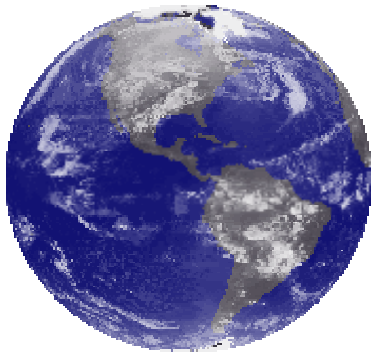
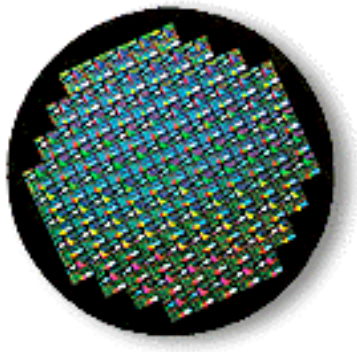
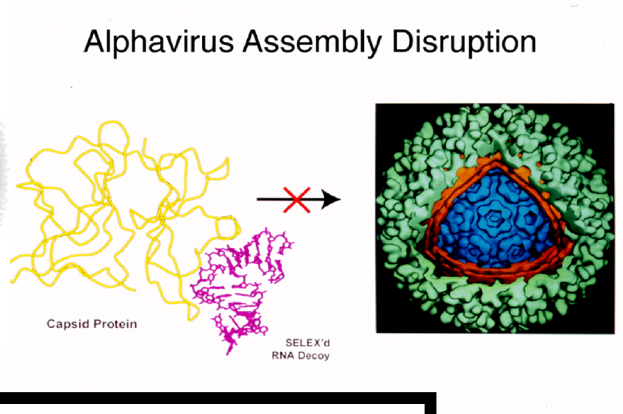


Foreign Participation In CRADAs

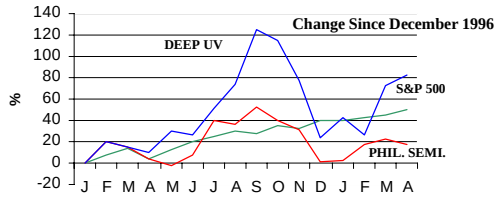




High Technology, High Rewards

A new Index that goes by the ungainly name of Deep UV Photolithography Food Chain tracks the performance of five companies that make equipment used for etching tiny wires into the surfaces of microchips. The demand for this equipment has made these companies investor favorites.

	Ticker	Yesterday's closing price	Change year to date	Est. price to earnings ratio
ASM Lithography	ASMLF	$95.75	41.9%	27.8
Cymer	CYMI	25.25	68.3	61.3
Dupont Photomask	DPMI	50.25	44.1	23.5
Etec Systems	ETEC	55.00	18.3	23.7
Photonics	PLAB	33.50	38.1	26.9



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Foreign Participation in CRADAs

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Executive Summary

Technology transfer between the United States and foreign entities occurs through a variety of mechanisms. These include corporate joint ventures or alliances, contracts with the U.S. Government, use of subsidiaries, establishment by foreign companies of research facilities in the United States, international coauthorships in academic research, as well as multinational corporate (MNC) mergers and acquisitions. Cooperative Research and Development Agreements (CRADAs) are one of many mechanisms that U.S. Government R&D organizations use in working with private industry and academia. Moreover, CRADAs facilitate collaborations outside the normal contracting process and are valued for their flexibility, responsiveness, and explicit control of intellectual property (IP) that may result from collaborations. Although CRADAs have played a comparatively minor role in transferring technology to foreign entities, some policy makers are concerned about the increasing internationalization of R&D and how U.S. interests are addressed in this environment.

Technology transfer from the United States to foreign entities has always been a concern for policy makers and national security analysts—self-sufficiency and R&D leadership have been hallmarks of the U.S. defense industry. However, in the current global economy, distinguishing military technology from commercial technology can be difficult. In addition, R&D leadership is not necessarily concentrated in the U.S. defense laboratories or industry. Furthermore, the issues of whether foreign companies should be allowed to participate in U.S. Government sponsored research and the lack of formal guidance on such collaboration remain technology transfer concerns.[*]

Objective

This study reviews existing CRADAs, focusing on those CRADAs that include foreign participation, and analyzes the processes used by U.S. Government agencies in determining whether to include foreign partners in CRADAs. In addition, this study proposes criteria and procedural options, consistent with national security and the economic interests of the United States, that agencies should consider in evaluating potential foreign involvement in CRADAs.

Approach

Analysis was conducted using extensive interviews with technology transfer practitioners and policy makers at various Federal agencies (e.g., Department of Energy [DOE], Department of Defense [DoD], National Institutes of Health [NIH], Department of Commerce [DoC]), as well as other study teams involved in evaluating foreign participation in CRADAs. In addition, existing research (e.g., case studies, cost share programs, academic literature) was reviewed and analyzed to understand how U.S. Government agencies and the military services interpret the legislative intent of various technology transfer statutes (i.e., Stevenson-Wydler Act, Technology Transfer Act of 1986 [15 USC 3701–3715 and 10 USC 2515]).

[*] Jacques Gansler, *Defense Conversion* (Cambridge, MA: MIT Press, 1995), p. 49.

This analysis was not intended to be comprehensive but only illustrative of how various organizations interpret provisions that deal with national security and economic security interests in public–private technology transfer partnerships. In addition to CRADAs (especially cases involving private sector "funds-in"), analysts considered practices and criteria in patent licensing and cost-shared contracting for technology development involving foreign entities.

As a point of departure, the study team used observations and insights gathered from the U.S. Government's recent experience regarding possible inclusion of foreign partners (i.e., lithography toolmakers) in the Extreme Ultraviolet Lithography Limited Liability Corporation (EUV LLC) CRADA with the DOE laboratories. The issues associated with the EUV LLC CRADA and the potential inclusion of foreign entities illuminate how decision makers assess national security, economic security, and technology policy factors that arise from public–private partnerships in sensitive technology areas.

During the course of the study, the objective evolved somewhat to take account of related political developments. In part in response to the specific circumstances surrounding the EUV LLC, the Congress proposed legislative language in the form of an amendment offered by Rep. Tauscher to H.R. 2544.[*] The amendment requires the Director of the Office of Science and Technology Policy (OSTP) to review policies and procedures Federal agencies use in gathering and considering the views of other agencies with respect to major proposed CRADAs (i.e., those that involve critical national security technology or may have a significant impact on domestic or international competitiveness). One aspect of the legislative language requires the Director of OSTP to determine the adequacy of existing procedures and methods for interagency coordination and to propose additional procedures, if necessary, for considering other agencies' views regarding major CRADAs.

Internationalization of CRADAs

Increasingly, R&D collaborations are conducted on a worldwide scale using multiple methods. Although the reasons are complex, globalization of the marketplace and rapid diffusion of new technology appear to be driven by competitive factors affecting all industries. These factors include rising R&D costs, risks associated with production, shortened product life cycles, increasing multidisciplinary complexity of applications, and intense foreign competition in domestic and global markets. In the last decade, foreign-funded research in the United States has concentrated in three industries, drugs and medicines (mostly funded by Swiss and British firms), industrial chemicals (mainly funded by German firms), and electrical and electronic equipment (one-third of which are funded by French affiliates).[+]

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[*] Subsequent to this report, H.R. 2544 did not pass in the 105th Congress. A revised version, H.R. 209 (the Technology Transfer Commercialization Act of 1999),has passed the House and is currently under consideration in the Senate. In this version, each Federal agency with a Federally funded laboratory that has one or more CRADAs is required to submit a report to the Committee on National Security (CNS) of the National Technology and Security Council and to the Congress.

[+] National Science Board, Science & Engineering Indicators—1998. Washington, DC: US Government Printing Office (NSB 98-1), p.4-55.

In light of these trends, it is not surprising that the U.S. Government is also experiencing an increased interest on the part of foreign partners in R&D collaboration through CRADAs. In fact, this survey corroborated the perception that, overall, the number of CRADAs with foreign participation remains relatively small (less than 5% of all CRADAs). However, it does appear that number of CRADAs that involve foreign participation is increasing, albeit at a slower rate than number of private industry or academic R&D collaborations involving such foreign involvement.

Although most CRADAs are still characterized by small-scale agreements between researchers, usually valued at under $50,000 (based on the estimated value of researchers' level of effort), some agencies have entered into CRADAs for scientific projects of significantly larger scale and using different types of financial arrangements. For example, a few cases of large "funds-in" CRADAs have permitted the private sector partner to pay for personnel, services, and property. In addition, umbrella CRADAs have facilitated multiparty (and multiple project) R&D in government and industry.

"Funds in" CRADAs, or other large-scale CRADAs, potentially introduce new considerations into R&D collaborations. In an era of downsizing and constrained funding, an industrial partner offering to put up a sizable amount of money for research could have a distorting impact on the resources and attention of the Federal laboratories—even though the agreements must be mission related. Could a large infusion of outside funding cause a potential divergence between the laboratory's interest in maintaining capabilities and the safeguards regarding U.S. national and economic security that are built into the CRADA review process? Although there is no evidence that such a divergence has occurred, some observers have indicated that this environment could make it more difficult for Federal laboratories to determine and protect the economic interests of the United States in the future.

Although the EUV LLC CRADA is unique, one of the concerns expressed by some agencies and Members of Congress focused on the size of the investment, the potential introduction of a foreign licensee, and the consideration of economic and national security. As a result of recent experiences, questions have emerged concerning the adequacy of current procedures for reviewing and approving CRADAs, especially those that may involve foreign participants. Questions include—

- Does the increasing size and type (e.g., funds-in) of CRADAs create additional need for oversight?

- Does the increasing internationalization of R&D, which could drive increased foreign participation in CRADAs, create a need for changes in the CRADA review process?

- If it were determined that additional oversight or changes were needed, how could this be done in a way that does not overly burden the process? This consideration may be particularly important for the vast majority (more than 95 percent) of small-scale CRADAs for which the present processes are most likely adequate.

The trend toward internationalization of R&D and CRADAs will likely increase in the future, thereby likely perpetuating the debate about foreign participation in U.S. Government R&D beyond case-specific CRADAs.

General Findings

Some agencies and laboratories provide guidance or a model CRADA designed to streamline the process and encourage partnership efforts (see Exhibit ES.1). Typically, a model CRADA addresses rules and responsibilities regarding the following: definitions; the work statement; term, funding, and costs; personal property; disclaimers; product liability; obligations regarding proprietary information; obligations regarding protected CRADA information; rights in generated information; export control; reports and abstracts; pre-publication review; copyrights; reports of intellectual property use; march-in rights; U.S. competitiveness (in the case of DOE); assignment of personnel; *force majeure*; administration of the CRADA; records and accounting for government property; notice; disputes; modifications; termination; and project management.

Exhibit ES.1 Model CRADAs on the Web

Agency	Web Site	Comments
DOE	http://www.doe.gov/techtran/cradam.html#ZZ0	Also has model for joint ventures with small business
DoD	http://www.dtic.mil/techtransit/	Provides models for each Military Service
NIH	http//www.nih.gov:80/od/ott/crada_inf.htm	Delineates roles and responsibilities for agency and collaborators

Under the Stevenson-Wydler Technology Innovation Act, as amended, the laboratory director is required, when deciding which CRADAs and licensing arrangements involving foreign parties to enter into, to address certain requirements regarding national and economic security. Specifically, the legislation requires agencies to—

- Give preference to substantial manufacture in the United States
- Ensure reciprocal access to foreign R&D and licensing arrangements
- Adhere to export control laws and re-transfers of strategic technology
- Determine whether the foreign entity has policies to control U.S. Intellectual Property Rights (IPR).

The specific language pertaining to these provisions of the Stevenson-Wydler Act are provided in Appendix A (see Executive Order 12591, Sec.4 International Science and Technology and 15 USC 3710a (c)(4)). Foreign entities are defined as *persons* or industrial organizations (where the entities are directly or indirectly controlled by a foreign company or government).

For the current study, representatives of several Executive agencies (or Executive departments) were interviewed to determine how they handle foreign participation in CRADAs. Interviews were conducted with technology transfer managers and/or general counsels who are involved in review and administration of CRADAs or Patent Licensing Agreements (PLA). In general, it appears that all agencies/departments engage in CRADAs with foreign participants only if no U.S. company has expressed an interest in the associated technology. This is particularly true where defense technologies are concerned.

The results of the survey of the agencies/departments, captured succinctly in Exhibit ES.2, provide some interesting insights and issues. Essentially, none of those interviewed felt additional layers of review outside the current processes would be necessary in most cases. Moreover, for the sample of agencies and departments surveyed in this study, only about 5 percent of their CRADAs were with foreign entities. This percentage is significantly below some of the percentages that are characteristic of academic and industrial collaborations that include foreign participants. This low percentage is even more significant when one considers the fact that the largest number of CRADAs with international participation is in the bio-medical areas (e.g., NIH, DoD), where many large, biomedical MNCs are headquartered outside the United States (see Exhibit ES.3).

In all cases, agencies have procedures in place to screen CRADAs that involve international participants, and there did not appear to be any significant deficiencies in implementing statutory and regulatory requirements. However, there were variations in the way agencies interpret and implement statutory and regulatory requirements. For example, not all agencies use the United States Trade Representative (USTR) to advise on trade and R&D reciprocity issues. Furthermore, the USTR does not necessarily have the resources and expertise to evaluate such R&D reciprocity issues.

This failure to consult with the USTR does not appear to be a significant issue; in most cases, the existing CRADAs are with close allies of the United States, and the approving agency need only consult as opposed to seek concurrence. Some agencies make their own determinations of reciprocity. However, the question remains—if all agencies were to seek USTR consultation, as spelled out in Executive Order 12591, would this over-tax the resources of the Trade Representative's office? Some agencies have already cited slow or unsatisfactory response by the USTR as a reason for not seeking regular foreign consultation. On the other hand, it is also worth noting that a number of agencies have had acceptable responses (in the range of 1 day to 2 weeks). However, some of those interviewed noted that the mandatory period for approval of a CRADA (30 days for government-owned, government-operated laboratories) and the consistent use of USTR consults by all agencies could conceivably lead to delays in the process as well as problems with compliance in the mandated period of time.

Executive Order 12591, as well as technology transfer legislation, addresses both economic and national security, however, no definitions or criteria for determining economic security or economic impact are given. In interviews, considerable concern was expressed about the possibility of burdening the CRADA approval process to the point that industry would find the process too problematic.

Another provision of existing legislation that has been interpreted differently by various agencies is the requirement to give preference to business units located in the United States that agree that any products embodying inventions made under the CRADA or produced through the use of such inventions will be manufactured substantially in the United States" (15 USC 3710a). "Manufactured substantially" is not defined, but is left to the interpretation of those implementing the legislation. However, all agencies stressed the need for substantial U.S. manufacturing of the products resulting from CRADAs, although several agencies noted that this represents a preference only, not a statutory requirement.

Exhibit ES.2 Overview for Foreign Participation, Various Agencies

Component	Air Force	Army	Navy	NIST	DOE	NIH	USDA
United States first?[1]	Not clear[3]	Not always	Yes	Not always[5]	Not US only	Yes	Yes
Substantial U.S. mfg?[2]	Yes, with flexibility	Yes	Yes. Navy alternate clause used little.	Required for products sold in the United States	Yes, or alternative net benefits for US economy	Yes, if product substantially sold in United States	Yes; some foreign cos. considered US if mfg/ R&D here
Trade Rep review?	Yes	Use USTR for gov't orgs., not foreign cos.	Yes	Not standard	Yes	Only in special cases (China, South Africa)	No
No./total of Int'l CRADAs	~ 3 since 1992	~ 25 since 1992[4]	~ 24 since 1992	50/813 (since 1988)	25/1600 (up to spring 1998)[6]	26/237 (March 1988–Jan 1995)	16/ 340 (since FY95)
% of Int'l CRADAs	3.3 % DoD-wide			6%	1.5 %	11 %	5%

[1] *"U.S. First" refers to the practice of some agencies not entering into a foreign CRADA if there is a U.S. company working in the same field. This is not a statutory requirement. It is also important to note that CRADA law expresses a "preference" for doing business with U.S.-located businesses but that patent-licensing laws do not contain such a preference.*

[2] *This category refers to how an agency handles the substantial manufacturing preference, although all agencies have discretion to waive this requirement. An unmodified "Yes" response means substantial U.S. manufacturing is required in all cases. Also, although patent-licensing law applies this requirement only when the licensee intends to sell the resulting product in the United States, the CRADA law does not address where a product will be sold.*

[3] *Prior to CRADA signing, the potential partner is investigated by AFRL International, AF Security Command, and SAF International Affairs, which consults with the State Department. DIA is also consulted.*

[4] *CRADAs included are traditional CRADAs for cooperative R&D. Not included are "short form" CRADAs, which are similar to Material Transfer Agreements (MTA). Inclusion of these instruments (which do require USTR review) would increase the Army's total number of CRADAs by about 40.*

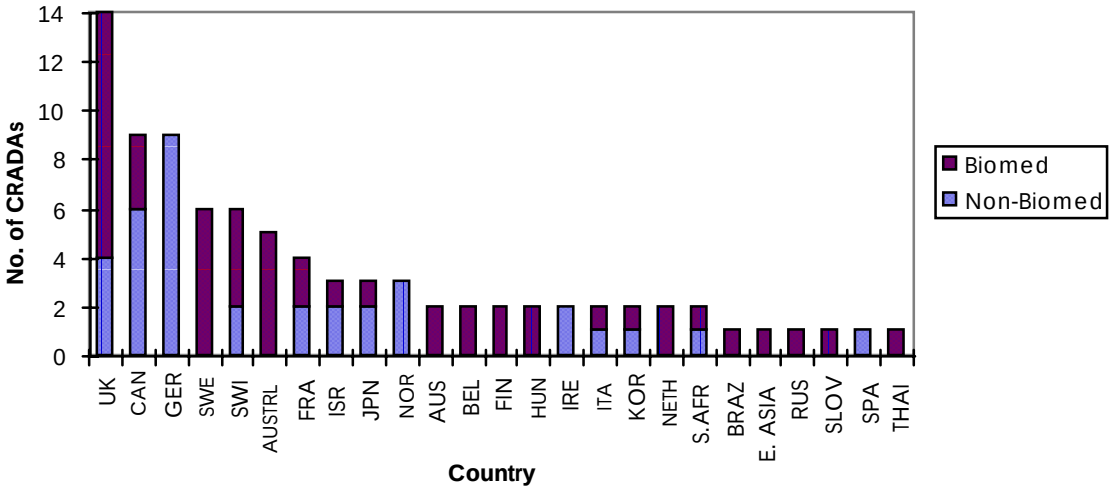
[5] *Many foreign partners in CRADAs may also be involved in Consortia with U.S. firms prior to CRADA application.*

[6] *~ 12 since 1990 in Defense Programs*

[7] *20 percent of patent licenses are issued to non-domestic licensees.*

Most agencies (i.e., NIH, DOE) have an "alternative benefit assessment" that can be applied in cases where the foreign or U.S. companies do not believe that they can comply with the substantial manufacturing requirement. Other agencies require U.S. manufacturing (and R&D) if the company plans to sell in the U.S. marketplace.

Exhibit ES.3 DoD CRADAs with Non-U.S. Partners



Source: Booz·Allen Analysis

Because of the variations in the way agencies implement these requirements, the study team believes that greater clarity, through the development of Government-wide guidance, would assist agencies in assessing key issues associated with CRADAs with international participation. In fact, although the study team did not detect significant problems resulting from the lack of formal guidance on implementation of these requirements, technology transfer practitioners agreed that a standardized checklist or set of questions for use in screening such CRADAs would be useful. The likely result of such guidance would be greater harmonization and improvement of procedures across Federal agencies and laboratories when considering CRADAs that might involve international participation, while at the same time, still affording individual agencies and laboratories the discretion to tailor guidelines to conform to specific situations.

Implementation Issues and Recommendations

In meetings with technology transfer practitioners from numerous agencies, a general consensus was reached that a standardized checklist or set of questions for use in screening CRADAs would be beneficial. Such a checklist would ensure that all the key issues associated with international participation in CRADAs were considered and that all applicable legislative and regulatory requirements concerning national security and economic competitiveness were addressed.

In addition, to supplement the existing criteria for CRADAs, the team devised the following illustrative elements that could be included in a comprehensive checklist:

- An identification of all potential participants in the CRADA, not just signatories. Any intention to involve a non-U.S. participant, whether as part of the supplier base, technology integrator, etc., should be disclosed at the outset or whenever the possibility of such participation became known.

- Detailed plans (e.g., a commercialization plan) concerning the contemplated use of the technology developed as part of the CRADA. For example, is there an intention to commercialize the technology developed by the CRADA? If so, then the competitive technologies, extended enterprise, as well as direct and indirect benefits should be addressed.

- A detailed rationale for inclusion of international, rather than domestic partners. Although most agencies have adopted policies that favor U.S. firms, a discussion of why foreign participation is essential and the alternatives that have been explored regarding domestic partners would help clarify issues at the outset.

- A requirement that all CRADAs with potential international participation and not meeting standard criteria (such as being a "major CRADA") automatically receive more intensive review within agencies. This review would act as an early-warning system for CRADAs that might raise sensitive issues.

- Consistent means for assessing statutory and regulatory requirements of export controls, reciprocal access, substantial manufacture, and intellectual property protection.

These elements are meant to be treated as additional guidance or serve as the basis for the issuance of formal instructions. They are not meant to replace existing criteria but are intended to supplement existing practices when potential or proposed international entities may be involved.

Process Issues and Recommendations

Although procedural issues were not a major concern at the outset of the study (i.e., since spring 1998), the Congress has focused on interagency process changes as a means to address perceived deficiencies in the CRADA review process as demonstrated by the EUV LLV experience. The Tauscher amendment to H.R. 2544, as originally drafted, as well as companion legislation introduced by Senator Rockefeller (S. 2120), would have required criteria for interagency review of a CRADA that involves "national security, or relates to a project which may have a significant impact on domestic or international competitiveness." However, the version of H.R. 2544 that ultimately passed the House contained considerably more flexibility for the Executive Branch (i.e., OSTP) to review and determine the adequacy of existing procedures and methods for interagency coordination, and to recommend additional procedures, if any, for gathering and considering the views of other agencies on certain CRADAs. Although the Congress adjourned before the Senate acted on H.R. 2544, there was no substantive disagreement with the House language (see footnote on page ES2).

It is important to note that despite criticism of the EUV-LLC and the resulting Tauscher amendment, the Congress continues to strongly support the CRADA concept as a tool for industry–government cooperation. Congressional personnel interviewed during this study agreed that the hallmark of CRADAs is flexibility and expressed the strong desire not to hamstring or encumber the CRADA process for the vast majority of cases for which the current process

appears to be appropriate and adequate. Moreover, the Congress did not take the position that international involvement is to be avoided, but in fact, recognized that there are instances where foreign participation is essential to further technology development.

However, congressional officials noted that some "major," far-reaching CRADAs have emerged in recent years that involve cutting-edge technology, the world's largest companies, and occasionally consortia of Federal laboratories.[*] Because of their potential to affect industry sectors, their suppliers, and jobs within the United States, the report language questions whether these CRADAs may have outgrown the current CRADA approval process. Accordingly, the House recommended that OSTP review and upgrade, if necessary, existing approval procedures for these major CRADAs. OSTP was charged with identifying criteria to separate out the small minority of major CRADAs that would benefit from interagency review. While calling for some change "to solve potential problems through better interagency coordination," the House bill clearly states that new procedures are to be added only to the extent that existing procedures are inadequate, and that "any new procedures are to lead to expedited, substantive interagency decisions" that minimize burdens on agencies.

Definition of a Major CRADA

Overall, this analysis has found that although CRADAs undergo satisfactory review at the agency level, the Government may benefit from an interagency review process that could assist in evaluating future major CRADAs involving international partners. However, to minimize unnecessary burdens for the vast majority of CRADAs, some clarification concerning what a major CRADA is must be provided.

For example, the DOE CRADA with the EUV LLC highlights some key aspects that could make CRADAs controversial. In this arrangement, the intellectual property and U.S. manufacturing provisions are carefully defined to ensure U.S. manufacture for a specified time period (i.e., assured first access) and to impose the same provisions on licensees of the technology. One prominent element of the controversy involves the *potential* inclusion of international lithographic toolmakers and the large amount of "funds-in" from industry. Some analysts have noted that this arrangement may threaten the well-being of U.S.-based toolmakers who are already party to the agreement. However, others have noted that the commitment of global semiconductor manufacturing leaders to the toolmaking industry, as well as the current provisions for control over manufacture (through licensing provisions), are a good example of how Federal laboratories can accommodate multinational industries and serve the public interest.

Controversy has not been a stranger to collaborations in the past.[+] An example of the need for careful scrutiny of R&D collaborations occurred in an agreement between Scripps Research Institute and Sandoz in 1992. In this case, NIH renegotiated a Sponsored Research Agreement (which is similar to, but not a CRADA) involving the not-for-profit Scripps Research Institute and Sandoz (Swiss-based) pharmaceutical company. Originally, Sandoz was to provide $300

[*]See House Report 105-620 Part 1—Technology Transfer Commercialization Act of 1998, to accompany H.R. 2544, section 6—*Review of Cooperative Research and Development Agreement Procedures.*

[+] *CRADA Mania*, Scientific American, October 1993.

million over 10 years for rights to the commercial fruits of the Federally funded research at Scripps. The agreement was not acceptable to the then-director of the NIH, Bernadine Healy, who felt it gave Sandoz "excessive control" of research and IP. About this time, NIH had developed guidelines to deal with the perception and controversy associated with serving the public interest. The institute found that more specificity in the field of use (FOU) is a critical part of developing an appropriate CRADA.[*]

Although no definitive definition of a major CRADA would accommodate all appropriate situations, there are a range of possibilities and illustrative criteria that could assist in narrowing the scope of CRADAs to be reviewed on an interagency basis.

Based on the House Science Committee's report language, it is obvious that there is no intention for all CRADAs to undergo interagency review; quite the contrary, only a "handful" of major CRADAs raise issues that the Committee believed would benefit from such a review. Likewise, because most of the concern about the potential effect of these major CRADAs on American jobs and companies centered on foreign participation in CRADAs, it seems appropriate to further limit the scope of the CRADAs requiring review to those involving foreign partners and meeting appropriate criteria.

To refine the subset of CRADAs triggering interagency review, it may be useful to consider a series of filters, or a funnel approach. The first filter concerns CRADAs with international participation. Based on data provided by agencies, the study team estimated that application of this criterion alone would eliminate 95 percent of all CRADAs, because, on average, only about 5 percent of CRADAs involve foreign participation. The second and subsequent filters could be drawn from the following list of illustrative criteria:

- Type of CRADA (i.e., funds-in, facility share, advanced product development, etc.)
- Monetary Threshold (i.e., comparison of the level of effort proposed with the laboratory budget for the area of concern)
- Critical Technologies (This criterion was qualitative, and no list was deemed specific enough, at this time, to serve as a good filter.)
- Sensitive Industries (This criterion was also qualitative, and no list was deemed specific enough, a this time, to serve as a good filter.)
- Waiver of U.S. Manufacturing Requirement (i.e., where the U.S. manufacturing requirement is expected to be waived and the foreign partner does not have both R&D and manufacturing in the United States in the field of use of the statement of work).

[*] As a result of the experience with Sandoz and Scripps, the NIH adopted several policy changes to avoid similar problems with their collaborative mechanisms in the future. Four changes, in particular, were incorporated into the CRADA review process: 1) evaluate the level of effort to be provided compared with the laboratory budget in the area of concern, 2) ensure that the CRADA has intellectual involvement by all parties (i.e., not money only), 3) evaluate whether a CRADA is the appropriate mechanism for the collaboration proposed, and 4) evaluate the level of the Principal Investigator's time commitment in the agreement.

The list above is not comprehensive, but is intended to be illustrative only. It provides a preliminary basis for discussion among agencies about what constitute appropriate criteria for CRADA consultation by other agencies. The most important aspect of such triggers is that they be quickly and easily ascertained in order to permit consistent application in the most efficient manner. As will be discussed in the following paragraphs, it is important for an interagency group to agree on consensus criteria to identify these major CRADAs, and these criteria should be shared on an interagency basis. Many practitioners believe that reducing many of these criteria to a readily administratible form will be a difficult challenge.

Interagency Review Process

After the criteria defining the character of CRADAs to be reviewed by an interagency group have been established, the next issue is what kind of interagency review process should be used. Because the congressional report language emphasizes use of existing procedures, to the extent possible, to minimize burdens on Federal agencies, the study team's focus has been on current interagency mechanisms that might be appropriate for the CRADA review process.

After examining various interagency mechanisms and discussing options with agencies' representatives, the study team arrived at the preferred option of using an existing mechanism. The Interagency Working Group (IAWG) on Technology Transfer is a existing group that could serve as a coordinating body for the sharing of inputs on CRADAs with international participation that meet interagency agreed-on criteria.

The IAWG on Technology Transfer was created following passage of the Federal Technology Transfer Act in 1986, as a way for the Department of Commerce (DoC) to carry out its statutory role under the legislation. The Secretary of the DoC invited other agencies involved in science and technology R&D with potential for commercialization to become members of the Interagency Committee. The Group initially focused on methods for commercialization, assistance to agencies regarding their cooperative R&D projects, and preparation of a model CRADA agreement. As interest in collaborative research with industry has increased in the past decade, agency participation has broadened to include NIST, DoD, DOE, NIH, SBA, NASA, and USDA. In addition to sharing best practices in technology transfer, the Group has also helped to coordinate agencies' positions on issues such as the application of the GATT Subsidies Code to government research programs during the Uruguay Round, management of technology transfer programs generally, and most recently, agencies comments on H.R. 2544 (now H.R. 209).

