Memorandum

Date NOV 18 1999

From Deputy Inspector General
for Audit Services

Subject Review of the Effectiveness of the National Institutes of Health's Administration of the Small Business Innovation Research Program (CIN: A-15-98-00031)

To Anthony L. Itteilag
Deputy Director for Management
National Institutes of Health

The attached final report provides you with the results of our review of the effectiveness of the National Institutes of Health's (NIH) administration of the Small Business Innovation Research Program (the SBIR Program). This review was conducted to determine whether NIH: (1) ensures that grantees under the SBIR Program are complying with invention reporting requirements; and (2) evaluates grantees' success in commercializing the results of their research projects.

In written comments dated September 8, 1999, NIH officials concurred with our first recommendation and generally agreed with our third, fourth and fifth recommendations. The NIH did not agree with our second and sixth recommendations. These comments are addressed in the body of the report. We appreciate the cooperation extended to us throughout the review by NIH officials responsible for the SBIR Program.

We would appreciate your views and the status of actions taken or contemplated on our recommendations within the next 60 days. If you have any questions, please call me or have your staff contact Joseph J. Green, Assistant Inspector General for Public Health Service Audits at (301) 443-3582.

To facilitate identification, please refer to Common Identification Number A-15-98-00031.

Thomas D. Roslewicz

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE EFFECTIVENESS OF THE NATIONAL INSTITUTES OF HEALTH'S ADMINISTRATION OF THE SMALL BUSINESS INNOVATION RESEARCH PROGRAM

JUNE GIBBS BROWN
Inspector General

NOVEMBER 1999
A-15-98-00031

EXECUTIVE SUMMARY

OBJECTIVES

Our objectives were to determine whether the National Institutes of Health (NIH) ensures that grantees under the Small Business Innovation Research Program (the SBIR Program) are complying with invention reporting requirements, and whether NIH evaluates grantees' success in commercializing the results of their research projects.

FINDINGS

Since 1983, NIH has provided $1.7 billion in financial support to small business concerns to perform research projects under the SBIR Program. The NIH developed the extramural invention data base system, known as Edison, in responding to previous Department of Health and Human Services (HHS) Office of Inspector General (OIG) reports that recommended NIH improve its oversight role in tracking grantee compliance with the Bayh-Dole Act and Commerce regulation 37 C.F.R. 401. The NIH also developed Edison Report-Lite (a module of Edison) to assist NIH Institute and Center (IC) staff in querying and reporting on inventions derived through grants and contracts for which they are responsible. After we completed our review, NIH told us it initiated other advances that it believes will improve compliance with invention reporting requirements for SBIR grantees. According to NIH, these advances include reference to the Edison Web Page in the 1999 SBIR Solicitation and the issuance of an NIH Grants Policy Statement, both of which contain information on invention reporting requirements. While NIH has taken these positive steps, we believe it could be more effective in protecting intellectual property rights. Our report discusses this matter, as well as one other area that we believe will improve the administration of NIH's SBIR Program.

Specifically, our findings indicate that NIH:

1. does not ensure SBIR grantees' compliance with invention reporting requirements;

- Our review noted that NIH does not ensure that all SBIR grantees comply with invention reporting requirements found in regulations that require grantees to disclose inventions and patents to the funding agencies. Specifically, NIH's extramural inventions office was aware of only one patent of the 12 identified in our sample of 100 Phase II projects. In our opinion, this condition resulted from inadequate instructions that NIH provided to the SBIR grantees, and from NIH's lack of internal controls to protect its intellectual property rights. As a result, the Federal Government may not be able to exercise its rights to inventions and patents developed with NIH funds, as well as promote their development and availability to the public.

2. **does not evaluate the success of its SBIR Program in commercialization of research.**

- The SBIR enabling legislation and implementing regulations clearly link the importance of private sector commercialization to the success of the Program. We believe that measuring such success should be an important management objective. However, our review found that NIH has insufficient data to determine if its SBIR Program is commercializing products resulting from its research projects, and does not measure the success of the SBIR Program in other areas NIH has identified where commercial success can be found. The NIH does not have a system in place to track the success of the SBIR Program in commercialization. As a result, the lack of knowledge of SBIR commercialization activities prevents NIH from measuring its own success in meeting a significant SBIR Program goal.

RECOMMENDATIONS

We recommend that NIH:

Finding 1:

(1) incorporate specific invention reporting requirements in the SBIR Solicitation including actions and time limits placed by law, as well as consequences when invention reporting requirements are not met;

(2) continue with efforts to link Edison with the PTO patent data base to identify patents that have been supported with NIH funds. In the interim, NIH should reconcile invention data between the PTO patent data base, the NIH IC grants offices, and Edison to insure that grantees are complying with invention reporting requirements;

(3) make direct contact with all NIH SBIR award recipients and urge them to adhere to all invention reporting requirements;

Finding 2:

(4) develop a system to evaluate the performance of the SBIR Program that will include measuring the success of SBIR award recipients in commercializing products resulting from their research projects;

(5) utilize Edison to track the commercialization success of SBIR award recipients by obtaining the information from utilization reports; and

(6) revise peer review evaluation criteria for SBIR proposals to emphasize the potential of the proposed research for commercial application.

In its September 8, 1999 written comments on our July 26, 1999 draft report, NIH concurred with our first recommendation to incorporate specific invention reporting requirements in the SBIR Solicitation and told us it will continue to inform SBIR applicants/awardees of their invention reporting requirements. Regarding recommendation two, although NIH did not agree with the specific recommendation, NIH indicated that it has drafted an internal policy document to describe the roles and responsibilities of NIH staff in ensuring that grant recipients are complying with invention reporting requirements. We believe that this document should include procedures to ensure that inventions disclosed to grants offices are recorded in Edison. The NIH generally agreed with recommendations three, four and five. With regard to our fourth recommendation for evaluating the success of the SBIR Program in commercialization of research, NIH told us that it is developing a methodology to tie the significant investments that NIH has made in the SBIR program to specific and measurable outcomes. The NIH disagreed with our sixth recommendation.

The NIH's comments, which we have incorporated in the body of the report following each of our recommendations, are included in their entirety as Appendix C of this report.

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BACKGROUND

The NIH is an operating division of HHS. The mission of NIH is to improve human health by increasing scientific knowledge related to disease and health. With a budget of approximately $15.6 billion in Fiscal Year (FY) 1999, NIH carries out its mission through the conduct and support of biomedical and behavioral research, research training, research infrastructure, and communications. These efforts take place intramurally (primarily at NIH) or extramurally through such funding mechanisms as grants and contracts. Grants and contracts to extramural research organizations will total approximately $12.9 billion in FY 1999.

Small Business Innovation Research Program

The SBIR Program was established under the Small Business Innovation Development Act of 1982 to include, among other things:

- stimulating technological innovation;
- using small business to meet Federal research and development needs; and
- increasing private sector commercialization of innovations derived from Federal R&D.

