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FEDERAL TECHNOLOGY TRANSFER REQUIREMENTS

A focused study of principal agencies' approaches with implications for the Department of Homeland Security

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EXECUTIVE SUMMARY

This report provides relevant information and analysis to the Department of Homeland Security (DHS) that will assist DHS in determining how to meet the requirements of federal technology transfer legislation. These legal requirements are grouped into five categories: (1) establishing an Office of Research and Technology Applications, or providing the functions thereof; (2) information management; (3) enabling agreements with non-federal partners; (4) royalty sharing; and (5) invention ownership/obligations. These five categories provide the organizing framework for this study, which benchmarks other federal agencies/laboratories engaged in technology transfer/transition[1] Four key agencies—the Department of Health & Human Services (HHS), the U.S. Department of Agriculture (USDA), the Department of Energy (DOE), and the Department of Defense (DoD)—and several of their laboratories have been surveyed. An analysis of DHS's mission needs for commercializing R&D compared to those agencies/laboratories is presented with implications and next steps for DHS's consideration.

Federal technology transfer legislation, requirements, and practices have evolved over the decades as agencies and laboratories have grown more knowledgeable and sophisticated in their efforts to conduct technology transfer and as needs and opinions in the federal sector have changed with regards to what is appropriate. The need to address requirements in a fairly thorough manner has, therefore, resulted in a lengthy paper. There are two ways to find summary information. Each chapter concludes with a summary, and there is an overall "Summary and Next Steps" chapter on pages 57–60. For those readers who are unable to read the entire document, we recommend referring to these pages.

[1] Throughout this paper, the term "technology transition" is used interchangeably with the term "technology transfer." This recognizes a convention that has arisen in the DoD and gained acceptance in DHS. The use of the term "technology transition" attempts to recognize the need to address transition across the life cycle of technology development, not just the transition from R&D to industry.

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CONTENTS

I. Introduction 11

Background: Factors Impacting Agency Approaches to Commercialization 13

II. Factors Affecting the Formulation of the DHS Office of Research and Technology Applications 21

Benchmarking: Organization of ORTAs 21

Implications for ORTA Functions in DHS 23

Implications for DHS 29

III. Information Collecting, Tracking, and Reporting 31

Benchmarking 32

Implications for DHS 34

Summary 41

IV. Mechanisms Enabling Agreements with Non-Federal Entitites 43

Non-Disclosure Agreements 43

Cooperative Research and Development Agreements 44

Licenses 45

Other Transactions 46

Implications for DHS 47

Summary 48

V. Royalty Sharing (Employee Rewards and Incentives) 49

Benchmarking 50

Implications for DHS 53

Summary 55

VI. Invention Ownership and Obligations 57

Benchmarking 57

Implications for DHS 57

Summary 58

VII. Summary and Next Steps 59

Appendix A: NDA Comparison 63

Appendix B: CRADA Comparison 67

Appendix C: Licensing Comparison 75

ACRONYMS

AAAS	American Association for the Advancement of Science
AFRL	Air Force Research Laboratory
AGR	adjusted gross royalty
ARL	Army Research Laboratory
ARS	Agriculture Research Service
BAA	Broad Agency Announcement
CIO	chief information officer
COTS	commercial off-the-shelf
CRADA	cooperative research and development agreement
DARPA	Defense Advanced Research Projects Agency
DHS	Department of Homeland Security
DOC	Department of Commerce
DoD	Department of Defense
DOE	Department of Energy
DOT	Department of Transportation
DTIC	Defense Technical Information Center
EPA	Environmental Protection Agency
FAA	Federal Aviation Administration
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FFMS	Federal Financial Management System
FFRDC	federally funded research and development center
FLC	Federal Laboratory Consortium
FOIA	Freedom of Information Act

FOU	field of use
FTE	full-time employee
GL	general ledger
GOCO	government-owned, contractor-operated
GOGO	government-owned, government-operated
GSA	General Services Administration
HHS	Health and Human Services
HR	human resources
HSARPA	Homeland Security Advanced Research Projects Agency
IE	Internet Explorer
IIS	Internet Information Server
INL	Idaho National Laboratory
IP	intellectual property
IT	information technology
ITAR	International Traffic in Arms Regulation
LANL	Los Alamos National Laboratory
LLNL	Lawrence Livermore National Laboratory
MDC	Master Data Center
MOU	memorandum of understanding
MTA	material transfer agreement
NAL	National Agricultural Library
NASA	National Aeronautics and Space Administration
NDA	non-disclosure agreement
NFE	non-federal entity
NIH	National Institutes of Health
NLM	National Library of Medicine

NNSA	National Nuclear Security Administration
NRL	Naval Research Laboratory
NTIS	National Technical Information Service
OGC	Office of General Counsel
ORD	Office of Research and Development (a division of DHS/S&T Directorate)
ORNL	Oak Ridge National Laboratory
ORTA	Office of Research and Technology Applications
OSTI	Office of Science and Technical Information
OT	other transaction
OTA	other transaction authority
OTT	Office of Technology Transfer
PI	principal investigator
PIADC	Plum Island Animal Disease Center
PM	program/project manager
PNNL	Pacific Northwest National Laboratory
POC	point of contact
PPR	Programs, Projects, and Requirements
QR	Quick Report
R&D	research and development
RDT&E	research, development, test, and evaluation
ROI	return on investment
SBIR	Small Business Innovation Research Program
SCA	specific cooperative agreement
SED	science and engineering design
SIP	subject intellectual property
SNL	Sandia National Laboratories

SRP	Super Report Pro
S&T	science and technology
STI	scientific and technical information
STIP	Science and Technical Information Program
TLO	technology licensing officer
TSL	Transportation Security Laboratory
TTC	technology transfer coordinator
TTPD	technology transition process development
UC	University of California
USDA	U.S. Department of Agriculture
VPN	virtual private network
WFO	Work for Others