The Interagency Committee was formed of Assistant Secretary-level representatives from various agencies and is chaired by Commerce's Assistant Secretary for Technology Policy. Most of the Committee's work, however, is accomplished through the IAWG on Technology Transfer, which is composed of senior managers from the agencies and departments responsible for technology transfer.

Of all the current interagency mechanisms reviewed, the IAWG alone had the advantage of being both a working-level technical group and higher-level policy/political committee for addressing issues. In addition, the IAWG is composed of technology transfer practitioners (i.e., subject-

matter experts) and has effectively served as a coordinating body on various technology transfer questions.

The following illustration demonstrates how the IAWG could serve as an effective consultative body for sharing insights on major CRADAs.

After the criteria regarding what constitutes a major CRADA are agreed to by agencies, any proposed CRADA agreement triggering these criteria would be identified by the responsible agency and in consultation with other IAWG agencies before a final approval decision was made. The consultation could be made several ways—for example, through posting on an intranet to which all member agencies had access or in the form of a written notification to the IAWG chair, which would then be distributed to all members. Optimally, an e-mail or electronic system should be devised, because the goal would be to avoid delays and ensure that the interagency review takes place within a limited time frame (e.g., 2 weeks).

Within the prescribed time frame, other agencies would then have the opportunity to review the proposed CRADA. The IAWG would serve as the first-order forum for vetting any questions and addressing concerns raised by agencies. If it were unable to satisfactorily address an agency's concerns regarding the CRADA, the IAWG would refer the matter to the Assistant-Secretary level Interagency Committee. At this point, appropriate political-level review among agencies would be assured, while at the same time allowing responsibility and authority for the final decision to be retained by the proposing agency. The benefit of this "default to decision" process is the increased sharing of CRADAs with international partners that could raise potential issues, but doing so in a time-limited, semi-automatic process.

Although no system is perfect, the study team believes this type of consultative IAWG process could effectively avoid unnecessary delays, provide for a thorough vetting of the issues associated with proposed CRADAs, and preserves ultimate decision-making authority for the proposing agency, subject to consideration of issues raised by other agencies. Such a process is also consistent with the intent of the proposed legislation, H.R. 2544 (now H.R.209), and the existing Executive Order (12591).

1.0 Introduction

Technology transfer between the United States and foreign entities occurs through a variety of mechanisms. These include corporate joint ventures or alliances, contracts with the U.S. Government, use of subsidiaries, establishment by foreign companies of research facilities in the United States, international coauthorships in academic research, as well as multinational corporate (MNC) mergers and acquisitions. Cooperative Research and Development Agreements (CRADAs) are one of many mechanisms that U.S. Government R&D organizations use in working with private industry and academia. Moreover, CRADAs facilitate collaborations outside the normal contracting process and are valued for their flexibility, responsiveness, and explicit control of intellectual property (IP) that may result from collaborations. Although CRADAs have played a comparatively minor role in transferring technology to foreign entities, some policy makers are concerned about the increasing internationalization of R&D and how U.S. interests are addressed in this environment.

Technology transfer from the United States to foreign entities has always been a concern for policy makers and national security analysts—self-sufficiency and R&D leadership have been hallmarks of the U.S. defense industry. However, in the current global economy, distinguishing military technology from commercial technology can be difficult. In addition, R&D leadership is not necessarily concentrated in the U.S. defense laboratories or industry. Furthermore, the issues of whether foreign companies should be allowed to participate in U.S. Government sponsored research and the lack of formal guidance on such collaboration remain technology transfer concerns.[1]

1.1 Objective

This study reviews existing CRADAs, focusing on those CRADAs that include foreign participation, and analyzes the processes used by U.S. Government agencies in determining whether to include foreign partners in CRADAs. In addition, this study proposes criteria and procedural options, consistent with national security and the economic interests of the United States, that agencies should consider in evaluating potential foreign involvement in CRADAs.

1.2 Approach

Analysis was conducted using extensive interviews with technology transfer practitioners and policy makers at various Federal agencies (e.g., Department of Energy [DOE], Department of Defense [DoD], National Institutes of Health [NIH], Department of Commerce [DoC]), as well as other study teams involved in evaluating foreign participation in CRADAs. In addition, existing research (e.g., case studies, cost share programs, academic literature) was reviewed and analyzed to understand how U.S. Government agencies and the military services interpret the legislative intent of various technology transfer statutes (i.e., Stevenson-Wydler Act, Technology Transfer Act of 1986 [15 USC 3701–3715 and 10 USC 2515]).

This analysis was not intended to be comprehensive but only illustrative of how various organizations interpret provisions that deal with national security and economic security interests

in public–private technology transfer partnerships. In addition to CRADAs (especially cases involving private sector "funds-in"), analysts considered practices and criteria in patent licensing and cost-shared contracting for technology development involving foreign entities.

As a point of departure, the study team used observations and insights gathered from the U.S. Government's recent experience regarding possible inclusion of foreign partners (i.e., lithography toolmakers) in the Extreme Ultraviolet Lithography Limited Liability Corporation (EUV LLC) CRADA with the DOE laboratories.[2] The issues associated with the EUV LLC CRADA and the potential inclusion of foreign entities illuminate how decision makers assess national security, economic security, and technology policy factors that arise from public–private partnerships in sensitive technology areas.

During the course of the study, the objective evolved somewhat to take account of related political developments. In part in response to the specific circumstances surrounding the EUV LLC, the Congress proposed legislative language in the form of an amendment offered by Rep. Tauscher to H.R. 2544.[3] The amendment requires the Director of the Office of Science and Technology Policy (OSTP) to review policies and procedures Federal agencies use in gathering and considering the views of other agencies with respect to major proposed CRADAs (i.e., those that involve critical national security technology or may have a significant impact on domestic or international competitiveness). One aspect of the legislative language requires the Director of OSTP to determine the adequacy of existing procedures and methods for interagency coordination and to propose additional procedures, if necessary, for considering other agencies' views regarding major CRADAs.

The study team interviewed congressional staff involved with this issue, and in response to questions from the agencies, has included recommendations in Chapter 5 on how a mandate to consider other agencies' views, if enacted, could be addressed. The preliminary data and conclusions associated with this analysis were widely briefed to the interagency community during the course of the study. Briefings were provided to the Department of Defense Technology Transfer Working Group, Interagency Working Group on Technology Transfer, and the Committee on National Security International Technology Transfer Working Group, all of which were addressing some aspects of the issues considered in this review.

This report on the analysis is structured in five chapters. Following this introductory chapter, Chapter 2 presents the background and environment in which CRADAs are developed and established. Chapter 3 identifies established procedures of agencies. Recommended changes to the evaluation process used for CRADAs with potential foreign involvement are included in Chapters 4 and 5 along with a template (i.e., a set of criteria and associated assessment questions) for case-by-case review of such CRADAs. Chapter 5 also addresses circumstances that may warrant interagency review of certain CRADAs. Government-to-Government Memoranda of Understanding, contracting, and other forms of technology transfer were excluded from this review.

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[1] Jacques Gansler, *Defense Conversion* (Cambridge, MA: MIT Press, 1995), p. 49.

[2] In the fall of 1997, Senator Lieberman was joined by Senators Cochran, Rockefeller, D'Amato, and Leahy in asking the DoD to review the DOE EUV-LLC CRADA in light of potential national security issues. This was one of several interagency correspondences and Congressional inquiries. In the area of economic security they also raised the issue of potential foreign involvement and the concern about its effect on the U.S. lithography industry. These concerns were addressed by the Secretary of Defense in a letter dated 2 January 1998. The Secretary noted the particular militarily critical items that are subject to export control review prior to licensing, export, or exposure to foreign nationals. He also noted that the CRADA requires that products embodying the IP developed under the CRADA be substantially manufactured in the United States. Furthermore, any changes to this requirement must be reviewed by DOE, and DOE will seek DoD concurrence prior to approval.

[3] Subsequent to this report, H.R. 2544 did not pass in the 105th Congress. A revised version, H.R. 209 (the Technology Transfer Commercialization Act of 1999),has passed the House and is currently under consideration in the Senate. In this version, each Federal agency with a Federally funded laboratory that has one or more CRADAs is required to submit a report to the Committee on National Security (CNS) of the National Technology and Security Council and to the Congress.

2. BACKGROUND

Increasingly, R&D collaborations are conducted on a worldwide scale using multiple methods. Although the reasons are complex, the globalization of the marketplace and rapid diffusion of new technology appear to be driven by competitive factors affecting all industries. These factors include rising R&D costs and risks associated with production, shortened product life cycles, increasing multidisciplinary complexity of applications, and intense foreign competition in domestic and global markets. The following discussion addresses technology transfer trends generally, in specific industry sectors, and within the CRADA instruments as they relate to international partners.

Technology transfer occurs through a variety of means: joint ventures funded by U.S. firms overseas; funding or establishment of R&D facilities by overseas firms in the United States; individual collaborations among scientists; academic work at universities; foreign acquisitions; and contracts.

2.1 TRENDS IN INTERNATIONAL R&D

Any analysis of the foreign participation in collaborative R&D must be considered against the backdrop of the changing worldwide scientific environment. Scientific endeavors are becoming increasingly international; this is particularly true of R&D activities. According to the *Science and Engineering Indicators-1998*, authored by the National Science Board (NSB) for the National Science Foundation, "movement toward the internationalization—often termed globalization—of R&D activities has expanded considerably during the past decade."[1]

Technology Transfer via Industrial Collaborations
One manifestation of internationalization is the increasing number of joint ventures between U.S. and foreign entities created to tackle common problems. According to the NSB, "[T]here is evidence of a sharp increase in transnational joint research funding throughout the industrialized world. Formation of these so-called strategic technology alliances are particularly extensive among high-tech firms.…"[2] Similarly, the National Academy of Engineering, in its 1995 report, *Foreign Participation in US Research and Development*, states that the extensive presence of foreign graduate students, postdoctoral researchers, and other long-term foreign visiting researchers at U.S. universities and Federal laboratories has, on balance, yielded significant benefits to the U.S. economy and its innovation system.[3]

U.S. and foreign companies are among those at the forefront of the trend in overseas investment. According to the NSB, in the decade from 1985 to 1995, "U.S. firms' investment in overseas R&D increased three times faster than did company-funded R&D performed domestically (10.1 versus 3.4 percent average annual constant-dollar growth)."[4] Likewise, overseas R&D from majority-owned foreign firms (i.e., those with greater than 50 % voting

equity) in the United States was equivalent to 12 percent (in 1995) of the U.S. industry's R&D expenditure in the US, or about double the figure in 1985.

Although Europe is still the primary destination for most of the overseas R&D performed by U.S. firms, the trend is shifting to the Far East. Asia, in particular Japan, has become an increasingly important focus for American R&D work. For instance, from 1982 to 1994, the percentage of total private U.S. R&D performed abroad that was performed in Japan and other Asian countries increased from 8 to 16 .

Exhibit 2-1. Comparison of U.S. and Foreign Firms' Investment by Country

U.S. Firms R&D Abroad	**1982 ($3.6 Billion)**	**1994 ($11.5 Billion)**
United Kingdom	22 %	15%
Germany	25 %	28%
France	11 %	10%
other Europe	13 %	19%
Canada	15 %	7%
Japan	3%	10%
Other Asia	5%	6%

Foreign Firms R&D in the United States	**1980 ($ 1.5 Billion)**	**1995 ($ 15.0 Billion)**
United Kingdom	16%	15%
Germany	19%	24%
Switzerland	22%	17%
France	3%	10%
other Europe	21%	11%
Canada	N/A	N/A
Japan	2%	9%
Other Asia	N/A	N/A

Source: Adapted from NSB and Bureau of Economic Analysis

Most recently, foreign-funded research in the United States was concentrated in three industries, drugs and medicines (mostly funded by Swiss and British firms), industrial chemicals (mainly funded by German firms), and electrical and electronic equipment (one-third of which was funded by French affiliates).

Technology Transfer via Academic Institutions

In addition to the significant private sector industrial collaborations described above, much of R&D outputs are transferred through individual interactions and the movement of researchers among academic institutions and as part of international research networks. For these reasons,

effective technology transfer still tends to occur when researchers are in proximity to each other[5,6].

U.S. academic institutions (which collectively receive more than 65 % of their R&D revenue from public funds) are increasingly attracting participation from foreign parties at multiple levels both by individuals and corporations listed below. In contrast to the well-documented situation with patent licenses, foreign students, post-doctoral researchers, and resident faculty; no national aggregate data exist in several areas:

- Degree to which faculty act as advisors, consultants, and board members
- Number, interest, and duration of stay of visiting foreign researchers
- Collaboration between U.S. research centers and their counterparts overseas
- Tracking of foreign funding of university-based research
- Extent of foreign endowments in science and engineering chairs
- Extent of hiring of prominent U.S. researchers[7].

Notwithstanding the relative fragmentary tracking of U.S. academic and foreign firm interactions, the trend in international collaboration (and technology transfer) is increasing significantly according to many observers[8,9]. For example, the Science Citation Index (which contains 142,800 scientific and technical articles by U.S. authors, primarily in academia) can serve as an indicator of the trend. In 1995, half the articles had multiple authors, and almost 30 percent of these involved international coauthors. This figure is significantly larger (i.e., 20 % more articles, 80 % more coauthored articles, and 200 % more international coauthors) than comparable figures from 1981.

Given these observations and the increasing trends in foreign involvement in R&D activity at U.S. universities, industrial collaborations, as well as establishment of foreign-owned research facilities in the United States (most notably in Silicon Valley, Detroit, Boston, greater Los Angeles, Princeton, and Research Triangle in North Carolina), many policy makers have been concerned about foreign exploitation and transfer of key technologies through academic and industrial channels.

Trends in R&D in the Microelectronics Industry

A vivid example of the increasing internationalization of technology is seen in the microelectronics sector. This industry is of increasing importance worldwide, and some studies have claimed that it has supplanted the auto industry as the leading driver of U.S. economic growth.[10] Thanks to technological advancement characterized by "Moore's law," which seems to consistently deliver improved performance and lower prices with every new product generation, the growth of the microelectronics industry has been spectacular. However, a corollary effect has also been noted, sometimes called "Moore's second law."[11] With each successive product generation, the cost of building the necessary fabrication facility has increased as well, often exceeding $2 billion each. In addition, as technology has allowed for

finer linewidths and features, the cost of R&D has risen "dramatically," according to a DRI/McGraw Hill study.[12]

While the profits of the semiconductor companies have stayed strong, the rising cost of doing business is gradually pushing one-time competitors into collaborative ventures. According to DRI, "International alliances among semiconductor companies have become the norm—a requirement for survival and growth in today's marketplace."[13] The researchers note that the largest percentage of these alliances occur between Japanese and U.S. firms (it should be noted that the DRI report was sponsored by the Electronic Industries Association of Japan); nevertheless, the underlying trend is undeniable. For example, recent joint ventures (JV) to build manufacturing facilities include: Dominion Semiconductor, between IBM and Toshiba; TwinStar Semiconductor, TI and Hitachi; WaferTech, between TSMC (Taiwan), Altera, Analog Devices, and ISSI; and White Oak Semiconductor, between Motorola and Siemens. In addition, the Cirent Semiconductor facility was announced, between two U.S. companies, Cirrus Logic and Lucent Technologies.[14]

As further evidence of the international collaborative nature of the electronics sector, it is interesting to note that in the area of consumer electronics, U.S. semiconductor manufacturers' chips and software are increasingly being incorporated in major next-generation products from foreign product manufacturers. Exhibit 2-2 describes this trend in which U.S. proficiency in the integration of software and digital technology offers U.S. manufacturers the highest margins (or value added)[15] in components. Some analysts have also noted that U.S. manufacturers have become more competitive in consumer electronics through the prudent use of multinational corporate alliances.

Exhibit 2-2. A Sampling of Products From Foreign Companies That Include U.S. Chips

Product	Includes Chips Made By
Sony Playstation	LSI Logic
Nintendo 64	Silicon Graphics
Nokia Cell Phone	Intel, Texas Instruments
Ericsson Cell Phone	Intel, Texas Instruments
Sony Cell Phone	Advanced Micro Devices
Sony DVD Player	LSI Logic
Goldstar DVD Player	C-cube Microsystems
Casio Digital Camera	LSI Logic
Canon EOS Camera	Motorola
Sony Portable CD Player	Motorola
Panasonic Portable CD Player	Motorola
Sony Minidisk Walkman	Dallas Semiconductor, Motorola

Source: Adapted from the Wall Street Journal, June 15, 1998.

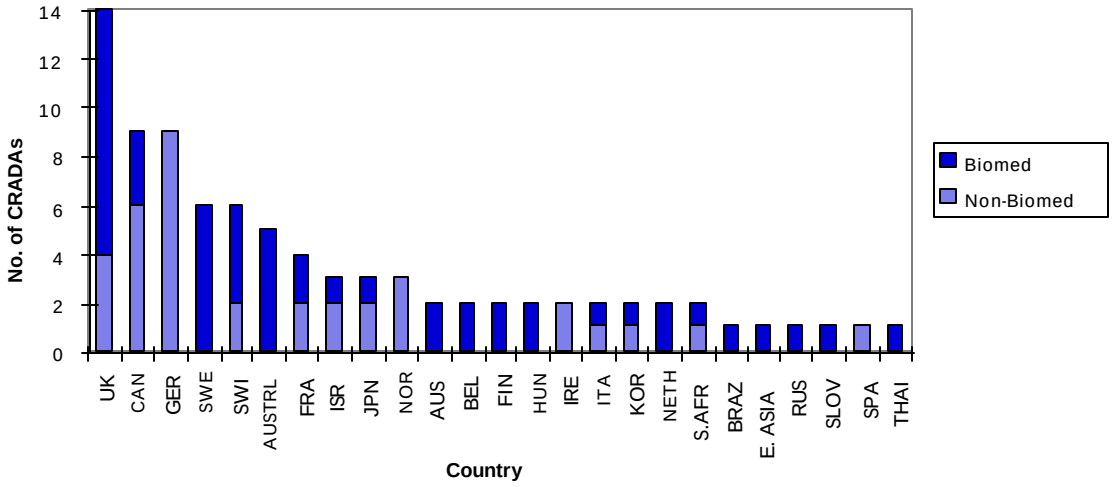
The trends in this industry suggest that we can anticipate more interest in future R&D collaborations, including CRADAs and licensing agreements. This has already been observed with the DOE EUV LLC CRADA where U.S. chipmakers (the private sector party in the agreement) have expressed interest in licensing technology to foreign suppliers of tools and components[16]. Similarly, the formation of International SEMATECH earlier this year is yet another indication of the need for global resources to stay competitive in the future.[17]

Trends in R&D in the Biomedical Industry

The largest share of foreign-based R&D activity (and the fastest growing area) is in the chemical industry, including pharmaceuticals. Drug companies alone accounted for 20 % of the total 1995 U.S. overseas R&D. In return, many pharmaceutical companies (mostly Swiss and British) invest in R&D in the United States. It is a fact that because of large mergers and acquisitions in the pharmaceutical industry, many of the leading companies are no longer U.S. owned, although most have U.S. operations. This situation, in turn, almost requires CRADAs with subsidiaries of foreign-owned pharmaceutical companies for certain types of research.

As Exhibit 2- 3 illustrates, the majority of DoD's CRADAs with foreign parties are in the biomedical area. The vast majority of these are Material Transfer Agreements (MTA)* with U.S. allies (89 %); most of the other agreements are with countries that are traditionally friendly to the United States (such as Switzerland) or with states in Eastern Europe and Russia.

Exhibit 2-3. DoD CRADAs with Non-U.S. Partners



Source: Booz•Allen Analysis

* Agreements used to transfer biomedical materials into and out of laboratories. For a good presentation of procedures and example agreements for profit and non-profit entities, see <<http://www.nih.gov>>.

Similarly, the CRADAs and patents executed by National Institutes of Health (NIH) reflect the growth of collaborations in the biomedical industry (see Exhibit 2-4.).

Exhibit 2-4. NIH Technology Transfer Activities (FY 1993 - FY 1997)

ACTIVITY	FY93	FY94	FY95	FY96	FY97
Invention Disclosures	232	259	271	196	268
Patent Applications	161	143	147	137	159
Issued Patents	88	75	95	107	119
Executed Licenses	75	125	160	184	208
Royalties ($$ in 000s)	13,494	18,487	19,388	26,995	35,692
Executed CRADAs	41	31	32	87*	153**

Source: NIH Technology Transfer Web site September 1998

* The number executed CRADAs includes 44 Standard and 43 Materials CRADAs (first CRADA).

** The number of executed CRADAs includes 32 Standard and 121 Materials CRADAs.

2.2 USE OF CRADAS

The trends previously discussed suggest that U.S. companies are increasingly performing R&D overseas and/or with foreign participants or partners. In light of these factors, it is not surprising that the U.S. Government is also experiencing an increased interest on the part of foreign partners in R&D collaboration through CRADAs. In fact, this survey corroborated the fact that the number of CRADAs with foreign participation overall remains relatively small (less than 5 % of all CRADAs). However, it does appear that the number of CRADAs that involve foreign participation is increasing, albeit at a slower rate than the number of private industry or academic R&D collaborations.

Most federal agencies do not appear to engage in international R&D collaborations to the degree that the private sector does. For instance, 3.3 % (32 out of 1039) of the U.S. Department of Defense CRADAs signed since 1995 involve foreign participants,[18] and 6.9 % (34 out of 500) of the CRADAs signed by the Department of Commerce (from1988 to 1995).[19] The most foreign participation may be with the NIH of the Department of Health and Human Services. For NIH, the number of CRADAs with foreign participation was 11% (26 out of 237 from 1988 to 1995). Similarly, roughly 20 % of their patent-licensing agreements (PLA) are with foreign firms.[20] This trend was observed in a recent Congressional Research Service Report that noted the "growing industrial interest in CRADAs" and "expanded use of this mechanism."[21]

Although Chapter 3 addresses the legislative background of CRADAs in greater detail, it is important to note the evolution in the use of CRADAs over the past decade. Beginning in 1980, the Congress enacted a series of laws to expand cooperation between Federal

laboratories and private industry. As originally conceived in the Federal Technology Transfer Act of 1986, CRADAs were intended to transfer Federally funded technology and manufacturing techniques to industry (with preference for domestic) for purposes of commercialization and to promote economic growth. One of the primary mechanisms for such transfers was individual or small-scale scientific interactions. Still typical for several government agencies are CRADAs primarily consisting of an agreement between two or three scientists, often beginning when a laboratory scientist meets an industry scientist at a technical conference or through literature searches.[22]

This perception was recently affirmed by the House Science and Technology Committee, which stated, "A CRADA, as envisioned at the time of the passage of the Federal Technology Transfer Act of 1986, was designed to help move individual ideas from the Federal laboratories into the private sector or lead to cooperation between industry and government labs in areas of mutual interest. A common benefit of such agreements has been the acquisition by small businesses of the technological expertise necessary to succeed that otherwise may not have been available to them. These CRADAs are small enough that they do not typically raise national issues; therefore, the appropriate approval process is one which is executed quickly without high level signoffs."[23]

In an effort to free these scientific interactions from bureaucratic red tape, the CRADA was designed to be a flexible instrument that avoided the onerous requirements of Federal contracting law, but still protected the Intellectual Property (IP) of the parties involved. At first, industry expressed frustration with the CRADA, but over time, as agency practices became more streamlined, its potential as a flexible instrument for industry–government cooperation has been more widely recognized.[24,25]

Although most CRADAs can still be characterized as small-scale agreements between researchers, usually valued at less than $50,000 (based on estimated value of researchers level of effort), some agencies have entered into CRADAs for scientific projects of significantly larger scale and using different types of financial arrangements. For example, a few cases of large "funds-in" CRADAs have permitted the private sector partner to pay for personnel, services, and property. In addition, umbrella CRADAs have facilitated multiparty R&D in an industry. Recent examples of such CRADAs include the following:

- EUV Lithography LLC/DOE—This CRADA, led primarily by Intel, is the largest funds-in CRADA (the so-called $250 million funds-in agreement). It actually involves $130 million funds-in, $84 million of subcontract support, and $34.5 million in waived depreciation and overhead from DOE.

- US Council on Automotive Research (USCAR)/DOC[**]—This CRADA, led by the "Big Three" US auto makers, is a model agreement with multiple public and private sector partners.

- SEMATECH/Sandia DOE—This CRADA to coordinate diverse microelectronics research activities at DOE laboratories, is a model agreement involving multiple public and private sector partners.

- Naval Medical Research Institute(NMRI)/Bristol-Meyers-Squibb—This CRADA to conduct cognitive and performance tests of cholesterol-lowering medications used a $300,000 funds-in CRADA (one of the largest for NMRI) and a visiting researcher arrangement.

- Walter Reed Army Institute of Research (WRAIR)/Ora Vax Inc.—This CRADA was used to conduct development for Phase 1 and 2 clinical trials of vaccines for infectious diseases using a $250,000 funds-in CRADA (one of the largest for WRAIR) and a visiting researcher arrangement.

"Funds in" CRADAs, or other large-scale CRADAs potentially introduce new considerations into R&D collaborations. In an era of downsizing and constrained funding, an industrial partner offering to put up a sizable amount of money for research could have a distorting impact on the resources and attention of the public laboratories. Could a large infusion of outside funding cause a potential divergence between the laboratory's interest in maintaining capabilities and the safeguards regarding US national and economic security that are built into the CRADA review process? Although there is no evidence that such a divergence has occurred, some observers have indicated that this environment could make it more difficult task for Federal laboratories to determine and protect the economic interests of the United States in the future.

Although the EUV LLC CRADA is unique, one of the concerns expressed by some agencies and Members of Congress focused on the size of the investment, the potential introduction of a foreign licensee, and the consideration of economic and national security. As a result of recent experiences, questions have emerged concerning the adequacy of current procedures for reviewing and approving CRADAs, especially those that may involve foreign participants. Questions include—

- Does the increasing size and type (e.g., funds-in) of CRADAs create additional need for oversight?

- Does the increasing internationalization of R&D, which could drive increased foreign participation in CRADAs, create a need for changes in the CRADA review process?

[**] Also responsible for the R&D associated with the Partnership for New Generation of Vehicles (PNGV).

- If it were determined that additional oversight or changes were needed, how could this be done in a way that does not overly burden the process? This consideration may be particularly important for the vast majority (more than 95 %) of small-scale CRADAs for which the present processes are most likely adequate.

The trend toward internationalization of R&D and CRADAs will likely increase in the future, thereby likely perpetuating the debate about foreign participation in U.S. Government R&D beyond case-specific CRADAs.

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[1] National Science Board, Science & Engineering Indicators—1998. Washington, DC: US Government Printing Office (NSB 98-1), p. 4-48
[2]Ibid, p. 4-49.
[3] National Academy of Engineering, "Foreign Participation in US Research and Development: Asset or Liability?", p.9.
[4] National Science Board, Science & Engineering Indicators—1998. Arlington, VA: National Science Foundation, 1998 (NSB 98-1), p. 4-52.
[5] David, P.A., D.C. Mowery, and W.E. Steinmuller, *"Analyzing the economic payoffs of basic research"*, Economics of Innovation and New Technology 2:73–90, 1992.
[6] Jaffe et al, *"Geographic localization of knowledge spillovers as evidenced by patent citations"*, Quarterly Journal of Economics 108(3): 577–598, 1993.
[7] Business Week, 1992. *"Pure Research Compliments of Japan,"* July 13: 136–137.
[8] Roberts, E.B., *"Benchmarking the Strategic Management of Technology-I,"* Research•Technology Management (January/February): 44–56, 1995.
[9] National Research Council, *"Foreign Company Access to US National Laboratories*", Report of a Workshop held on December 16, 1993, Committee on Japan, Office of International Affairs, unpublished.
[10] Robert J. Damuth, Nathan Associates, "America's Semiconductor Industry: Turbocharging the Economy," 1998. As Mr. Damuth divides the automotive industry into three parts, his methodology is suspect when it comes to making quantitative comparisons of [scale] between the industries.
[11]Philip E. Ross, "Moore's Second Law," *Forbes*, March 25, 1995, p. 116.
[12] DRI/McGraw-Hill, *The Globalization of the Semiconductor Industry*, p. 9. Sponsored by Electronic Industry Association of Japan (EIAJ), available at http://www.eiaj.org/study.
[13] DRI/McGraw-Hill, *Globalization*, Executive Summary, p. 3.
[14] Integrated Circuit Engineering, *Status 1998*, Chapter 2, page 2-61.
[15] Thurm, Scott, *"On the Comeback Trail,"* Wall Street Journal, June15, 1998.
[16] US News & World Report, *"US-funded technology stays here, for now,"* May 18, 1998.
[17] Wafernews, February 9, 1998 <<http://www.wafernews.com/#pagetop>>.
[18]DoD Domestic Technology Transfer Information System (DTTIS).
[19] Meeting with NIST ATP and Technology Transfer personnel, including Ralph Richter, Mike Rubin, Marc Stanley, and Bruce Matson, June 19, 1998.
[20] Phone conversation with Theodore Roumel, NIH, June 9, 1998.
[21] Wendy H. Schacht, Congressional Research Service, Cooperative Research and Development Agreements and Semiconductor Technology: Issues Involving the "DOE-Intel CRADA," January 22, 1998, pp. CRS-17 and Summary.
[22] Organizations describing their typical CRADA in this way in discussions with the study team included NIST, the Department of the Navy, and the USDA.
[23] House Science and Technology Committee, Technology Transfer Commercialization Act of 1998.
[24] National Academy of Engineering, "Foreign Participation in US Research and Development: Asset or Liability?", p.115.
[25] Office of Technology Policy, Department of Commerce, "Effective Partnering: A Report to Congress on Federal Technology Partnerships, Washington, April 1996, p. 40–44.