Federal agencies with extramural research and development budgets in excess of $100 million must set aside a certain percentage of these budgets for the SBIR Program. This set aside, which began as 0.2 percent in FY 1983, increased to 1.25 percent in FY 1986, 1.5 percent in FY 1993, 2.0 percent in FY 1995, and 2.5 percent in FY 1997. Since the SBIR Program's beginning, NIH has awarded almost $1.7 billion in SBIR awards (see Appendix A). The amount available for FY 1999 is estimated at $307 million.

The Small Business Administration (SBA) coordinates and administers the SBIR Program. It sets guidelines for the 10 participating SBIR agencies, reviews their progress, and reports annually to Congress on its operation. Guidance is provided by SBA's Office of Innovation Research and Technology through SBA's SBIR Policy Directive. The program must follow a uniform competitive process of three phases:

- Phase I is the start-up phase. Awards of up to $100,000 for approximately 6 months support exploration of the technical merit or feasibility of an idea or technology;
- Phase II expands on Phase I results. Awards of up to $750,000 are made for as many as two years. During this time, the R&D work is performed and the developer evaluates commercialization potential. Only Phase I award winners are considered for Phase II; and

- Phase III is the period during which Phase II innovation moves from the laboratory into the marketplace. No SBIR funds support this phase. The small business must find funding in the private sector or other non-SBIR Federal agency funding.

Proposals for SBIR awards from NIH must follow a process very similar to that of other grant programs. One difference is that the SBIR applicants must identify possible commercialization of the proposed product. The SBIR grant proposals are subjected to a two-step review process:

- First, the NIH's Center for Scientific Review (CSR) assigns all proposals to the Scientific Review Groups (SRG) that perform a scientific merit review. The SRG is composed primarily of nonfederal scientists selected for their competence in particular scientific fields. In considering the scientific and technical merit, the SRGs rate proposals based on the potential of the proposed research for commercial application, and the scientific and technical merit of the proposed research.

- Second, CSR assigns the grant proposals that have been approved by SRGs to the Advisory Councils or Boards of the awarding ICs for review. Funding decisions by the ICs take into account elements such as program balance, overlapping support from other sources, and the availability of funds.

Governing Statutes and Regulations

The Small Business Innovation Development Act of 1982 established the SBIR Program and named SBA as the program's Governmentwide administrator. The Small Business Research and Development Enhancement Act of 1992 expanded the SBIR Program to: (1) emphasize increased private sector commercialization of technology developed through Federal SBIR R&D; (2) increase small business participation in Federal R&D; and (3) improve the Federal Government's dissemination of information concerning the SBIR Program, particularly with regard to program participation by women-owned small business concerns and by socially and economically disadvantaged small business concerns.

The Patent and Trademark Amendments Act, commonly known as the Bayh-Dole Act of 1980 (Public Law (P.L.) 96-517), allows small businesses and non-profit organizations to retain title to inventions produced with Federal research funding. Objectives of the Bayh-Dole Act include:

(1) promoting utilization of inventions arising from federally supported research;

(2) encouraging maximum participation of small business firms in federally supported research and development efforts;

(3) promoting commercialization and public availability of inventions made in the United States (U.S.) by U.S. industry and labor; and

(4) ensuring that the Government obtains certain rights in federally supported inventions.

In 1984, the Bayh-Dole Act was amended by the Trademark Clarification Act (P.L. 98-620), which assigned responsibility to the Department of Commerce for developing regulations to implement the Bayh-Dole Act for all Federal agencies. Accordingly, Commerce regulation 37 C.F.R. 401, "Rights to Inventions Made by Non-Profit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," was developed. It contains the standard patent rights clauses that must be incorporated in all NIH funding agreements.

The NIH's Responsibilities

The SBA's SBIR Policy Directive requires NIH to: (1) unilaterally determine the categories of projects to be included in its SBIR Program; (2) release SBIR solicitation announcements; (3) unilaterally determine research topics; (4) unilaterally receive and evaluate proposals resulting from SBIR solicitations; (5) make awards and administer its own funding agreements; (6) include provisions in its funding agreement with respect to intellectual property rights; (7) make payments to recipients of SBIR funding agreements on the basis of progress toward or completion of the funding agreement requirements; and (8) make annual reports on the SBIR Program to SBA.

The NIH's SBIR Program is coordinated by the Office of Extramural Programs within the Office of Extramural Research (OER), NIH, located in Bethesda, Maryland. The NIH SBIR Coordinator is responsible for ensuring that NIH carries out the directives set forth in SBA's SBIR Policy Directive, including issuing the SBIR Solicitation that sets the SBIR process in motion at NIH. The grants offices within the awarding ICs administer the grants by ensuring that the grants follow good business and financial practices and comply with established grants policies. In contrast, program management offices within the ICs focus on ensuring that NIH grants meet their programmatic objectives by defining the technical or program objectives of the grant, monitoring the recipients' performance, and evaluating the recipients' achievements.

With regard to intellectual property rights, NIH's OER is responsible for ensuring that grantees comply with Federal regulations regarding compliance with the Bayh-Dole Act and Commerce regulation 37 C.F.R. 401. The NIH informs its grantees of their invention

reporting responsibilities through the SBIR Solicitation[1] and various documents in the grants process, including the NIH Grants Policy Statement,[2] a welcome wagon memorandum for new grantees, and a reminder letter accompanying NIH's notices of grant award.

The NIH's Edison

The NIH's extramural invention data base system, known as Edison, was developed by NIH's OER. The Edison system was developed to enhance invention reporting compliance related to NIH's responsibility with regard to intellectual property rights. Deployed in October 1995, Edison contains a tickler system that is activated automatically once an invention disclosure is entered to remind the grantee of time-sensitive invention reporting actions that must be taken. Using Edison, grant recipients can directly input their invention data as well as update information in real time on a fully-interactive basis.

The NIH's CRISP

The CRISP (Computer Retrieval of Information on Scientific Projects) is a searchable data base of federally funded biomedical research projects maintained by NIH's OER. The data base includes projects funded by NIH and a relatively small number of other research grants funded within HHS.

Patent and Trademark Office

The PTO's role is to grant patents for the protection of inventions and to register trademarks. In conducting its patent-related duties, PTO examines applications and grants patents on inventions when applicants are entitled to them. The PTO makes patent information available to the public over the Internet using the PTO Web Patent Data Base. The PTO Web Patent Data Base contains information on patents that were issued from January 1, 1976 to the most recent weekly issue date. Patent information can be accessed by querying data fields such as the inventor's name, title of the invention, or the patent assignee.

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[1] *Omnibus Solicitation of the National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration for Small Business Innovation Research Grant Applications* (Calendar Year 1998).

[2] The NIH Grants Policy Statement, effective beginning October 1, 1998, supercedes the Public Health Service (PHS) Grants Policy Statement, dated April 1994, for all NIH grants and cooperative agreements.

OBJECTIVES, SCOPE, AND METHODOLOGY

OBJECTIVES

Our objectives were to determine whether NIH ensures that grantees under the SBIR Program are complying with invention reporting requirements, and whether NIH evaluates grantees' success in commercializing the results of their research projects.