I. INTRODUCTION

In a report to Congress in April 2005, Dr. Charles McQueary, Undersecretary of the Department of Homeland Security's (DHS's) Science and Technology (S&T) Directorate, stated, "*The primary mission of the Science and Technology Directorate is to develop cutting-edge homeland security technologies and to successfully transition them to end users within the department, other federal agencies, state and local government entities, and the private sector. Successful technology transition is the capstone of our mission.*"

For most homeland security products, end users—whether federal agencies or non-federal emergency responders—will turn to the commercial sector. Non-commercial providers of research and development (R&D) must find ways to successfully transition their technologies to the commercial sector. The Office of Research and Development (ORD) within the DHS S&T directorate funds federal laboratories and universities to do long-term R&D of technologies for homeland security. ORD will not be successful at fulfilling the DHS mission unless those technologies become products that protect the homeland. In its future technology transition efforts, DHS will be targeting technologies and systems that are needed to:

- Detect, deter, defeat, and mitigate the impact of radiological/nuclear and chemical/biological attacks.
- Detect, disable, characterize, protect from, and dispose of threats from explosives.
- Protect commercial travel and transportation.
- Identify and eliminate security threats at U.S. ports and borders.
- Protect U.S. transportation systems and supervise the entry of people and goods into the country.
- Protect the nation's critical information and communication infrastructure and cybersecurity against threats and vulnerabilities.
- Assist in the response to and recovery from natural and man-made disasters.

There are significant challenges to achieving commercialization of these technologies. In the best case, transitioning inventions to the commercial sector can be difficult. Laboratory and university inventions are usually immature and require significant investment before there is a commercial-ready product. Furthermore, in this situation, there is a high degree of uncertainty regarding the size and existence of markets.

ORD requested assistance from Sandia National Laboratories (SNL) to determine how to successfully commercialize ORD technologies within the context of an overall DHS/S&T technology transition process. This project has three tasks:

1. Assist DHS in determining how the agency will meet the requirements of federal technology transfer legislation.
2. Identify and describe alternative paths to commercialization.
3. Initiate two pilots to experiment with paths to commercialization.

Task 1 became an urgent need as this project started, both because DHS had not yet addressed the legislative requirements and because establishing an infrastructure for technology transition would enable the implementation of tasks 2 and 3 (i.e., actual deployment of commercialization). This report principally addresses task 1.

There is a body of law that establishes the requirements for federal agencies to conduct technology transfer. The principal technology transfer legislation was initiated in the 1980s with new legislation continuing through the 1990s. The principal legislation includes the following:

- Stevenson-Wydler Technology Innovation Act of 1980 (PL 96-480) (15 USC 3701-3714)
- Bayh-Dole Act of 1980 (PL 96-517) H.R. 6933 Public Law 96-517
- Trademark Clarification Act of 1984 (PL 98-620) H.R.6163 Public Law 98-620
- Federal Technology Transfer Act of 1986 (PL 99-502) H.R. 3773 Public Law 99-502
- National Competitiveness Technology Transfer Act of 1989 (PL 101-189) (included as Section 3131 et seq. of DoD Authorization Act for FY 1990) H.R. 2461 Public Law 101-189

To complete task 1, the legal requirements were grouped into the following five categories:

1. Organization for an Office of Research and Technology Applications (ORTA)—Create and fund an ORTA).
2. Information Collection, Tracking, Dissemination, and Reporting—Establish systems to meet the following requirements:
    - Provide and disseminate information on federally owned or originated products, processes, and services that have potential applications to state and local governments and private industry.
    - Cooperate with and assist the National Technical Information Service (NTIS), the Federal Laboratory Consortium (FLC), and other organizations that link federal laboratory R&D resources to potential users.
    - Provide an annual technology transfer report to the Department of Commerce (DOC).
    - Maintain records.
3. Technology Transfer Mechanisms—Establish templates and/or guidance to enable engagement in the following technology transfer/transition agreements:
    - non-disclosure agreements (NDAs).
    - Cooperative research and development agreements (CRADAs).
    - Licenses of intellectual property (IP).
    - Other transactions (OTs).
    - Invention disclosures (completed by DHS legal staff prior to project and, therefore, not included in this report).
    - Additional transactions as needed, such as commercial test agreements, user facilities agreements, material transfer agreements, and cooperative agreements. (These are used less often and are not being addressed in this paper. They will be addressed by the staff of the ORTA when established.)

4. Royalty Distribution (and Rewards) Program—Adopt or develop a royalty distribution scheme for government-owned, government-operated (GOGO) laboratories.
5. Invention Ownership and Obligations—Promote DHS employee rights and obligations by training DHS employees about their obligations.

These five categories became the organizing principles for this study, which began with benchmarking other major agencies engaged in technology transfer/transition. The study includes benchmarking key technology transfer/transition provisions in four key agencies—Health and Human Services (HHS),[2] the U.S. Department of Agriculture (USDA),[3] the Department of Energy (DOE), and the Department of Defense (DoD)—and analyzing DHS needs and intent compared to those agencies.

Because of the National Institutes of Health's (NIH's) lead role in HHS research and in that agency's technology transfer implementation, that agency will be referred to as HHS/NIH from this point forward. A similar relationship exists for the Agricultural Research Service (ARS) within USDA, and that agency will be referred to as USDA/ARS.

Each of the five chapters addressing the above requirements summarizes the benchmarking results, describes the implications for DHS, and concludes with a summary. This report's intent is neither to conduct an exhaustive benchmarking of federal agency technology transfer/transition nor to make decisions or recommendations. The objective is to provide relevant information, analysis, and insights that will enable DHS to make some key decisions about how to comply with technology transfer legislation while meeting the agency's mission needs of commercializing R&D.