3. Overview of Agency Practices

This section describes the legal and regulatory context for the CRADA mechanism, as well as intellectual property licensing. In addition, this chapter surveys the practices of the various agencies in dealing with the issues raised by foreign participation in CRADAs.

3.1 THE LEGISLATIVE BACKGROUND

The primary legislation affording industry access to the Federal laboratory system is Public Law (PL) 96-480, the Stevenson-Wydler Technology Innovation Act of 1980, as amended by PL 99-502, the Federal Technology Transfer Act of 1986; PL 101-189, the FY 1990 Defense Authorization Act (the relevant title is known as the National Competitiveness Technology Transfer Act); PL 104-113, the Technology Transfer Improvements and Advancement Act; and others. Although technology transfer was ongoing prior to its passage, the Stevenson-Wydler Technology Innovation Act provided the Federal departments, agencies, and affiliated laboratories with a specific legislative mandate to pursue such activities. The Act specifically states that it is the responsibility of the Federal Government to ensure "full use of the results of National Federal investment in research and development" and mandates that where appropriate, technology be transferred to state and local governments and the private sector.

Additional incentives to promote technology transfer from government-owned, contractor-operated (GOCO) laboratories—primarily those of the Department of Energy—were included in PL 96-620, Amendments to the Patent and Trademark Laws (the Bayh-Dole Act). Under Title V, Federal laboratories run by universities and nonprofit institutions may retain title to inventions made in the laboratory within certain defined limitations while specific rights are reserved for the Government. The law permits decisions to be made within GOCO laboratories regarding award of licenses for patents generated in-house. The contractor may receive royalties generated by the license for use in R&D, for awards to individual inventors on staff, or for educational activities. A cap is defined on the amount of royalties returning to laboratory.

The initial response to new opportunities for use of Federal laboratory resources was less than expected from both the private and public sectors. As a consequence, additional incentives were considered by the Congress, resulting in enactment of PL 99-502, the Federal Technology Transfer Act of 1986. This law established a new tool, the "cooperative research and development agreement (CRADA)," to be used for joint work between Federal laboratories and the business community. First limited to GOGO laboratories, the authority to enter into CRADAs was extended to GOCO laboratories of the Department of Energy by PL 101-189, the National Competitiveness Technology Transfer Act. The Technology Transfer Improvements and Advancement Act of 1996 (PL 104-113) provided additional guidelines to simplify the negotiation of CRADAs and to reduce private sector uncertainty in working with the Government.

Cooperative R&D Agreements (CRADA)

A CRADA is a legally binding agreement outside the Federal Acquisition Regulations (FAR) (not a procurement contract) that defines the collaborative venture. The specific legal requirements for CRADAs are described in 15 USC 3710a (see Appendix A). The CRADA is intended to be developed at the laboratory level, with limited agency review. In agencies that operate their own laboratories, the laboratory director is permitted to make decisions to participate in CRADAs in an effort to decentralize and expedite the technology transfer process. The agreement, although negotiated by the research institution, must also be approved by headquarters within a specified time period. The conference report to accompany the legislation permitting GOCO laboratories to enter into cooperative R&D agreements states—

> Technology transfer is most successful when agencies handle their own affairs and when government officials, technology transfer experts, and scientists at the local level have latitude in designing and carrying out CRADAs. Any regulations must recognize that a purpose of section 12 of Stevenson-Wydler is to allow prompt consideration and disposition of proposed CRADAs.[1]

The work performed under a CRADA must be consistent with the laboratory's mission: technology transfer and cooperative efforts are expressly forbidden to interfere with the laboratories' R&D mission-related responsibilities. In pursuing these joint efforts, the laboratory may accept funds, personnel, services, and property from the collaborating party and may provide personnel, services, and property to the participating organization. The Government can cover overhead costs incurred in support of the CRADA but is explicitly prohibited from providing direct funding to the industrial partner. In most agencies, support for the joint work comes from R&D program funding.

The relevant legislation does not specify the dispensation of patents derived from the collaborative work, allowing the agencies to develop their own policies. However, under a CRADA, title to, or licenses for inventions made by a laboratory employee may be granted in advance to a participating company by the director of the laboratory. The director may also negotiate licensing agreements for related Government-owned inventions previously made at the laboratory if it facilitates cooperative ventures. In addition, he can waive, in advance, any right of ownership the Government might have in inventions resulting from the joint effort. Further clarification of the assignment of intellectual property rights is provided in PL 104-113. The House Science Committee report states that in considering intellectual property, " the important factor is that industry selects which option makes the most sense under the CRADA."[2] *In all cases, the government retains a nonexclusive, nontransferable, irrevocable, paid-up license "to practice, or have practiced," the invention for its own needs*. Appendix B provides a more expanded discussion related to the IP licensing and CRADAs.

Some agencies/laboratories provide guidance or a model CRADA designed to streamline the process and encourage partnership efforts. Typically, a model CRADA addresses rules and responsibilities regarding the following: definitions; the work statement; term, funding, and costs;

personal property; disclaimers; product liability; obligations regarding proprietary information; obligations regarding protected CRADA information; rights in generated information; export control; reports and abstracts; pre-publication review; copyrights; reports of intellectual property use; march-in rights; U.S. competitiveness (in the case of DOE); assignment of personnel; force majeure; administration of the CRADA; records and accounting for Government property; notice; disputes; modifications; termination; and project management.

Model CRADAs on the Web

DOE	http://www.doe.gov/techtran/cradamd.html	Also has model for joint venture with small business
DoD	http://www.dtic.mil/techtransit/	Models for each military service are provided
NIH	http//www.nih.gov:80/od/ott/crada_inf.htm	Roles and responsibilities delineated for agency and collaborators

International Participation

Under the Stevenson-Wydler Technology Innovation Act, as amended, the laboratory director, in deciding which CRADAs and licensing arrangements involving foreign parties to enter into, is required to address certain requirements regarding national and economic security. Specifically, the legislation requires agencies to—

- Give preference to substantial manufacture in the United States
- Ensure reciprocal access to foreign R&D and licensing arrangements
- Adhere to export control laws and retransfers of strategic technology
- Determine whether the foreign entity has policies to control U.S. Intellectual Property Rights (IPR).

The specific language pertaining to these provisions of the Stevenson-Wydler Act are provided in Appendix A (see Executive Order 12591, Sec.4 International Science and Technology and 3710a (c)(4)). It is interesting to note that foreign entities are defined as *persons* or industrial organizations (where these entities are directly or indirectly controlled by a foreign company or government).

3.2 SURVEY OF AGENCY PRACTICES

Several agencies were interviewed to determine how they handle foreign participation in CRADAs. Interviews were conducted with technology transfer managers and/or general counsels who are involved in review and administration of CRADAs or Patent Licensing Agreements (PLA). Some U.S. agencies engage in a rigorous review to ascertain that no U.S.

companies are interested in commercializing a technology before licensing it or entering into an agreement with to a foreign entity. Other agencies are less rigorous but still exercise care in approval of CRADAs with foreign partners.

NASA does not use CRADAs but uses a similar technology transfer mechanism known as the NASA Space Act of 1958, which is based on a separate statutory basis (CRADAs were modeled on this agreement). NASA has a number of Space Act Agreements with international parties, but in general, most of these involve cooperative, not collaborative research. NSA does not permit CRADAs with foreign owned or controlled companies as a matter of policy.

The results of the present survey with the agencies are captured succinctly in Exhibit 3.1, with further discussion in the following paragraphs. None of the people interviewed felt that additional layers of review outside the current processes would be necessary in most cases. Moreover, for the sample of agencies and services surveyed for this study, less than 5 % of the CRADAs are with foreign entities. This percentage is significantly below some of the percentages that were characteristic of academic and industrial collaborations. This low percentage is even more significant when one considers that the largest areas of participation are in the bio-medical areas (NIH, DoD).

During interviews, all agencies stressed the need for substantial U.S. manufacturing, although it was noted by several agencies that this represents a preference only, not a statutory requirement. Some agencies have a "net benefit assessment," which can be applied in cases where the foreign or U.S. companies do not believe that they can comply with the substantial manufacturing requirement. Most other agencies require U.S. manufacturing if the company plans to sell in the U.S. marketplace, or at least enough U.S. manufacturing to satisfy the demands of the U.S. marketplace.

Some Federal agencies do not consult the U.S. Trade Representative (USTR) on a consistent basis for CRADAs or licenses involving international participation. Although the number of consultations on CRADAs is not large, agencies expressed the concern as to whether the USTR would have the necessary resources to respond expeditiously to these consultation requests if several CRADAs were submitted at the same time. In addition, USTR personnel indicated that their review is to determine reciprocity as it relates to trade, not necessarily reciprocal access for R&D. Further investigation may be needed to determine the advisability of continuing the existing arrangement, but it may be useful to consider supplementing the input of the USTR with that from other agencies that are knowledgeable on these questions (e.g. the Departments of Commerce, State, and the International Programs Office of DoD). The Department of Commerce's Interagency Technology Transfer Working Group may be an appropriate venue for supplementing the work of the USTR's office (see further discussion of this issue in Section 4.2.2.).

Exhibit 3.1 Overview for Foreign Participation, Various Agencies

Component	Air Force	Army	Navy	NIST	DOE	NIH	USDA
United States first?[1]	Not clear[3]	Not always	Yes	Not always[5]	Not U.S. only	Yes	Yes
Substantial U.S. mfg?[2]	Yes, with flexibility	Yes	Yes. Navy alternate clause used little.	Required for products sold in the United States	Yes, or alternative net benefits for U.S. economy	Yes, if product substantially sold in United States	Yes; some foreign cos. considered U.S. if mfg/ R&D here
Trade Rep review?	Yes	Use USTR for gov't orgs., not foreign cos.	Yes	Not standard	Yes	Only in special cases (China, South Africa)	No
No./total of Int'l CRADAs[4]	~ 3 since 1992	~ 25 since 1992	~ 24 since 1992	50/813 (since 1988)	25/1600 (up to spring 1998)[6]	26/237 (March 1988–Jan 1995)	16/ 340 (since FY95)
% of Int'l CRADAs	3.3 % DoD-wide			6%	1.5 %	11 %	5%

[1] *"U.S. First" refers to the practice of some agencies not entering into a foreign CRADA if there is a U.S. company working in the same field. This is not a statutory requirement. It is also important to note that, CRADA law expresses a "preference" for doing business with U.S.-located businesses but that patent-licensing laws do not contain such a preference.*
[2] *This category refers to how an agency handles the substantial manufacturing preference, although all agencies have discretion to waive this requirement. An unmodified "Yes" response means substantial U.S. manufacturing is required in all cases. Also, although patent-licensing law applies this requirement only when the licensee intends to sell the resulting product in the United States, the CRADA law does not address where a product will be sold.*
[3] *Prior to CRADA signing, the potential partner is investigated by AFRL International, AF Security Command, and SAF International Affairs, which consults with the State Department. DIA is also consulted.*
[4] *CRADAs included are traditional CRADAs for cooperative R&D. Not included are "short form," CRADAs, which are similar to Material Transfer Agreements (MTA). Inclusion of these instruments (which do require USTR review) would increase the Army's total number of CRADAs by about 40.*
[5] *Many foreign partners in CRADAs may also be involved in Consortia with U.S. firms prior to CRADA application.*
[6] *~ 12 since 1990 in Defense Programs*
[7] *20 % of patent licenses are issued to non-domestic licensees.*

3.2.1 Department of Defense (DoD)

The DoD has defined technology transfer as spin-off, spin-on, and dual-use technology development. These three efforts are accomplished in a variety of ways, including contracts,

cooperative agreements, CRADAs, patent license agreements, educational partnerships, state and local government partnerships, exchange of personnel, and work for others (WFO).

DoD was first authorized to enter into CRADAs in 1986 (under 15 USC 3701-3715, Technology Innovation) when the Federal Technology Transfer Act allowed Federal laboratories to implement such public–private technology transfer partnerships; DoD began actively using CRADAs in 1990. The FY 1994 Defense Authorization Act, (10 USC 148, Sections 2415 and 2515) specifically encouraged DoD technology transfer activities and established an Office of Technology Transition in the Office of the Secretary of Defense. The responsibilities of the new Office were to monitor DoD R&D activities, identify technology transfer advancements, serve as a clearinghouse to coordinate and actively facilitate technology transfer, and report to the Congress annually on its activities.

For CRADAs with non-domestic partners, an enhanced process was laid out, requiring laboratories to address questions regarding technology, export controls, and partner selection (i.e., why the foreign partner is the best choice over potential domestic partners) and requiring the submission of such CRADAs to a headquarters program manager for a timely (30-day) review. The process also includes time for USTR consultations (see Appendix C and D).

Foreign participation in DoD research or the results of DoD research typically occurs in the following categories:

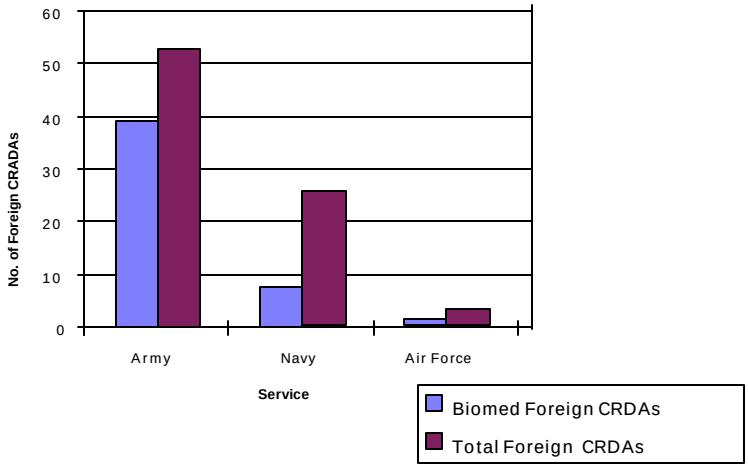
- Biomedical/Pharmaceutical—Many areas of interest to DoD—research into tropical diseases and vaccines, for instance—are not generally of interest to U.S. companies that sell only to the U.S. market but can be of interest to foreign companies who sell to foreign markets or who sell to large numbers of people traveling into those markets.

- Licensing of R&D Activities—One example, the CORE-LOC armor program, involved a number of our allies in development and testing.[3] The CORE-LOC armor is an innovative coastal protection unit that was developed at the Army's Waterways Experiment Station (WES). The WES is the largest civil engineering R&D organization in the DoD. Royalties that have been negotiated with 30 foreign countries are expected to reach the $2 million level. This may prove to be one of the largest sources of royalty payments to result from the licensing of technology that was model tested under a CRADA.

- Facility Share Agreements—Some cooperative R&D involves allies seeking to use DoD facilities to test new weapons. Facility sharing permits construction of fewer costly, limited-use test facilities around the world and benefits both DoD and its allies.

The number of foreign CRADAs per service is shown in Exhibit 3-3. Because they are a significant portion of the international CRADAs, the biomedical CRADAs are broken out and displayed next to the total number of CRADAs with foreign partners.

Exhibit 3-3. DOD Foreign CRADAs, by Service



Air Force

The Air Force has developed what appears to be the most explicit process (see Appendix D), which routinely includes a Defense Intelligence Agency (DIA) investigation of foreign ownership and consultation with the USTR. To avoid problems associated with the 30-day CRADA approval time limit, these investigations and consultations take place before the CRADA is formally authorized. Although the Air Force has a rigorous process in place for the review of CRADAs with foreign participants, it has not entered into many agreements with foreign entities. (Three were noted in this survey.) It is difficult to say precisely how well the process would work if a larger number of applications were presented for evaluation.

Navy

For a Navy laboratory, the process typically proceeds as follows. The laboratory sends a cover sheet describing the CRADA, its partners, and certification of whether the technology is on the Militarily Critical Technologies List (MCTL) to its central technology transfer office at Office of Naval Research (ONR), along with a copy of the actual proposed CRADA. This information is also sent to the USTR, who responds, typically in less than 2 weeks and sometimes within 1 day, with information concerning the foreign country's R&D and trade practices. ONR has noted that they find the USTR responsive. The Navy appears to have developed and implemented clear policies and procedures that are well understood at the local and headquarters levels[4] (see Appendix C).

Army

As a matter of policy, the Army process is similar to that of the other services but as a matter of practice, they have not always consult with the USTR. Consultations with the USTR generally

occur when Army agencies are concluding agreements with foreign governments but not with foreign companies. In large part, this is because of concerns about the length of time several such requests required in the past. They do certify that no Militarily Critical Technologies are involved and send the CRADA to headquarters for approval. It is also interesting to note that in the biomedical area, the Army has authority to enter into international agreements through the Army Surgeon General's office as well as the CRADA office, although it is not clear whether this option has ever been used.

3.2.2 Department of Commerce (NIST)

A number of mechanisms are used to transfer technology developed at the National Institute of Standards and Technology (NIST). The prevalent mechanisms used are CRADAs, patent licensing, facility use agreements, guest researcher arrangements, inter-institutional agreements, and informal technical assistance. Widespread dissemination of research data and results are achieved through publications in journals and conference proceedings, electronic publication, and presentations at international, national, and regional conferences.

NIST (like the Department of Energy) includes a statement in its CRADAs that the CRADA exists for the purpose of improving the competitiveness of U.S. industry. NIST staff characterized many of their CRADAs as being focused on scientific collaboration. Typically, two scientists, one from NIST and another from industry, meet at a conference and decide to work together on an area of mutual interest or a common problem facing both NIST and the collaborator. These CRADAs are typically one staff-year of effort or less per year. In fact, many funds-in CRADAs at NIST (25 % estimate) are typically measured in thousands of dollars that are essentially consortia fees.

When a foreign company wants to participate, it needs to identify itself as such, and a specific review process is used. As a matter of policy, to be eligible for a CRADA, NIST requires that foreign companies have U.S. manufacturing and R&D facilities. CRADA research also must be conducted primarily in the United States. The laboratory director makes the final determination whether to approve the foreign participation.[5] NIST requires substantial manufacturing for products that will be sold in the United States. They do not accept net benefits in lieu of U.S. manufacturing, although it is unclear what restrictions, if any, are placed on the technology if it will not be used in the US.[6] This may be a case-by-case determination.

Partnership for Next-Generation Vehicles

The DOC Technology Administration is the lead agency for the Partnership for Next-Generation Vehicles (PNGV) program, which uses a large umbrella CRADA to facilitate the research interactions using the DOE "Competitiveness Article" to address the concerns that MNCs had with the U.S. manufacture provisions. PNGV has some similarities with the EUV LLC CRADA. In particular, the umbrella CRADA signed with the big three U.S. auto makers is with a "sensitive industry" and has some limited involvement of foreign companies as subcontractors. Another similarity with the EUV LLC is that the R&D will be done in the United

States and in the event of any manufacturing, the manufacture will be done predominantly in the United States for the first 2 to 3 years and will continue in the United States where practical thereafter.

3.2.3 Department of Energy (DOE)

The technology transfer mechanisms that DOE uses are similar to the DoD, namely, CRADAs, PLAs, privately funded WFOs, private use of facilities, and personnel exchanges. However, the DOE situation is slightly different than that of DoD or DOC, in that the DOE laboratories are GOCO laboratories. The basic authority to enter into CRADAs that was extended to the Federal laboratories in 1986 was not extended to DOE until passage of the National Competitiveness Technology Transfer Act of 1989 (PL 101-189).

The CRADA processes are administered locally at DOE field elements working closely with DOE laboratories. Negotiations and review are performed locally. In addition, licensing of contractor-owned patents arising from GOCO laboratories is performed locally at the laboratory. Licensing of Government-owned patents not arising from Government-operated laboratories is performed at DOE headquarters. Legal authority and terms and conditions for licensing of Government-owned patents are contained in 35 USC 207-209 and 37 CFR 404. Laboratory contractors must follow guidelines for licensing in their operating contract and the appropriate U.S. statutes cited above. The guidelines include addressing disposition of royalty income and sharing of royalties with inventors.

The processes used by DOE are decentralized and designed to facilitate rapid responses based on concerns previously expressed by industry. Regarding consultations with the USTR, DOE has taken the position that Executive Order 12591 is not mandatory but is applicable to the contractors operating the national laboratories. Since the summer of 1998 (and the experience with the DOE-EUV LLC CRADA), DOE is considering new instructions to clarify this process.[7] Discussions with the USTR indicate that consultation requests from the DOE laboratories have increased noticeably in the past 6 months.

As observed in the National Academy of Engineering report,[8] DOE originally allowed its labs less discretion than today in the negotiation of CRADAs. The report notes that—

> In contrast [to other Federal laboratories], DOE, whose 10 multiprogram laboratories had entered into over 1,200 CRADAs as of early 1995, allows less discretion to its contractor-operated labs in the negotiations of CRADAs in general and in the implementation of performance requirements in particular. Exercising a higher degree of centralized control, the DOE initially developed strict guidelines for compliance with the "substantial U.S. manufacturing requirement" (referred to as the U.S. Competitiveness Article within the modular CRADA), extending its scope to include all intellectual property generated under a CRADA, including subject inventions, patents, copyrights,

> trademarks, protected CRADA data, and mask works.[9] Furthermore, these early DOE guidelines stipulated that such intellectual property should be practiced only in the United States.
>
> Both large and small U.S. companies expressed concern about the highly restrictive nature of DOE's initial set of guidelines, which they believed would weaken their ability to compete globally. Required to manufacture some products abroad in order to meet foreign content laws, provide just-in-time delivery services, and maintain competitive freight charges, and unwilling to accept wholesale liens on CRADA-related intellectual property, the big three U.S. auto makers and the nation's leading computer manufacturers insisted that the competitiveness article be waived or modified in the DOE CRADA agreements. Several major U.S. multinational companies (MNC) have indicated that delays in the CRADA negotiation process related to the U.S. competitiveness article discouraged them from concluding CRADAs with DOE.

The DOE took steps in 1993 to address the concerns of industry through a revised policy. A February 10, 1993, memorandum issued by the Department, and later codified in 48 CFR Part 970, states that in negotiating an agreement, the laboratory is to give preference to "business units located in the US that agree to substantially manufacture resulting technology in the United States." In instances where this is not possible, individual exceptions may be made based on "contractual commitments to appropriate alternative benefits to the U.S. economy." When there are multiple partners and limited resources, preference is to be given to those partnerships that meet the U.S. manufacturing requirement. These "U.S. competitiveness" issues are to be resolved before the completion of the joint work statement between the laboratory and the partner, prior to forwarding it to the relevant DOE program office.

Article XXII of the model DOE CRADA states that a "purpose...is to provide substantial benefit to the U.S. economy." The guidelines in the model established by DOE for use in determining issues of U.S. competitiveness regarding foreign participation affirms that the agency is—

> Seeking to transfer technology to companies with significant manufacturing and research facilities in the United States in a way which will provide short and long term benefits to the U.S. economy and the industrial competitiveness of such companies. The preferred benefit to U.S. economy is the creation and maintenance of manufacturing capabilities and jobs within the United States.

However, if an increased number of jobs cannot be substantiated as a result of the transfer, the participants are required to "furnish a description of specific economic or other benefits to the U.S. economy which are related to the commercial use by the Participant(s) of the technology being funded under the CRADA.…The benefits criteria on DOE's U.S. competitiveness work sheet include—

1. Direct or indirect investment in U.S.-based plant and equipment.
2. Creation of new and/or high quality U.S.-based jobs.
3. Enhancement of the domestic skills base.
4. Further domestic development of the technology.
5. Significant reinvestment of profits in the domestic economy.
6. Positive impact on the U.S. balance of payments in terms of product and service exports as well as foreign licensing royalties and receipts.
7. Appropriate recognition of U.S. taxpayer support for the technology (e.g., a quid pro quo commensurate with the economic benefit that would be domestically derived by the U.S. taxpayer from U.S.-based manufacture).
8. Cross-licensing, sublicensing, and reassignment provisions in licenses that seek to maximize the benefits to the U.S. taxpayer."[10]

It is important to note that this "net benefits" assessment applies not only to foreign participants, but U.S. MNCs that do not feel they can meet the preference for substantial manufacturing in the United States. DOE has used the net benefits assessment (or modified the standard competitiveness language) a number of times (77 times in 2 years, or 16 % of the total DOE CRADAs from October 1995 through October 1997).[11]

In establishing a collaborative venture, the CRADA must contain language that notifies participants that the resulting technologies and information may be subject to existing exports controls. The statement is to be "conspicuous" so that there is no misunderstanding. Should "...access to classified information, access to special nuclear materials, or unescorted access to security areas of Departmental facilities [be involved], the requirements of the Atomic Energy Act of 1954, as amended, also must be met." The procedure for determining and addressing foreign ownership and control is delineated in an appendix included in the model agreement. Essentially, all existing export control and other laws, policies, and regulations apply whether foreign or domestic participants are involved.

In 48 CFR Part 970, the Department states that the laboratory contractor shall "... take all reasonable measures to ensure widespread notice of availability of technologies suited for transfer and opportunities for exclusive licensing and joint research arrangements." In providing for "fairness of opportunity," the House conference report on PL 101-189 states that although the laboratories are directed to broadly disseminate information on technology transfer, "…this would not require a laboratory to solicit bids or publicize each potential CRADA.…" The conferees also noted their intent "that the laboratory managers be granted authority to facilitate technology transfer to the fullest extent authorized by law."[12]

1992 Energy Policy Act

Other examples of how legislation mandates DOE's treatment of substantial manufacturing include the Energy Policy Act of 1992, an omnibus Energy bill that addressed R&D into

advanced materials and basic energy research. For a company to be eligible to participate in DOE programs and receive funds, the DOE Secretary must find—

> …that the company's participation in the Program would be in the economic interest of the United States, as evidenced by investments in the United States in research, development, and manufacturing (including, for example, the manufacture of major components or subassemblies in the United States); significant contributions to employment in the United States; and agreement with respect to any technology arising from assistance provided under this section to promote the manufacture within the United States of products resulting from that technology (taking into account the goals of promoting the competitiveness of United States industry). and to procure parts and materials from competitive suppliers.…[13]

This language applies to grants and cooperative agreements, but not to CRADAs.[14] Identical language was included in the authorization of the Department of Commerce's Advanced Technology Program (ATP) in 1991. Note that this "finding" applies to all companies, not just foreign companies or U.S. subsidiaries of foreign companies. As with the ATP program, the only foreign participants allowed would be U.S. subsidiaries of foreign companies, and the same reciprocity and open access requirements under the ATP apply here as well. After the passage of this Act, both General Electric and AlliedSignal lodged complaints with the DOE, alleging that the eligibility requirements for foreign firms were not being adequately enforced.[15]

In mid-1998, some contractors at DOE facilities drafted a set of guidelines for "Evaluating the Appropriateness of International Partnerships." These guidelines listed five criteria categories. One of the criterion addressed whether a proposed "partnership has no anticipated adverse impact on the U.S. economy." Project evaluation was to be particularly rigorous when a foreign company was the CRADA partner:

> Detailed assessment of the impact of the partnership on the U.S. economy is especially important when the prospective partner is a foreign company. Factors to be considered include the location of the foreign company's principal operations and markets, and the access that the project affords the foreign partner to the laboratory's background intellectual property and commercially valuable information. A project with a foreign partner can have an adverse impact on the U.S. economy in several ways. A project can result in the transfer of technology to a country with lower development and manufacturing costs, making equivalent U.S.-manufactured products commercially noncompetitive. A project might also improve the partner's technology with innovations developed under the project, allowing it to leapfrog ahead of existing U.S. technology.[16]

This document does seem to indicate that there is an increased caution emerging when dealing with foreign entities in some agreements.

3.2.4 Department of Health and Human Services/ National Institutes of Health (NIH)

NIH has a well-established technology transfer program that generates substantial revenues for the U.S. Government. Many of the agreements are with large multinational firms, typically headquartered offshore, but often with manufacturing operations in the United States. NIH also is careful to ascertain that no U.S. companies are interested in the subject technology before entering into an exclusive license or CRADA with a foreign entity. Many times, the application of a U.S. company can cause the technology to be licensed to the U.S. company rather than the foreign one. However, the commercialization plan is an important factor taken into consideration.

NIH's mission is to improve the public health, so a company that appears to have a more realistic commercialization plan and a greater commitment to bringing a product to market may have an edge over a company whose commercialization plan is not as attractive, even if the latter company is U.S. owned. U.S. ownership is seen as a significant preference but not an absolute requirement. The importance of a good commercialization plan is underscored by the fact that NIH as an agency is under increasing pressure from patient advocacy groups to bring new drugs to the market more quickly. NIH prefers non-exclusive or co-exclusive licenses where possible.

Since the 1980 passage of the Bayh-Dole Act, NIH has been dealing with issues of technology transfer, including foreign participation. According to NIH policy—

> The Bayh-Dole Act requires that products developed with Federal funds and used and sold in the United States, must be substantially manufactured here. In granting exclusive rights to use or sell any subject invention in the United States, recipients must ensure that each agreement requires that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. In individual cases, a request for waiver may be considered by the NIH. Waivers can be made in individual cases, but the recipient must show that reasonable efforts have been made to grant licenses to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. In granting a waiver of the U.S. manufacture requirement, the NIH may consider other benefits conferred on the United States by the potential license including the rapid availability for a product of benefit to the health of the American people.[17]

Substantial manufacture is not defined in this statement, but the confluence of "manufactured substantially in the United States" with "U.S. manufacture requirement" would seem to indicate that U.S. manufacture of the product is what NIH has in mind.