SCOPE

Our audit covered SBIR grants awarded by NIH during FYs 1988 through FY 1998. During FYs 1994 and 1995, NIH funded approximately 546 SBIR Phase II grant projects. We selected a statistical sample of 100 of these projects to determine the extent that NIH was ensuring that grantees who obtained patents related to the projects had: (1) disclosed their inventions to NIH; (2) provided NIH with a copy of the patents; and (3) provided NIH with a confirmatory license.[3]

We looked at 32 SBIR grant projects awarded in FYs 1988 and 1990 to 29 grantees that were among the 50 highest-funded SBIR companies (between FYs 1984 and 1994) to determine: (1) the companies' success in commercializing the results of their research and development projects; and (2) whether NIH has a system for measuring the success of the SBIR Program's goal of increasing private sector commercialization from SBIR research and development.

Our review of internal controls was limited to obtaining an understanding of the SBIR grant awards process in determining how NIH: (1) ensures grantees' compliance with invention reporting requirements; and (2) measures the success of its SBIR Program in meeting the program's legislative goals. In this regard, we identified NIH's plans for including the SBIR Program under its Government Performance and Results Act performance plans.

METHODOLOGY

To accomplish our objectives, we reviewed authorizing legislation of the SBIR Program, Commerce regulations codified at 37 C.F.R. 401, "Rights to Inventions Made by Non-profit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements," SBA's SBIR Policy Directive, and GAO reports relating to the SBIR Program.

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[3] Our review did not include making a determination of whether the grantees elected to retain title to their inventions and file a patent application in a timely manner, or efforts to ensure the invention was manufactured substantially within the U.S. if it is to be used or sold in the U.S.

We interviewed SBA Office of Innovation Research and Technology Officials and NIH SBIR officials, including the NIH SBIR Program Coordinator and grants and program officials in NIH's awarding components, including the: (1) National Institute of Arthritis and Musculoskeletal and Skin Diseases; (2) National Cancer Institute; (3) National Institute on Deafness and Other Communication Disorders; (4) National Institute of Diabetes and Digestive and Kidney Diseases; (5) National Eye Institute; (6) National Institute of Child Health and Human Development; (7) National Heart, Lung, and Blood Institute; (8) National Institute of Mental Health; (9) National Institute of Neurological Disorders and Stroke; (10) National Center for Research Resources; (11) National Institute on Aging; (12) National Institute of Dental Research; (13) National Institute of General Medical Sciences; and (14) National Institute on Drug Abuse.

For each of the 100 Phase II projects selected in our random sample, we reviewed the NIH's CRISP data base to obtain grant information about the projects, including abstracts of the research, the principal investigators (PI), and grantee institutions. We then searched the PTO Web Patent data base to match the CRISP data against any related patents obtained by the PI. We provided OER with a list of grants with related patents from our search to determine what information was recorded in Edison. To verify the patent information, we wrote to 21 SBIR grantees. Based on replies from grantees whose patents were NIH-supported, we determined reasons for non-compliance with invention reporting requirements. We did not visit any small businesses that received SBIR funding from NIH.

For each of the 32 SBIR grant projects awarded in FYs 1988 and 1990, we conducted a brief telephone survey of the grantees to obtain commercialization data as of February 1999.

Our review was conducted in NIH intermittently from October 1997 through March 1999 in various NIH locations in Bethesda, Maryland; and Rockville, Maryland. Our audit was made in accordance with generally accepted government auditing standards.

FINDINGS IN DETAIL

Since 1983, NIH has provided $1.7 billion in financial support to small business concerns to perform research projects under the SBIR Program. The NIH developed the extramural invention data base system, known as Edison, in responding to previous HHS OIG reports that recommended NIH improve its oversight role in tracking grantee compliance with the Bayh-Dole Act and Commerce regulation 37 C.F.R. 401. The NIH also developed Edison Report-Lite (a module of Edison) to assist NIH IC staff in querying and reporting on inventions derived through grants and contracts for which they are responsible. After we completed our review, NIH told us that it initiated other advances that it believes will improve compliance with invention reporting requirements for SBIR grantees. According to NIH, these advances include reference to the Edison Web Page in the 1999 SBIR Solicitation and the issuance of an NIH Grants Policy Statement, both of which contain information on invention reporting requirements. While NIH has taken these positive steps, we believe it could be more effective in protecting intellectual property rights. Our report discusses this matter, as well as one other area that we believe will improve the administration of NIH's SBIR Program.

Specifically, our findings indicate that NIH:

1. does not ensure SBIR grantees' compliance with invention reporting requirements;

- Our review noted that NIH does not ensure that all SBIR grantees comply with invention reporting requirements found in regulations that require grantees to disclose inventions and patents to the funding agencies. Specifically, NIH's extramural inventions office was aware of only one patent of the 12 identified in our sample of 100 Phase II projects. In our opinion, this condition resulted from inadequate instructions that NIH provided to the SBIR grantees, and from NIH's lack of internal controls to protect its intellectual property rights. As a result, the Federal government may not be able to exercise its rights to inventions and patents developed with NIH funds, as well as promote their development and availability to the public.

2. does not evaluate the success of its SBIR Program in commercialization of research.

- The SBIR enabling legislation and implementing regulations clearly link the importance of private sector commercialization to the success of the Program. We believe that measuring such success should be an important management objective. However, NIH has insufficient data to determine if its SBIR Program is commercializing products resulting from its research projects, and does not measure the success of the SBIR Program in other areas NIH has identified where commercial success can be found. The NIH does not have a system in place to track the success of the SBIR Program in commercialization. As a result, the lack of knowledge of SBIR commercialization activities prevents NIH from measuring its own success in meeting a significant SBIR Program goal.

FINDING 1: NIH DOES NOT ENSURE GRANTEES' COMPLIANCE WITH INVENTION REPORTING REQUIREMENTS

CRITERIA: REGULATIONS AND NIH POLICIES THAT REQUIRE GRANTEES TO DISCLOSE INVENTIONS

Commerce regulation 37 C.F.R. 401 sets forth the requirements that NIH must include in its funding agreements to small business firms regarding standard patent rights clauses. The NIH, by including these provisions in its funding agreements, is responsible for ensuring grantee compliance with invention reporting requirements. The NIH uses Edison to facilitate these reporting requirements in tracking the following information disclosed by the grantees to NIH: (1) inventions; (2) patent data; (3) confirmatory licenses; and (4) invention utilization data.

Specifically, 37 C.F.R. 401 calls for contractors[4] who develop a new technology that was supported with Federal funds, among other requirements, to:

> ". . . disclose each subject invention to the Federal Agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters.";
> (37 C.F.R. 401.14(c)(1))
>
> ". . . file its initial patent application on a subject invention to which it elects to retain title within one year after election of title . . . .";
> (37 C.F.R. 401.14(c)(3))
>
> "With respect to any subject invention in which the Contractor retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up [confirmatory] license to practice or have practiced for or on behalf of the United States the subject invention throughout the world."; and
> (37 C.F.R. 401.14(b))
>
> ". . . include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, 'This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention.'."
> (37 C.F.R. 401.14(f)(4))

[4] The term "contractor" used in the text of the regulation applies equally to NIH grantees.