Background: Factors Impacting Agency Approaches to Commercialization

Four factors discussed below are critical to an agency's approaches to technology transfer/transition: (1) the structure and assets of the agency, (2) the relationship of commercialization to the mission, (3) the end users, and (4) the type of mechanisms being used to achieve commercialization.[4] These factors are not independent variables. As the discussion below illustrates, a strong relationship exists between structures and mission, mission and end users, and mission and the type of mechanisms used to achieve commercialization.

Agency Structure and Assets

The relative size of an agency's R&D budget generally correlates positively with the degree to which the agency engages in technology transfer/transition, as measured by federal activity metrics and outcomes. Figure 1 shows the breakdown of federal R&D funds in FY03. The agencies with the largest federal R&D budgets—DoD, HHS/NIH, the National Aeronautics and Space Administration (NASA), DOE, and USDA/ARS—are also the agencies with the most significant results as measured by output of IP, licensing, CRADAs, and licensing revenue.

[2] HHS has delegated agency technology transfer responsibility to NIH, which represents over 90% of the HHS federal R&D budget.
[3] USDA has delegated all of that agency's intramural licensing and other technology transfer (e.g., CRADAs) to ARS, which represents about 85% of all the technology transfer for intramural research in USDA.
[4] Commercialization in this context means production of product by the commercial sector, not production for commercial use. Therefore, production of defense products by companies for the federal market (e.g., defense contractors) is considered commercialization.

NASA was not included in the in-depth benchmarking study because its mission is less closely related to the DHS mission than the other agencies. USDA/ARS was relevant because of its long-standing ownership of Plum Island Animal Disease Center (PIADC), a government laboratory moved into DHS. HHS/NIH was important because of its strong technology transfer results and its drug and biotechnology connections. DoD and DOE are particularly important because of their national security missions, their transfer of staff and programs from those agencies into DHS, and the relationship of the DOE national laboratories to DHS. NASA was not included in this study due to time constraints.

Figure 1: Federal R&D Budget by Agency[5] FY03 Outlays ($ in billions)

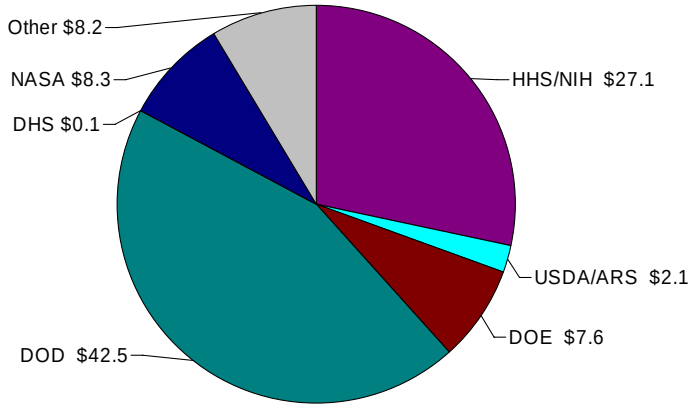
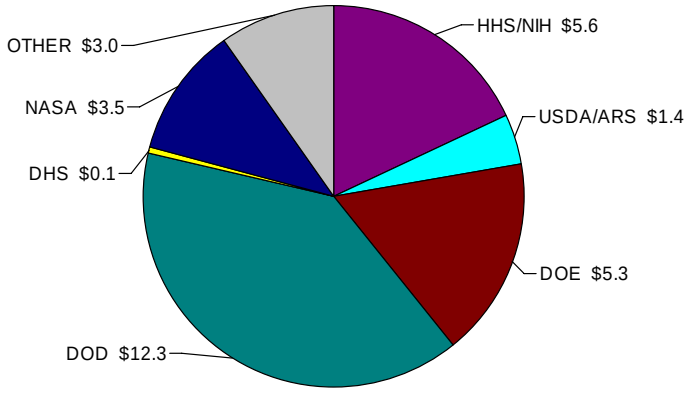


Figure 2: Federal Intramural and FFRDC R&D Budgets by Agency[6] FY03 Obligations ($ in billions)



Within the group of five agencies that have the largest R&D budgets and that show strong results in technology transfer/transition measures, there is not a one-to-one correlation between these two measures (R&D budget and technology transfer/transition). Figure 1 shows the total federal R&D budget for these five agencies, plus DHS for FY03. However, some agencies contract out a sizeable portion of their R&D budgets, especially to universities and colleges. Figure 2 provides a more valid comparison of federal R&D budgets across these agencies—the portion of their budgets that are conducted by intramural laboratories plus other federally funded research and development centers (FFRDCs). This is more relevant because it is the inventions, licenses, and CRADAs from intramural and other FFRDCs that are reported as technology transfer/transition measures. R&D that is contracted to universities and industries is owned by those institutions and not subject to the same technology transfer/transition requirements.

In all subsequent graphs in this section, R&D budget numbers refer to the intramural plus FFRDC budgets shown in the pie chart to the left.

To fully understand an agency's commercialization approach and results, it is necessary to understand the three other variables impacting their focus and performance in commercialization—mission, end users, and mechanisms used.

[5] National Science Foundation, *Federal Funds for Research and Development, Fiscal Years 2002, 2003, 2004*, NSF05-307.
[6] National Science Foundation, Federal Funds for Research and Development, Fiscal Years 2002, 2003, 2004, NSF05-307.

Mission and Technology Transfer/Transition Approach

A strong relationship exists between an agency's mission and its approaches to technology transfer/transition. These technology transfer/transition approaches are reflected in an agency's results as reported to DOC, which publishes an annual report. Figures 3 through 7 are extracted from the FY2003 annual report.[7]

DHS views technology transition for commercialization as squarely in its mission space, that is, commercialization is necessary to achieving its principal mission. Other agencies vary in the degree to which they view commercialization as critical to the mission.