Some NIH personnel indicated that they require "substantial U.S. manufacture" if the product is going to be largely sold in the United States. NIH also does a lot of technology transfer through patent license agreements (PLA). These are divided into two categories, exclusive and non-exclusive. For exclusive licenses, NIH will license to all appropriate companies with a reasonable commercialization plan. For exclusive licenses, NIH follows a special process in which the availability of the technology for exclusive license is advertised. Once the proposals are analyzed, an announcement is made of the intent to award the exclusive license. Other companies can intervene in the process at any point. NIH gives preference to U.S. firms in the exclusive licensing process, but in many cases the U.S. companies are not interested.[18]

As is the case with several other U.S. Government agencies, NIH has a policy for waiving the U.S. manufacturing requirement. This authority is granted by 35 USC 204:

> Notwithstanding any other provision of this chapter, no small business or firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of such invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.[19]

As delineated in 35 USC 204, there are two grounds on which a waiver could be granted: reasonable but unsuccessful efforts to license the invention to licensees who would manufacture in the United States or a lack of commercial feasibility for U.S. manufacture.

NIH has established the following criteria for making these evaluations:

> **Reasonable But Unsuccessful Efforts to License:**
>
> (1) The significance of the technology, the availability of alternative products, size of intended patient populations, whether requiring U.S. manufacture will delay entry of the product into the U.S. or foreign markets, and the effect such delay may have on the U.S. and foreign public

health

(2) Past marketing strategy and efforts for the technology, including i) number of companies contacted; ii) methods used for marketing and contacting companies; iii) types of licenses and terms offered to potential licensees; iv) comparison of terms offered to potential foreign licensee and those offered to U.S. companies; and v) responses of companies to marketing efforts.

Not Commercially Feasible:

(1) The state of the worldwide market for the potential product, including what companies, if any, make the same or similar products and where such products are manufactured, whether requiring U.S. manufacture will delay entry of the product into the U.S. or foreign markets, and the effect such delay may have on the U.S. and foreign public health

(2) The part or percentage of products arising from the invention that would be manufactured outside the United States

(3) The applicant's manufacturing capabilities within the United States and the efforts made by the applicant to locate, develop, or contract for such manufacturing capabilities

(4) The circumstances that make foreign manufacture necessary

(5) The factors making domestic manufacture not commercially feasible, including the relative costs of U.S. and foreign manufacturing

(6) The importance of the technology to the public health, including a discussion of alternative products or therapies available and the size of the intended patient population

(7) The value or benefit to the United States of licensing the technology even if it will not be manufactured in the United States, including i) the direct or indirect investment in U.S. plants or equipment, ii) the creation of new or higher quality U.S.-based jobs, iii) the enhancement of the domestic skills base, iv) the further domestic development of the technology, v) a positive impact on the U.S. trade balance considering product and service exports as well as foreign licensing royalties and receipts, vi) cross-licensing, sublicensing, and reassignment provisions in the license that seek to maximize benefits to the United States, and vii) balance between the use of government resources in furtherance of agency program goals.

Because many companies that object to the substantial manufacturing requirement do so on the grounds that it is not commercially feasible, there may be value in applying a template like NIH uses (or DOE's net benefits analysis). Supplying the information required by the template demands a fairly rigorous analysis, but the burden of analysis and supplying the data is on the company petitioning to be relieved of the requirement for substantial U.S. manufacturing.

3.2.5 U.S. Department of Agriculture (USDA)

The Department of Agriculture has a number of CRADAs, including some with international partners. For purposes of this study, the survey was limited to identifying practices that are notable and distinct from what was observed in the other agencies that deal with non-domestic partners.

When considering non-domestic partners, the USDA has instituted policies distinct from other agencies, but they are interesting from the standpoint of their potential general applicability. More specifically, the USDA—

- Makes a comprehensive determination that U.S. companies are not interested in the technology, including calling the top 5 U.S. companies in that field who conceivably could be interested (SIC codes are used in this process)
- Considers a foreign firm with large U.S. manufacturing and research operations to be "essentially domestic" for the purposes of technology transfer
- Does not use the USTR for review—they make their own determinations of research access and reciprocity.

3.3 OTHER COOPERATIVE R&D PROGRAMS

The NIST ATP and former DARPA Technology Reinvestment Program programs are cost-shared R&D ventures among government and industry and/or academic teams. Like CRADAs, these collaborations are outside the FAR and permit foreign involvement. However, because the Government may be a significant source of funds,[*] the eligibility criteria for foreign entities are more restrictive. Moreover, the guidance provided for establishing eligibility for foreign participation offers some additional perspective regarding foreign participation in general and seems fairly consistent with the intent of the CRADA legislation.

Incidentally, it is worth noting that the ATP personnel and legal staff opposed applying the eligibility criteria and process on foreign (U.S. subsidiary) participation in the ATP on the grounds that it would be overly burdensome. The eligibility criteria based on differing statutory criteria for ATP are more restrictive due to the cost shared nature of the collaboration (see

[*] In a CRADA the Government cannot offer funds. This is distinct from the ATP and TRP that do offer funds on a cost-shared basis.

Appendix E). They were also concerned that doing so might raise issues with the World Trade Organization (WTO).

Advanced Technology Program (ATP)
The Department of Commerce's ATP also has a goal of improving the competitiveness of U.S. economy. One of the five basic selection criteria is potential broad-based net economic benefits to the US As a result, the ATP does not allow foreign companies to participate in the program, but U.S. subsidiaries of foreign companies may be eligible to participate.

The Director of the ATP must find that the company's participation is in the U.S. economic interest. The country where the foreign parent is incorporated must provide U.S. companies similar opportunities to participate in programs like the ATP, as well as local investment opportunities comparable to those of other companies and adequate protection of intellectual property rights.[20]

For all companies participating in the program (not just foreign companies' U.S. subsidiaries) the ATP Director is required to find—

> …that the company's participation in the Program would be in the economic interest of the United States, as evidenced by investments in the United States in research, development, and manufacturing (including, for example, the manufacture of major components or subassemblies in the United States); significant contributions to employment in the United States; and agreement with respect to any technology arising from assistance provided under this section to promote the manufacture within the United States of products resulting from that technology (taking into account the goals of promoting the competitiveness of United States industry), and to procure parts and materials from competitive suppliers.…[21]

No investigation is done until the proposal in which the foreign subsidiary is participating is identified as a likely winner. To make findings about reciprocity and fairness of opportunity, the ATP staff conducts an investigation with the goal of presenting a document on the U.S. subsidiary of foreign company's situation. They contact the USTR and the U.S. embassy staff in that country. In some cases, the State Department is contacted as well.[22] Of the 51 U.S. subsidiary finalists, only 2 have been turned down in this process. Both had parent companies in Japan, and both were turned down "on the basis of the national policies of Japan."[23]

Technology Reinvestment Program (TRP)
The Department of Defense's Technology Reinvestment Program, administered by DARPA, represented a sizable commitment to cooperative R&D. The program differed in a number of significant ways from CRADAs and other technology transfer mechanisms, but the foreign eligibility guidelines are similar to those of ATP. The DARPA manual states that—

> An "eligible firm" as defined by legislation is a company or other business entity that conducts a significant level of its research, development, engineering, and manufacturing activities in the United States. A firm not meeting this test may still be an "eligible firm" if its majority ownership or control is by United States citizens. In addition, a foreign-owned firm may be an "eligible firm" if its parent company is incorporated in a country whose government encourages the participation of U.S.-owned firms in research and development consortia to which that government provides funding, if that government also affords adequate and effective protection for the intellectual property rights of companies incorporated in the United States. Determination of eligibility of firms in this last category [foreign-owned firms] will be made by the Secretary of Commerce as mandated by 10 USC. 2491(9). No prior certification of eligibility will be issued or accepted, and the burden of establishing eligibility will ultimately rest on the proposer."[24]

Like the ATP program, a determination of eligibility would not be made until after judgment had been passed on the appropriateness of the proposal (i.e., the technical merits). Note that this particular determination emphasizes both reciprocity and U.S.-based corporate activities. Because one of the goals of this program was to strengthen U.S. industry, it is not clear how often foreign-owned companies were certified as eligible to participate in TRP projects.

3.4 SUMMARY

The survey of the CRADA process as practiced governmentwide raises a number of issues and provides some interesting insights. In general, it appears that all agencies that engage in CRADAs with foreign participants do so very conscientiously. Most will do so only if no U.S. company has expressed an interest in the technology. This is particularly true where defense technologies are concerned. In fact, it was noted that CRADAs with foreign entities constitute less than 5 % of the agreements approved, which is a small percentage compared with other forms of technology transfer.

In all cases, agencies have procedures in place to screen CRADAs that involve international participants, and there did not appear to be any deficiencies in the implementation of statutory and regulatory requirements. However, there were significant variations in the way agencies interpret and implement statutory and regulatory requirements. For example, not all agencies use the USTR to advise on trade and R&D reciprocity issues.

This failure to consult with the USTR does not appear to be a significant issue; in most cases, the CRADAs are with close allies of the United States, and the approving agency need only consult as opposed to seek concurrence. Some agencies make their own determinations of reciprocity. However, the question remains—if all agencies were to seek USTR consultation, as spelled out in Executive Order 12591, would this would over-tax the resources of the Trade Representative's office? Some agencies have already cited slow or unsatisfactory response by

the USTR as a reason for not seeking regular foreign CRADA process. On the other hand, it is also worth noting that a number of agencies have had acceptable responses (in the range of 1 day to 2 weeks). Because the mandatory period for approval of a CRADA is 30 days and some agencies do not engage the USTR until after the CRADA is initially signed, consistent use of USTR consults by all agencies could conceivably lead to delays in the process and problems with compliance with the mandated period for approval. (See Chapter 4, Section 4.2.2 for a further discussion of this issue.)

Executive Order 12591, as well as technology transfer legislation, addresses both economic and national security, however, no definitions or criteria for determining economic security or economic impact are given. In interviews, considerable concern was expressed about the possibility of burdening the CRADA approval process to the point that industry would find the process too problematic.

Another provision of existing legislation that has been interpreted differently by various agencies is the requirement to "...give preference to business units located in the United States that agree that any products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions will be manufactured substantially in the United States" (15 USC 3710a). "Manufactured substantially" is not defined, but is left to the interpretation of those implementing the legislation. However, both NIH and DOE have special processes in place to accommodate

Exhibit 3-4. Summary Comments

Area of Interpretation	Comments from Interviews
Economic Security	• Economic security, competitiveness not well-defined. – Too much consideration of these areas could shut down the process.
Foreign Participation	• What constitutes a foreign company? Role of multinationals brings into question what a foreign company is. – Should a U.S. company manufacturing in Spain be given preference over a Belgian company manufacturing in Pennsylvania? – Technology Investment Agreements offer a specific definition[25]
Substantial Manufacturing	• Many agencies prefer leaving flexibility for individual negotiations – Meaning of "substantial" is unclear. Is it > 50% of the manufacturing? – Several agencies require U.S. manufacturing for products that will be sold in the United States, or sufficient manufacturing to meet the U.S. share – Several agencies use checklists emphasizing different factors – What about inventions that are part of a process (e.g., coatings)? Would products resulting from the entire process have to be manufactured in United States? – One agency negotiated a trade settlement by implementing a point system for components to ensure the U.S. manufacturing plant was not solely a "screwdriver" facility – Some foreign companies argue "offsets"—the fact that they have substantial U.S. manufacturing and research operations should allow them at times to manufacture offshore. One agency told us they treat such companies as "essentially domestic."
Trade Representative (USTR) Consultation	• In general, there is confusion about the role of the USTR – Some practitioners asked for a new list of countries for which USTR consultation is required – Several agencies do not consistently use the USTR, believing that, in many cases (e.g., Canada, Britain), the determinations are obvious and non-complex – Some consult with USTR "as needed" – Some do not use USTR at all – Confusion exists about how USTR makes determinations of reciprocity – Questions have been raised about whether the USTR, which makes judgments on *trade* reciprocity, can make meaningful judgments on *R&D* reciprocity.

the needs of MNCs or foreign entities that want to alter the substantial U.S. manufacture requirement.

In addition, a number of comments (from technology transfer practitioners), were noted regarding issues that could benefit from greater clarification (see Exhibit 3-4). Although the following list is in no way exhaustive, the responses are indicative of the wide variety of interpretations agencies use in implementing CRADA requirements. In general, it was found that flexibility is important, and many practitioners prefer to deal with specific situations as they arise. Chapters 4 and 5 expand on the issues identified here and offer some suggestions for improving the consistency across Federal agencies.

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[1] House, *Conference Report to Accompany H.R. 2461*, 101st Congress, 1st session,7 November 1989, H. Rpt. 101-331, 1149.
[2] House Committee on Science, *National Technology Transfer and Advancement Act of 1995*, 104th Congress, 2nd session, 20 December 1995, H. Rpt. 104-390, 16.
[3] CRADAs were signed with partners in Germany (x2), South Africa, Japan, and Spain. For more information on the CORE-LOC, see "Army Coastal Protection Unit Raises Money," *The FLC Newslink*, September 1997.
[4] Meeting with Frank Nieman, Roger Ericson, and Nancy Groves, ONR, May 28, 1998.
[5] Meeting between Booz·Allen team and NIST ATP personnel, June 19, 1998.
[6] Ibid.
[7] Phone Conversation with Jud Hightower, DOE General Counsel's Office, August 19, 1998.
[8] NAE Report, p. 115.
[9] DOE Legal staff had indicated to us that DOE still requires the competitiveness article to cover intellectual property, not just subject inventions. According to NAE, in the modular CRADA, intellectual property is defined as 'patents, trademarks, copyrights, mask works, protected CRADA information and other forms of comparable property rights protected by Federal Law and other foreign counterparts.' With the permission of their regional operations office, DOE laboratories may work with a more narrow definition of intellectual property that includes only patents, trademarks, copyrights, and mask works." NAE Report, p. 135–136 39n.
[10] National Academy of Engineering, "Foreign Participation in U.S. Research and Development: Asset or Liability," p. 135 (39n).
[11] Attachment to Victor Reis letter to Congressman John Dingell, October 21, 1997.
[12] House Committee, *Conference Report to accompany H.R. 2461*, p. 1148.
[13] National Academy of Engineering, "Foreign Participation in U.S. Research and Development: Asset or Liability," p. 136 (41n), citing 42 USC 13525.
[14] Phone conversation with Jud Hightower, DOE General Counsel's Office, August 19, 1998.
[15] NAE Report, p. 116.
[16] Gary J. Jones, et. al, "Partnering in a Global Economy: Proposed Guidelines for Evaluating the Effectiveness of International Partnerships," July 15, 1998, p. 7.
[17] "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts," Reprinted from the Federal Register, vol. 59, No. 215, Tuesday, November 8, 1994, pp. 55674–55679. Accessible at http://www.nih.gov/od/ott/text-com.htm.
[18] Phone conversation with Theodore Roumel, June 9, 1998.
[19] 35 USC 204, cited in United States Public Health Service, Technology Transfer Manual, Chapter No. 604, "NIH Procedures for Handling Requests for Waivers of the U.S. Manufacturing Requirement in Licenses to Extramural Inventions." Accessible at http://www.nih.gov/od/ott/604new.htm.
[20] C. Chang, *ATP Criteria for U.S. Subsidiaries of Foreign-Owned Companies: Legislation, Implementation, and Results*, (NIST: 1998), pp. iii-iv. See enabling legislation in 15 USC 278n (9).
[21] 15 USC 278n (9)(A).
[22] Meeting between Booz·Allen team and NIST ATP personnel, June 19, 1998.
[23] Chang, p. iv.
[24] ARPA Technology Reinvestment Project, section 2.2.2, "Guidelines for Assembling a Team of Eligible Participants," cited in National Academy of Engineering, "Foreign Participation in U.S. Research and Development: Asset or Liability," p. 136 (48n).
[25] Foreign Firm or Institution means a firm or institution organized or existing under the laws of a country other than the US, its territories, or possessions. The term includes, for purposes of this Agreement (i.e., a

TIA) any agency or instrumentality of a foreign government; and firms, institutions or business organizations that are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

4. Implementation Issues and Recommendations

As noted in the review of individual agency practices in Chapter 3, there are significant variations in the way agencies interpret and implement the statutory and regulatory requirements regarding CRADAs that may involve foreign participation. Although there do not appear to be significant deficiencies in the legal and regulatory requirements, each agency (or service) laboratory takes a somewhat different approach in determining how to address the national security and economic security considerations.

The differences in agencies' practices stem, in part, from the fact that the national security and economic competitiveness requirements contained in the various technology transfer statutes, as well as Executive Order 12591, do not provide for uniform or even consistent definitions. As a result, each agency has differing interpretations and procedures to implement such requirements, although all agree that the national security and economic security considerations are addressed through the following general categories called out in either the statutes or the Executive Order:

- National Security
  - Export Controls

- Economic Security
  - Reciprocal Access to R&D and Licensing Arrangements
  - Protection of Intellectual Property Rights
  - Preference for Substantial Manufacturing in the United States.

Because of variations in the way agencies implement these requirements, the study team believes that greater clarification—through the development of Governmentwide guidance—would assist agencies in assessing key issues associated with CRADAs with international participation. In fact, the study team did not identify a lack of formal guidance concerning implementation of these requirements the study team that resulted in significant problems. However, there was a consensus among technology transfer practitioners that a standardized checklist or set of questions for use in screening such CRADAs would be useful. The likely result of such guidance would be greater harmonization and improvement of procedures across Federal agencies and laboratories when considering CRADAS that may involve international participation, while at the same time, continuing to allow individual agencies and laboratories the discretion to tailor guidelines to conform to specific situations.

4.1 ILLUSTRATIVE ELEMENTS OF CHECKLIST/GUIDANCE

In meetings with technology transfer practitioners from numerous agencies, a general consensus was reached that a standardized checklist or set of questions for use in screening CRADAs would be beneficial. Such a checklist would ensure that all applicable legislative and regulatory requirements concerning national security and economic competitiveness were addressed and

that all of the key issues associated with international participation in CRADAs were considered.

As addressed in Chapter 3, most agencies already have individual guidelines that govern various aspects of their review of CRADAs. Attachments to this report include the Foreign Eligibility Guidelines used by the Advanced Technology Program of the Department of Commerce, the U.S. Air Force's Decision Guide for the review of international R&D agreements, NIH's Criteria for Waiver of Substantial Manufacture, DOE's Model CRADA and Alternative Benefits Worksheet, and the Office of Naval Research list of checkpoints. All of these provide samples of the types of questions or issues that are addressed by agencies or laboratories as part of the CRADA review process.

In addition to the existing criteria for CRADAs, the team also devised the following illustrative elements that could be included in a comprehensive checklist:

- Identification of all potential participants formally or informally involved in the CRADA, not just signatories. Any intention to involve a non-U.S. participant, whether as part of the supplier base, technology integrator, etc., should be disclosed at the outset, or whenever the possibility of such participation becomes known. (In the case of the EUV LLC, the possibility of foreign equipment manufacturers would have been included as potential participants, instead of just Intel, Motorola, and AMD.)

- More detailed plans (e.g., a commercialization plan) describing the contemplated use of the technology developed as part of the CRADA. For example, is there an intention to commercialize the technology developed by the CRADA? If so, then the competitive technologies, extended enterprise, as well as direct and indirect benefits should be identified.

- A rationale for the inclusion of international participation, rather than domestic partners. Although most agencies have adopted policies that favor U.S. firms, an articulation of why foreign participation is essential, and alternatives explored regarding domestic partners, would help clarify issues at the outset.

- Requirement that all CRADAs with potential international participation and that do not meet standard criteria (such as being a "major CRADA") automatically receive more intensive review within agencies, thereby acting as an early-warning system for CRADAs that might raise sensitive issues.

- Consistent means to assess statutory and regulatory requirements of export controls, reciprocal access, substantial manufacture, and intellectual property protection.

These elements are intended as additional guidance or to serve as the basis for the issuance of formal instructions and are not meant to replace existing criteria. Essentially, these recommendations are intended to supplement existing practices when potential or proposed international entities are involved.

4.2 DISCUSSION AND CLARIFICATION OF NATIONAL SECURITY AND ECONOMIC COMPETITIVENESS REQUIREMENTS

Just as a checklist of questions can help ensure a more harmonized and consistent evaluation across agencies of issues raised by international participation in CRADAs, further clarification or guidance concerning the national and economic security requirements would also help assure that all such requirements had been met when considering foreign partners. The following sections discuss the requirements addressed in the Executive Order, and provide illustrative examples of the type of guidance that could be developed and disseminated to assist laboratories, agencies, and private sector partners in the more harmonized and consistent interpretation of these requirements when considering international participation in CRADAs. Proactive guidance, as described in the following discussion, would also have the benefit of expediting and standardizing the review process of CRADAs with foreign partners.

The primary requirements for consideration of national security and economic competitiveness are spelled out in Executive Order 12591. Section 4 requires the agency director, when negotiating or entering into CRADAs or licensing agreements with foreign persons, to consult with the United States Trade Representative and give "appropriate consideration—

> (1) to whether such foreign companies or governments permit and encourage U.S. agencies, organizations, or persons to enter into cooperative research and development agreements and licensing agreements on a comparable basis; [1]
>
> (2) to whether those foreign governments have policies to protect the United States intellectual property rights; and
>
> (3) where cooperative research will involve data, technologies, or products subject to national security export controls...to whether those foreign governments have adopted adequate measures to prevent the transfer of strategic technology to destinations prohibited under such national security export controls.…"[2]

4.2.1 Export Controls

The primary mechanism for addressing national security concerns is through export controls. Although the requirement to consider the adequacy of the foreign government's controls on the transfer of strategic technology is part of section 4.0 of E.O. 12591's consultative requirement with USTR, in fact, USTR does not provide any review or advice on export control matters.

Instead, agencies must use their own initiative to determine whether the goods or technology subject to the CRADA are controlled by the United States, and if so, what licensing or prior review requirements exist.

Each agency addresses the export control requirements in a somewhat different way, with some, such as the military services, seeking the advice of DoD's export control agency, the Defense Technology Security Agency (DTSA). Others include a clause in the CRADA agreement stating that parties understand information resulting from the CRADA may be subject to export control laws and stipulating that each party is responsible for its own compliance with such laws.

For example, in the case of EUV LLC, some confusion seemed to exist regarding the applicability of export control requirements. It was assumed that products resulting from the CRADA would be reviewed by appropriate government agencies (the Commerce Department for dual-use goods, and the State Department for munitions items) to determine export control requirements. However, under current export control procedures, there is no prior U.S. Government review or approval required for participation by close allies such as the Netherlands and Japan[3]. Thus, export controls were not, and are not, a significant barrier to the inclusion of most foreign participation in CRADAs. The only export control hook in the EUV LLC was the potential State Department-controlled laser (for which a license would be required and likely approved) and a letter of assurance from foreign partners regarding the retransfer of technical data to countries such as China and Russia.

It is worth commenting at this point that confusion over the export control requirements may not be limited to the EUV LLC. This is not an unusual situation, in that export controls are a complicated and highly specialized area that few outside of the responsible agencies understand. Many of the individuals involved with technology transfer interviewed seem to believe that export control requirements state that technology is prohibited, or prohibited without having passed through a rigorous government review process. In reality, the current system of export controls is designed to prevent the export of goods and technology to a small subset of nations such as Iran, Iraq, Libya, North Korea, or China. Exports to other countries, especially those who are partners in restricting technology to the countries of concern, require no prior approval, only a letter indicating parties agree to safeguard the technology against the unauthorized retransfer.

It is also worth emphasizing that the export control process is a national security mechanism that attempts to keep controlled technologies from falling into the hands of potential enemies of the United States. It is not an economic security mechanism, designed to keep state-of-the-art technology from America's trade rivals. In fact, export controls are neither an appropriate nor effective means for denying participation of countries such as the Netherlands or Japan in collaborative R&D measures. Other mechanisms, such as the CRADA, intellectual property agreements, contracts, etc., exist to condition or restrict foreign involvement, should the U.S. Government so desire.

Recommendation:

Given the unfamiliarity and uncertainty surrounding export control requirements, some clarification of export control procedures would be helpful to agencies considering CRADAs. Although the specific circumstances of the goods/technology and end-users/end-use dictate the detailed export control requirements, it is possible for export control agencies (Commerce's Bureau of Export Administration and State's Defense Trade Control office) to provide some level of proactive guidance and/or to establish expedited procedures and designated personnel to respond to agencies inquiries.

As most CRADAs are with major U.S. allies (and members of Wassenaar Arrangement) clarification could be offered regarding under what circumstances individual licenses are required, when Letters of Assurance are required for retransfer of technical data to certain countries, and which countries, technologies, or conditions raise concerns. Such guidance would, by necessity, be general in nature and not obviate the need for formal review of the CRADA if certain export control requirements are triggered. However, it would have the benefit of providing a roadmap to help technology transfer practitioners navigate the complicated maze of export control requirements. Such guidance could help raise awareness among both the Federal and private sector partners of their obligations, thereby alerting parties to potential national security issues at the outset.

Likewise, it would be helpful for export control agencies to designate a point-of-contact to respond to agencies' inquiries and provide guidance, as well as to institute some form of expedited review of government agencies' CRADAs that propose international participation.

4.2.2 Reciprocal Access

As observed in the survey of agencies' practices (Chapter 3), a number of the Federal agencies have not traditionally used the USTR's office on a consistent basis for review of international participation in CRADAs or licenses. Information from the USTR indicates that from September 1997 through September 1998, 25 CRADAs were reviewed by USTR's Office of General Counsel—4 from the Army, 8 from the Navy, 1 from the Coast Guard, and 12 from DoE. This volume marks a sharp increase from the previous trend of "a few per year," Concern was expressed about whether the USTR would have adequate resources to respond in a timely way to a significant increase in these CRADA consultation requests.

Although no guidance exists on how USTR should implement the provisions of the Executive Order, over time USTR has developed a practice of reviewing CRADAs for adherence to the first requirement on general reciprocal access and, more specifically, adherence to the second requirement concerning intellectual property protection. The USTR does not address export control considerations.

Regarding the review of reciprocal access, USTR personnel acknowledge limited information on foreign governments' reciprocal access to cooperative research and development, especially because the USTR's mission is to focus on reciprocal *trade* access. In fact, the only U.S. Government agency that regularly follows the issue of foreign countries' practices concerning R&D is the Department of State (DOS). DOS is responsible for bilateral Science and Technology Agreements and is most familiar, though U.S. embassies' science officers, with cooperative research between U.S. persons and agencies and foreign governments. Currently, there is no systematic means of including DOS information or input, although some agencies indicated that they do consult with DOS desk officers on occasion. In addition to the DOS, other agencies knowledgeable on certain aspects of R&D activities and agreements in foreign countries include, among others, the Department of Commerce's NIST and the Defense Department's International Program Office (i.e., both the Under Secretaries Defense for Acquisition & Technology and for Policy).

Recommendation:

Although further investigation may be needed to determine the adequacy of the existing arrangement, it might be useful to consider supplementing the input of the USTR with information from other Federal agencies that would be knowledgeable on questions of reciprocal access.

For example, proactive reference lists regarding the R&D practices of other countries, including reciprocity for U.S. persons or entities, could be developed and disseminated. The notion of annual assessments of certain practices by other countries (e.g., trade practices, human rights policies, etc.) is well established. Performing such assessments in an informal manner (i.e., not published, but for the use of U.S. Government agencies) would not seem to be an onerous undertaking, especially because Executive Order 12591 requires agencies to consider (and thereby investigate) the issue of reciprocal access. Drawing upon the information of all relevant agencies (including State, Defense, Commerce), a list could be developed as an easy reference document that agencies could use for a quick check of the reciprocal access requirement.

Because assessments of reciprocal access are fluid and depend on ongoing bilateral developments, the document would need to be updated regularly. Ideally, a "living document" could be created and maintained via intra-agency web site. The Department of Commerce's Interagency Technology Transfer Working Group may be an appropriate venue for gathering the information from all relevant agencies and supplementing the work of the USTR in developing such a tool.

4.2.3 Intellectual Property

In the area of intellectual property (IP) protection, a statutory process is already in place to consider and control who makes, uses, and sells the results of an R&D collaboration. Some of the practitioners interviewed for this study noted that a well-structured intellectual property

agreement (IPA) addresses issues of how new IP is systematically "harvested" during the collaboration so as to minimize misunderstandings and allow for effective tracking of progress. This approach is particularly important in large, multiparty CRADAs (e.g., USCAR, EUV LLC). In fact, the DoE competitiveness worksheet (see Chapter 3) contains several criteria to consider, including one that specifically addresses cross-licensing, sublicensing, and reassignment provisions in licenses that seek to maximize benefits to the U.S. taxpayer.

Recommendation:

Some additional criteria that analysts highlighted as useful to clarify on a case-by-case basis included—

- Adequacy of candidate partner(s)' protection of U.S. IPR;
- What happens if a new domestic source arises after an agreement is signed
- Contingencies if a signatory to the IPA is acquired by a foreign party
- Clear understanding/definition of the field(s) of use (FOU)
- Clear understanding of the background IPR in the FOU beyond the signatories of a CRADA
- Financial arrangements, e.g., maintenance fees, royalties
- Whether preferential arrangements are possible when a partner improves the licensed technology or develops patents in the future
- Future licensing plans and how the IPA fits in the context of the commercialization plans
- Whether the licensing plan affects other cross-cutting technologies of interest to the U.S. Government
- Exit criteria and the duration of agreements, if any.

Overall, technology transfer practitioners expressed a need to increase the laboratories' awareness of their options and obligations with respect to intellectual property management.

4.2.4 Substantial U.S. Manufacturing

The provision for laboratory directors, under Stevenson-Wydler (now codified as 15 USC 3710a(c)(3)(B)(4)(B)), to "give preference to business units located in the United States which agree that products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions, will be manufactured

substantially in the United States.…"[4] has been identified as one area that might benefit from further clarification. It has also been noted by a number of practitioners that specific guidelines are not available regarding "substantial" and that it is preferable for decision makers to have flexibility for case-by-case determinations.