The Small Business Research and Development Enhancement Act of 1992 requires the following of each participating agency with regard to intellectual property rights:

> "Each funding agreement under the SBIR Program shall include provisions setting forth the respective rights of the United States and the small business concern with respect to intellectual property rights . . . ."

The NIH, in its October 1998 NIH Grants Policy Statement, which contains the provisions of 37 C.F.R. 401, directs grantees to submit to OER, all NIH-related disclosures, confirmatory licenses to the Government, face page of the patent applications, and utilization reports. The NIH also requires its grantees to file a Final Invention Statement and Certification with the NIH awarding office within 90 days of expiration of the grants, whether or not an invention results from work under the grant.

The NIH, in its 1998 SBIR Solicitation, informs grantees that:

> "The reporting of inventions can be accomplished by submitting paper documentation, including fax [to OER], or electronically through the NIH Edison Invention Reporting System. Use of the Edison system satisfies all mandated invention reporting requirements and access to the system is through a secure interactive Web site (**http://era.info.nih.gov**) to ensure that all information submitted is protected."

CONDITION: NIH'S EXTRAMURAL INVENTIONS OFFICE WAS UNAWARE OF INVENTIONS AND PATENTS IDENTIFIED IN OUR SAMPLE OF SBIR PHASE II PROJECTS

Our sample of 100 NIH SBIR Phase II grant projects in FYs 1994 and 1995,[5] revealed 22 patents that appeared to have been developed with underlying support from NIH. We were able to verify that at least 12 of the 22 were funded by NIH. In projecting this result, we estimate that the universe of 546 funded projects in FYs 1994 and 1995 should include approximately 66 patents (with a 95 percent confidence interval of 37 to 106). However, NIH has a record of only 22 patents.

The 22 patents in our sample were identified by querying the PTO's patent data base and comparing it with grant information in NIH's CRISP. We were looking for information that would help us determine whether patents recorded by PTO were actually supported by NIH funding. Our premise was that if the PTO abstract, inventor, and/or assignee matched the

[5] We selected FYs 1994 and 1995 grant projects to allow time for inventions supported by the grants to have been patented.

CRISP abstract, principal investigator and/or grantee, we considered the patent to have possibly been funded by NIH.

We then looked at Edison to determine if it contained a record of any inventions, patents, and confirmatory licenses from the grantees in our sample. We determined that Edison contained only one patent out of the 22, and four inventions out of the 22. We then wrote to the 21 grantees for whom some data was missing in Edison to verify whether NIH funds supported the patents. As summarized below and in the following chart, we verified that 12 patents were supported with NIH funding. Six grantees said that the inventions were put to practice prior to NIH funding or denied that NIH supported the patents. We deferred resolution of these six responses to NIH. Four grantees who did not report patents to NIH did not respond to our letter.

Invention Reporting Information at NIH Relating to 22 SBIR Phase II Grant Projects		
Patents Supported With NIH Funds		12
Inventions Recorded in Edison	3	
Patent Recorded in Edison (related invention and confirmatory license also recorded)	1	
Inventions Disclosed in Grant Files, Not Recorded in Edison	4	
No Invention Reporting Information Recorded in Edison or in NIH Grant Files	4	
Grantees That Denied Patents Were Supported With NIH Funds		6
Grantees That Did Not Respond - Unable to Verify NIH Support		4

For the 12 patented inventions for which we were able to verify NIH funding, we evaluated the extent NIH ensured the grantees' compliance with invention reporting requirements in the following areas:

Inventions Recorded In Edison

The NIH requires grantees to disclose their inventions to OER within 2 months after the inventor discloses them in writing to grantee personnel responsible for patent matters. The Edison contained a record of only four inventions resulting from the 12 NIH-supported patents.

Patents Recorded in Edison

The NIH requires grantees to file a patent within 1 year of electing title and provide a copy to NIH. For the 12 NIH-supported patents, Edison contained a record of one patent. In projecting our sample containing 12 patents to all 546 projects, we estimate that NIH's Edison should contain approximately 66 patents (with a 95 percent confidence interval of 37 to 106) for FYs 1994 and 1995 SBIR grant projects. However, NIH informed us that Edison contains only 22 patents related to the 546 projects.

Inventions Disclosed in Grant Files, Not in Edison

The NIH requires grantees to disclose their inventions on the Invention Statement and Certification to the grants offices within 90 days following the close of the grant. The grants offices are then required to submit a copy of the certification to OER for entry into Edison. Four inventions related to the 12 NIH-supported patents were disclosed in the NIH grant files by the grantees but were not recorded in Edison.

Confirmatory Licenses Recorded in Edison

Upon election of title, NIH requires that grantees provide it with a confirmatory license. However, for the 12 NIH-supported patents, Edison contained a record of one confirmatory license. There were two other instances involving confirmatory licenses. In one, the confirmatory license appeared on the patent; in the other, the confirmatory license had been submitted to the NIH grants office by the grantee.

CAUSES: THE NIH'S GUIDANCE PROVIDED TO SBIR GRANTEES ON INVENTION REPORTING REQUIREMENTS, AND ITS CONTROLS TO PROTECT THE GOVERNMENT'S RIGHTS NEED IMPROVEMENT

We identified the following causes at NIH that contributed to SBIR grantees' non-compliance with provisions of Commerce regulation 37 C.F.R. 401:

(1) The NIH's Guidance on Invention Reporting Requirements Provided to SBIR Grantees Needs Clarification

The NIH's up-front guidance provided to SBIR grantees on their responsibilities for invention reporting is not clear. The guidance that SBIR grantees rely upon for invention reporting requirements, namely the SBIR Solicitation for Phase I and the SBIR Phase II application package, does not provide grantees with specific information on time-sensitive invention reporting deadlines, nor does it provide a definition of an invention critical for invention reporting purposes. In addition, the SBIR Solicitation for Phase I and the SBIR Phase II application package do not include consequences for failure to comply with invention reporting

requirements, including the Government's "march-in" rights when, for instance, an invention is not achieving practical application in its field of use. The grantees we contacted that did not comply with invention reporting requirements indicated they did not comply for the following reasons:

- four misunderstood invention reporting requirements;
- one indicated receiving poor or frequently changing instructions from NIH;
- one erroneously considered that because NIH's contribution to the patent was minimal (20 to 30 percent), it was not required to disclose invention information to NIH;
- two were unaware of invention reporting requirements;
- one believed the requirement to submit a confirmatory license to NIH required no action on the part of the grantees due to phrases contained in the SBIR Solicitation indicating that, "the government receives a royalty-free license . . .," and "the government reserves the right . . ."; and
- one did not know the deadline for filing a confirmatory license.

One grantee suggested that NIH include in the SBIR Solicitation, a one to two-page sheet on all of the grantees' requirements for invention reporting. Whatever form the corrective action takes, we believe that NIH needs to more effectively communicate invention reporting responsibilities directly to the SBIR grantees.