Like DHS, the mission need for commercial sources is extremely high for DoD, but the DoD situation is unique. It has acquisition responsibility for end users residing within DoD. As a significant consumer of technologies generated from their inventions, DoD drives the federal market for national defense products. Therefore, much of DoD is focused on promoting and/or achieving commercialization through acquisition mechanisms [e.g., acquisitions, OT authority, Broad Agency Announcements (BAAs)] more than through typical technology transition mechanisms. Furthermore, because sales are for federal government use, licensing revenues are not generated for the inventing federal laboratories. All these factors likely contribute to a lower level of IP generation and licensing by DoD. DoD investments in technology lead to enhanced capabilities that are utilized by contractors in DoD systems with permission but without IP ownership. It is important to note that DoD views technology transfer as an integral part of its acquisition strategy. As a large procurer of both military and commercial products, DoD is interested in dual use and in the two-way flow of technology—transfer in and transfer out.

Despite having the largest federal R&D budget (39.4%), DoD does fewer licenses and generates much lower licensing revenue than HHS/NIH or DOE. DoD licensing activity is on par with USDA/ARS, which represents only about 4.5% of the federal R&D budget. To fully understand this, it is necessary to delve further into the breakdown of the federal budget between research and development. Most of DoD's R&D budget is in development. Within the DoD, the Naval Research Laboratory (NRL) has a greater research budget and does more licensing, while the Army Research Laboratory (ARL) has a smaller research budget and does much more CRADA work with industry.

For HHS/NIH, USDA/ARS, and DOE, the efforts at technology transfer for commercialization are generally secondary to their R&D missions. There is not the same level of agency responsibility for ensuring product for end users as there is for DoD. In these cases, technology commercialization is usually achieved through typical mechanisms, like licensing and CRADAs. For DOE, technology transfer often is successful when technologies have dual use.

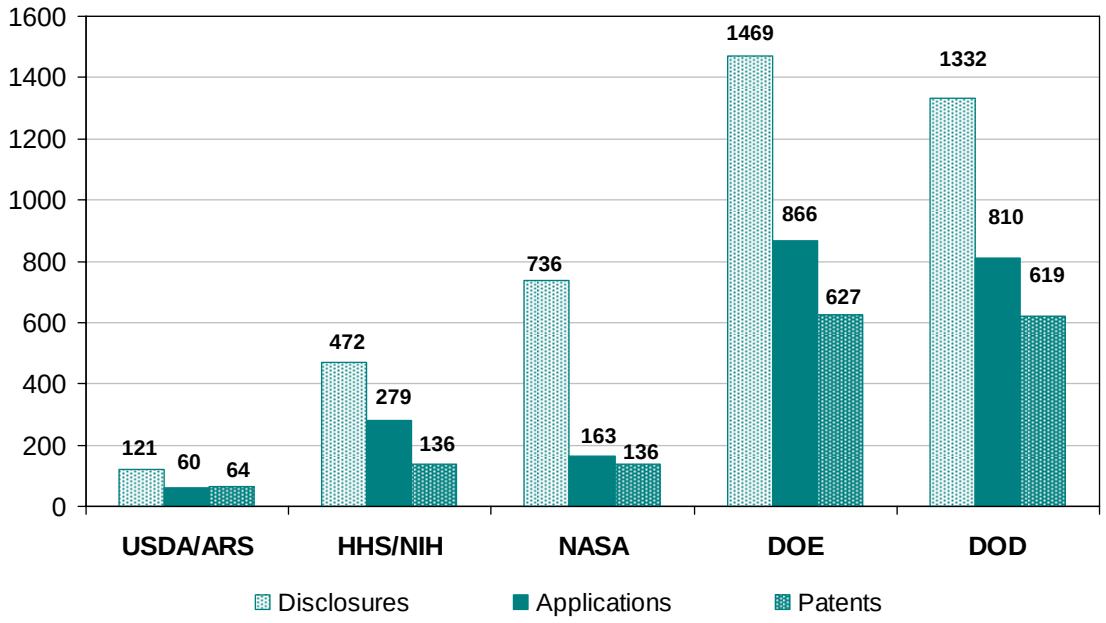
Despite viewing technology transfer as secondary to its R&D mission, HHS/NIH transfers technology for applications, and to industry sectors, directly applicable to its mission. Transfer is most often to pharmaceutical companies who are developing drugs and vaccines. HHS/NIH has few CRADAs—and almost no funds-in CRADAs—a reflection of its policy of not doing funds-in work for industry because of conflict of interest concerns.

[7] U.S. Department of Commerce, *Summary Report on Federal Laboratory Technology Transfer, Activity Metrics and Outcomes, FY2003.*

This is a particular concern for HHS/NIH because most of its industry engagements are with a single industry sector—pharmaceuticals—and HHS/NIH does not want to create the perception or reality of the industry influencing the HHS/NIH mission of improving public health. Because it is such a highly competitive sector and because time-to-market is critical to success and profit, the pharmaceutical industry is quite ready to license new technology that provides market advantage. This is reflected in the licensing numbers, but especially the income, which is more than double that of the next highest revenue generator, DOE. HHS/NIH accomplishes this with less IP generation.