As a result of this survey of agency practices and review of related literature, a persuasive case can be made that the (identical) language in the Technology Administration Authorization Act of 1991 (15 USC 278n) and the Energy Policy Act of 1992 (42 USC 13525) reflects a refinement of the congressional intent expressed in the Stevenson-Wydler Act of 1986. The Energy Policy Act of 1992 and the Technology Administration Act of 1991 state—

> …[T]he company's participation in the Program would be in the economic interest of the United States, as evidenced by investments in the United States in research, development, and manufacturing (including, for example, the manufacture of major components or subassemblies in the United States); significant contributions to employment in the United States; and agreement with respect to any technology arising from assistance provided under this section to promote the manufacture within the United States of products resulting from that technology (taking into account the goals of promoting the competitiveness of United States industry), and to procure parts and materials from competitive suppliers....[5]

Some analysts may argue that these two Acts apply to programs where Federal funds are involved and not to situations like CRADAs, where the industrial partner is providing the funding. However, it could be argued that regardless of the applicability of the employment and competitiveness provisions of this section, the Congress offers more clarity concerning a definition of substantial U.S. manufacturing, namely, the manufacture of major components and subassemblies in the United States.

This language seems to eliminate from consideration U.S. manufacturing facilities that are for assembly only and contribute little added value (i.e., screwdriver assembly shop). However, situations could always occur that require case-by-case consideration. For example, Boeing aircraft have key components manufactured in Japan, Korea, Israel, and other countries.[6] Some analysts argue it is the integration that requires the high-end labor and therefore constitutes what many people consider "substantial U.S. manufacturing," even though integration could be perceived by some as simply "screwdriver" assembly.

Another aspect of the language concerning U.S.-based manufacture is the provision for showing *preference*. Most agencies/laboratories do not develop CRADAs in a competitive manner if multiple sourcing may be involved. In fact, many collaborations may only involve single researchers from the government and/or private sector. This situation essentially makes the preference provision meaningless unless there is a requirement to notify other sources in the area of interest.

In this study we have found that some agencies (i.e., NIH and DOE) already have practical approaches for dealing with the interpretation of "substantial" that balance flexibility and the protection of U.S. national security and economic interests. Therefore, the following recommendations are proposed.

Recommendations:

If a proposed CRADA partner (either U.S. multinational or foreign entity) does not intend to meet the substantial (essentially defined as 100 percent) manufacture provision, then the parties could use a waiver or alternative benefits process similar to the DOE Competitiveness Worksheet or the NIH U.S. manufacturing waiver criteria [see Chapter 3]. This procedure would avoid burdening the process for "typical" CRADAs while requiring companies (U.S. and foreign) who want to avoid substantial manufacturing in the United States to justify their actions in terms of economic benefits to the United States. Moreover, these procedures are already in practice and have not raised any notable complaints.

Moreover, an interagency group should consider using a model like that of NIH *for CRADAs involving foreign participation only*. The NIH licensing and CRADA process ensures that the opportunity to enter into a CRADA involving a given technology is advertised before an agreement is signed. In addition, once a potential CRADA partner is identified, U.S. industry receives a second opportunity to raise objections. In the past, this process has resulted in the modification of the terms of the CRADA, or, in the case of PLAs, a decision to grant nonexclusive licenses rather than exclusive ones.

The detailed provisions of the NIH model might not work precisely for all other Federal agencies. NIH closely monitors the technologies it is developing and their potential value to industry and the public health. Advertising the availability of certain technologies might not be the best approach for other agencies that rely on industry to approach the laboratory regarding areas of interest in collaboration. It is likely, however, that advertising the intent to grant a CRADA—again, only for CRADAs involving foreign participation—could avoid situations were U.S. industry feels unfairly closed out of collaborative opportunities. The advertising could appear in the Commerce Business Daily or the Federal Register or some other appropriate publication; on Web sites; or, following the lead of the USDA, the laboratory could contact by mail or by phone the five leading U.S. companies in the technology area. The advertising should be done in such a way as to attract both the attention of U.S. industry for their comment, and interested policy makers in other U.S. government agencies.

4.2.5 Other Considerations

In the sections above, the national security and economic security (or competitiveness) requirements of E.O. 12591 are addressed, as well as the issue of substantial manufacture and

alternative benefits. However, during this study additional issues and considerations arose that are discussed below, including additional suggestions for clarification and guidance.

National Security

In the national security arena, the primary mechanism to address national security concerns with foreign participation is through the export control process. However, the general authorization in the Executive Order does state that "the head of any Executive department or agency may exclude from consideration, under this Order, any technology that would be, if transferred, detrimental to the interests of national security."[7]

An additional national security consideration is access. The Department of Defense needs timely and assured (or reliable) access to critical technologies. The concern is not necessarily one of foreign sourcing but one of vulnerability due to lack of alternative sources of core capabilities[8] and thus, loss of control (due to shipping issues and incompatible political agenda of country of origin). It is interesting to note that global companies (e.g., auto makers and semiconductor manufacturers) are often concerned about the very same issue for economic reasons.

To determine whether the technology in a CRADA is or will remain accessible for defense needs, decision makers may want to also consider the following:

- Clarification of whether the technology in question is largely commercial or defense specific
- Who the viable vendors are that will support production and thus access
- Whether other technologies or relationships could be affected by the collaboration
- Whether the business practices of viable vendors would deter access in a timely manner
- Whether the partner(s) in question have posed access problems in the past
- Whether U.S. partners (government or industry) have alternate means to assure access from the foreign entity.

Economic Competitiveness

The Executive Order does not provide specifics regarding the interpretation of economic competitiveness, but improving America's economic competitiveness was clearly an intention of the 1986 Stevenson-Wydler Act. However, as noted earlier, the provisions for substantial manufacture in the United States, the right of reciprocal access for U.S. companies to participate in cooperative research and development in a partners' country, and the protection of U.S. intellectual property by the foreign country collectively address the concern for technologies that are essentially going to be available (or proliferated) in the commercial sector.

To assess economic security considerations beyond the current provisions requires a specialized and more extensive analysis incorporating an evaluation of many factors. These include trends in the industry in question (e.g., growth, mergers and acquisitions, foreign acquisition, foreign capabilities, and participation in R&D) and relationships in the "food chain" or extended enterprise (for instance, a domestic industry such as the semiconductor industry is supported by multiple tiers, such as the semiconductor tools industry and component suppliers).

A comprehensive analysis of economic security would also include how a technology being transferred compares with the incumbent technology and other alternative technologies. It is worth noting that competition can have many beneficial consequences—it can spur innovation, and it can also inspire improvements in the incumbent technology that beat back the challenge of new technologies.[9,10]

It is also worth reviewing the benefits of international relationships, including the management of risk. International cooperation can open markets that might have been closed as a retaliatory measure. Competitive participants can also bring additional innovation and more pressure to reduce costs—this is typically what occurs in the commercial environment—which can be of benefit to U.S. public and private sectors if they are procuring the products or services resulting from the technology.

For major CRADAs that have ability to influence the competitive landscape in certain industries, decision makers may also want to consider issues such as those raised in the DOE competitiveness worksheet:

- Are conflicting U.S. interests involved? For instance, does this deal have the capability of helping one segment of the U.S. economy while hurting another?
- Is a viable U.S. industrial base associated with the technology? Is this base willing to pursue R&D cooperatively? Is licensing alone of interest to U.S. entities? Clarify the methods used to determine U.S. interest.
- What consequences are anticipated if the agreement does not come about? For example: Could key individuals be hired by prospective participants without restrictions? Could development take place elsewhere? Will other R&D relationships be affected (i.e., politically, technically)?

In summary, although the preceding recommendations for additional guidance or clarification could be accomplished without any change to the existing Executive Order, the differing interpretations by agencies of the E.O.'s requirements beg the question of whether further clarification of E.O. 12591 or a new Executive Order would be helpful. E.O. 12591 was drafted during the early stages of experience with CRADAs, and before recent large-scale, funds-in CRADAs such as DoE's EUV LLC. The study team did not find specific deficiencies

in the E.O.'s requirements—although the requirements are broad in scope, the national security and economic competitiveness considerations are generally addressed.

However, given the differing interpretations of these requirements by agencies, one way to ensure more consistent implementation is to clarify certain requirements in the E.O. for major CRADAs with foreign participation. For example, the E.O. as currently drafted implies that agencies are to consult USTR regarding export control requirements, yet USTR has no competence in this area and does not claim to. The mere clarification of the appropriate export control authorities to consult could be helpful. Likewise, the formation of an interagency group or process to address some of these implementation issues could also be handled through an E.O. In addition, revised procedures could be drafted as part of an E.O. to provide for more harmonized predictable interagency procedures, while still protecting agencies' prerogatives and expediting the review process .

Although the study team is not recommending a new or revised Executive Order, we believe it would be beneficial for an interagency group to examine the structure and operation of the E.O. to determine whether additional changes are warranted.

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[1] This language is nearly identical to that included in the Stevenson-Wydler legislation, 15 USC 3710a (c)(4)(B).
[2] Executive Order 12591, Section 4 (a), April 10, 1987, as amended by Executive Order 12618, December 22, 1987.
[3] Japan and the Netherlands are both members, along with the United States, of the Wassenaar Arrangement, a successor agreement to the Cold War COCOM, previously aimed at denying the Warsaw Pact advanced technology. The Wassenaar Arrangement includes 33 countries that control sensitive dual-use technology and munitions to countries whose behavior becomes cause for concern (defined by the United States to be Iran, Iraq, Libya, and North Korea). Although goods are controlled on a worldwide basis, there is limited licensing or prior government approval for most exports to other members of the control regime.
[4] 15 USC 3710a (c)(4)(B).
[5] 15 USC 278n (9)(A).
[6] Robert M. White, "It's Morning in American Industry," *MIT's Technology Review*, Feb/Mar 1997, p. 68.
[7] *CRADA Mania*, Scientific American, October, 1993
[7] DOE response to the Hill's questions.
[7] The DOC Partnership for Next Generation Vehicles (PNGV) uses an umbrella CRADA to facilitate research interactions with the Big Three U.S. auto makers, but with limited involvement of foreign companies as subcontractors / licensees. Some DOE CRADAs associated with this program used language to modify the requirement for U.S. substantial manufacture.
[77] Executive Order 12591, April 10, 1987, 52 F.R. 13414, as amended by Executive Order 12618, December 22, 1987, 52 F.R. 48661.
[8] Jacques Gansler, *Defense Conversion* (Cambridge, MA: MIT Press, 1995), p. 44–45.
[9] Smith, D.G., et al, "Superconducting Filters for Wireless Communications: A Reappraisal," *IEEE Proceedings of the 1998 Applied Superconductivity Conference*.
[10] Smith, D. G., et al, "Identifying Pathways for Technology Commercialization," *Proceedings of the 20th Annual Meeting of the Technology Transfer Society*, July 1995, pp.83–93.

5. Process Issues and Recommendations

Chapter 4 addressed issues related to implementation that arose during the course of this study and a review of the EUV LLC; this chapter focuses almost exclusively on process-related issues. In addition to discussing congressional considerations, this chapter addresses the question of defining a major CRADA and proposes options for the creation of an interagency review process for certain CRADAs.

5.1 CONGRESSIONAL CONSIDERATIONS

Although procedural issues were not a major concern at the outset of the study, since spring 1998, the Congress has focused on interagency process changes as a means to address perceived deficiencies in the CRADA review process as demonstrated by the EUV LLV experience. The Tauscher amendment to H.R. 2544, as originally drafted, as well as companion legislation introduced by Senator Rockefeller (S. 2120), would have required criteria for interagency review of a CRADA that involves "national security, or relates to a project which may have a significant impact on domestic or international competitiveness." However, the version of H.R. 2544 that ultimately passed the House contained considerably more flexibility for the Executive Branch (i.e., OSTP) to review and determine the adequacy of existing procedures and methods for interagency coordination, and to recommend additional procedures, if any, for gathering and considering the views of other agencies on certain CRADAs. Although the Congress adjourned before the Senate acted on H.R. 2544, there was no substantive opposition to the House language, and it has been reintroduced in the 106th Congress as H.R. 209, which is expected to be considered early this session.

It is important to note that despite criticism of the EUV LLC and the resulting Tauscher amendment, the Congress continues to strongly support the CRADA concept as a tool for industry–government cooperation. All congressional personnel interviewed during this study agreed that the hallmark of CRADAs is flexibility and expressed the strong desire not to hamstring or encumber the CRADA process for the vast majority of cases for which the current process appears to be appropriate and adequate. Moreover, the Congress did not take the position that international involvement is to be avoided, but in fact, recognized that there are instances where foreign participation is essential to further technology development.

However, congressional officials noted that some "major," far-reaching CRADAs have emerged in recent years that involve cutting-edge technology, the world's largest companies, and occasionally consortia of Federal laboratories.[1] Because of their potential to affect industry sectors, their suppliers, and jobs within the United States, the report language questions whether these CRADAs may have outgrown the current CRADA approval process. Accordingly, the House recommended that OSTP review and upgrade, if necessary, existing approval procedures for these major CRADAs. OSTP was charged with identifying criteria to separate out the small minority of major CRADAs which would benefit from interagency review. While

calling for some change "to solve potential problems through better interagency coordination," the House bill clearly states that new procedures are to be added only to the extent that existing procedures are inadequate, and that "any new procedures are to lead to expedited, substantive interagency decisions" that minimize burdens on agencies.

Ultimately, the legislation that emerges from the Congress is likely to require some form of interagency review of major CRADAs, while allowing discretion for OSTP to define the which CRADAs are reviewed. This discretion represents an opportunity for the executive branch to structure any procedural changes in a manner most conducive to minimizing delays and consistent with the continuing need for flexibility.

Before discussing options for interagency review of major CRADAs, one must first define the universe of CRADAs that would be affected. The following section presents some ideas on the type of criteria that could be developed for triggering an interagency review of a subset of CRADAs.

5.2 DEFINITION OF MAJOR CRADA

Overall this analysis has found that although the majority of CRADAs undergo satisfactory review at the agency level, the Government may benefit from an interagency review process that could assist in evaluating future major CRADAs involving international partners. However, to minimize unnecessary burdens for the vast majority of CRADAs, some clarification concerning what a major CRADAs is must be provided.

More recently, the DOE EUV LLC CRADA highlights some key aspects that could make CRADAs controversial. In this arrangement, the intellectual property and U.S. manufacturing provisions are carefully defined to ensure U.S. manufacture for a specified time period (i.e., assured first access) and to impose the same provisions on licensees of the technology. One prominent element of the controversy involves the *potential* inclusion of international lithographic toolmakers and the large amount of "funds-in" from industry. Some analysts have noted that this arrangement may threaten the well-being of U.S.-based toolmakers who are already party to the agreement. However, others have noted that the commitment of global semiconductor manufacturing leaders to the toolmaking industry, as well as the current provisions for control over manufacture (through licensing provisions), are a good example of how Federal laboratories can accommodate multinational industries and serve the public interest.

Incidentally, this has not been the first time that DOE and the DOC have dealt with the concerns of multinational industries. For example, General Motors and Ford Motor Company have clashed with DOE over product liability and the substantial U.S. manufacture provision. In response to the need for more discretion associated with U.S.-based multinationals (1993), DOE refined the U.S. Competitiveness Worksheet to serve as a guide in articulating the rationale for changes to the more restrictive manufacture provisions.

Controversy has not been a stranger to cooperative R&D in the past. An example of the need for careful scrutiny of R&D collaborations occurred in an agreement between Scripps Research Institute and Sandoz in 1992. In this case, NIH renegotiated a Sponsored Research Agreement (which is similar to but not a CRADA) involving the not-for-profit Scripps Research Institute and Sandoz (Swiss-based) pharmaceutical company. Originally, Sandoz was to provide $300 million over 10 years for rights to the commercial fruits of the Federally funded research at Scripps. The agreement was not acceptable to the-then director of the NIH, Bernadine Healy, who felt it gave Sandoz "excessive control" of research and IP. About this time, NIH had developed guidelines to deal with the perception and controversy associated with serving the public interest. The institute found that more specificity in the field of use (FOU) is a critical part of developing an appropriate CRADA[2].

Although no definitive definition of a major CRADA would accommodate all appropriate situations, there are a range of possibilities and illustrative criteria that could assist in narrowing the scope of CRADAs to be reviewed on an interagency basis.

5.3 CRITERIA FOR MAJOR CRADAS

There are three main options for defining the scope of interagency review. Review could encompass all CRADAs, all CRADAs involving foreign participants, or CRADAs involving foreign participants AND meeting appropriate criteria.

Based on the House Science Committee's report language, it is obvious that there is no intention for all CRADAs to undergo interagency review; quite the contrary, only a "handful" of major CRADAs raise issues that the Committee believed would benefit from such a review. Likewise, because most of the concern about the potential effect of these major CRADAs on American jobs and companies centered on foreign participation in CRADAs, it seems appropriate to further limit the scope of the CRADAs requiring review to those involving foreign partners and meeting appropriate criteria.

To refine the subset of CRADAs triggering interagency review, it may be useful to envision a series of filters, or a funnel approach. The first filter concerns CRADAs with international participation. Based on data provided by agencies, the study team estimates this criteria alone to eliminate nearly 95 percent of all CRADAs, because nominally 5 percent of CRADAs involve foreign participation. The second and subsequent filters could be drawn from the following list of illustrative criteria:

- Type of CRADA
- Monetary Threshold
- Critical Technologies
- Sensitive Industries
- Waiver of U.S. Manufacturing Requirement.

CRADA Type

The type of CRADA is an important aspect of any evaluation. As discussed in Chapter 2, CRADAs can involve simple collaborations of individual researchers, Material Transfer Agreements (MTA) in the biomedical field, work for others, funds-in, as well as "blanket" CRADAs that encompass entire industries (e.g., Partnership for Next Generation Vehicles[3], and Sandia-SEMATECH). It is instructive to note that many CRADAs are not necessarily designed to commercialize a product or service directly (i.e., advanced product development or licensing) but are used to facilitate access to unique resources (e.g., the NMRI and WRAIR CRADAs for vaccine development and approvals) or to allow two researchers to work together on a project.

In addition, a critical aspect of potential CRADAs with international participation concerns the intent to commercialize. Commercialization (and an associated plan) is probably the biggest concern (from an economic competitiveness standpoint) when considering the intent of the industrial partner involved. However, the authors have observed that large CRADAs involving complex relationships and/or high levels of resources get careful scrutiny from the agency or laboratory that reviews the agreement.

Monetary Threshold

Specific monetary threshold as a criterion is appealing because it is a simple quantitative measure. Given the experience with CRADAs to date, the number of extraordinarily large monetary agreements that appear to be a problem (such as those serving industrial over public interests) is still small. In fact, practitioners remarked that most CRADAs do not involve substantial resources (people and/or funds from industry). More specifically, where funds-in are concerned, the majority of the funds totals are below $50,000. The largest funds-in CRADAs seem to be associated with the biomedical field and some DOE projects. Some of the larger funds-in projects typically involve more than a few million dollars.

Although funds-in CRADAs are not necessarily new, they have posed questions because of the potential perception of private sector concerns driving the research agendas of government laboratories (as previously discussed in the Sandoz-Scripps case). Some have characterized this as the "lab-for-hire" problem. Therefore, a potential defining criterion could include the specific type of CRADAs that has raised concerns in the past, e.g., funds-in CRADAs.

One possible threshold for interagency review could be CRADAs that exceed a level such as $5 million. As many researchers noted, a million dollars does not buy much in R&D, especially if the emphasis is on development. Although somewhat arbitrary, many would agree that such a threshold would serve to simplify the decision-making process and help focus on the subset of CRADAs that may benefit from additional perspectives.

Another criterion for identifying major CRADAs is to consider whether the proposed funding represents a significant (e.g., greater than 50) investment compared with the laboratory's total

investment exclusive of the CRADA (not the laboratory's in-kind contribution) for the technology in question. Use of this criterion would involve more work on the part of the laboratory but would serve as an early warning of possible issues that may arise concerning perception of the laboratory's motivations in the collaboration.

Critical Technologies

There are several existing lists of "Critical Technologies " serving various purposes—the so-called Bingaman Critical Technology list, the Military Critical Technology List (MCTL), the Wassenaar List of Sensitive and Very Sensitive Technologies, to name a few. In many cases, these lists refer to technologies in such broad terms as to eliminate them as practical criteria for establishing an indicator for interagency review. However, the concept of the Government establishing lists of important technologies has been firmly established, and developing a listing of specific technologies over which concern about CRADAs with foreign participation requires additional review is certainly possible. For example, those technologies in which the U.S. Government has already made substantial investments through agencies and laboratories' annual budgets could also serve as a source for a useful list.

Sensitive Industries

Sensitive industries is also a qualitative term that would require more definition by the Government. From an economic security and national security point of view, sensitive industries could be considered those industries with limited domestic sources or access due to single (or high concentration of) sources overseas or U.S.-based sources that are experiencing significant competition internationally. For a CRADA evaluation, the FOU for licensing purposes should be specific enough to identify what industries the technology licensing will cover.

Waiver of U.S. Manufacturing Requirement

Because of the legislative requirement for substantial manufacture and concerns about inconsistent interpretation of this requirement, an additional criterion triggering interagency review of the CRADA could be the expectation that the U.S. manufacturing requirement would be waived and the foreign partner does not have both R&D and manufacturing in the United States in the field of the statement of work (SOW). Waiver of the requirement does not mean that the CRADA should not proceed; rather waiver of the prerequisite would serve as a trigger to solicit other agencies views because such a CRADA departs from typical requirements.

The list above is not comprehensive but is intended to be illustrative only. It provides a preliminary basis for discussion among agencies about what constitutes appropriate criteria for CRADA consultation with other agencies. The most important aspect of such triggers is that they are quickly and easily recognized in order to permit consistent application in the most efficient manner. As will be discussed in the following section, it is important for an interagency group to agree on consensus criteria to identify these major CRADAs. and these criteria should be shared on an interagency basis. Many practitioners believe that reducing many of these criteria to a readily administratible form will be a difficult challenge.

5.4 INTERAGENCY REVIEW PROCESS

After the criteria defining the character of CRADAs to be reviewed on an interagency basis have been established, the next issue is what kind of interagency review process should be used.

Options for an interagency review process range from the existing informal decentralized system, which permits interagency consultation on an ad hoc basis (e.g., EUV LLC) to the creation of new formalized interagency groups for the review and approval/disapproval of CRADAs meeting certain criteria. Between these two options are gradations of instituting new procedures but using existing interagency mechanisms to provide for an informal consultations and exchange of information or instituting new mechanism to permit interagency review and consultation of a subset of CRADAs meeting certain criteria.

Because the congressional report language emphasizes use of existing procedures, to the extent possible, to minimize burdens on Federal agencies, the study team's focus has been on current interagency mechanisms that might be appropriate for the CRADA review process. Several models of existing interagency groups could undertake such a task. Ranging from the formal to informal, these mechanisms include the following:

- Committee on Foreign Investment in the US (CFIUS)—a formalized interagency mechanism (statutory and Executive Order based) that reviews foreign acquisitions, mergers, or takeovers of American business that threaten to impair national security.

- National Science and Technology Council, Committee on National Security International Technology Transfer Working Group (NSTC-CNS-ITTWG)—an administratively created interagency committee chaired by OSTP that focuses on ways to improve national policy mechanisms governing international technology transfer interactions.

- Interagency Working Group on Federal Technology Transfer (IAWG)—a working group and higher level policy committee chaired by the Department of Commerce charged with examining technology transfer issues and problems.

- Informal information-sharing by agreement among agencies—examples of the type of informal consultations among agencies on various issues include Memoranda of Understanding related to Bilateral Defense Cooperation Letters of Agreement and Excess Defense Articles. Such mechanisms allow agencies to consult on an ad hoc basis and raise issues of concern regarding specific transactions without formal review and concurrence rights.

Recommended Interagency Process

After examining various interagency mechanisms and discussing options with agencies' representatives, the study team arrived at the preferred option of using an existing mechanism, such as the Interagency Working Group (IAWG) to serve as a coordinating body for the sharing of the subset of CRADAs with international participation and meeting interagency agreed-on criteria.

The IAWG on Technology Transfer was created following passage of the Federal Technology Transfer Act in 1986 as a way for DOC to carry out its statutory role under the legislation. The Secretary of the DOC invited other agencies involved in science and technology R&D with potential for commercialization to become members of the Interagency Committee. The Group initially focused on methods for commercialization, assistance to agencies regarding their cooperative R&D projects, and preparation of a model CRADA agreement. As interest in collaborative research with industry has increased in the past decade, agency participation has broadened to include NIST, DoD, DOE, NIH, SBA, and USTR. In addition to sharing best practices in technology transfer, the Group has also helped to coordinate agencies' positions on issues such as the application of the GATT Subsidies Code to government research programs during the Uruguay Round, management of technology transfer programs generally, and most recently, executive branch comments on H.R. 2544. (now H.R. 209)

The Interagency Committee members are Assistant Secretary-level representatives from various agencies, and the Committee chaired by Commerce's Assistant Secretary for Technology Policy. Most of the Committee's work, however, is accomplished through the IWAG on Technology Transfer, which is composed of senior managers from the agencies and departments responsible for technology transfer.

Of all the current interagency mechanisms reviewed, the IWAG alone had the advantage of being both a working-level technical group and higher-level policy/political committee for addressing issues. In addition, the IAWG is composed of technology transfer practitioners and has effectively served as a coordinating body on various technology transfer questions.

The following illustration demonstrates how the IAWG could serve as an effective consultative body for sharing insights on major CRADAs.

After the criteria regarding what constitutes a major CRADA are agreed to by agencies, any proposed CRADA agreement triggering these criteria would be identified by the responsible agency and in consultation with other IAWG agencies before a final approval decision was made. (It is assumed that the checklist or guidance discussed in Chapter 4 will have already been completed, and based on a thorough analysis by the proposing agency, the recommendation is to approve the CRADA.) The consultation could be made several ways, for example through posting on an intranet to which all member agencies had access, or in the form of a written notification to the IAWG chair, which would then be distributed to all members. Optimally, an e-mail or electronic system should be devised, because the goal will be

to avoid delays and ensure that the interagency review takes place within a limited timeframe (e.g., 2 weeks).

Within the prescribed time frame, other agencies would then have the opportunity to review the proposed CRADA. The IAWG would serve as the first-order forum for vetting any questions and addressing concerns raised by agencies. If it were unable to satisfactorily address an agencies' concerns regarding the CRADA, the IAWG would refer the matter to the Assistant-Secretary level Interagency Committee. At this point, appropriate political-level review among agencies would be assured, while at the same time allowing responsibility and authority for the final decision to be retained by the proposing agency. The benefit of this "default to decision" process is the increased sharing of CRADAs with international partners that could raise potential issues, but doing so in a time-limited, semi-automatic process.

Although no system is perfect, the study team believes this type of consultative IAWG process could effectively deal with the range of issues in a manner that avoids unnecessary delays, provides for a thorough vetting of the issues associated with proposed CRADAs, and preserves ultimate decision-making authority for the proposing agency, subject to consideration of issues raised by other agencies. Such a system is also consistent with the intent of both the recent legislation, H.R. 209, and the existing Executive Order (12591).

If the IAWG were designated as such a consultative body, there are other functions that would make sense for the it to perform, including—

- Developing the checklist or procedural guidelines referenced in Chapter 4 for use by all agencies contemplating CRADAs with international involvement

- Deciding upon the criteria that would define major CRADAs and would trigger interagency review of certain CRADAs;

- Developing additional guidance to promote consistent interpretation across agencies of reciprocal access and substantial manufacture, and acting as a repository of information and developing reference lists for agencies' use.

- Organizing training programs and workshops to assist agencies and laboratories in understanding and increasing awareness among technology transfer officers and technical staff of CRADA requirements

- Exploring the advisability of consistent procedures to gather and track data on R&D cooperation. (During the course of the study, individuals noted that currently there is no timely, consistent means of gathering data on CRADAs, licenses, and sublicenses involving collaborative R&D. The IAWG might wish to consider a common system, such as DoD's Defense Technology Transfer Information System, for the more convenient retrieval of R&D information for managers and policy makers.)

5.5 SUMMARY COMMENTS

Although no system is perfect, the study team believes this type of consultative IAWG process could effectively deal with the range of issues in a manner that avoids unnecessary delays, provides for a thorough vetting of the issues associated with proposed CRADAs, and preserves ultimate decision-making authority for the proposing agency, subject to consideration of issues raised by other agencies. Such a system is also consistent with the intent of both the recent legislation, H.R. 209, and the existing Executive Order (12591).

In the period preceding the signing of a major CRADA, a number of actions could be taken to "separate out the small minority of major CRADAs which need interagency review from those which do not."[4] Here, policy makers must balance the need for well-thought out agreements that safeguard U.S. national and economic security concerns with the desire not to overly encumber the CRADA approval process with its 30-day deadline.

Exhibit 5- 1 is a summary flowchart that depicts the highlights of the criteria and steps that have been discussed in this chapter of the report. It is important to remember that the number of major CRADAs that are likely to go through this consultative process will be small. Overall, the number of CRADAs with foreign participation is less than 5 percent of the total number of CRADAs signed, and those meeting additional filters or criteria in Section 5.2 will be even fewer. This focus on the "handful of major CRADAs" is intended to meet the congressional objective of not impeding or encumbering implementation of the vast majority of CRADAs.

