken bones, for example).

The AAPM meets twice a year: once in conjunction with RSNA and once on its own, because medical physicists are a “fiercely independent” group, according to Dr. Loevinger.[72] At one of these AAPM/RSNA conferences, Dr. Loevinger pointed out that national methods were needed in this area. His comment was received with interest, and a task group[73] under the Radiation Therapy Committee was appointed. The Radiation Therapy Committee, in turn, was under the AAPM Science Council. At first, the committee had only six to eight members, but it grew to include representatives of all the large cancer organizations. Dr. Loevinger was on the

[71] The article, which described his analysis, received the journal’s “best-paper-of-the-year” award.

[72] Interviews with Dr. Loevinger, August 27, 1996, November 12, 1997, and December 9, 1997.

[73] Called “TG-3."

committee, but did not chair it because it would look too much like "the government telling them what to do." It took about two years for the committee to get started, but once it did, it was very effective. Because AAPM's task groups were temporary, the task group was changed to a subcommittee.

Technology and Applications

As in other highly technical areas, radiation measurements are traceable to the international measurement standards. Among the base units of measurement in the international measurement system are: length, time, mass, weight, temperature, and electrical charge. Other units, such as energy, are derived units. Defined physical quantities can be obtained from these basic units.

In the field of radiation therapy, the key quantities are (1) exposure and (2) absorbed radiation dose.[74] A dose is the quantity of radiation absorbed by a mass of tissue. The absorbed dose depends upon the strength and distance of the x-ray beam and the duration of exposure.[75] The process of measuring the dosage of x-rays or radiation is known as dosimetry, and the portion of the x-ray machine doing the measuring is known as an ionization chamber. The chamber measures the electrical charge in the air. The complete dosimetric system is comprised of the ionization chamber, an electrometer and its capacitor, and a voltmeter.[76]

Hospitals can build their own x-ray machines or buy them.[77] In either case, each x-ray instrument requires detailed documentation that shows on a step-by-step basis how the final dosage measurements are derived from the national and international standards. Thus, calibrations are the fundamental step in the determination of tumor doses for cancer patients. This x-ray dosimetry traceability system is the technology that was transferred.

Before the national x-ray dosimetry system was established, in principle, radiation measurements in the United States were done according to the international standards for dosimetry. In practice, however, these measurements were done in a vague, uncontrolled, and amateurish way in many institutions around the country. NIST's standards existed and NIST calibrated the x-ray machines for some national laboratories, certain Veterans Administrations

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[74]"Guidelines for Use of the Modernized Metric System," *Dimensions/NBS* (December): 13-19, 1979.

[75]See R. Loevinger and T. P. Loftus, "Uncertainty in the Delivery of Absorbed Dose," *Ionizing Radiation Metrology: Collected Papers from the International Course, Varenna, Italy, 1974*, E. Casnati, editor, Sponsored by CEC, CNEN and CNR, 1977.

[76]Another way to measure absorbed dose is to measure the rise in temperature in energy imparted per unit mass using a calorimeter; although this method is more reliable, it is also very difficult and expensive and involves much equipment.

[77]The latter is more common.

hospitals, and various other institutions. But, there was no systematic process in place for hospitals, x-ray laboratories, and clinics so that patients could be assured that the dosage of radiation they were receiving would be accurate and consistent with the national standards.

However, instrument calibration is only the first step in the system, as established. There is also a protocol for calculating the amount of a patient's radiation dose (the subject of Dr. Loevinger's award-winning paper). The physics of establishing and documenting traceability relates to calculating the dosages. With traceability, the proper dose each patient should get from a radiation worker operating an x-ray machine or a megavoltage linear accelerator can be traced back to NIST. For example, for cancer patients, overall radiation therapy should be accurate to five percent.[78] For the overall radiation therapy to be accurate to five percent, the x-ray's beam and the machine have to be calibrated to one to three percent accuracy. A five percent level of error in each would result in a ten percent error in the overall treatment.

The Laboratory

The National Institute of Standards and Technology (NIST) was founded in 1901 with the explicit mission to work with industry to maintain national standards of measurement so that measurements are done in consistent units and terms. The physics laboratory that is the subject of this case is one of several major laboratories at NIST. Other laboratories deal with building and fire research, electronics, computing, manufacturing, materials, and chemistry.

As national laboratories for industry standards, many of the NIST facilities available for cooperative and proprietary use focus on measurements of all types. This includes, for example, facilities for measuring acoustics, high-voltages, and the flow of water and other fluids.

The standard-setting system in the United States is predominantly voluntary. NIST assists associations and groups establishing standards and funds research related to standards. NIST staff members make presentations and consult with industry groups and other organizations on the importance of traceability to national standards. About one third of NIST's employees, or 1,175 people, are members of standards committees.