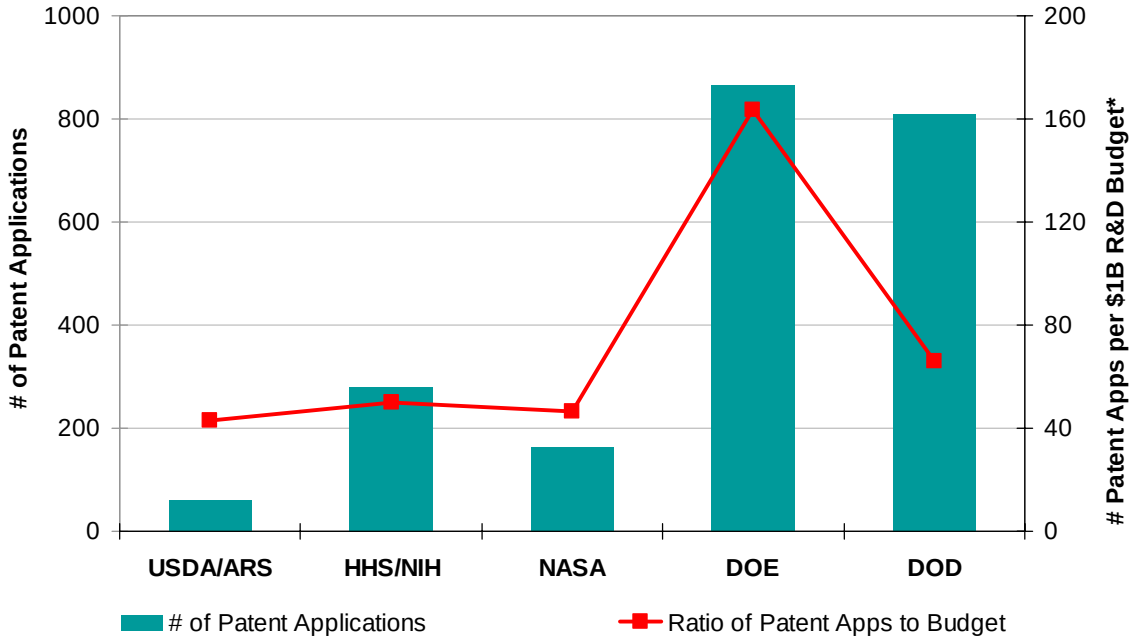
For USDA/ARS, transfer is to a broader group of applicable industry sectors, for example, food, food processing and packaging, agriculture, and clothing, as well as for dual use.

Figure 3: IP Generated by Agency (FY03)



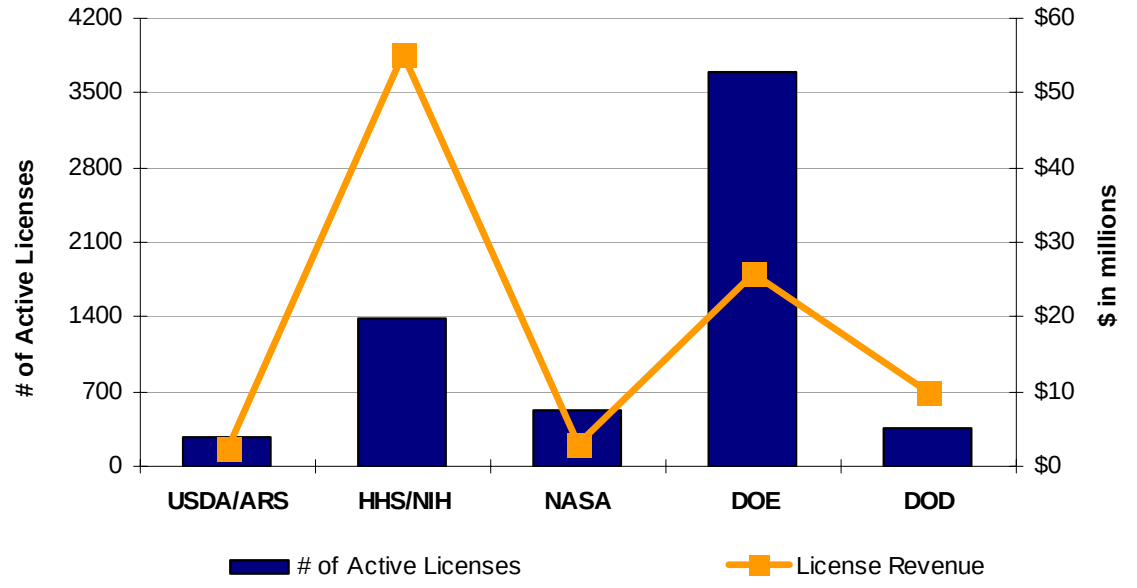
All the federal agencies engage in generating IP, although not at the same rate or level.

Figure 4: Patent Applications per $1B of Federal R&D Budget Obligations (FY03)



Normalizing patent applications as a ratio of the R&D budget shows the relative level of patenting across the agencies. DOE's government-owned, contractor-operated (GOCO) national laboratories generate a high level of IP compared to the other agencies.

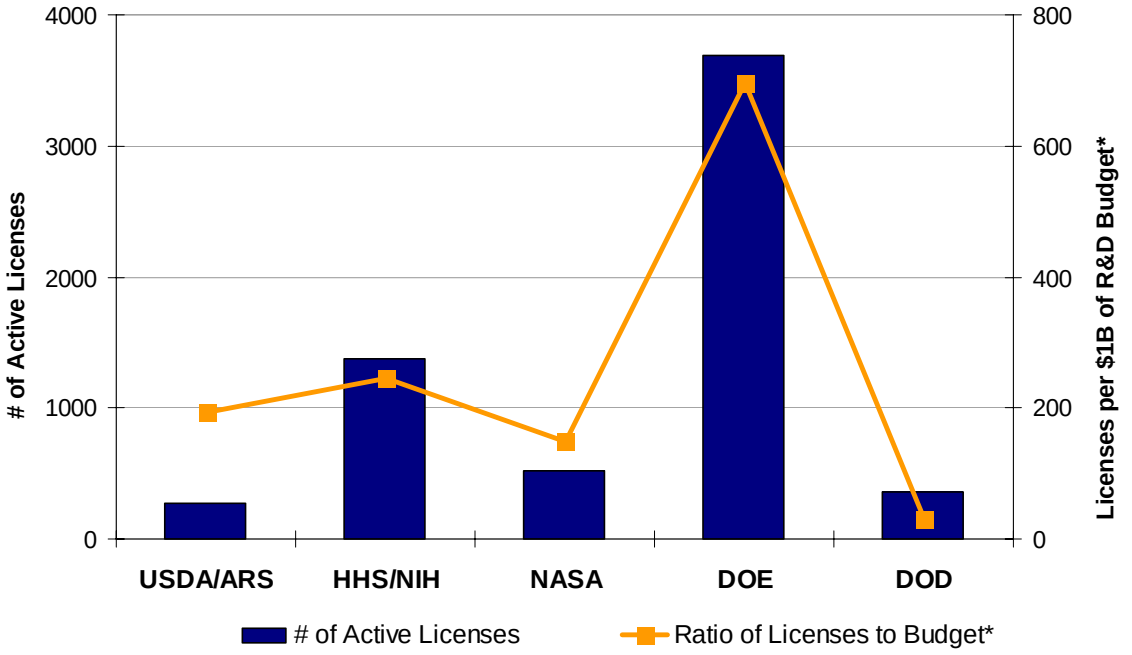
Figure 5: Active Licenses and Revenue from Licensing (FY03)



While HHS/NIH has by far the highest income from licensing, DOE has the highest volume of licensing.