It is interesting to note that the EUV LLC CRADA would have been identified as a major CRADA based on several criteria contained in Chapters 4 and 5:

- An intention to involve foreign partners (in the past or the future)
- Type of CRADA (funds in)
- The monetary threshold (over $5 million)
- (possibly) Critical technologies or sensitive industries (advanced lithography equipment).

For the limited number of CRADAs with international participation, the criteria and process suggested are meant to ensure that national and economic security concerns are identified and the full range of issues are presented to the decision maker. This process in no way precludes U.S. industries from raising concerns or special situations with responsible executive branch officials or congressional representatives. This option will always remain a viable avenue to address issues regardless of the criteria or process established.

[1] See House Report 105-620 Part 1 - Technology Transfer Commercialization Act of 1998, to accompany H.R. 2544, section 6 - *Review of Cooperative Research and Development Agreement Procedures*,

[2] As a result of the experience with Sandoz and Scripps, the NIH adopted several policy changes to avoid similar problems with their collaborative mechanisms in the future. Four changes, in particular, that were incorporated into the CRADA review process: evaluate the level of effort to be provided compared with the laboratory budget in the area of concern, ensure that the CRADA has intellectual involvement by all parties(i.e., not money only), evaluate whether a CRADA is the appropriate mechanism for the collaboration proposed, and evaluate the level of the Principal Investigator's time commitment in the agreement.

[3] The DOC Partnership for Next Generation Vehicles (PNGV) uses an umbrella CRADA to facilitate research interactions with the Big Three U.S. auto makers, but with limited involvement of foreign companies as subcontractors / licensees. Some DOC CRADAs associated with this program waived the U.S. manufacture preference.

[4] H.R. 2544 Report Language

Appendix A.
Stevenson Wydler Act and Executive Order 12591

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§ 3710a. Cooperative research and development agreements

(a) General authority

Each Federal agency may permit the director of any of its Government-operated Federal laboratories, and, to the extent provided in an agency-approved joint work statement, the director of any of its Government-owned, contractor-operated laboratories—

(1) to enter into cooperative research and development agreements on behalf of such agency (subject to subsection (c) of this section) with other Federal agencies; units of State or local government; industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations); public and private foundations; nonprofit organizations (including universities); or other persons (including licensees of inventions owned by the Federal agency); and

(2) to negotiate licensing agreements under section 207 of Title 35, or under other authorities (in the case of a Government-owned, contractor-operated laboratory, subject to subsection (c) of this section) for inventions made or other intellectual property developed at the laboratory and other inventions or other intellectual property that may be voluntarily assigned to the Government.

(b) Enumerated authority

Under agreements entered into pursuant to subsection (a)(1) of this section, a Government-operated Federal laboratory, and, to the extent provided in an agency-approved joint work statement, a Government-owned, contractor-operated laboratory, may (subject to subsection (c) of this section)—

(1) accept, retain, and use funds, personnel, services, and property from collaborating parties and provide personnel, services, and property to collaborating parties;

(2) grant or agree to grant in advance, to a collaborating party, patent licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory

employee under the agreement, retaining a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government and such other rights as the Federal laboratory deems appropriate;

(3) waive, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government, in advance, in whole or in part, any right of ownership which the Federal Government may have to any subject invention made under the agreement by a collaborating party or employee of a collaborating party;

(4) determine rights in other intellectual property developed under an agreement entered into under subsection (a)(1) of this section; and

(5) to the extent consistent with any applicable agency requirements and standards of conduct, permit employees or former employees of the laboratory to participate in efforts to commercialize inventions they made while in the service of the United States.

A Government-owned, contractor-operated laboratory that enters into a cooperative research and development agreement under subsection (a)(l) of this section may use or obligate royalties or other income accruing to such laboratory under such agreement with respect to any invention only (i) for payments to inventors; (ii) for the purposes described in section 3710c(a)(l)(B)(i), (ii), and (iv) of this title; and (iii) for scientific research and development consistent with the research and development mission and objectives of the laboratory.

(c) Contract considerations

(1) A Federal agency may issue regulations on suitable procedures for implementing the provisions of this section; however, implementation of this section shall not be delayed until issuance of such regulations.

(2) The agency in permitting a Federal laboratory to enter into agreements

under this section shall be guided by the purposes of such regulations.

(3)

(A) Any agency using the authority given it under subsection (a) of this section shall review standards of conduct for its employees for resolving potential conflicts of interest to make sure they adequately establish guidelines for situations likely to arise through the use of this authority, including but not limited to cases where present or former employees or their partners negotiate licenses or assignments of titles to inventions or negotiate cooperative research and development agreements with Federal agencies (including the agency with which the employee involved is or was formerly employed).

(B) If, in implementing subparagraph (A), an agency is unable to resolve potential conflicts of interest within its current statutory framework, it shall propose necessary statutory changes to be forwarded to its authorizing committees in Congress.

(4) The laboratory director in deciding what cooperative research and development agreements to enter into shall

(A) give special consideration to small business firms, and consortia involving small business firms; and

(B) give preference to business units located in the United States which agree that products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions will be manufactured substantially in the United States and, in the case of any industrial organization or other person subject to the control of a foreign company or government, as appropriate, take into consideration whether or not such foreign government permits United States agencies, organizations, or other persons to enter into cooperative research and development agreements and licensing agreements.

(5)

(A) If the head of the agency or his designee desires an opportunity to disapprove or require the modification of any such agreement presented by the director of a Government-operated laboratory, the agreement shall provide a 30-day period within which such action must be taken beginning on the date the agreement is presented to him or her by the head of the laboratory concerned.

(B) In any case in which the head of an agency or his

designee disapproves or requires the modification of an agreement presented, by the director of a Government-operated laboratory under this section, the head of the agency or such designee shall transmit a written explanation of such disapproval or modification to the head of the laboratory concerned.

(C)

(i) Any agency which has contracted with a non-Federal entity to operate a laboratory shall review and approve, request specific modifications to, or disapprove a joint work statement that is submitted by the director of such laboratory within 90 days after such submission. In any case where an agency has requested specific modifications to a joint work statement, the agency shall approve or disapprove any resubmission of such joint work statement within 30 days after such resubmission, or 90 days after original submission, whichever occurs later. No agreement may be entered into by a Government-owned, contractor-operated laboratory under this section before both approval of the agreement under clause (iv) and approval under this clause of a joint work statement.

(ii) In any case in which an agency which has contracted with a non-Federal entity to operate a laboratory disapproves or requests the modification of a joint work statement submitted under this section, the agency shall promptly transmit a written explanation of such disapproval or modification to the director of the laboratory concerned.

(iii) Any agency which has contracted with a non-Federal entity to operate a laboratory or laboratories shall develop and provide to such laboratory or laboratories one or more model cooperative research and development agreements, for the purposes of standardizing practices and procedures, resolving common legal issues, and enabling review of cooperative research and development agreements to be carried out in a routine and prompt manner.

(iv) An agency which has contracted with a non-Federal entity to operate a laboratory shall

review each agreement under this section. Within 30 days after the presentation, by the director of the laboratory, of such agreement, the agency shall, on the basis of such review, approve or request specific modification to such agreement. Such agreement shall not take effect before approval under this clause.

(v) If an agency fails to complete a review under clause (iv) within the 30-day period specified therein, the agency shall submit to the Congress, within 10 days after the end of that 30-day period, a report on the reasons for such failure. The agency shall, at the end of each successive 30-day period thereafter during which such failure continues, submit to the Congress another report on the reasons for the continuing failure. Nothing in this clause relieves the agency of the requirement to complete a review under clause (iv).

(vi) In any case in which an agency which has contracted with a non-Federal entity to operate a laboratory requests the modification of an agreement presented under this section, the agency shall promptly transmit a written explanation of such modification to the director of the laboratory concerned.

(6) Each agency shall maintain a record of all agreements entered into under this section.

(7)

(A) No trade secrets or commercial or financial information that is privileged or confidential, under the meaning of section 552(b)(4) of Title 5, which is obtained in the conduct of research or as a result of activities under this chapter from a non-Federal party participating in a cooperative research and development agreement shall be disclosed.

(B) The director, or in the case of a contractor-operated laboratory, the agency, for a period of up to 5 years after development of information that results from research and development activities conducted under this chapter and that would be a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-Federal party participating in a cooperative research and development agreement, may provide

appropriate protection against the dissemination of such information, including exemption from subchapter II of chapter 5 of Title 5.

(d) Definitions As used in this section—

(1) the term "cooperative research and development agreement" means any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory; except that such term does not include a procurement contact or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of Title 31;

(2) the term "laboratory" means—

(A) a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government;

(B) a group of Government-owned, contractor-operated facilities under a common contract, when a substantial purpose of the contract is the performance of research and development for the Federal Government; and

(C) a Government-owned, contractor-operated facility that is not under a common contract described in subparagraph (B), and the primary purpose of which is the performance of research and development for the Federal Government, but such term does not include any facility covered by Executive Order No. 12344, dated February 1, 1982, pertaining to the Naval nuclear propulsion program; and

(3) the term "joint work statement" means a proposal prepared for a Federal agency by the director of a Government-owned, contractor-operated laboratory describing the purpose and scope of a proposed cooperative research and development agreement, and assigning rights and responsibilities among the agency, the laboratory, and any other party or parties to the proposed agreement.

(e) Determination of laboratory missions

For purposes of this section, an agency shall make separate determinations of the mission or missions of each of its laboratories.

(f) Relationship to other laws

Nothing in this section is intended to limit or diminish existing authorities of any agency.

(g) Principles

In implementing this section, each agency which has contracted with a non-Federal entity to operate a laboratory shall be guided by the following principles:

(1) The implementation shall advance program missions at the laboratory, including any national security mission.

(2) Classified information and unclassified sensitive information protected by law, regulation, or Executive order shall be appropriately safeguarded

(Pub.L. 96-480, § 12, as added and renumbered § 11, Pub.L. 99-502, §§ 2, 9(e)(1), Oct. 20, 1986, 100 Stat. 1785, 1797; renumbered § 12, Pub.L. 100-418, Title V, § 5122(a)(1), Aug. 23, 1988, 102 Stat. 1438; Pub.L. 100-519, Title III, § 301, Oct. 24, 1988, 102 Stat. 2597; Pub.L. 101-189, Div. C, Title XXXI, § 3133(a), (b), Nov. 29, 1989, 103 Stat. 1675-1677.)

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EXECUTIVE ORDERS
EXECUTIVE ORDER NO. 12591

Apr. 10, 1987, 52 F.R. 13414, as amended Ex.Ord. No. 12618,

Dec. 22, 1987, 52 F.R. 48661

FACILITATING ACCESS TO SCIENCE AND TECHNOLOGY

By the authority vested in me as President by the Constitution and laws of the United States of America, including the Federal Technology Transfer Act of 1986 [Public Law 99-502] [Pub.L. 99-502, Oct. 20, 1986, 100 Stat. 1785], the Trademark Clarification Act of 1984 [Public Law 98-260] [Pub.L. 98-620, Nov. 8, 1984, 98 Stat. 3335], and the University and Small Business Patent Procedure Act of 1980 [Public Law 96-517] [Pub.L. 96-517, Dec. 12, 1980, 94 Stat. 3015], and in order to ensure that Federal agencies and laboratories assist universities and the private sector in broadening our technology base by moving new knowledge from the research laboratory into the development of new products and processes, it is hereby ordered as follows:

Section 1. Transfer of Federally Funded Technology

(a) The head of each Executive department and agency, to the extent permitted by law, shall encourage and facilitate collaboration among Federal laboratories, State and local governments, universities, and the private sector, particularly small business, in order to assist in the transfer of technology to the marketplace.

(b) The head of each Executive department and agency shall, within overall funding allocations and to the extent permitted by law:

(1) delegate authority to its government-owned, government-operated Federal laboratories:

(A) to enter into cooperative research and development agreements with other Federal laboratories, State and local governments, universities, and the private sector; and

(B) to license, assign, or waive rights to intellectual property developed by the laboratory either under such cooperative research or development agreements and

from within individual laboratories.

(2) identify and encourage persons to act as conduits between and among Federal laboratories, universities, and the private sector for the transfer of technology developed from federally funded research and development efforts;

(3) ensure that State and local governments, universities, and the private sector are provided with information on the technology, expertise, and facilities available in Federal laboratories;

(4) promote the commercialization, in accord with my Memorandum to the heads of Executive Departments and Agencies of February 18, 1983, of patentable results of federally funded research by granting to all contractors, regardless of size, the title to patents made in whole or in part with Federal funds, in exchange for royalty-free use by or on behalf of the government;

(5) administer all patents and licenses to inventions made with federal assistance, which are owned by the non-profit contractor or grantee, in accordance with Section 202(c)(7) of Title 35 of the United States Code as amended by Public Law 98-620 [35 U.S.C.A. § 202(c)(7)], without regard to limitations on licensing found in that section prior to amendment or in Institutional Patent Agreements now in effect that were entered into before that law was enacted on November 8, 1984, unless, in the case of an invention that has not been marketed, the funding agency determines, based on information in its files, that the contractor or grantee has not taken adequate steps to market the inventions, in accordance with applicable law or an Institutional Patent Agreement;

(6) implement, as expeditiously as practicable, royalty-sharing programs with inventors who were employees of the agency at the time their inventions were made, and cash award programs; and

(7) cooperate, under policy guidance provided by the Office of Federal Procurement Policy, with the heads of other affected departments and agencies in the development of a uniform policy permitting Federal contractors to retain rights to software, engineering drawings, and other technical data generated by Federal grants and contracts, in exchange for royalty-free use by or on behalf of the government.

Sec. 2. Establishment of the Technology Share Program

The Secretaries of Agriculture, Commerce, Energy, and Health and Human Services and the Administrator of the National Aeronautics and Space Administration shall select one or more of their Federal laboratories to participate in the Technology Share Program. Consistent with its mission and policies and within its overall funding allocation in any year, each Federal laboratory so selected shall:

(a) Identify areas of research and technology of potential importance to long-term national economic competitiveness and in which the laboratory possesses special competence and/or unique facilities;

(b) Establish a mechanism through which the laboratory performs research in areas identified in Section 2(a) as a participant of a consortium composed of United States industries and universities. All consortia so established shall have, at a minimum, three individual companies that conduct the majority of their business in the United States; and

(c) Limit its participation in any consortium so established to the use of laboratory personnel and facilities. However, each laboratory may also provide financial support generally not to exceed 25 percent of the total budget for the activities of the consortium. Such financial support by any laboratory in all such consortia shall be limited to a maximum of $5 million per annum.

Sec. 3. Technology Exchange — Scientists and Engineers

The Executive Director of the President's Commission on Executive Exchange shall assist Federal agencies, where appropriate, by developing and implementing an exchange program whereby scientists and engineers in the private sector may take temporary assignments in Federal laboratories, and scientists and engineers in Federal laboratories may take temporary assignments in the private sector.

Sec. 4. International Science and Technology

In order to ensure that the United States benefits from and fully exploits scientific research and technology developed abroad,

(a) The head of each Executive department and agency, when negotiating or entering into cooperative research and development agreements and licensing arrangements with foreign persons or industrial organizations (where these entities are directly or indirectly controlled by a foreign company or government], shall, in consultation with the United States Trade Representative, give appropriate considerations:

(1) to whether such foreign companies or governments permit and encourage United States agencies, organizations,

or persons to enter into cooperative research and development agreements and licensing arrangements on a comparable basis;

(2) to whether those foreign governments have policies to protect the United States intellectual property rights; and

(3) where cooperative research will involve data, technologies, or products subject to national security export controls under the laws of the United States, to whether those foreign governments have adopted adequate measures to prevent the transfer of strategic technology to destinations prohibited under such national security export controls, either through participation in the Coordinating Committee for Multilateral Export Controls (COCOM) or through other international agreements to which the United States and such foreign governments are signatories.

(b) The Secretary of State shall develop a recruitment policy that encourages scientists and engineers from other Federal agencies, academic institutions, and industry to apply for assignments in embassies of the United States; and

(c) The Secretaries of State and Commerce and the Director of the National Science Foundation shall develop a central mechanism for the prompt and efficient dissemination of science and technology information developed abroad to users in Federal laboratories, academic institutions, and the private sector on a fee-for-service

basis.

Sec. 5. Technology Transfer from the Department of Defense

Within 6 months of the date of this Order, the Secretary of Defense shall identify a list of funded technologies that would be potentially useful to United States industries and universities. The Secretary shall then accelerate efforts to make these technologies more readily available to United States industries and universities.

Sec. 6. Basic Science and Technology Centers

The head of each Executive department and agency shall examine the potential for including the establishment of university research centers in engineering, science, or technology in the strategy and planning for any future research and development programs. Such university centers shall be jointly funded by the Federal Government, the private sector, and where appropriate, the States and shall focus on areas of fundamental research and technology that are both scientifically promising and have the potential to contribute to the Nation's long-term economic competitiveness.

Sec. 7. Reporting Requirements

(a) Within 1 year from the date of this Order, the Director of the Office of Science and Technology Policy shall convene an interagency task force comprised of the heads of representative agencies and the directors of representative Federal laboratories, or their designees, in order to identify and disseminate creative approaches to technology transfer from Federal laboratories. The task force will report to the President on the progress of and problems with technology transfer from Federal laboratories.

(b) Specifically, the report shall include:

(1) a listing of current technology transfer programs and an assessment of the effectiveness of these programs;

(2) identification of new or creative approaches to technology transfer that might serve as model programs for Federal laboratories;

(3) criteria to assess the effectivenes's and impact on the Nation's economy of planned or future technology transfer efforts; and

(4) a compilation and assessment of the Technology Share Program established in Section 2 and, where appropriate, related cooperative research and development venture programs.

Sec. 8. Relation to Existing Law

Nothing in this Order shall affect the continued applicability of any existing laws or regulations relating to the transfer of United States technology to other nations. The head of any Executive department or agency may exclude from consideration, under this Order, any technology that would be, if transferred, detrimental to the interests of national security.

Ronald Reagan

Appendix B.
Excerpts from DOC Technology Policy Office re: CRADAs and Intellectual Property Licensing

Two Categories of International Technology Transfer: Federal Laboratory Technology Transfer Activities and International Science and Technology Agreements

1. Scope:

This review covers two general types of technology transfer interactions between federal agencies and foreign public and private organizations. The first type involves transactions pursuant to federal agency authority to transfer intellectual property arising from agency research to the private sector for commercial development and application. The second category consists of scientific and technological activities, primarily between U.S. government agencies and foreign government organizations, pursuant to bilateral agreements between the governments. These two types of transactions will be discussed separately.

2. Federal Laboratory Technology Transfer: Cooperative Research and Development Agreements and Intellectual Property Licensing

Federal research and development accounts for only a small part of the international technology transfers occurring in the United States today. Federal expenditures on research and development continue to decline both in real terms and as a fraction of total expenditures in the U.S. and accounted for no more than 30 percent of the national total in 1997 and for an even smaller percentage if testing of weapons systems is excluded.[1]

The information produced by the research work performed and supported by the federal government is made available to the public, domestic and international, in many different ways-- ranging from formal agency publications to articles published by the researchers in professional journals and presentations made at seminars by those researchers. Technology transfers also occur informally as a result of personal contacts between federal researchers and others interested in their work.

One subset of these transfers involves efforts by the federal government to transfer its knowledge to the private sector for commercial development. These transfers can occur through the licensing of intellectual property, collaborative research efforts (using the CRADA mechanism or for NASA, through Space Act Agreements), privately funded work to be performed by federal researchers (often called "Work for Others"), private use of unique federal research facilities and personnel exchanges. The transfer of technology through licensing of intellectual property and collaborative research under CRADAs are still relatively new and less frequently used mechanisms than the other, less formal mechanisms for technology transfer, but they are more visible and easier to quantify. They may also involve important areas of knowledge with great commercial potential and thus attract more public attention than the other modes of transfer.

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[1] National Science Board, *Science and Engineering Indicators-1998*, Arlington, VA: national Science Foundation, 1998 (NSB 98-1) pp. 4-2-4-9.

The balance of this section describes the legal and regulatory context for the CRADA mechanism and for intellectual property licensing, describes the apparent magnitude of foreign participation in them, and the practices of the agencies in dealing with the issues raised by foreign participation.

2.1. Legal and Regulatory Context for CRADAs and Licensing

2.1.1. Congressional Intent: Enhanced Domestic Industrial Competitiveness

The laws authorizing formal technology transfer activities involving federally funded intellectual property and industry collaboration with federal laboratories were enacted beginning in the 1980's. The objective was to provide additional sources of new technologies for U.S. industry, which was then beginning to feel the full force of foreign competition. In passing the first of these laws, the Bayh-Dole Act, Congress observed:

> Ultimately, it is believed that these improvements in Government patent policy will lead to greater productivity in the United States, provide new jobs for our citizens, create economic growth, foster increased competition, make Government research and development contracting more competitive, and stimulate a greater return on the billions of dollars spent each year by the Government on its research and development programs. S. Rep. No. 96-517 , 96th Cong. 1st Sess. (1979).

In passing the later Federal Technology Transfer Act, Senator Hollings, one of the bill's sponsors, expressed similar objectives, stating, "At a time when the U.S. economy faces unprecedented foreign competition, the Federal Technology Transfer Act will help government, industry and academia work together to maintain America's technological leadership." Cong. Rec., 99th Cong., 2nd Sess., S-15131 (Oct. 3, 1986)

2.1.2. Federal Agency Licensing of Intellectual Property (the Bayh-Dole Act)

The licensing of intellectual property arising from federally funded research can occur in two ways, depending on whether the intellectual property originated directly from the work of federal employees working in federal laboratories or from federally funded work performed by others. The former category includes the employees of all GOGO (Government-owned, Government-operated) laboratories. The latter category includes federally funded work performed by non-federal parties operating federal GOCO (Government-owned, Contractor-operated) laboratories[2]. Many of the large DOE laboratories, such as Los Alamos, Sandia and Livermore, along with Federally Funded Research and Development Centers (FFRDC) such as NASA's Jet Propulsion Laboratory, fall into this category.

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[2] This category of licensing also includes the licensing of federally funded inventions by universities and others receiving grants and other financial awards from federal agencies. However, that category of licensing activities is not addressed in this review.

2.1.2.1. Domestic Manufacture Preference for GOGO Laboratories

If the intellectual property is owned by a federal agency, as in the case of inventions arising in the GOGO laboratories, that agency is authorized by the Bayh-Dole Act to grant exclusive or nonexclusive licenses to others. 35 U.S.C. §§ 207-209; 37 CFR 404. Because Congress intended the knowledge licensed in this way to provide a competitive boost to domestic industries, it included limits on the scope of licensing under the law designed to achieve that purpose. With respect to agency licensing of intellectual property, the law states that an agency

> shall normally grant the right to use or sell any federally owned invention in the United Sate only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States. 35 U.S.C. § 209(b).

This initial expression of Congress on this subject is directed to ensuring that, when an agency licensed a party to use or sell an invention in the United States, resulting products would be "manufactured substantially" in the United States. The law and implementing regulations provide a preference for small business licensees and, in fact, the great majority of licenses entered into by the agencies are with small businesses.

The law and regulations also require the giving of public notice when an agency is contemplating the granting of an exclusive license, thus affording interested parties an opportunity to seek a license for themselves or to oppose the proposed grant of exclusivity. In the agencies experience, the notice procedure has been extremely useful in helping them to discharge their licensing responsibilities and in some instances has helped them to identify small domestic firms better able to commercialize the technology than other larger domestic and foreign applicants.

2.1.2.2. Domestic Manufacture Preference for GOCO Laboratories

Intellectual property originating at DOE's GOCO laboratories presents a more complicated legal situation. If the operator of the laboratory is a non-profit (university), it would be able to claim rights to its inventions under the Bayh Dole Act and license those rights as provided for by that law unless DOE applied the "exception" allowed in subsection 35 USC 202(a)(iv). Under that exception, unless a non-profit, laboratory operating contractor agree to fund the costs for licensing and patenting activities from their own institutional funds, DOE applies its "large business" contract provisions concerning intellectual property management to its contractors. In the case of such GOCO contractors, rights similar to those granted under Bayh-Dole are generally available on the basis of patent waivers provided by the DOE. For example, DOE provides intellectual property rights waivers to such laboratory operators and imposes requirements of substantial manufacture in the United States consistent with the requirements applicable to other federal laboratory operators. For DOE's non-profit operators funding their own patenting and licensing activities, the full rights provided under Bayh-Dole are applicable.

The provisions of the Bayh-Dole Act applicable to universities and relating to domestic manufacture are slightly different from those applicable to the federal agencies. The law provides that neither such entities, nor their assignees,

> shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. 35 U.S.C. §204.

This language provides more explicit authority for the waiver of the "substantial manufacturing" requirement than is contained in the provisions governing agency licensing practices. However DOE, in overseeing the management of its GOCO laboratories, applies the provisions of 35 U.S.C. 204 and 209 to its contractors, and has provided written guidance concerning the circumstances under which a waiver of the "substantial manufacturing" requirement can be granted. If those provisions and/or circumstances cannot be met, then DOE's laboratories must first secure the approval of the Department for each specific waiver sought under that guidance.

2.1.3. Cooperative Research and Development Agreements and Intellectual Property

A second set of laws governs the use of Cooperative Research and Development Agreements (CRADAs) by the federal GOGO and GOCO laboratories. The Federal Technology Transfer Act of 1986 made these agreements available for use by GOGO laboratories. The National Competitiveness Technology Transfer Act of 1989 later made these agreements available for use by GOCO laboratories as well. Once again, there are differences in the standards and procedures for the two categories of laboratories.

2.1.3.1. Requirements Applicable to Both GOGO and GOCO Laboratories

In both GOGOs and GOCOs, the laboratories are obligated to give preference to U.S.-located business entities in selecting parties to these agreements. More specifically, the laboratories are required to:

> give preference to business units located in the United States which agree that products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions will be manufactured substantially in the United States and, in the case of any industrial organization or other person subject to the control of a foreign company or government, as appropriate, to take into consideration whether or not such foreign

government permits United States agencies, organizations, or other persons to enter into cooperative research and development agreements and licensing agreements. 15 U.S.C. § 3710a(c)(4)(B).

Once a CRADA is entered into, the laboratories are authorized to "negotiate licensing agreements" pursuant to the authorities of the Bayh Dole Act already discussed.[3] This triggers the "substantial manufacturing" requirements and other procedural requirements already discussed.

A second set of procedural requirements with respect to CRADAs is contained in Executive Order 12591.[4] That order, based on the Federal Technology Transfer Act and the Bayh-Dole Act and other executive orders implementing those laws, directs agency heads to delegate the necessary authorities to their laboratories to make the technology transfer mechanisms effective. It also contains special provisions designed "to ensure that the United States benefits from and fully exploits scientific research and technology developed abroad" in instances where CRADAs or licensing arrangements are negotiated with foreign persons or industrial organizations. Agencies are directed, to "give appropriate consideration" "in consultation with the United States Trade Representative" to several different factors:

(1) whether such foreign companies or governments permit U.S. participation in comparable cooperative research and licensing arrangements,

(2) whether the foreign governments "have policies to protect the United States intellectual property rights", and

(3) whether the foreign governments have "adequate measures" to prevent unauthorized transfers of technologies subject to U.S. national security export controls.

While these requirements are applicable to both licensing and CRADA activities, it appears that they are more often used in connection with CRADAs. It is likely that this is because of the infrequency of licensing intellectual property to foreign parties but more information is needed to be certain.

2.1.3.2. Special Requirements for GOCO Laboratories

The CRADA process has several special requirements applicable to GOCO labs. First, as noted in the discussion of patent licensing, the specific language defining the preference for domestic manufacturing where intellectual property is licensed is somewhat different from that applicable to GOGOs. Second, time limits are set for the approval of GOCO CRADAS (and the related joint work statements used by the DOE laboratories as a preliminary step to CRADAs). The joint work statement, which must clearly identify foreign entities involved in a CRADA, must be submitted to the DOE for approval, prior to the execution of the CRADA. The joint work statement must be approved or rejected for cause by the DOE within 90 days and the resulting CRADA must be approved for

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[3] More specifically, the laboratory is obligated "to grant, or agree to grant in advance, to a collaborating party patent licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory employee under the agreement, for reasonable compensation when appropriate." 15 U.S.C. §3710a(a)(2) and (b)(1).

[4] 52 Fed. Reg. 13414 (April 10, 1987)

signature by the laboratory director within an additional 30 days after being submitted to the DOE by the laboratory.

In addition, because of the complexity of the process when GOCO laboratories are involved, agencies with GOCO laboratories are required to develop "one or more model cooperative research and development agreements, for the purpose of standardizing practices and procedures, resolving common legal issues, and enabling review of cooperative research and development agreements to be carried out in a routine and prompt manner." 15 U.S.C. §3710a(c)(5)(C)(iii). Pursuant to this requirement, DOE has developed and given broad circulation to a model CRADA which has optional clauses designed to meet the different types of collaborative activities and/or needs of the private sector participants.

Appendix C.
USAF Decision Guide

International

CRDAs or Licenses with Foreign Persons or Organizations

Executive Order No. 12591, Section 4, establishes guidelines for negotiating or entering into CRDAs or licensing arrangements with foreign persons or industrial organizations. Furthermore, the Federal Technology Transfer Act of 1986 states preference should be given to foreign entities when they agree that products and inventions developed under a CRDA will be manufactured substantially in the United States provided the entity meets the guidelines below. The purpose of these guidelines is to ensure that the United States benefits from, and fully exploits, scientific technology developed abroad. By entering into cooperative agreements with foreign entities, the United States creates synergy between the best of the U.S. capabilities and that of the foreign partner.