To assist this process, NIST provides more than five hundred calibration services to ensure that users of precision instruments around the country achieve measurements of the highest possible quality. These services link a customer's precision equipment to national standards. More specifically, for calibrations, NIST personnel check, adjust, or characterize an instrument or device. When these instrument calibrations are done, customers are assured that measurements are consistent with national standards. These NIST instrument calibration services are available for a fee to outside organizations such as hospitals, universities, industry, other calibration laboratories, nuclear energy establishments, the U.S. Department of Defense, and other government laboratories. NIST's calibration services have grown over the years. For

[78]A level of accuracy of more than that is not considered medically important.

example, in 1984, the laboratory provided 468 calibrations; in 1995, NIST performed 9,200 calibrations.

NIST calibration services encompass seven major areas. These are the measurement of: dimensions, time, frequency, mechanics, thermodynamics, electromagnetics, and optical and ionizing radiation. The subject of this case is ionizing radiation. Credibility of ionizing radiation measurements has been a critical issue for the U.S. radiation medical diagnostics and therapy communities. Ensuring the accuracy of radiation doses in this country depends heavily upon NIST calibrations, reference materials, and laboratory accreditation services. NIST scientists work to disseminate the standards and technology required for reliable measurement of ionizing radiation to the medical community. In addition, they monitor and evaluate radiation measurement needs and participate in radiation research, metrology development, and quality control activities.

The NIST scientist in this case initiated the development of a method for improving the accuracy of field measurements used in radiation therapy in this country through a national system of secondary standards laboratories. As a result, in this area, NIST has had a strong influence on the design and implementation of a quality assurance program accredited under AAPM. In support of this program, NIST continues to provide technical expertise for traceability to national standards through on-site assessments.

University Involvement

As noted, some of the hospitals involved in the national quality assurance system are university hospitals.

Funding, Financing

Each of the quality assurance systems described in this case are voluntary and self-supporting, that is, the Regional Calibration Laboratories (RCLs) are not subsidized. Yet there are no official incentives such as regulations for tertiary-level users to utilize the system, with the exception of Nuclear Regulatory Commission regulations for specific units. Unofficially, legal implications and AAPM protocols are the incentives. According to an AAPM-conducted, NIST-funded study, there are incentives to become an RCL, including prestige, convenience for the operating institution, and its role as an outreach function for the operating institution.[79] On the other hand, it also appears that there are incentives not to become an RCL. Not all of the RCLs had reached a financial break-even point and financial self-sufficiency as of the time of the study conducted in the late 1970s. The situation differs from one institution to the next in that certain of the for-profit institutions housing RCLs are doing well and performing efficiently because they must be financially self-sufficient. Other institutions have agreed to house an RCL mostly to

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[79]Lawrence H. Lanzi, Martin Rozenfeld and Peter Wootton, "The Radiation Therapy Dosimetry Network in the United States," *Medical Physics* 8 (1): 49-53, 1981.

meet their own in-house needs, and in those cases the RCL laboratory is subsidized by the institution itself. None of the RCLs is subsidized by the government or other outside source. Each RCL laboratory provides its own equipment for the purpose of performing calibration services.

Dr. Loevinger's work with AAPM and its committees was covered by his government salary. The AAPM committee sponsoring the national program was initially hoping to receive some monetary support from the American Cancer Society until the Society decided it didn't have enough money to support the program. NIST's Radiation Research Center provided financial support for the study conducted by the AAPM committee evaluating the network.

Intellectual Property

[Not applicable.]

Technology Transfer Mechanisms

Through the subcommittee, it was proposed that three, and later five, RCLs be certified by the AAPM according to AAPM-developed accreditation criteria. While national standards are considered primary standards, this system of five RCLs would be deemed the "secondary standards" level. The five RCLs would ship their x-ray dosimetry instruments to NBS to be calibrated according to the national standards. For those instruments to be suitable for that kind of transportation, the beams would be measured and checked against NBS's instruments and then calibrated. It was agreed that the measurements should agree to within a half percent of the NBS measurements. Then, at the next AAPM meeting, the results would be reported for the committee (now called the Regional Calibration Laboratory Accreditation Subcommittee) to review, and the source of any problems could be identified and taken care of. All other hospitals and medical physicists would have their instruments calibrated at the RCLs. This next level down is called tertiary standards, or the "field instruments" level. This level includes, for example, hospitals and radiation therapists in doctors' offices grouped together to form a clinic. Some field instruments are moved around and used at more than one institution.

Before each RCL was officially accepted, a visiting AAPM committee conducted site visits.[80] Although the committee members would change, there was always someone from NIST involved. They consulted with laboratory staff, examined the instruments and equipment, watched the procedures as practiced at that site, and observed the staff doing calibrations. Also, the committee would bring along "test case" instruments and have them calibrated. If accepted, that site would receive the official seal of approval from AAPM as an RCL.