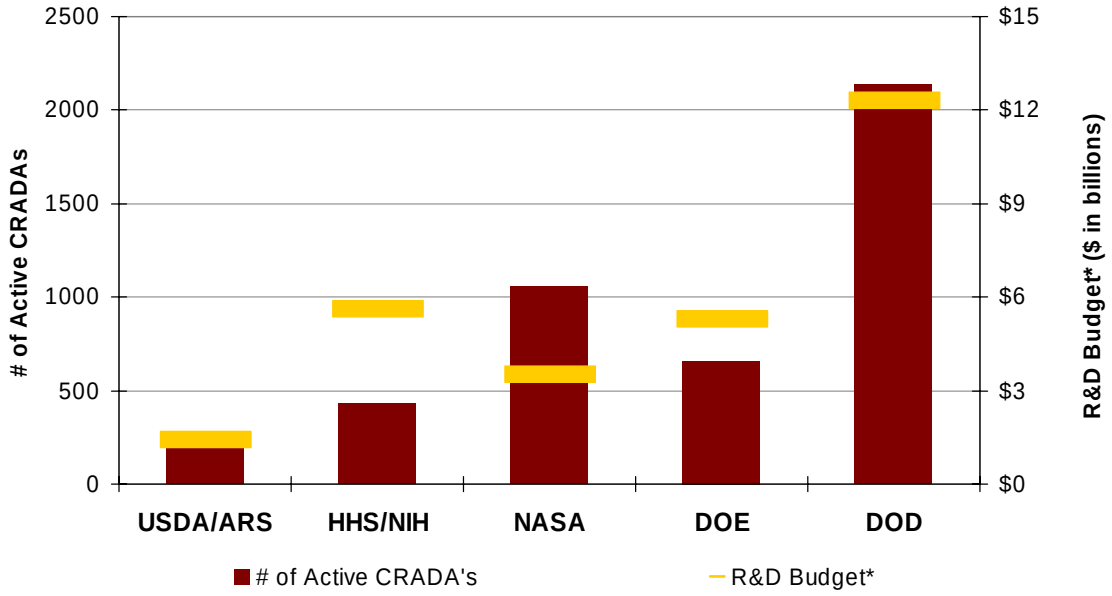
* R&D budget refers to the agency''s federal R&D budget for intramural and other FFRDCs, as per Figure 2.

Figure 6: Active Licenses per $1B of Federal R&D Budget (FY03)



Licensing volume across agencies can be normalized by showing it relative to the R&D budget. DOE stands out as engaging in a high volume of licensing relative to its R&D budget.

Figure 7: Active CRADAs and Federal R&D Budget by Agency (FY03)



A comparison of CRADA activity with the R&D budget reveals the prevalence of CRADAs in USDA/ARS, NASA, and DoD relative to their funding levels and the low level of CRADAs for HHS/NIH.

* R&D budget refers to the agency's federal R&D budget for intramural and other FFRDCs, as per Figure 2.

End Users and Industry Suppliers

As inferred above, DHS is faced with a very different situation from all the other agencies with regard to end users and industry suppliers. DoD has a well-defined, highly structured, mature supplier base (military/industry combined) that is very skilled at supplying the DoD programs and at adopting IP from external sources and building it into its procurements. In addition, the DoD's current stable of first- and second-tier contractors is small in number and well-defined. In both of these areas, the picture at DHS is very different. As with DoD, the products are for national security, but unlike DoD, the end users are generally not captured within the federal government. In addition, the likely supplier base is broader than the well-established defense contractors who represent the major supplier base for DoD. Nor are homeland security end users the typical private or commercial sector consumers of dual-use technologies. The industry supplier base is more varied and less well-known than that of HHS/NIH or USDA/ARS. The lack of a federal market, coupled with the lack of substantial non-federal markets, presents the biggest challenge for DHS commercialization. DHS may need to take proactive measures to stimulate its vendor base for technologies needed by its end users. This is similar to the DoD situation in some circumstances.

Types of Agreement Mechanisms and Deployment

The types of mechanisms used by agencies relate to what they are trying to achieve, what they have been given authority to exercise, and what has been supported by executive management.

HHS/NIH strongly emphasizes IP protection and licensing. It engages only external patent attorneys and agents whom are assessed for quality, not for low bids. HHS/NIH requires prior art searching and employs a rigorous process for making decisions to patent. The agency hires high-level staff with technical Ph.D.s for licensing. HHS/NIH generates far more income from licensing than any other agency—more than 56% of the total licensing income from federal laboratories in 2003 and more than twice the income from the next agency (DOE). At the same time, HHS/NIH generates less IP than either DOE or DoD. HHS/NIH appears to be more deliberate and rigorous in its review and decision-making on what to patent. This may stem from the high level of rigor associated with the Food and Drug Administration's (FDA's) approval of new drugs. This time-consuming process (often lasting in excess of seven years) provides ample time to assess the viability of a given discovery as it progresses through pre-clinical research, clinical studies, and trials. Finally, the pharmaceutical industry, as the principal recipient of HHS/NIH inventions and the supplier of drugs, values the IP in its high-stakes business, that is, the potential large revenue streams.