Additional information must be collected when dealing with entities with foreign connections. The ORTA shall, in consultation with the U.S. trade representative, give appropriate consideration to three factors:

1. to whether such foreign companies or governments permit and encourage U.S. agencies, organizations, or persons to enter into CRDA and licensing arrangements on a comparable basis;

2. to whether those foreign governments have policies to protect the U.S. intellectual property rights; and

3. to whether the data and technology involved fall under national export control restrictions and whether the foreign governments have adopted adequate measures to prevent the transfer of strategic technology to destinations prohibited under such national security export controls, either through the New Forum for Multilateral Export Control or through other international agreements to which the United States and such foreign governments are signatories.

First, the laboratory must determine the status of the cooperating organization. Only non-government foreign entities qualify for CRDA partnerships with AFMC laboratories according to 15 USC § 3710a. The review process begins with a background check of proposed organization. Each AFMC laboratory is responsible for developing a production requirement, through HQ AFMC/INAT, for the Defense Intelligence Agency (DIA/PAQ-4B) to do background investigations on industrial organizations (see Production Requirement Sample below). When contacted by an AFMC technology-owning organization, and upon request, DIA researches the business affiliations of candidate CRDA-partner firms for foreign ownership (greater than 5 percent owned by a foreign entity) and for ties with unfriendly "front" companies. The request for DIA research should be

made as early as possible in the CRDA negotiation process. DIA requires the information from the cover page and the signature page of the CRDA document. Negative information from DIA on this investigation can "veto" any potential or actual CRDAs considered by the AFMC entity above. Upon determining that a foreign entity is a viable cooperative partner, the laboratory is required to follow all appropriate foreign disclosure and export control guidelines as well as ensure all information transfer mechanisms are in place.

Production Requirement Sample

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PRODUCTION REQUIREMENT

1. **PR Number:** E411-95-0027 (HQ Aeronautical Systems Center, Director of Intelligence) - Priority 2A

2. **Subject:** International Technology Transfer

3. **Customer's Organization:** Aeronautical Systems Center, Director of Intelligence (ASC/NAIC/POA), Attn: Ms Diane Arend, Stewart Hall, 2640 Loop Rd West, Wright-Patterson AFB, OH 45433-7106
Msg: NAIC WRIGHT-PATTERSON AFB OH//POA//
DOD Intelligence Information System-DLA69@DBMS-FTD.DODIIS
Unclassified E-Mail ARENDDL@AMC1.MAIL.WPAFB.AF.MIL
Classified FAX-DSN 785-3177 Comm (513) 255-3177
Unclassified FAX-DSN 785-3515 Comm (513) 255-3515
Phone/STU III--DSN 785-8113 Comm (513) 255-8113
NAIC ISS III User ID--DLA69

4. **Date of Request:** 950221

5. **Date Product Required:** 950601

6. **Form and Frequency of Response:**
Media: This product should be a hard-copy document, FAX, Message, or E-Mail.
Frequency: Monthly
Revised Product: N/A
Classification and Releasability of Product: The product may be classified up to SECRET/NOFORN/WNINTEL/NO CONTRACT.

7. **Statement of Requirement:** The purpose of this PR is to establish the requirement for short-notice responses to requests for verification of whether or not a business entity or organization, which wishes to enter into a Cooperative Research and Development Agreement (CRDA) or licensing agreement with ASC, is directly or indirectly controlled by a foreign company or government.

8. **Comments:** The information will be provided to the ASC Office of Research and Technology Applicaitons (ORTA) to prepare application assessments for selected R&D projects in which Wright Laboratory is engaged, and which (in the opinion of the Laboratory) may have potential commercial applications. The information is required to satisfy

UNCLASSIFIED

requirements for foreign technology transfer in U.S. Code Annotated Title XV. This PR supports the ASC Office of Research and Technology Applications. Modeling and simulation are not supported. This PR does not supersede a previous PR. This PR is not CIP-based. No documents exist which satisfy this requirement.

9. **Security Classification:** This PR is unclassified.

10. **Supporting Intelligence Office:**
HQ AFMC/INAT, Attn: Mrs Alice Rawls, 4225 Logistics Ave STE 11, Wright-Patterson AFB OH 45433-5750
Message Address: HQ AFMC WRIGHT PATTERSON AFB OH//INAT//
E-Mail Address: (Rawlsa@WPGATE1.WPAFB.AF.MIL)
DOD Intelligence Information System-RAR986@DBMS-FTD.DODIIS
Phone: DSN 787-5047, Comm (513) 257-5047
Classified FAX: DSN 986-1150, Comm (513) 476-1150
Unclassified FAX: DSN 787-2146, Comm (513) 257-2146

11. **Validation Office:** HQ AIA/DOXS, 102 Hall Blvd Suite 229, San Antonio,TX 78243-7029

12. **Primary IFC:** Not Applicable

13. **Other IFCs:** Not Applicable

14. **Primary AOR Codes:**

15. **Other AOR Codes:**

16. **Primary Country Code:** W

17. **Other Country Codes:** RS

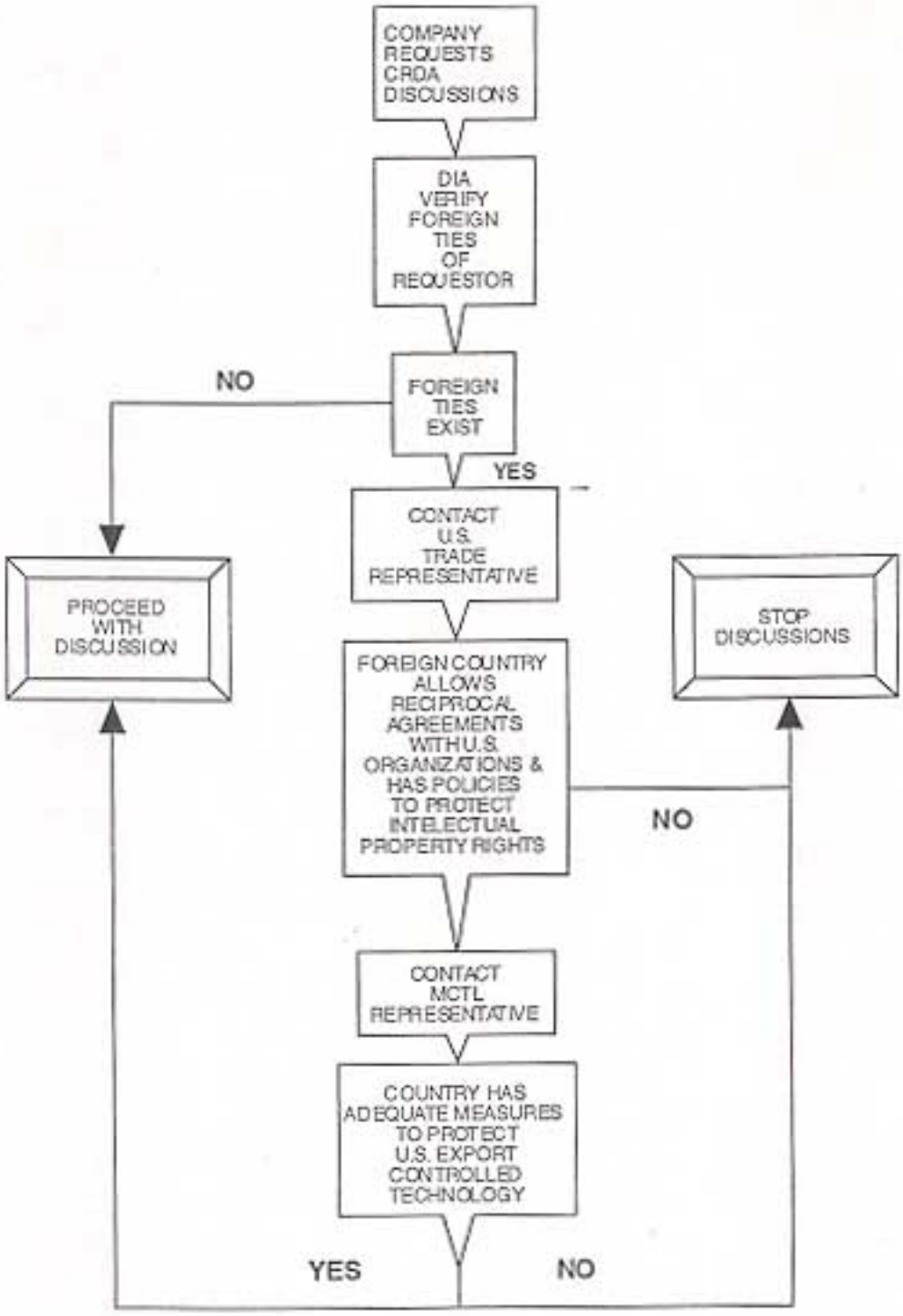
18. **Primary Production Center Assigned:** DIA

19. **Possible Collaborative Production Centers:** Not Applicable

20. **Date of Validation Office Assignment:**

21. **Date Customer Recertified the PR:**

Flow Chart for Negotiating or Entering into CRDAs or Licensing Arrangements with Foreign Persons or Industrial Organizations



CRADAs WITH NON-DOMESTIC PARTNERS

As of 10 Oct 98

Developed by HQ AFRL/XP/JA, AFSAC/IP, and SAF/IA/AQ

POC: Steve Guilfoos
HQ AFRL/ XPTT
DSN 986-9021

Email: guilfoos@afrl.af.mil

WHY?

- In order to safeguard our technologies and to assure that non-domestic potential partners meet existing trade export criteria and treaty conditions

The Process

- Approves the partner prior to final CRADA negotiations. It does not replace the existing CRADA signature and approval process
- Domestic partners, as determined by the first steps of this process, do not need to go through this process

TECHNOLOGY TRANSFER PROCESS FOR NON-DOMESTIC PARTNERS

- Directorate/Center performs self certification
- Directorate/Center sends package to AFSAC/IA
- AFSAC forwards package to SAF/IA for review and approval of partner

NEW

TECHNOLOGY TRANSFER PROCESS FOR NON-DOMESTIC PARTNERS

- Directorate/Center performs self certification
- DIA or AFOSI Filter
- Directorate/Center sends package to AFRL/XPTT

OLD #1

TECHNOLOGY TRANSFER PROCESS FOR NON-DOMESTIC PARTNERS

- AFRL/XPTT coordinates with AFOSR and AFRL/CC for approval
- Package is forwarded to AFSAC/IP for their approval/coordination with SAF/IA
- Package approved and Directorate/Center is notified

OLD #2

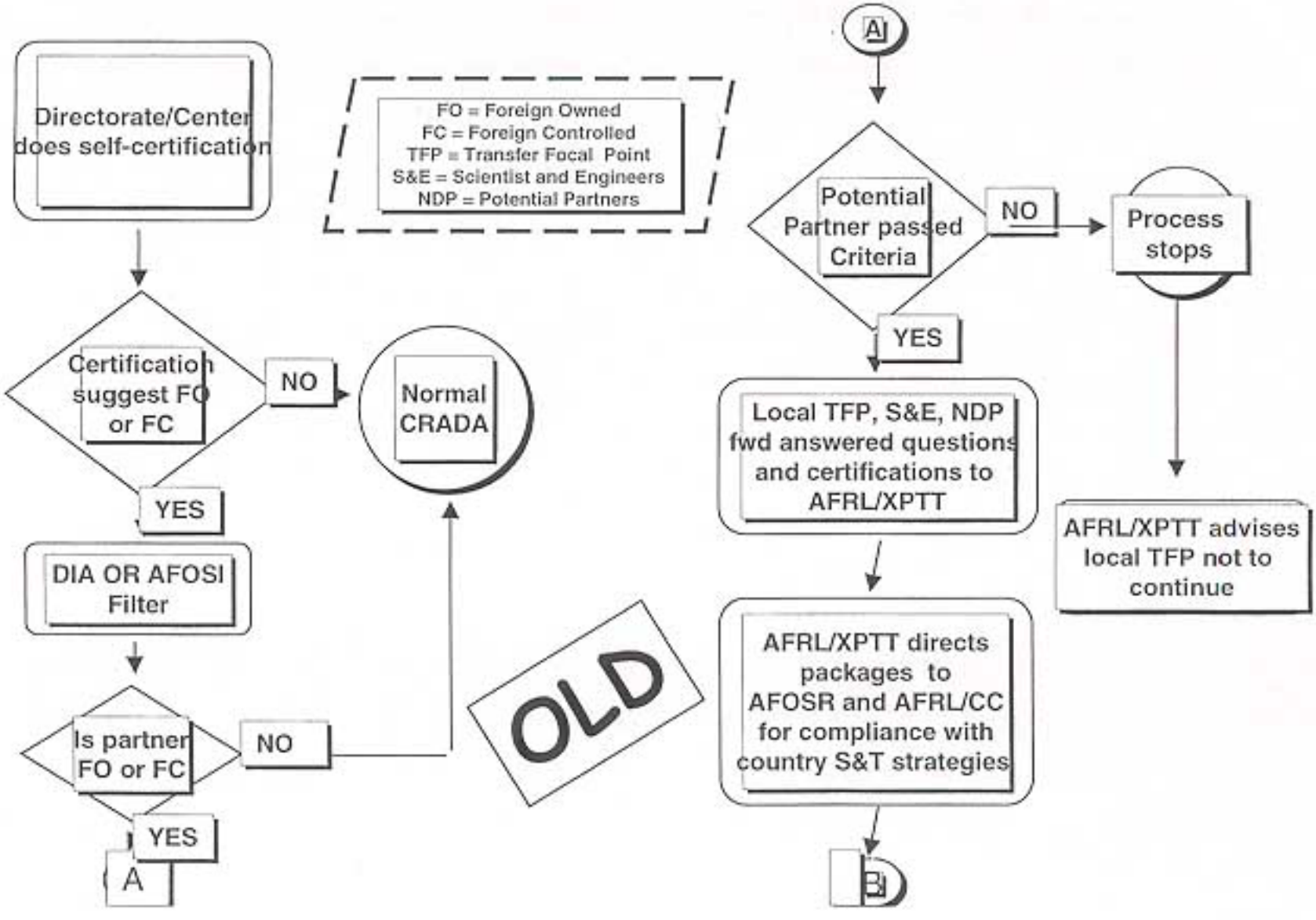
The Non-Domestic Technology Transfer Request Summary Sheet

- Required by SAF/IA
- Very important part of the package
- Will speed package through process
- Should be short and to the point
- Simple layout of items required
- Answer seven questions

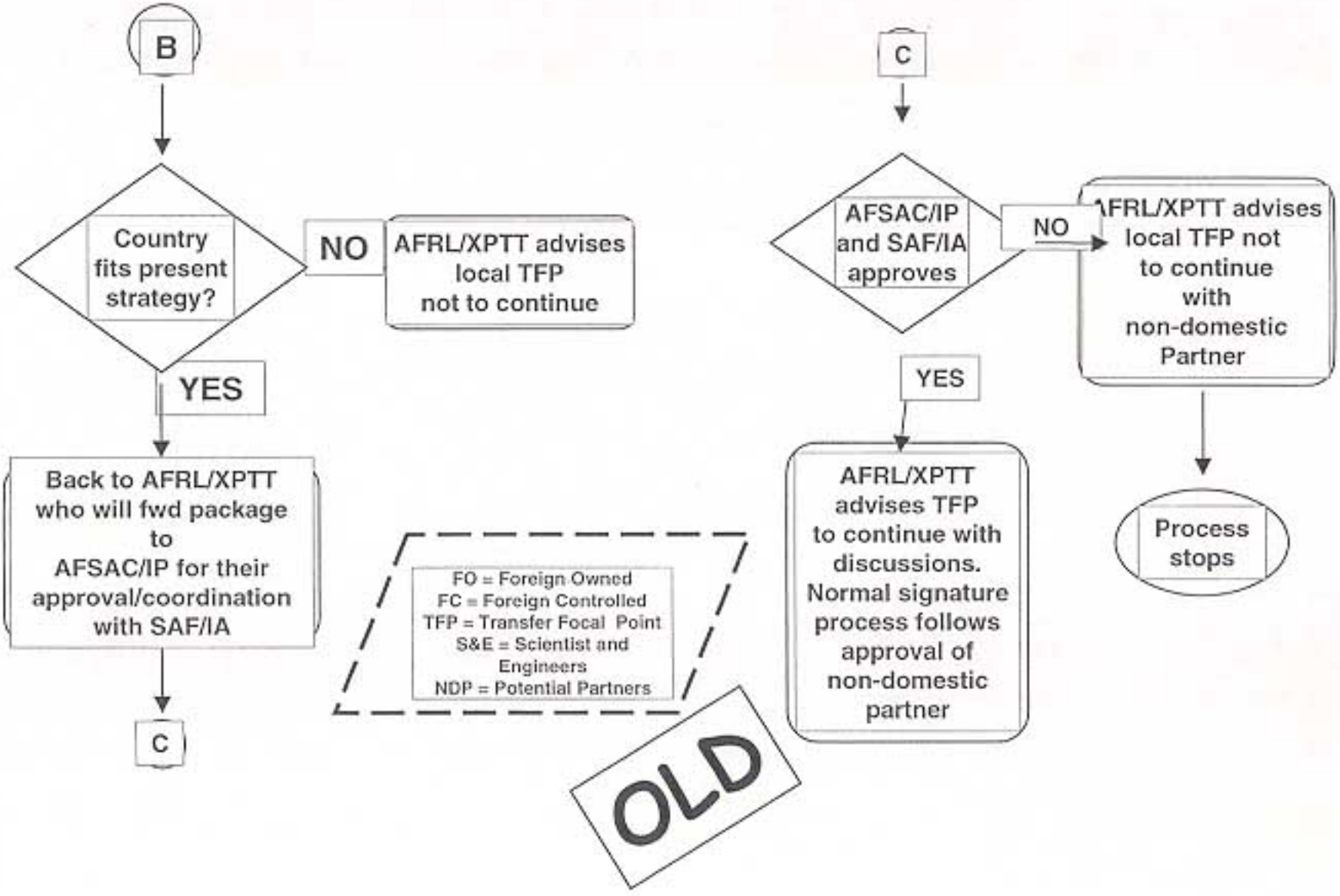
Request Summary Sheet Questions

1. Identify Foreign-ownership of potential collaborator
2. Country of origin
3. Name of technology involved
4. Detailed explanation of why collaborator is the best choice over potential domestic collaborators
5. Explanation of purpose and benefits
6. Information classification level
7. Whether technology is export controlled

TECHNOLOGY TRANSFER PROCESS FOR NON-DOMESTIC PARTNERS



TECHNOLOGY TRANSFER PROCESS FOR NON-DOMESTIC PARTNERS



Appendix D.
ONR CRADA Process for Foreign Participation

Navy Implementation

- **Laboratory Tasks**
  - Modify CRADA document
  - Determine if technology is export controlled
  - Provide 1-page summary
- **Headquarters Tasks**
  - Review CRADA
  - Coordinate with US Trade Representative
  - Authorize signature of CRADA

Navy Implementation: Laboratory

- **Modify CRADA document**
  - **7.2.6** [Non-Navy Partner] is **not** directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4.(a)).
  - **13.2.4.3** In the event that [Non-Navy Partner] or its successors or assignees shall become, during the term of this Agreement, directly or indirectly controlled by a **different** foreign company or government (Executive Order 12591, Section 4.(a)), [Non-Navy Partner] shall immediately notify [Navy Partner] to that effect. If **the foreign-controlled status of** [Non-Navy Partner] **changes** ~~**becomes foreign-controlled**~~ during the term of this Agreement, ...

Navy Implementation: Laboratory

- ***Determine if technology is export controlled by consulting***
  - 15 CFR Part 774 The Commerce Control List,
  - 22 CFR Part 121 U.S. Munitions Lists,
  - the DoD Military Critical Technology List
- **Provide 1-page summary that includes**
  - Brief description of CRADA purpose & scientific objectives
  - Statement of export control determination
  - Partner information (includes Partner name, address, POC (Name/Phone) and similar information for Affiliate/Owner (if appropriate)
  - Signature

MEMORANDUM September 21, 1998

To: Carol Balassa

From: William Clement ONR 362

Subj: CRADA between Naval Medical Research Institute and Smithkline Beecham Biologicals, S.A.

Encl: (1) Proposed CRADA between Naval Medical Research Institute and Smithkline Beecham

(2) Information on CRADA technology, export control and partner

(3) USTR clearance information

1. Enclosures (1) and (2) are submitted for your consideration under Executive Order 12591. We request approval to proceed with this CRADA with Smithkline Beecham. This CRADA will be placed with Smith Kline Beecham Biologicals, S.A. In Rixensart, Belgium. The parent company is located in London, England.

2. Articles 2 (summary), 3 (Background) and Appendix A (Statement of Work) summarize the collaborative effort proposed under the CRADA.

3. Enclosure (2) contains the foreign partner information for Smithkline Beecham.

4. Phone approval, (703) 696-4792, followed by written confirmation, enclosure 3, will be very much appreciated. I may be reached at the above number if there are any questions.

William S. Clement

FOREIGN INSTITUTE INFORMATION FOR CRADA BETWEEN NMRDC'S NMRI (NAVAL MEDICAL RESEARCH INSTITUTE) AND SKB (SMITHKLINE BEECHAM (SB))

Description

The Parties are collaborating in research and development on evaluation, expression, and testing of *Plasmodium falciparum* parasite antigens for their potential utility as components of Malaria Vaccines.

The Federal Technology Transfer Act of 1986, as amended, provides for making Federal laboratories' developments accessible to private industry, and to state and local governments, and for the improvement of economic, environmental and social well-being of the United States by stimulating the civil utilization of Federally-funded technology developments. NMRI has extensive expertise and information in Malaria Vaccines, and in keeping with the Federal Technology Transfer Act desires to make this expertise and technology available for use in the public sector.

Export Control Statement

After consultation with 15 CFR Part 799 Commodity Control List and Related Matters, U.S. Munitions List, and the DoD Military Critical Technologies List, it is my opinion that the technology, refrigerated storage of red cells, is not export controlled.

Partner Information

SmithKline Beecham (SB) is one of the world's leading healthcare companies. SB discovers, develops, manufactures and markets pharmaceuticals, vaccines, over-the-counter medicines and health-related consumer products, and provides healthcare services, including disease management, clinical laboratory testing, and pharmaceutical benefit management.

- Corporate headquarters: London, United Kingdom; U.S. headquarters: Philadelphia, PA.
- Employs 57,000 people world wide with operations in 160 countries (year end 1997).

ENCLOSURE (2)

United States Trade Representatative Clearance

For

Navy Cooperative Research and Development Agreement

Executive Order 12591 requires consultation with the United States Trade Representative when negotiating or entering into CRADAs with foreign persons or industrial organizations (where these entities are directly or indirectly controlled by a foreign company or government). The proposed CRADA between

Naval Medical Research Institute

And

Smithkline Beecham Biologicals, S.A.

Has been submitted and cleared for approval by the United States Trade Representative

_____

Name and Title

_____

Date

Please fax this document to William Clement at (703) 696-4884

ENCLOSURE (3)

Appendix E.
ATP Foreign Eligibility Guidelines

ADVANCED TECHNOLOGY PROGRAM

NISTIR-6099
ATP Eligibility Criteria for U.S. Subsidiaries of Foreign-owned Companies: Legislation, Implementation and Results

EXECUTIVE SUMMARY

Since 1990, the Advanced Technology Program (ATP) has been investing directly in the growth of the nation's economy by cost sharing with industry in the development of high-risk, enabling technologies that form the basis for new and improved products, manufacturing processes, and services. Congress created the ATP in the Omnibus Trade and Competitiveness Act of 1988 (P.L. 100-418, codified at 15 U.S.C. 278n) and charged the U.S. Department of Commerce's National Institute of Standards and Technology (NIST) with administering the program to help U.S. companies accelerate the creation and commercialization of highly innovative technologies with strong potential for generating broad-based economic benefits for the nation.

ATP multi-year awards are made to individual companies and to joint research and development ventures (hereafter referred to as "joint ventures") through a highly competitive, merit-based, peer-reviewed selection process. According to the ATP Statute (authorizing legislation), only U.S.-owned companies and U.S. subsidiaries of foreign-owned companies (i.e., U.S.-incorporated companies that are majority owned or controlled by individuals who are not citizens of the U.S.) are eligible to receive awards for technology development, provided selection criteria are met. The ATP bases its selection of all project proposals on how well each proposal addresses five selection criteria: scientific and technical merit; potential net broad-based economic benefits to the U.S.; adequacy of plans for eventual commercialization; level of commitment and organizational structure; and experience and qualifications. Proposals are evaluated against these criteria and those judged to have the highest merit receive further consideration and are referred to as "semifinalists." Semifinalists are invited to the ATP for an oral review after which all semifinalist proposals are scored and ranked. From the list of finalists, proposals are selected for awards.

All funded projects, regardless of the country of ownership of the participating companies, must score high against the five selection criteria outlined above. U.S. subsidiaries of foreign-owned companies must meet additional eligibility requirements, according to the ATP Statute. For an award to be given to a U.S. subsidiary of a foreign-owned company, the Secretary of Commerce (or the Secretary's designee) must find that the company's participation is in the economic interest of the U.S. Furthermore, the Secretary of Commerce (or the Secretary's designee) must find that the country of incorporation of the foreign parent provides U.S.-owned companies: opportunities comparable to those provided to any other company to participate in programs similar to the ATP; local investment opportunities comparable to those provided to any other company; and, adequate and effective protection of their intellectual property rights. The first special eligibility requirement is already covered under the first of five project selection criterion - - "potential for net broad-based benefits to the U.S." - - focused on the project's impact on the U.S. economy as described above. However, this requirement is reviewed and scrutinized, taking into account the likely impact of foreign ownership of the particular foreign-owned company in question. The determination of eligibility for foreign-owned companies will be referred to herein as "the foreign eligibility finding."

In implementing its legislative mandate, the ATP initiates a foreign eligibility finding in situations where a foreign-owned company is selected as a finalist in a competition; or seeks to join an existing ATP joint venture project. In addition, if a U.S.-owned company which is already participating in a project experiences a change ownership and becomes majority-owned or -controlled by non-U.S. citizens, and wishes to continue its participation in the project, a foreign eligibility finding is initiated. Program implementation of this statutory requirement is carried out by the Director of the ATP, the Secretary of Commerce's designee, who bases the determination of a foreign-owned company's eligibility to receive an award on evidence gathered from a number of sources. For a foreign eligibility finding to be determined positive, each of the four special eligibility requirements must be found positive. A positive foreign eligibility finding means that the applicant is determined eligible to participate in an ATP-supported project, provided all other requirements - - common to all ATP award candidates - - are met.

Since its inception, the ATP has received over 3,000 applications submitted to thirty competitions. ATP's fiscal year 1998 budget is $192.5 million. Through 1997, the ATP has funded 352 projects, involving 842 participants, including for-profit companies, universities, and non-profit organizations - - not counting subcontractors, and informal partners and collaborators. Slightly over $2.3 billion in advanced research has been committed, with industry providing more than half the funds and the ATP supporting the remainder.

The ATP has carried out a total of fifty-one foreign eligibility findings through 1997. Of these, forty-eight foreign eligibility findings were for companies whose projects were selected as finalists for awards. The rest were for companies seeking to join existing projects, or to continue participating in existing ATP projects after experiencing a change in their ownership status. The total number of findings does not correspond directly to the number of projects in which U.S. subsidiaries of foreign-owned companies sought participation. There are a few instances in which joint venture projects had more than one foreign-owned company seeking participation. Also note that the total number of findings does not correspond directly to the number of foreign-owned companies currently participating in projects for a variety of reasons. Some findings, for example, were determined to be positive, but for other reasons the foreign-owned company never participated in the project. Of the fifty-one foreign eligibility findings carried out through 1997, only two were negative. h of these findings were for Japanese-owned firms, and they did not pass on the basis of the national policies of Japan rather than any shortcomings of the companies themselves. Of the total 352 projects in ATP's portfolio, twenty-nine active and completed projects involve thirty-three participants who are U.S. subsidiaries of foreign-owned companies. They are participating in 18 out of a total of 119 joint venture projects and 11 out of a total of 233 single-company projects. These participants represent twenty-one distinct foreign-owned companies from twelve different countries. A few of these companies are participating in more than one project.

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Go to Chapter 1: OVERVIEW OF THE U.S. ADVANCED TECHNOLOGY PROGRAM

ADVANCED TECHNOLOGY PROGRAM

ADVANCED TECHNOLOGY PROGRAM

NISTIR-6099
ATP Eligibility Criteria for U.S. Subsidiaries of Foreign-owned Companies: Legislation, Implementation and Results

1. OVERVIEW OF THE U.S. ADVANCED TECHNOLOGY PROGRAM

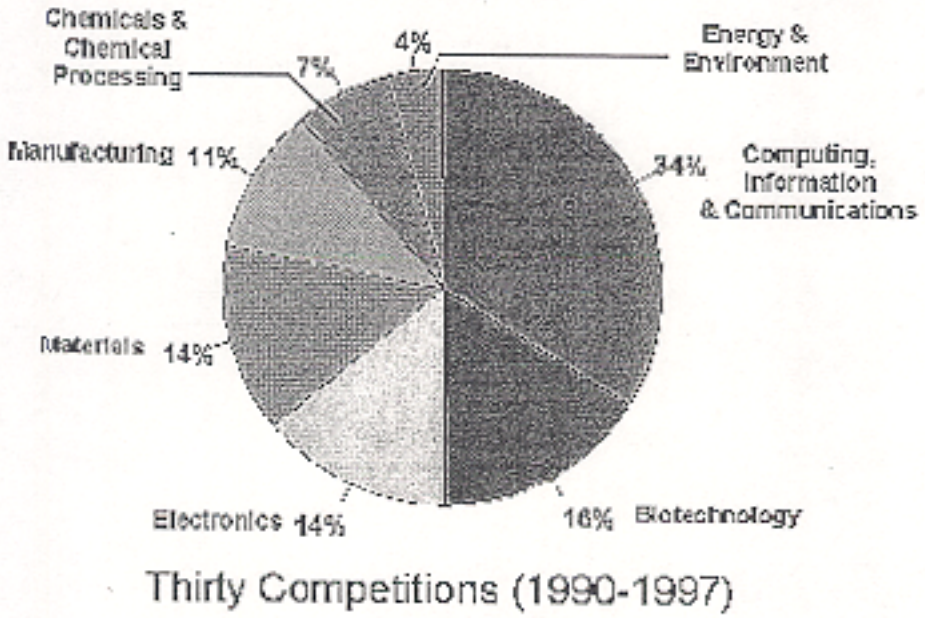
Congress created the Advanced Technology Program (ATP) in the Omnibus Trade and Competitiveness Act of 1988 (P.L. 100-418), codified in Title 15 of the United States Code, Section 278n (15 U.S.C. 278n), and amended in the American Technology Preeminence Act of 1991 (P.L. 102-245). The ATP invests directly in the growth of the nation's economy by cost sharing with industry in the development of high-risk, enabling technologies. These technologies, once developed, are expected to form the basis for new and improved products, manufacturing processes, and services. Stated in another way, the goal of ATP's cost-shared investment is to help U.S. companies accelerate the creation and commercialization of highly innovative technologies with strong potential for generating broad-based economic benefits for the nation. These broad-based economic benefits are expected to extend significantly beyond the direct benefits to companies receiving awards.