The NIH also provides grantees with the NIH Grants Policy Statement which includes guidance on invention reporting requirements. The NIH Grants Policy Statement became effective in October 1998. Its predecessor, the PHS Grants Policy Statement, contained text of 37 C.F.R. 401.14 in an appendix which we believe was poorly located and difficult to follow. The NIH hopes the NIH Grants Policy Statement which contains a separate section on invention reporting will be an improvement over its predecessor in communicating these invention reporting responsibilities. However, it is too early to determine how successful the NIH Grants Policy Statement will be at improving SBIR grantees' compliance with invention reporting requirements.

The NIH provides additional guidance to grantees on invention reporting requirements that does not mention specific actions and time limits on invention reporting: (1) a "welcome wagon memorandum" for first-time grantees states that the grantees, in accepting an award, agree to comply with Governmentwide patent regulations found at 37 C.F.R. 401; and (2) a "reminder letter," initiated in May 1997, accompanies NIH's notices of grant award to SBIR grantees to remind them of invention reporting responsibilities. However, the letter does not

mention the annual utilization report of subject inventions. During the course of our review, NIH staff told us that they plan to draft a personalized letter to all SBIR grantees to advise them of all their invention reporting responsibilities.

(2) The NIH's Controls to Protect the Government's Rights Need Improvement

There were three areas where NIH's controls over invention tracking and monitoring need improvement:

- The NIH is not insuring that inventions disclosed by SBIR grantees are being recorded in Edison, and that patent information contained in the PTO data base agrees with Edison for patents that were supported with NIH funds;

- The NIH does not link patent information between Edison and the PTO patent data base to provide a means of identifying and recording patent information supported with NIH funds; and

- The NIH does not ensure that grantee organizations and their inventions are recorded in Edison so that NIH can utilize Edison's tickler system that will automatically remind grantees of time-sensitive reporting deadlines (title election, confirmatory license, patent, and utilization reporting). The tickler system is not effective in instances where Edison has no record of a grantee with an invention.

With regard to establishing a link with the PTO patent data base, NIH suggested an improvement to PTO's patent process that NIH indicated would help all Federal agencies better ensure grantee compliance with invention reporting requirements. Specifically, NIH suggested that PTO require patent filers to: (1) indicate on the patent applications whether the Government supported their inventions; and (2) file a confirmatory license if Federal support is indicated. According to NIH, these added procedures would be performed simultaneously to minimize instances where patent assignees do not follow through with submission of a confirmatory license to the funding agency.

With regard to NIH's use of Edison, NIH recently made Edison accessible to NIH grants officers via a module of Edison known as Edison Report-Lite. The NIH officials told us the system was deployed while we were conducting our audit, and several grants officers were obtaining passwords to use the system. Currently, however, NIH encourages, but does not require grants officers to verify invention disclosures with Edison.

EFFECT: EXISTING MONITORING EFFORTS DO NOT ENSURE THE GOVERNMENT'S RIGHTS TO INVENTIONS

The NIH does not know whether all SBIR grantees comply with invention reporting requirements and is, therefore, unable to ensure the Federal Government's ability to exercise its rights to inventions that were developed with NIH's SBIR funds.

OIG RECOMMENDATIONS

We recommend that NIH:

(1) incorporate specific invention reporting requirements in the SBIR Solicitation including actions and time limits placed by law, as well as consequences when invention reporting requirements are not met;

(2) continue with efforts to link Edison with the PTO patent data base to identify patents that have been supported with NIH funds. In the interim, NIH should reconcile invention data between the PTO patent data base, the NIH IC grants offices, and Edison to insure that grantees are complying with invention reporting requirements; and

(3) make direct contact with all NIH SBIR award recipients and urge them to adhere to all invention reporting requirements.

THE NIH COMMENTS TO OIG RECOMMENDATIONS AND OIG RESPONSE

On September 8, 1999, we received NIH's written comments to the recommendations contained in a draft of this report, dated July 26, 1999. We have incorporated NIH's comments to recommendations one through three along with our responses in the discussion below. The NIH comments are included in their entirety as Appendix C of this report.

Recommendation 1

The NIH Comment

The NIH concurs. The NIH told us it will implement specific invention reporting requirements through use of an invention reporting time line chart that appears as part of the NIH Interagency Edison web site. The NIH believes that the chart more effectively communicates invention reporting obligations directly to SBIR awardees.

Recommendation 2

The NIH Comment

The NIH did not agree with the specific recommendation. However, NIH told us that it has drafted an internal policy document to describe the roles and responsibilities of NIH staff, including Program and Grants Management staff in ensuring that grant recipients are complying with invention reporting requirements. With regard to NIH's efforts to link Edison with the PTO data base, NIH indicated PTO has declined to give NIH access to any information other than issued patent records. The NIH further indicated that it generally takes several years for a patent to be issued relative to when it was derived. Therefore, NIH believes issued patent records from PTO are of limited value for NIH's purposes because they are not timely with respect to the awarding of SBIR grants.

The OIG Response

As NIH develops the internal policy document, it should include measures to ensure that inventions disclosed to grants offices are also recorded in Edison. Without assurance that grantee organizations and their inventions are recorded in Edison, Edison's tickler system will not be effective in reminding grantees of their time-sensitive reporting deadlines.

Although NIH's access to the PTO data base has been limited to issued patent records, we continue to believe that this resource, although not ideal, has value. It allows NIH to cross-check patents with underlying grant data, providing a measure of assurance that NIH and its grantees are complying with the terms and conditions of Commerce regulation 37 C.F.R. 401.

Recommendation 3

The NIH Comment

The NIH agreed. The NIH told us that it has recently taken some positive approaches to directly contact NIH SBIR awardees by preparing personalized letters to advise them of their invention reporting responsibilities. In addition, NIH plans to modify the FY 2000 NIH award letter to highlight for all awardees, their responsibility for reporting inventions.

FINDING 2: NIH DOES NOT EVALUATE THE SUCCESS OF ITS SBIR PROGRAM IN COMMERCIALIZATION OF RESEARCH

CRITERIA: AUTHORITIES THAT PROVIDE A NEED TO MONITOR COMMERCIALIZATION SUCCESS

Two statutes and one regulation provide a need for monitoring commercialization success of SBIR grantees:

(1) The Small Business Innovation Development Act of 1982 states that one of the SBIR Program's goals is to increase private sector commercialization from SBIR research and development.

(2) The Government Performance and Results Act of 1993 (GPRA) (P.L. 103-62) requires agencies, among other things, to: (1) establish measurable performance goals to define the level of performance to be achieved by a program activity; (2) express such goals in an objective, quantifiable, and measurable form; (3) establish performance indicators to measure or assess relevant outputs of each program activity; and (4) compare actual program results with the established performance goal.

(3) Commerce regulation 37 C.F.R. 401.14 (h), requires grantees to:

> "submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify."

The SBA's SBIR Policy Directive defines commercialization as:

> "The process of developing markets and producing and delivering products for sale (whether by the originating party or by others) . . . ."