Compared to its licensing, HHS/NIH does a low volume of CRADAs. In fact, discussions with the HHS/NIH technology transfer office revealed that the agency's policy is to avoid industry-funded CRADA work because it creates a conflict of interest. HHS/NIH does not want to put itself in the position of compromising the direction of the U.S. public health mission by accepting contract R&D from the pharmaceutical industry. None of the other agencies have a situation comparable to HHS/NIH. USDA/ARS, DoD, and DOE all engage in higher volumes of CRADAs. They all have a broader set of applications of their inventions, including dual use, and a more numerous set of industry sectors that are potential recipients of their technologies.

USDA/ARS places a greater emphasis on collaborative agreements than on licenses. It values the strategic negotiation and coordination of those agreements by technology transfer coordinators (TTCs) over strict licensing, patenting, and IP management functions. USDA/ARS also uses a mechanism called a specific cooperative agreement (SCA), which is an alternative to a grant. It enables USDA/ARS to fund collaborative research with a university, retaining no IP rights, as is standard under Bayh-Dole.

It is difficult to generalize the DoD situation because DoD is so decentralized. Each service or agency seems to have a different focus and interest, which in some cases have become part of its culture or management decisions. The Army emphasizes CRADAs, the NRL emphasizes licensing, and the Defense Advanced Research Projects Agency (DARPA) is an acquisition agency that uses acquisition tools like OTs and BAAs to transition technology. These mechanisms are not considered technology transfer mechanisms in the federal legislation. Nevertheless, they achieve the transition of products from federal R&D to end users, and the DoD has stated that they consider these mechanisms important for achieving technology transition. The head of NRL's technology transition office pursues licensing because it has historically been supported by the NRL director. In contrast, ARL stands out as embracing the CRADA as an important mechanism. The DoD technology transition office related that CRADAs have become an important source of operational R&D funds for that laboratory.

Like DoD, there is quite a bit of diversification across DOE laboratories. With a few exceptions, most laboratories engage in both licensing and CRADA activities.

Adopting a full complement of mechanisms would give DHS flexibility to achieve commercialization. This includes the traditional technology transfer mechanisms of licensing and CRADAs, as well as acquisition-related mechanisms used by DoD, such as OTs, grants, and BAAs. Test beds are another tool that can assist the movement of technology to the market and end users. For DHS, the ability to strategically apply the mechanisms, singly or in combination, to create the right incentives and overcome barriers could be particularly important.

II. FACTORS AFFECTING THE FORMULATION OF THE DHS OFFICE OF RESEARCH AND TECHNOLOGY APPLICATIONS

Federal legislation requires each agency that operates one or more federal laboratories to create and fund an ORTA. Throughout the technology transfer legislation, Congress has made it clear that it intends to provide incentives directly to researchers and their laboratories to invent and commercialize. There are therefore provisions for decentralization of technology transfer directly to laboratories as opposed to central agency control. Pertaining to the ORTA, each federal laboratory having 200 or more technical full-time employees (FTEs) must provide one or more FTEs as staff for its ORTA. DHS laboratories currently employ in excess of 500 technical staff members, so the creation of an ORTA within DHS is legislatively required.[10] Only the Transportation Security Laboratory (TSL) begins to approach the numbers requiring that laboratory to have its own ORTA.

This chapter provides information and analysis for use in making decisions on the composition of a DHS ORTA. The FLC Green Book lists ORTA functions. The following list diverges only slightly from that list to recognize particular functions based upon the benchmarking of other agencies and analysis of DHS needs.

- Policy and process development and management
- Patenting and IP protection
- Legal support for agreements
- IP management and reporting
- Strategy, planning, and coordination
- Business intelligence and market research
- Marketing and competitive process management
- Contract negotiation (licenses, CRADAs, OTs, etc.)

Benchmarking: Organization of ORTAs

It should be noted that all the agencies reviewed have a central office responsible for establishing uniformity of policy, processes, and agreement terms; maintaining relationships with other agencies; developing overall technology transfer strategy; and ensuring training and communication across entities within the agency. Beyond that, most agencies decentralize some deployment. DOE and DoD conduct their major technology transition activities from their key distributed facilities—laboratories or agencies—which are large and geographically dispersed. HHS/NIH conducts most technology transfer from a centralized office in NIH that serves a large number of the institutes located on the same campus. USDA/ARS centralizes its office in ARS, where all staff report organizationally, with some key staff physically located at regional research facilities. The research facilities of USDA, while geographically dispersed, are quite small.

[10] "ORTA" is a generic term for the office that facilitates achievement of the technology transition mission. In reality, ORTAs are given a wide range of titles by the agencies that establish them. For DHS, this office probably will be named something like the Office of Technology Transition.

DoD Organization

While DoD has a centralized technology transition function, its principal functions include those roles listed above for high-level, central coordination. The performance of technology transfer is decentralized to individual laboratories within the DoD. Each laboratory develops its own focus and organizational configuration to pursue that focus. For example, while the NRL emphasizes licensing and staffs accordingly, the ARL does little licensing. The focus of the ARL technology transition is to engage in collaborative research with industry, hence its large numbers of CRADAs. Investigating the different offices in detail is beyond the resources of this report. It should be noted that both DOE and DoD have numerous, sizeable facilities that make this decentralization of ORTAs feasible and necessary.

DOE Organization

DOE is unique, with several large GOCO laboratories across the country that perform a significant amount of R&D. Potentially, a different company (for-profit or not-for-profit) or university operates each. These factors suggest that decentralization of ORTAs within the laboratories, consistent with their own operating philosophies and management structures, is an approach that makes sense. DOE retains policy and oversight authority for consistency and uniformity.