[80]Generally comprised of Dr. Loevinger and couple of members of the "mother committee."

The five RCLs certified by the AAPM include large private hospitals, a state university hospital, a Veterans Administration hospital, and a small privately-run group of physicists who calibrate machines. More specifically, they are:

- Memorial Sloan Kettering Cancer Center in New York,
- M.D. Anderson Hospital in Texas,
- University of Wisconsin in Wisconsin,
- Allegheny General Hospital in Pennsylvania,
- K&S Associates, Inc. in Tennessee, a relatively newly-formed commercial standards laboratory.

Decisions as to how often the machines need to be calibrated are made by the committee and depend upon time and money available. They are not legally binding. At first, the committee continued to require that the RCLs' instruments be calibrated by NIST once a year via mail.[81] However, NIST's charges were high enough that this was eventually changed to every second year. During the in-between year, the RCLs cross-check in a round-robin fashion among themselves; that is, each sends their instruments to one or more other RCLs and the results are compared. This is less expensive than doing it through NIST. The results should continue to be in close agreement, about a half to one percent level of error. If it becomes apparent that a machine is not calibrated accurately, it would then be checked with NIST. Meanwhile, the site visits are repeated every three to five years. When the RCLs perform their calibration service for the tertiary level hospitals and institutions, they know an instrument's calibration needs to be accurate to one percent in order to conform with NIST's standards. At the tertiary level, it varies as to how often a piece of equipment is calibrated. For example, some machines are calibrated more than once a year, and others are only calibrated when they are first received at the hospital or clinic.

NIST is not allowed to close its doors to individual hospitals, so it still performs the calibration service for some hospitals and other government institutions, particularly Veterans Administration hospitals. However, it is now primarily interested in performing the service for RCLs.

User Groups

The calibration involves x-ray machines and accelerators used for radiation therapy, almost exclusively for cancer treatment. They are not used for treating non-malignant disorders because they are too dangerous. In the United States, approximately 600,000 people undergo radiation therapy for cancer each year. It is estimated that one-third of the population will get cancer; about half are treated with radiation, and the other half undergo surgery. Cancer therapy involves a large portion of the population.

[81]There are AAPM-established shipping protocols.

Barriers to Commercialization

The technology was not commercialized, but transferred into general use. It was moved into general use "quickly and painlessly" according to the FLC Winner's publication, so it appears that there were few barriers to implementation and that the program must have been sorely needed at the time it was initiated.

Other Factors

The NIST program staff publishes a regularly updated annual catalog of measurement facilities and other types of instruments available to outside groups, along with the cost of using each device. It also describes several hundred types of services offered[82] including its x-ray calibration service, describes the calibration protocols, and lists the fee schedule. The charge for calibrating x-ray instruments averages $500. Dr. Loevinger[83] said he didn't want to charge outside institutions for that service, but NIST rules required it.

User Benefits/Economic Impact/Outcomes

In the late 1970s, NIST funded a study to determine the adequacy of the RCL system at that time. The study determined that the system as established[84] was working well, but that two additional RCLs would be needed. However, no systematic studies have been conducted since then, so there are no quantitative measures of the impact of the system. The current chair of the AAPM committee, Dr. Geoffrey Ibbott,[85] director of the University of Kentucky's Department of Radiation Medicine, indicated it would be difficult to do a quantitative comparison between the process of twenty to thirty years ago with the current system.[86]

However, anecdotal evidence indicates that this quality assurance system has been successful and will probably continue to be successful. The direct beneficiaries of the system are the nation's hospitals. They benefit financially because it is less expensive to obtain a secondary standard than to obtain a primary standard from NIST. Before this, NBS was the only source in

[82] Related to calibrating scales, weights, etc.

[83] Interviews with Dr. Loevinger, August 27, 1996, November 12, 1997, and December 9, 1997.

[84] There were only three RCLs at the time.

[85] Interview with Dr. Ibbott, September 23, 1996.

[86] A federally funded ongoing study, called the "Patterns of Care Study," of the care provided to radiation-treated cancer patients in this country was a possible source of data. But when the investigators involved in this study at the American College of Radiology in Philadelphia were contacted, it was determined that their inquiry did not include data concerning the accuracy of calibration equipment measurements. (Interview with Dr. Jean Owens, October 1, 1996.)

the United States of authoritative calibration of radiation equipment, which made certified calibration costly. Also, calibrations through NIST were more difficult to arrange for many health clinics and laboratories. A regional laboratory is usually closer, so there is less risk in transporting the equipment. As a result, more calibrations are being done by private sector laboratories, so there is better local service to the end users, the hospital patients. This has been an excellent network, serving as a model for other such networks. (See "Unanticipated Government Benefits," below.)