CONDITION: THE NIH HAS INSUFFICIENT DATA TO DETERMINE IF SBIR GRANTEES ARE COMMERCIALIZING THEIR TECHNOLOGY

Although NIH has awarded $1.7 billion in SBIR-funded R&D, it does not track the Program's success in commercializing the results of the R&D.

To determine the extent that grantees had developed any commercialized products and whether NIH had knowledge of them, we identified 50 of the highest-funded SBIR grantees from

FYs 1984 through 1994. Of these 50, we selected the 29 grantees that were awarded SBIR Phase II grants during FYs 1988 through 1990.[6] These 29 grantees were awarded 32 grants during that period. We attempted to contact the grantees to ask whether they commercialized any products and to obtain information on sales of the products. We were able to speak with 21 of the 29 grantees. As shown in the chart below, the grantees indicated that 10 of their SBIR products had been commercialized, nine of which resulted in cumulative sales of $72.6 million through February 1999 (see Appendix B for more details). According to the grantees, none of these products have been sold to the Government. Fourteen projects resulted in no commercialized products. Five of the 14 indicated they have not yet commercialized. We were unable to contact eight grantees because they could not be reached or their telephone numbers were no longer in service.

Results of 32 SBIR Phase II Projects Awarded in FYs 1988 and 1990	
Products That Commercialized	10
- nine had sales of $72.6 million	
Products That Did Not Commercialize*	14
Unable to Determine	8
* five of the 14 indicated they have not yet commercialized	

Reasons provided by grantees for not commercializing their research products were:

- two grantees indicated other products in the U.S. market performed the same function as their product, prompting one grantee to seek marketing the product in Europe;
- four grantees indicated their products had become obsolete, were too difficult to use, or were no longer marketable;
- one grantee indicated they lacked the necessary funding to produce and market a product;
- one grantee indicated they are pursuing general development of the research topic; and

[6] Our selection of grant projects awarded in FYs 1988 to 1990 was made because experts on technology development, according to the General Accounting Office (GAO), concluded that at least 5 to 9 years are needed for a company to progress from a concept to a commercial product.

- one grantee indicated their priorities had changed, and the product was not marketed.

The NIH SBIR Coordinator was not aware of these results. Furthermore, NIH's Edison contains a record of only one patent for the ten products.

CAUSES: THE NIH DOES NOT HAVE A SYSTEM IN PLACE TO EVALUATE COMMERCIALIZATION ACTIVITIES OF SBIR GRANTEES; DOES NOT USE THE CAPABILITIES OF EDISON; AND HAS DECREASED EMPHASIS ON COMMERCIALIZATION IN SBIR EVALUATION CRITERIA

The NIH does not have a system in place to evaluate commercialization activities.[7] During our review, NIH indicated to us that it had little information in Edison on the utilization of inventions derived from SBIR grants. Regarding NIH's criteria for evaluating SBIR proposals, NIH has recently revised the criteria to place decreased emphasis on commercial potential. These causes are explained in more detail in the following three sections:

(1) NIH Does Not Have a System In Place to Evaluate Commercialization Activities

Although SBIR legislation emphasizes the SBIR Program's goal of commercialization, NIH indicated during our review that it does not need to evaluate commercialization activities because:

- The SBA does not require SBIR agencies to obtain this information;
- The SBA and GAO have performed their own commercialization studies in the past; and
- The NIH does not have resources because the SBIR Program currently does not provide an allowance to SBIR agencies to administer the SBIR Program. The NIH indicated that the SBIR Program already requires a significant effort by NIH's grants offices to administer awards.

Further, NIH officials indicated that commercial success can be gauged in many different ways, including: (1) the number of start-up companies the SBIR Program supports;

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[7] After we completed our review, NIH told us it recognizes the importance of evaluation and tracking of awards made through the SBIR program, and it is taking steps toward initiating a planning study to identify measurable outcomes of the SBIR Program. In addition, NIH told us that commercialization of SBIR awards is now being monitored via annual utilization reports when NIH funding results in a subject invention pursuant to Commerce regulation 37 C.F.R. 401.

(2) economic factors such as fueling the economy based on the requirement for U.S. manufacture; and (3) absorption or merger of a small business with another company. However, NIH does not measure the success of SBIR grantees in any of these areas.

With regard to GPRA, NIH has not established performance criteria and does not plan to include the SBIR Program in its GPRA performance plans. The NIH indicated that it will not include the SBIR Program in its GPRA performance plans, mainly because: (1) the SBIR Program is separated within the responsibility of each Institute and Center; and (2) the focus of the SBIR Program is unclear. Consequently, NIH has not established a system to evaluate SBIR grant recipients' performance or other information from grantees on what technologies are being commercialized.

(2) The NIH Has Not Used the Capabilities of Edison To Evaluate Commercialization Activity

In addition to the reasons provided by NIH for not evaluating commercialization, we found that NIH was not using the capabilities of Edison for this purpose. The NIH, under the NIH Grants Policy Statement (per reporting requirements of 37 C.F.R. 401.14 (h)), requires SBIR grantees to submit information annually on their utilization of inventions. Utilization reports should include information regarding the status of development and the date of first commercial sale or use. Although this requirement exists, NIH told us that it had little information on the utilization of inventions derived from SBIR grants. We believe that having this information would be useful in evaluating the success of grantees in commercializing their products. When we completed our review, NIH told us that commercialization of SBIR awards is now monitored via required annual utilization reports when NIH funding results in a subject invention pursuant to Commerce regulation 37 C.F.R. 401.

(3) The NIH's Revised Evaluation Criteria for SBIR Proposals Places Decreased Emphasis on Commercial Potential

The NIH believes that its award process funds applicants with the highest commercial potential. However, in reviewing NIH's latest evaluation criteria used for peer review of SBIR proposals, we noted that the criteria that tests the proposed SBIR projects' potential for commercial application has been revised, effective in 1998. The criteria now reads, "potential of the proposed research for commercial application **or societal impact**" [emphasis added]. The term, "or societal impact" was added to the criteria. The NIH indicated that in changing the criteria it is pushing for a broader range of research topics to better reflect NIH's behavioral research mission.

EFFECT: LACK OF KNOWLEDGE OF SBIR COMMERCIALIZATION SUCCESS PREVENTS NIH FROM MEASURING ITS OWN SUCCESS IN MEETING A SIGNIFICANT PROGRAM GOAL

By not evaluating the commercialization success of its SBIR Program, NIH does not know whether it is meeting the Program's legislative goal of increasing private sector commercialization. Further, NIH does not know whether its process for reviewing SBIR grant proposals on the basis of commercial potential is successful and that the most worthy proposals are approved for funding.

THE OIG RECOMMENDATIONS

We recommend that NIH:

(4) develop a system to evaluate the performance of the SBIR Program that will include measuring the success of SBIR award recipients in commercializing products resulting from their research projects;

(5) utilize Edison to track the commercialization success of SBIR award recipients by obtaining the information from utilization reports; and

(6) revise peer review evaluation criteria for SBIR proposals to emphasize the potential of the proposed research for commercial application.