The ATP relies on U.S. companies to conceive and propose technology development projects, carry out the research of funded projects, and share in the costs. U.S. companies seeking financial assistance from the ATP must submit proposals that address published selection criteria, including a detailed research plan; a plan for future commercialization of the proposed technology; and an explanation of how the technology is expected to result in net broad-based economic benefits for the nation. The ATP emphasizes integrated planning across all aspects of a project by encouraging participants to form a team that includes people who are involved with the development of the technology and others who will be responsible for the eventual commercialization of the proposed technologies. Although funding is only provided for research activities, the ATP requires at least preliminary upfront planning for downstream activities, such as marketing, production, and distribution, for at least one potential application of each technology proposed to be developed during the project. It encourages applicants to incorporate into the process the voice of the customer or end-user as early as possible. If companies successfully complete their research projects, they - - or their allies or licensees - - are expected to undertake subsequent commercialization activities with private-sector or other sources of funds and to promote the diffusion of the technologies for broader benefits to the U.S. economy.

Proposals are accepted only in response to announced competitions, of which there are two types: general competitions, open to proposals in all areas of technology, and focused program competitions, open only to proposals that support specific, pre-defined technology and business goals. ATP awards are made to individual companies and to joint research and development ventures (hereafter referred to as "joint ventures") through a highly competitive, merit-based, peer-reviewed selection process. Only U.S.-owned companies and U.S. subsidiaries of foreign-owned companies that meet ATP's selection requirements are eligible to receive awards. Single-company proposers that are small-to-medium size can receive up to $2 million in ATP support for direct project costs over three years, but must cover their own indirect costs, whatever they may be.

Beginning in 1998, single-company proposers that are large in size must cover a minimum of sixty percent of total project costs. [1] Joint venture proposers - - comprised of a minimum of two, separately-owned, ...-profit companies both performing the research and sharing in the costs of the research, often in ...bination with other companies, universities and non-profit research laboratories as additional partners - - can propose projects of any size for up to five years of funding, but must cover more than fifty percent of total project costs.

With a Congression appropriatio of $10 million in FY 1990, the ATP held its first competition in 1990, and selected 11 projects for awards. Since then, the ATP has received over 3,000 ...plications ...mitted in thirty competition ATP's FY 1998 appropriatio is $192.5 million.



Through 1997, the ATP has funded 352 projects, involving 842 participants, including for-profit companies, universities, and non-profit organizations - - not counting subcontractors and informal partners and collaborators. Slightly over $2.3 billion in advanced research has been committed, with industry providing more than half the funds and the ATP supporting the remainder. Over half of the projects funded - - 52.5% - - are led by small businesses. In addition, over 100 universities and academic institutions have been involved in ATP projects through 1997, either as subcontractors to private companies or as members of industry-led joint ventures. By technology area, of the 352 projects funded, 34% involve computing, information, & communications, 16% biotechnology, 14% electronics, 14% materials, 11% manufacturing, 7% chemicals & chemical processing, and 4% energy & environment, with many overlaps across the areas.

---

1. The change in cost-share ratio for single-company proposers that are large in size provides an incentive for large companies to participate in joint ventures and is one of several policy changes and initiatives designed to strengthen the ATP which was announced by Secretary of Commerce William M. Daley in July 1997. These policy changes and initiatives are the result of a sixty-day study of the ATP which was initiated ... Secretary Daley in March 1997 to solicit comments on the program from the public on improving the program while ensuring that its fundamental strengths remain unchanged. Additional details can be found on ATP's home page on the World Wide Web, specifically, http://www.atp.nist.gov/www/press/n97-32.htm.

ADVANCED TECHNOLOGY PROGRAM

ADVANCED TECHNOLOGY PROGRAM

NISTIR-6099
ATP Eligibility Criteria for U.S. Subsidiaries of Foreign-owned Companies: Legislation, Implementation and Results

2. ATP'S PUBLISHED PROJECT SELECTION CRITERIA THAT APPLY TO ALL

This section provides ATP's published criteria -- *that apply all participating companies regardless of country of ownership* -- for selecting proposed technology development projects as background and context for a discussion of additional eligibility requirements that apply only to foreign-owned companies. The ATP bases its selection of all project proposals on how well each proposal addresses five selection criteria established in the ATP Rule.[2] The five selection criteria, with their respective weights in parentheses, are scientific and technical merit (30%); potential net broad-based economic benefits to the U.S. (20%); adequacy of plans for eventual commercialization (20%); level of commitment and organizational structure (20%); and experience and qualifications (10%).[3]

Project Selection Criteria

- Scientific and Technical Merit - 30%
- Broad-based U.S. Economic Benefits - 20%
- Commercialization Planning - 20%
- Level of Commitment and Organizational Structure - 20%
- Experience and Qualifications - 10%

Scientific and technical merit is determined by assessing the quality, innovativeness, and cost-effectiveness of the proposed technical plan; its technical risk and feasibility; the appropriateness of the project's technical risk and feasibility; the plan's coherency and clarity of vision of technical objectives; whether the project has an integrated, forward-looking, team approach; and, the potential broad impact on U.S. technology and knowledge base. Potential net broad-based economic benefits to the U.S. are assessed based on the potential of the project to improve U.S. economic growth and productivity; timeliness of the proposed work; the degree to which ATP support is essential; strength of the project's potential to generate spillover benefits extending well beyond those accruing to the award recipients; and, the project's cost-effectiveness (i.e., probable benefits relative to the total cost of the project). Adequacy of plans for eventual commercialization is based on evidence that if the project is successful, the proposer - - or its allies or licensees - - will pursue further development of the technology toward commercial application; the degree to which the proposal identifies potential applications of the technology; evidence of credible plans to assure prompt and widespread use of the technology once developed; and the protection of intellectual property.

The proposer's level of commitment and organizational structure is assessed based on the level of commitment the proposer has for the project as demonstrated by contributions of cash, personnel, equipment, and facilities; the type of organizational structure; the participation of small businesses in the case of joint venture proposals; the participation and relationship of subcontractor/supplier/collaborators to the project; and, the clarity and appropriateness of the management plan. Experience and qualifications are assessed based on adequacy of facilities, equipment, design and manufacturing tools, and other technical, financial, and administrative resources; quality and appropriateness of technical and business staff; past performance of the company or joint research venture participants in carrying out similar kinds of efforts successfully; and, factors and resources that bear on the technical and business success of the project.[4]

Project proposals submitted to the ATP are scored against these selection criteria. Those which score highest are selected as semi-finalists and invited to the ATP for an oral review to give the selection board an opportunity to ask applicants questions related to how well their proposal meets the criteria. Proposals are then ranked in descending order of their scores, taking into consideration information obtained during the oral review. From the list of finalists, only highly ranked proposals receive awards. To be eligible to receive funding under the ATP, all companies must be incorporated in the U.S., or must be sole proprietorships or partnerships established in the U.S.

ATP-funded projects are expected to generate net economic benefits for the U.S. Although companies are not forbidden from carrying out research and other activities in other countries, such proposals will tend to receive low scores on the criterion, "potential net broad-based economic benefits to the U.S.," and will be judged as non-competitive in the selection process. This point holds equally for all projects - - whether proposed by U.S.-owned companies with foreign subsidiaries or affiliates, or by foreign-owned, U.S. subsidiaries.

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2. For those who are unfamiliar with the term, the ATP Rule guides the agency's implementation of the ATP Statute, its authorizing legislation.

3. Note that no project will be funded unless the ATP determines it has high scientific and technical merit, no matter how meritorious the proposal might be with respect to the other four selection criteria.

4. Additional details on the subfactors of each of these five selection criteria can be found in the *ATP Proposal Preparation Kit*, the latest copy of which is December 1997, and the ATP Rule under *Sec. 295.6 Criteria for Selection*, which can be found in Appendix B. In addition, the ATP holds annual workshops around the country for potential applicants, and discusses these criteria in depth.

ADVANCED TECHNOLOGY PROGRAM

ADVANCED TECHNOLOGY PROGRAM

NISTIR-6099
ATP Eligibility Criteria for U.S. Subsidiaries of Foreign-owned Companies: Legislation, Implementation and Results

3. ADDITIONAL FOREIGN ELIGIBILITY REQUIREMENTS

U.S. subsidiaries of foreign-owned companies - - i.e., U.S.-incorporated companies that are majority owned or controlled by individuals who are not citizens of the U.S. and that have a parent company headquartered outside the U.S. - - must satisfy not only the project selection criteria outlined in Section 2 above that apply to all companies, but also four additional eligibility requirements, as specified in the ATP Statute and described below.[5]

The Secretary of Commerce (or the Secretary's designee) must find that:

- the company's participation is in the economic interest of the U.S.

  This requirement is already largely covered under the "potential for net broad-based benefits to the U.S." criterion which is one of the five main project selection criteria that all funded projects must pass, as described earlier. But, whereas in the project selection criterion the emphasis is on the project's potential for providing net broad-based economic benefits to the U.S., the emphasis in the foreign eligibility finding is on the effect of the participation of a specific U.S. subsidiary of a foreign-owned company in the project. It is possible, therefore, for a particular foreign-owned company's participation in a joint venture project to be found not to be in the economic interest of the U.S., but for the project overall to score high on broad-based economic benefits to the U.S. In this case, the joint venture may be given the opportunity to replace the ineligible foreign member and go forward as an award recipient.

  The other three eligibility requirements pertain not to the project or the company, but rather to the national policies of the country in which the parent company is incorporated and are generally beyond the control of the individual company applicant.

The Secretary of Commerce (or the Secretary's designee) must also find that:

- the foreign parent's country of incorporation provides U.S.-owned companies opportunities [in the foreign parent country], comparable to those provided to any other company, to participate in programs similar to the ATP;
- the foreign parent's country of incorporation provides U.S.-owned companies local investment opportunities [in the foreign parent country] comparable to those provided to any other company; and,
- the foreign parent's country of incorporation provides U.S.-owned companies adequate and effective

protection for their intellectual property rights [in the foreign parent country].

The determination of eligibility for foreign-owned companies will be referred to herein as "the foreign eligibility finding."

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5. The terms under which foreign-owned companies are eligible to participate in the ATP were established by Congress in the Omnibus Trade and Competitiveness Act of 1988 (P. L. 100-418, codified in 15 U.S.C. 278n), as amended by the American Technology Preeminence Act of 1991 (P. L. 102-245) under Subpart C, Sec. 28 (d)(9)(B)(ii), and are contained in the ATP Statute, the program's authorizing legislation. The ATP Statute can be found in its entirety in Appendix A.

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Go to Chapter 4: IMPLEMENTATION PROCEDURES FOR A FOREIGN ELIGIBILITY FINDING

ADVANCED TECHNOLOGY PROGRAM

ADVANCED TECHNOLOGY PROGRAM

NISTIR-6099
ATP Eligibility Criteria for U.S. Subsidiaries of Foreign-owned Companies: Legislation, Implementation and Results

4. IMPLEMENTATION PROCEDURES FOR A FOREIGN ELIGIBILITY FINDING

4.1 IDENTIFYING FOREIGN-OWNED COMPANIES

When submitting their proposals, applicants are asked to self-identify if they are foreign-owned on either the form 1262 for single company proposals or the form 1263 for joint venture proposals.[6] Proposers are asked to state whether or not they have a parent company located outside the U.S., if they are majority-owned by dividuals who are not citizens of the U.S., and if they are subject to control by individuals who are not ..tizens of the U.S.

Some companies fail to self-identify.[7] In any case, while their identity as foreign-owned will be discovered in the later stages of the review process, if not before, their failure to self-identify can lead to an understatement of foreign-owned applicants in ATP's "applicant database" which relies on data from forms 1262 and 1263. Applicants are urged to self-identify correctly; they gain nothing from the failure to do so.

4.2 SITUATIONS THAT TRIGGER A FOREIGN ELIGIBILITY FINDING

The following situations trigger an initiation of a foreign eligibility finding for U.S. subsidiaries of foreign-owned companies:

- a U.S. subsidiary of a foreign-owned company leads or participates in a project selected as a finalist in an ATP competition;
- a U.S. subsidiary of a foreign-owned company seeks to join an existing ATP project; or,
- a U.S.-owned company which is already leading or participating in a project experiences a change in ownership and becomes majority-owned or controlled by non-U.S. citizens, and wishes to continue its participation in the project.

A foreign eligibility finding would be initiated under any one of the above situations to ensure that the foreign-owned company meets the four special foreign eligibility requirements specified in the ATP Statute. The foreign eligibility finding will be carried out at, or near to the time, of the triggering event.

..3 WHO PERFORMS THE FOREIGN ELIGIBILITY FINDING

Congress provided the Secretary of the Department of Commerce with the authority to determine the eligibility of foreign-owned, U.S.-incorporated companies for receiving ATP awards. This authority was subsequently delegated to the Director of NIST, who, in turn, delegated it to the Director of the ATP. The Director of the ATP bases the foreign eligibility finding on evidence gathered from a number of sources.

4.4 SOURCES OF INFORMATION IN PREPARING A FOREIGN ELIGIBILITY FINDING

Note that under each of the situations listed in Section 4.2, the project will already have scored high on the proposal selection criteria covered in Section 2. When a foreign eligibility finding is initiated, additional information is collected from a number of sources, as discussed under each eligibility requirement below.

Eligibility Requirement 1: Participation of the Company is in the Economic Interest of the U.S.

Whether or not a project is in the economic interest of the U.S. is largely based on the project selection criterion, "evidence of net broad-based benefits to the U.S." To determine if participation of a particular foreign-owned company in the project is in the economic interest of the U.S., information provided in the proposal is reviewed and further scrutinized, taking into account the likely impact of foreign ownership. Additional analysis takes into consideration evidence of the following: that the company has a U.S. location(s) for the project's research, is making investments in research, development, and manufacturing in the U.S., and agrees to promote the manufacture in the U.S. of any products resulting from the ATP-supported technology; anticipated positive effects on U.S. employment and on sources of supply; and other aspects relevant to the project's potential to produce net broad-based benefits to the U.S. economy. To clarify and/or to supplement information in the proposal, the applicant may be requested to submit additional information to satisfy this requirement. Information is also obtained from other sources, including Dun & Bradstreet.

Eligibility Requirement 2: Comparable Opportunities for U.S. Firms to Participate in Programs Similar to the ATP in the Parent Country

Evidence to satisfy eligibility requirement 2 - - whether or not the country of incorporation of the foreign parent affords U.S.-owned companies opportunities comparable to those afforded to any other company to participate in programs similar to the ATP - - is derived primarily from analysis of similar program(s) in the parent country. This information is obtained from the managing organizations of the program(s), embassies, other official government sources, and public information.

Eligibility Requirement 3: Comparable Local Investment Opportunities for U.S. Firms in the Parent Country

Evidence to satisfy eligibility requirement 3 - - whether or not the country of incorporation of the foreign parent affords U.S.-owned companies local investment opportunities - - is based primarily on information supplied by the Office of the U.S. Trade Representative through its annual National Trade Estimate report, its annual "Special 301" Fact Sheet, and updates from desk officers. Additional information on barriers to investment and trade may also be obtained from other federal agencies.

Eligibility Requirement 4: Adequate and Effective Protection of Intellectual Property Rights of U.S. Firms in the Parent Country

Evidence to satisfy eligibility requirement 4 - - whether or not the country of incorporation of the foreign parent provides adequate and effective protection of U.S.-owned intellectual property rights - - is based primarily on information supplied by the Office of the U.S. Trade Representative through its annual National Trade Estimate report, its annual "Special 301" Fact Sheet, and updates from desk officers. Note that this provision is stated in absolute terms and is not relative to how other companies

are treated. Additional information may also be sought from other organizations, including the U.S. Patent and Trademark Office, the U.S. Department of State, and U.S. embassies abroad.

5 POSITIVE AND NEGATIVE FINDINGS

For a foreign eligibility finding to be determined positive, each of the four eligibility requirements must be found positive. A positive foreign eligibility finding means that the applicant is determined eligible to participate in an ATP-supported project, provided all other requirements - - common to all ATP award candidates - - are met.

A negative decision with respect to eligibility requirements 2 to 4 does not preclude a positive finding in the future for the country in question. Similarly, a positive finding would not preclude a negative finding in the future for the country in question. The ATP recognizes that national policies regarding opportunities for U.S. companies to participate in similar R&D programs, or opportunities for foreign investment in the foreign country, or the adequate and effective protection of intellectual property rights, may change over time. Therefore, it is ATP's policy to prepare a foreign eligibility finding at the time of a triggering event. The ATP does not determine in advance the countries that meet or do not meet the country-specific, foreign eligibility requirements.

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6. Note that these forms can be found in the *ATP Proposal Preparation Kit* . The *Kit* also contains background material, proposal cover sheets, other required forms, and guidance on the preparation of proposals to the ATP. The currently available version is dated December 1997 and reflects all changes to the ATP Rule and to the ATP Statute through that date. An electronic version of the Kit is available on ATP's home page on the World Wide Web, specifically, http://www.atp.nist.gov/atp/kit2/mainmenu.htm.

7. This failure to self-identify has resulted in an understatement of the number of foreign-owned companies in ATP's applicant database. This understatement in the applicant database may lead one to miscompute the percentage of foreign-owned applicants that receive ATP awards; namely, it may lead to an overstatement.

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5. FOREIGN-OWNED PARTICIPANTS IN ATP PROJECTS

From its inception in 1990 through 1997, the ATP has carried out a total of fifty-one foreign eligibility findings. Of these, forty-eight foreign eligibility findings were for companies whose projects were selected as finalists for awards. The rest were for companies seeking to join existing projects, or to continue participating in existing ATP projects after experiencing a change in their ownership status. The total number of findings does not correspond directly to the number of projects in which U.S. subsidiaries of foreign-owned companies sought participation. There are a few instances in which joint venture projects had more than one foreign-owned company seeking involvement, each requiring a foreign eligibility finding. Also note that the total number of findings does not correspond directly to the number of foreign-owned companies currently participating in projects for a variety of reasons. The total number of findings include findings for U.S. subsidiaries of foreign-owned companies which:

- had positive findings, officially joined the projects, and are still currently participating in active projects;
- had positive findings, officially joined the projects, but have now completed their research;
- had positive findings, but for various reasons never participated in the project;
- had positive findings, but decided to take an informal role in projects, as a subcontractor, for instance;
- had positive findings, but were in projects which did not receive an award for other reasons, or which were cancelled before the project started;
- had negative findings, and were not allowed to participate;
- were determined not to have a U.S. subsidiary, and were, therefore, ineligible to participate; or,
- became majority U.S.-owned during the life of the project.

Of the fifty-one foreign eligibility findings carried out through 1997, only two were negative. Both of these findings were for Japanese-owned firms, and they did not pass on the basis of the national policies of Japan rather than any shortcomings of the companies themselves.

Of the 352 projects, involving 842 participants, receiving support from the ATP, thirty-three participants in twenty-nine active and completed ATP projects are U.S. subsidiaries of foreign-owned companies. They are participating in 18 out of a total of 119 joint venture projects and 11 out of a total of 233 single-company

projects. These participants represent twenty-one, distinct foreign-owned companies from twelve different countries. A few of these companies are participating in more than one project. Specifics are provided in the attached tables. Table 1 lists in alphabetical order the names of participants which are U.S. subsidiaries of foreign-owned companies participating in active and completed projects, and Table 2 displays the same list of participants by their parent country. Table 3 provides active and completed projects involving U.S. subsidiaries of foreign-owned companies by project year and by project title.

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6. QUESTIONS AND ANSWERS ON FOREIGN ELIGIBILITY AND PARTICIPATION

To clarify ATP's policies on the eligibility of foreign-owned companies, this section poses questions concerning foreign eligibility and participation, and provides answers.

Q. Are green card holders who own a company incorporated in the U.S. eligible to receive an ATP award? Do they have to go through a foreign eligibility finding process?

No, green card holders (resident aliens) are ineligible to receive an award from the ATP. Green card holders do not go through a foreign eligibility finding process. If a proposal by a green card holder is submitted for consideration, it will undergo the selection process. If the proposal is selected as a semi-finalist, the applicant will be asked during the oral review if ownership has transferred from the green card holder to a U.S. citizen(s). According to Sec. 295.39 (c) of the ATP Rule (December 1997),

> *Companies owned by legal residents (green card holders) may apply to the Program, but before an award can be given, the owner (s) must either become a U.S. citizen or ownership must be transferred to a U.S. citizen (s).*

Q. What are the eligibility requirements for foreign-owned companies seeking to participate as subcontractors in an ATP project? Is a foreign eligibility finding required?

A. No, a foreign eligibility finding is not required in this case, but the participants will be required to justify the use of any foreign-owned subcontractors and explain how their participation will benefit the U.S. economy. It is important for proposers to identify which facility and where (in the U.S. or outside the U.S.) the research will be carried out by all participants, including subcontractors. The ATP has provided a response on page 31 of the *ATP Proposal Preparation Kit* (December 1997) as noted below:

> *. . . because ATP's goal is to create economic growth in the U.S., ATP awardees are expected to use U.S. subcontractors located in the U.S. with benefits accruing to the U.S. Proposals which include foreign subcontractors that do not fully justify such use would normally score low in the ATP selection criterion that ensures that economic benefits must accrue to the U.S. Substantial foreign subcontractors are not encouraged. If [sic] foreign subcontractors are proposed, a clear statement that U.S. sources for the expertise have been investigated and why they are judged to be inadequate to meet the project goals is required.*

Q. I am interested in applying to the ATP, but I am a foreign-owned company without a

U.S. subsidiary. Can I still apply and receive an award?

No. According to the ATP Statute, only U.S.-owned companies and U.S. subsidiaries of foreign-owned npanies that meet certain requirements are eligible to receive financial assistance from the ATP. Foreign-owned companies located outside of the U.S. are ineligible for an award.

Q. I am a foreign-owned company with a U.S. subsidiary interested in applying to the ATP. But I am not sure if I will pass the foreign eligibility finding. Could you tell me in advance if my parent country would pass the country-specific, eligibility requirements before I apply?

A. No, the ATP cannot give an opinion on whether the parent country of a foreign-owned company would pass the country-specific eligibility requirements prior to the time of application. Just because a country's national policies were determined to meet the eligibility requirements in one year, does not mean that the country's policies will be acceptable in a subsequent year - - and vice versa - - because national policies can change. An opinion given today may not reflect the situation at the time of application.

Q. I am curious about when the process begins for a foreign eligibility finding. I was just notified by the ATP that I'm a semi-finalist, but I have a foreign parent. Will the ATP tell me at the oral review if I pass the foreign eligibility finding?

A. No. A determination of foreign eligibility will not be made until after the oral review. During your oral review, the selection board will ask you questions to clarify how well you meet the ATP criteria, including questions related to the foreign eligibility finding - - questions such as where you intend to carry out the research. Information collected at the oral review is used in the foreign eligibility finding process. Only those projects which reach the finalist stage, and whose participants are determined to be the U.S. subsidiaries of foreign-owned companies will be subject to a foreign eligibility finding.

I don't understand how a foreign eligibility finding is carried out. What do you do?

A. The ATP relies on information collected by federal agencies (e.g., the Department of Commerce; the U.S. Trade Representative; the U.S. Patent and Trademark Office; the Department of State) and received from foreign embassies, U.S. embassies abroad, foreign programs, and other sources to help us make the determination of eligibility. Note that the ATP does not conduct broad surveys of the national policies of other countries.

Q. I am a U.S. -owned company currently participating in an ATP project. We are in the process of being acquired by a foreign-owned company. We would like to continue our participation in the project. What do you do in a case like ours?

A. First, you must notify the ATP of any change in ownership as stipulated in your cooperative agreement with NIST. When a change in ownership from majority U.S.-owned to foreign-owned is official, a foreign eligibility finding will be carried out to determine whether your company's continued participation in the project is in the economic interest of the U.S., taking into account foreign ownership, and whether your new foreign parent's country of incorporation meets the country-specific eligibility requirements mandated by Congress. Please refer to the ATP Proposal Preparation Kit (December 1997), p. 37, which describes this reporting requirement as noted below:

> *If at any time within the life of an ATP award, any recipient ceases to have a majority control or ownership by individuals who are citizens of the United States, the recipient shall notify the ATP of that fact within 15 days. As stipulated in Chapter 1, C. [page 2 of the Kit], a finding will be made by NIST in accordance with 15 CFR 295.3 [see Appendix B: The ATP Rule].*

If the foreign eligibility finding is determined to be positive on all four special eligibility requirements, you will be allowed to continue your participation in the project.

Q. Once a foreign-owned company is determined eligible to participate in the ATP, is a determination of continued eligibility carried out every year?

As stipulated in the cooperative agreement an awardee signs with NIST, the ATP subjects every funded project to an analysis of the criteria listed in Section 2 in this report to decide if it merits continuation of funding. The ATP does not carry out a foreign eligibility finding every year for every company and project. However, under the ATP Statute, and as further mentioned in the ATP Rule, a foreign-owned company can be suspended from continued assistance if it is determined that it fails to satisfy any of the special eligibility requirements. The following are excerpts from the ATP Statute and the ATP Rule:

> *(e) The Secretary [of the Department of Commerce] may, within 30 days after notice to Congress, suspend a company or joint venture from continued assistance under this section if the Secretary determines that the company, the country of incorporation of the company or a parent company, or the joint venture has failed to satisfy any of the criteria set forth in subsection (d)(9), and that it is in the national interest of the United States to do so. [ATP Statute]*
>
> *(b) The Program may, within 30 days after notice to Congress, suspend a company or joint venture from continued assistance under the Program if the Program determines that the company, the country of incorporation of the company or a parent company, or the joint venture has failed to satisfy any of the criteria contained in paragraph (a) of this section, and that it is in the national interest of the United States to do so.* [ATP Rule]

It is current ATP practice not to require foreign-owned participants to undergo yearly foreign eligibility findings once they are determined eligible to participate at the time of application. Should a foreign-owned company cease to be foreign-owned during the life of a project, or a U.S.-owned company ceases to be majority U.S.-owned, the ATP must be given notification and, in the case of the latter, a foreign eligibility finding will be required in order to determine whether the company is eligible to continue its participation in the project.

It is important to note that every year, the ATP reviews the progress of all awarded projects against the five project selection criteria and against their original goals, and determines whether or not continued assistance is appropriate. During the annual review process, the ATP assesses whether each project is making sufficient progress toward its goals, including whether it continues to have the potential to generate net broad-based benefits to the U.S. In other words, even though the ATP does not carry out a foreign eligibility finding each year for currently participating foreign-owned companies, whether the company's participation continues to be in the economic interest of the U.S. is considered under the normal annual project review, while the other three country-specific eligibility requirements related to the national policies of the parent country are not.

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7. ATP CONTACT INFORMATION

If you have questions or comments regarding this report, please submit them to the ATP at the following address:

Economic Assessment Office
Advanced Technology Program
Gaithersburg, Maryland 20899-0001

you wish to speak with someone at the Economic Assessment Office, please contact either:

Connie Chang
Economist, Economic Assessment Office
301-975-4318 (voice); 301-975-4776 (fax)
connie.chang@nist.gov

or,

Rosalie Ruegg
Director, Economic Assessment Office
301-975-6135 (voice); 301-975-4776 (fax)
rosalie.ruegg@nist.gov

To request a proposal preparation kit, and/or request that your name be added to the ATP mailing list for future mailings and announcements of ATP workshops and other activities, call our toll-free "hotline" number, 1-800-ATP-FUND, or 1-800-287-3863; or send an email to: atp@nist.gov. For answers to general questions concerning the Advanced Technology Program, please feel free to browse our home page on the World Wide Web (http://www.atp.nist.gov).

We welcome your comments and suggestions.

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REFERENCES

National Institute of Standards and Technology. *Advanced Technology Program Proposal Preparation Kit* . Gaithersburg, MD. U.S. Department of Commerce, Technology Administration, December 1997.

Advanced Technology Program Statute. Originally authorized by Section 5131 (a) of the Omnibus Trade and Competitiveness Act of 1988 (P.L. 100-418); codified in Title 15 of the United States Code, Section 278n (15 U.S.C. 278n); and amended by the American Technology Preeminence Act of 1991 (P.L. 102-245).

dvanced Technology Program Rule. Title 15, Code of Federal Regulations, Part 295 (15 CFR Part 295).

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