The system ultimately is important because people's lives are at stake. People can be injured in radiation therapy due to faulty calibrations. The program works not only to ensure public health and safety, but also to reduce the probability of lawsuits, thereby holding down health costs. Virtually all the lawsuits related to a patient being injured have resulted from a medical physician or physicist being careless or ignorant.

International Activity

In all countries, a government laboratory such as NIST (or group of government laboratories) maintains the national standards that are considered primary standards. Virtually every country's national (or primary) measurement standards are the same because they can be traced to international measurement standards which are provided by the "Bureau International des Poids et Mesures" (BIPM)[87] in Paris. All industrialized countries are members of this organization so that measures are done consistently around the world. If not for this international measurement system, for example, it would not be efficient for American automobile parts to be manufactured in different countries.

Every two years in Paris, the United States and other countries come together and compare each country's primary standards with those of the international system. The international measurement system is independent of politics; it includes countries in both the East and West. The only time the system did not work and all countries did not meet was during World War II.

National or primary standards and BIPM's standards, referred to as "independent primary" standards, are considered co-equal for all practical purposes because BIPM compares differences in the instruments to plus or minus a half percent standard deviation in the level of error from the mean. In the area of ionizing radiation, it is rare for a national primary standard to be more than one percent different from BIPM's.

Government Gains

The accreditation system set up with AAPM served as a model for another program established through NIST, which is also a spinoff of Dr. Loevinger's original quality assurance

[87]International Bureau of Weights and Measures.

system. This program established standards and "certified" laboratories among the federal laboratories for calibrations for the x-ray protection instruments used by radiation workers. This involves workers primarily in federal laboratories such as NIST, but also some private institutions. Dr. Loevinger said that although he did "bug" the radiation protection community to get started in this area, he was not involved in setting it up.[88]

Occupational exposure does not need to be measured to such a high level of accuracy as direct x-ray beams aimed at a patient because this type of exposure involves a much lower level of intensity. A ten to twenty percent level of accuracy is acceptable. In these situations, the measurement system is more of an ongoing process. It is also a bigger operation, because 1.3 million radiation workers are affected.[89] As part of the protective gear for radiation workers, they all wear film badges or carry pocket chambers which measure their exposure over a period of time.

The system for calibrating radiation protection measurement equipment involves the radiation workers themselves as users, rather than patients. Also, a different bureaucracy checks the equipment. For example, NIST might receive a batch of 500 to 1,000 film badges at a time from, say, Brookhaven National Laboratory. Nevertheless, this system involved establishing a similar measurement quality assurance network with industrial and federal laboratories.

In this case, links were established with three U.S. Department of Energy laboratories involved in radiation work -- Argonne National Laboratories in Chicago, Pacific Northwest National Laboratory in the State of Washington, and Lawrence Livermore National Laboratory in California; a Food and Drug Administration (FDA) laboratory, the Center for Devices and Radiological Health, in Rockville, Maryland; a private laboratory called Radcal in California; and another private laboratory called Eberline located in both South Carolina and New Mexico.

Elapsed Time

Dr. Loevinger joined NIST in 1968, and began working with the AAPM subcommittee around 1970. The first three RCLs took form in 1972. An AAPM committee was established to conduct an independent study of the adequacy of the RCL network beginning in 1976, and subsequently the two additional RCLs were added to it.

The RCL Accreditation Subcommittee was chaired by the same individual, Martin Rozenfeld of the Department of Therapeutic Radiology, Rush-Presbyterian-St. Luke's Medical Center in Chicago for almost two decades, from 1975 until 1995. It is now chaired by Dr. Geoffrey Ibbott.

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[88]Interviews with Dr. Loevinger, August 27, 1996, November 12, 1997, and December 9, 1997.

[89]Radiation workers handle not only patients undergoing radiation therapy, such as for cancer, but also those patients x-rayed for diagnostic purposes or several million patients each year.

The system for the radiation protection community was put into place about ten years after the radiation therapy system was established.

PRE-LEGISLATION FINDINGS SUMMARY

Appendix D summarizes the findings for each of the selected pre-legislation cases organized according to the questions addressed in the interviews. Whereas, the earlier Level II analysis (appearing in this chapter as the introduction) addressed only certain key questions for the eight FLC awardees for the years 1985 and 1986, the appendix addresses all of the questions for the selected cases documented in this chapter. The summary combines all the cases and presents them in the same topic order as the selected cases except the topic, "Other Factors," which is incorporated into the concluding section of this dissertation. In the appendix, the cases appear in the following order:

a. Penetrometer
b. Thermoplastic Polymer
c. Substance Tracer
d. Alginate Herbicide
e. Root-Control Barrier
f. Radiation Measurement Standards.

The next chapter presents the cases and findings summary from the 1992 to 1993 (post-legislation) time frame.