THE NIH COMMENTS TO OIG RECOMMENDATIONS AND OIG RESPONSE

On September 8, 1999, we received NIH's written comments to the recommendations contained in a draft of this report, dated July 26, 1999. We have incorporated NIH's comments to recommendations four through six along with our responses in the discussion below. The NIH comments are included in their entirety as Appendix C of this report.

Recommendation 4

The NIH Comment

The NIH told us it is currently taking steps to conduct a full SBIR evaluation. The NIH's plan is to develop criteria for success and identify measures of success, potential data sources, tools for data collection, and develop a methodology that will tie in the significant investments that NIH has made in the SBIR program to specific and measurable outcomes. Once a methodology is established, NIH plans to conduct a pilot study and a full SBIR evaluation.

The OIG Response

We believe that for NIH's plan to be most effective, the plan should incorporate our recommendation to measure the success of SBIR award recipients in achieving the SBIR goal of commercializing products resulting from their research projects.

Recommendation 5

The NIH Comment

In NIH's September 8, 1999 comments to our draft report, NIH told us that the Edison system does track commercialization through utilization reports of inventions when NIH funding results in a subject invention pursuant to the Bayh-Dole Act. In addition, NIH told us it becomes aware of anecdotal information on commercial success through outreach efforts such as the NIH SBIR List Serv[8] and encouraging SBIR awardees to communicate to NIH Phase III success stories that resulted from NIH SBIR funding.

The OIG Response

During the course of our review NIH indicated that it had little information in Edison on the utilization of inventions derived from SBIR grants, and we found no indication that NIH was using Edison for analyzing commercial success. Nevertheless, as NIH implements the recommendations in our report related to improving grantee compliance with invention reporting requirements, NIH should ensure that utilization data is collected to fulfill the requirements of Commerce regulation 37 C.F.R. 401 (which implements the Bayh-Dole Act). In addition, NIH should continue to develop other methods it has currently begun using to track the commercialization success in its SBIR Program.

Recommendation 6

The NIH Comment

The NIH told us that it disagrees with our statement that it has decreased its emphasis on commercial potential of SBIR proposals based on the addition of the term "or societal impact." The NIH indicated that Section IV.B.2 of SBA's SBIR Policy Directive implies that additional criteria may be added at NIH's discretion.

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[8] An electronic mailing list management tool used by NIH to disseminate information relating to the NIH SBIR Program.

The OIG Response

We understand that the statutory requirements allow the participating agencies some flexibility in the content and operation of their individual SBIR Programs. However, we believe that including, "or societal impact," in criteria for measuring a proposal's commercial potential could possibly be misinterpreted to fund proposals that may in fact have societal impact, but do not have the potential for commercial application. If NIH added societal impact to reflect the behavioral research mission, the criteria should be clarified to include both **commercial potential and societal impact**.

APPENDICES

APPENDIX A

The NIH SBIR Program Awards

Fiscal Year	Amount (in millions)
1983	6.5
1984	21.0
1985	40.0
1986	52.5
1987	61.6
1988	66.4
1989	70.9
1990	74.0
1991	80.5
1992	88.7
1993	120.7
1994	128.7
1995	174.6
1996	184.3
1997	246.2
1998	265.6
Total	**1,682.2**

Approximately 95 percent of NIH's SBIR funding agreements consist of grants.

APPENDIX B

Commercialized Products Related to 10 SBIR Projects Funded in FYs 1988 and 1990		
Company	**Product**	**Approximate Cumulative Sales[9] (as of 2/99)**
Abiomed, Inc.	In Vivo Total Body Lead Analysis by X-Ray Fluorescence	$1,000,000
Audiological Engineering, Corp.	A Multiple Modality Assistive Listening Device	$50,000
Biomagnetic Technologies, Inc.	Magnetoencephalography (MEG) Positioning Apparatus	$50,000,000
Candela Laser Corp.	Infrared Fundus Videoangiography System	$500,000
Alacron, Inc.	A Digital Signal Processing Evoked Potential Machine	$3,000,000
Martek Bioscience Corp.	Omega-3 Polyunsaturated Fatty Acids from Algae	$2,000,000
Science Research Laboratory	Novel Accelerator for Radioisotope Production for Positron Emission Tomography	$6,000,000
Surmodics	Improved Biocompatibility of Intraocular Lenses	Not Available
Technical Research Associates	Enhanced Centrifugation Device	$10,000,000
Whalen Biomedical, Inc.	An Extracorporeal Pulsatile Assist Device	$10,000
Total		**$72,560,000**

[9] Several grantees provided us with a range of cumulative sales. In these instances, the amounts recorded indicate the highest end of the range.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

SEP 0 8 1999

TO: Joseph J. Green
Assistant Inspector General for Public Health Service Audits

FROM: Deputy Director for Management

SUBJECT NIH Comments on the Office of Inspector General (OIG) Draft, *Review of the Effectiveness of the National Institute's of Health Administration of the Small Business Innovation Research Program* (CIN: A-15-98-00031)

Thank you for providing the NIH an opportunity to review and comment on the draft report referenced above. This report of findings for the evaluation of the Small Business Innovation Research program incorporates much of the information that was earlier provided to the OIG. We have included comments specifically related to the draft report in **Attachment A.**

Our comments are intended to provide information to enable a comprehensive description of the dynamic nature of the Small Business Innovation Research program and to acknowledge program improvements that have occurred especially in the areas of invention reporting compliance and information dissemination since the review was initiated in 1997. Should your staff have any questions, please ask them to call Mary Jane Meyers, Office of Management Assessment, NIH at (301) 402-8482.

Anthony L. Itteilag

Attachment

NIH COMMENTS ON THE DRAFT REPORT: Review of the Effectiveness of the National Institutes of Health's Administration of the Small Business Innovation Research Program (CIN: A-15-98-00031)

This report of preliminary findings for the evaluation of the SBIR program restates information previously expressed to the OIG. We hope that our responses will provide information to enable a more comprehensive and balanced description of the dynamic nature of the SBIR program.

First, however, we believe it is important to note that past evaluations by the Small Business Administration and General Accounting Office (GAO) have determined that NIH's SBIR program is indeed a success. Specifically, in the GAO report entitled "Federal Research: Small Business Innovation Research Shows Success But Can Be Strengthened" (GAO/RCED-92-37), NIH was pleased that, of the five major SBIR agencies, the Department of Health and Human Services achieved the highest level of sales per project as well as the highest percentage of private-sector activity for sales and additional developmental funding. The flexibility in the program design has enabled NIH to manage the program to effectively meet its broad medical research objectives.

As you noted, your review was conducted in NIH intermittently from October 1997 through March 1999. In light of the timing of the review, our comments reflect the *current* efforts we are taking, especially with respect to ensuring that SBIR awardees are complying with invention reporting requirements. We hope that your final report will acknowledge NIH's improvements both in invention reporting compliance and in adequately providing reporting information to all parties involved.

We also hope your final report will acknowledge that NIH does, in fact, recognize the need to evaluate the success of the Program, as indicated by the steps we are taking to evaluate the specific outcomes of the NIH SBIR program, including one of the Program' s goals of stimulating technological innovation and commercialization. The efforts we are making are explained in more detail below.

Response to Finding #1:

NIH does not ensure SBIR grantees' compliance with invention reporting requirements.

SBIR grantees' compliance with invention reporting is an area of emphasis and many advances have been made. In addition to the areas you specifically mention, we have initiated other positive steps, listed below, that will improve compliance with invention reporting requirements.

- We have provided grantees with a web site (**http://www.iedison.gov/**) that satisfies all mandated invention reporting requirements. The NIH Interagency Edison (Iedison)

Reporting System includes a timeline in chart form with references to the requirements set forth by the Commerce regulation 37 CFR 401, as well as what and to whom documentation is to be reported. In addition, a phone number, fax number and e-mail address are made available for the broadest range of contact with NIH staff.

- Standardized terms of award for SBIR/STTR recipients were implemented (4/99).

- A web site has been developed for NIH staff to help them be more effective in providing information for invention reporting compliance.

- A letter has been prepared for dissemination to all SBIR awardees to raise awareness and advise them of their invention reporting obligations.

Outreach efforts by NIH, including presentations to professional societies, user groups, universities, and research institutes, ongoing user-support via a help-desk, and the design of the Interagency Edison WebPage, have greatly improved awareness and compliance. We have now included a presentation on intellectual property as a standard concurrent session in all NIH Regional Grants Administration Seminars. It should be noted that invention reporting requirements are uniform for all grantees and contractors. As a consequence, our efforts are expended uniformly with the goal of improving compliance for all recipients of NIH funding.

Responses to OIG recommendations:

Finding 1

(1) **OIG Recommendation:**
Incorporate specific invention reporting requirements in the SBIR Solicitation including actions and time limits placed by law, as well as consequences when invention reporting requirements are not met.

NIH Response:
We concur with this recommendation and will continue to inform SBIR applicants/awardees of their invention reporting requirements. NIH intends to include in future SBIR and STTR Solicitations, a copy of the invention reporting time line chart that appears as part of the Interagency Edison web site. The chart clearly summarizes "Extramural Invention Reporting Compliance Responsibilities" to more effectively communicate invention reporting obligations directly to SBIR and STTR awardees.

(2) **OIG Recommendation:**
Continue with efforts to link Edison with the Patent and Trademark Office (PTO) patent database to identify patents that have been supported with NIH funds. In

the interim, NIH should reconcile invention data between the PTO patent database, the NIH Institute and Center grants offices, and Edison to insure that grantees are complying with invention reporting requirements;

NIH Response:

The NIH has drafted an internal policy document to describe the roles and responsibilities of NIH staff, including Program and Grants Management staff, in ensuring that grant recipients are complying with invention reporting requirements. As we've commented before, however, the recommendation that NIH continue with efforts to link Edison with the PTO data base has value but cannot be done unilaterally. PTO has declined to give NIH access to any information other than issued patent records. It generally takes several years for a patent to be issued relative to when it was derived. Thus, as a resource it provides very little value since the information is not timely with respect to the awarding of NIH SBIR/STTR grants.

(3) **OIG Recommendation:**

Make direct contact with all NIH SBIR award recipients and urge them to adhere to all invention reporting requirements;

NIH Response:

NIH staff have recently taken some positive approaches to directly contact NIH SBIR awardees. We have prepared a personalized letter, to be sent to SBIR awardees to advise them of their invention reporting responsibilities. In addition, we plan to modify the Fiscal Year 2000 NIH award letter to highlight for *all* awardees their responsibility for reporting inventions.

Response to Finding #2:

Does not evaluate the success of its SBIR program in commercialization of research.

See OIG COMMENT below.

We disagree with the statement on page ii and page 17: "NIH does not recognize the need to track commercialization activities, and has no plan in place to track the success of the SBIR Program in commercialization." The NIH recognizes the importance of evaluation and tracking of awards made through the SBIR program and has a plan to formally evaluate the success of the Program. Specifically, NIH was recently approved for a planning study, using NIH One Percent Evaluation Set-aside Funds, to evaluate the NIH SBIR programs. This represents the first systematic and centralized effort toward evaluating the NIH investment in the NIH program. Commercialization of SBIR awards is currently monitored via required annual utilization reports when NIH funding results in a subject invention pursuant to the Bayh-Dole Act. Through the NIH Edison system, grantees and contractors report efforts to commercialize, including efforts to

OIG COMMENT: We revised the report to delete the statement that NIH does not recognize the need to track commercialization activities.

license and the amount of sales. In addition to monitoring commercialization success through required annual utilization reports to Edison, NIH also becomes aware of commercialization successes anecdotally. Through our outreach efforts via the NIH SBIR List Serv and conference presentations, we have encouraged SBIR awardees to communicate to us Phase III success stories that resulted from NIH SBIR funding.

Responses to OIG recommendations under Finding 2:

(4) **OIG Recommendation:**
Develop a plan to evaluate the performance of the SBIR Program that will include measuring the success of SBIR award recipients in commercializing products resulting from their research projects;

NIH Response:
It is not clear what additional efforts should be made to develop a plan to evaluate the SBIR Program. As mentioned, in addition to ongoing efforts to monitor commercialization of SBIR awards, NIH is currently taking steps toward evaluating the NIH SBIR program. The elements of the initial planning study include an expert panel on program evaluation who will advise on criteria for success, identify measures of success, potential data sources, and tools for data collection, and develop a methodology to tie the significant investments that NIH has made in the SBIR program to specific and measurable outcomes. It is anticipated that it will take six to nine months to complete this portion of the evaluation. Once a methodology is established, a pilot study will be initiated, after which a full SBIR evaluation will be conducted.

(5) **OIG Recommendation:**
Utilize Edison to track the commercialization success of SBIR award recipients;

NIH Response:
The Edison system does track commercialization through utilization reports of inventions for which the awardee has elected title pursuant to the Bayh-Dole Act. However, not all commercialized outcomes result from subject inventions.

(6) **OIG Recommendation:**
Revise peer review evaluation criteria for SBIR proposals to emphasize the potential of the proposed research for commercial application.

NIH Response:
It is not clear how the peer review evaluation criteria should be revised. In addition to the evaluation criteria specified to be "considered as a minimum" by the SBA in its Policy Directive for the SBIR Program, NIH does, in fact, include **"the potential of the proposed research for commercial application** [emphasis added] or societal impact."

NIH disagrees with the statement that, "NIH has decreased its emphasis on commercial potential of SBIR proposals" based on the addition of the term "or societal impact" to the evaluation criteria. The term "societal impact" was not added to decrease emphasis on commercial potential; rather, it was added to reflect the NIH's behavioral research programs. Section IV.B.2 of the SBA Policy Directive, which states, "The factors in subparagraph B.1 and **other appropriate evaluation criteria**, [emphasis added] if any, shall be specified in the *Method of Selection* section of SBIR Program Solicitations" implies that additional criteria may be added at our own discretion. It is also interesting to note that the National Science Foundation lists as one of its SBIR review criteria, **"the commercial and societal benefits** [emphasis added] of the proposed activity."