The importance of various ORTA functions differs from one laboratory to the next. The Office of Science laboratories tend to emphasize licensing. The National Nuclear Security Administration (NNSA) laboratories do a large number of "funds-in" CRADAs and Work for Others agreements with nonfederal entities (WFO/NFEs) in addition to commercial licenses. This is consistent with their broader applications focus. Generally, the laboratories embrace technology transfer and have robust functions across the board. There are, however, differences in the degree to which one function is emphasized over another. To the extent DHS utilizes the DOE laboratories for R&D and invention, DHS should work collaboratively with DOE and its laboratory ORTAs to fulfill their shared objectives in commercializing technologies for homeland security end users.

HHS/NIH Organization

HHS/NIH is highly centralized for both policy and implementation. The NIH ORTA manages all IP management and patenting, which is contracted out to high-quality legal firms; conducts all licensing; and develops policies and processes for all of HHS. Many of the 20 institutes are quite small, making full, independent ORTAs unwarranted. The larger institutes do, however, have technology transfer points-of-contact (POCs) who negotiate and place their own CRADAs, which are almost exclusively "no funds-in," that is, no funding is provided by industry partners. The trend is toward increasing centralization.

The HHS/NIH R&D budget is large, and the licensing results are significant. The agency owns the IP from its numerous, NIH GOGO laboratories (institutes); they represent 90% of the HHS technology transfer activity. NIH has a very strong technology transfer function, emphasizing licensing and IP management.

USDA/ARS Organization

The USDA/ARS centralized Office of Technology Transfer (OTT) supports a highly decentralized collection of numerous, small R&D facilities around the country. The OTT balances centralization with decentralization through location of staff, communications, and organizational cooperation. Most functions are centrally located in the ARS offices in Beltsville, MD, including patenting, licensing, and marketing. Patent advisors are included in the technology transfer office rather than in the Office of General Counsel (OGC). (Patent agents and lawyers are usually assigned to the OGC in other organizations.) The relations among staff appear to be very positive and collaborative.

Key to establishing intimate working relationships between technical line organizations and OTT is a group of TTCs who report to the centralized technology transfer office but are located with the regional offices they support. The TTC is the principal POC for tapping into OTT services and expertise—the coordinator who works closely with technical line management and staff to strategize industry partnerships and craft agreement conditions and the negotiator for collaborative agreements. This function represents a very different approach to technology transfer than most agencies. TTCs also perform an important liaison function with the ARS central program management function, ensuring that work with industry represents and is well coordinated with the ARS program objectives. The TTC brings in other technology transfer staff as needed and appropriate—patenting, licensing, and marketing.

Both TTCs and patent advisors are high-level staff with strong technical backgrounds (GS 13 and 14 for staff; GS 15 for management). Many patent advisors also have law degrees. The licensing staff members have a mix of technical and business backgrounds.

Implications for ORTA Functions in DHS

To define the composition of the DHS ORTA, the following questions must be addressed for each function within the ORTA.

- Should the capability be developed in-house or contracted?
- Should the function be provided from a central organization, or should the function be decentralized to the inventing facility/laboratory?
- What is the relative importance of each function?
- What is the required size of each function?
- What are the staff and management qualifications for each function?

One further question needs to be kept in mind as the DHS ORTA evolves. How will DHS coordinate with other agencies with related missions?

This question is extremely important because DHS was structured deliberately to be dependent on other agencies for completion of its mission. Key roles include R&D for the DOE laboratories, early drug discovery from USDA/ARS, military technologies from DoD, and recovery from the Environmental Protection Agency (EPA). DHS needs to discover and embrace a unique approach to leveraging assets from other agencies.

Following is a discussion of each functional element based upon the needs of DHS compared with the practices of the other agencies. Tables included with each section capture the conclusions with regards to each function. The tables do not dictate the precise composition of the ORTA, but they can be used to begin laying out a skeleton organization and identifying initial staffing guidelines.

Function: Policy and Process Management

Developing and implementing agency policy and process is likely to be an important function for DHS in general and for technology transition in particular, as it is for every other large R&D agency. In the case of DHS, there are a variety of processes and technology transition mechanisms to employ; DHS is an immature organization with a common infrastructure, operations, and interactions to establish; and DHS has been formed from a number of organizations from numerous agencies with different cultures and operating practices.

	Implementation Preference		Relative Importance	Relative Priority	Relative Size
	In-house	Contract	High Medium Low	High Medium Low	≤1 2-4
Policy Process & Management	★		**H**	**H**	

Summary Qualifications: Mid-level management experience developing functions and organizations. Broad and deep skills to develop, implement, and enforce policies and processes. Federal agency experience. Familiarity with federal technology transition and acquisition policies.

Function: Patenting

DHS will principally patent inventions developed only within the laboratories it owns. Factors influencing how to fulfill the patenting function include the following:

- Volume of patenting
- Variety of inventions
- Importance of quality in patenting – requiring prior art searches and extensive office actions

The following factors tend to suggest contracting the patenting function rather than building an in-house capability.

- DHS-owned laboratories are few and small. They do not generate great volumes of IP.
- While the volume of inventions is expected to be modest in the near term, it is expected that they will also cover a variety of technical areas—biological, physical sciences, devices, etc. Contracting with different firms would allow DHS to acquire deep expertise as needed.
- The quality of patenting may be important, given the importance of commercialization to DHS. It would be difficult for a small function to provide a high level of expertise for a wide range of technologies.

The small size and modest volume of IP suggest centralization rather than decentralization. As seen with the other agencies, technology transition functions are decentralized when the agency is large and varied, and when it generates a high volume of IP and agreements. If DHS can find an attorney qualified to do both patenting and provide support for agreements, such a person would be ideal as an agency hire.[11]

	Implementation Preference		Relative Importance	Relative Priority	Relative Size
	In-house	Contract	High Medium Low	High Medium Low	≤1 2-4
Patenting	★	★	**H**	**M**	

Summary Qualifications: Extensive education and experience in patenting and management of other attorneys. May be combined with agreement support function below.

NOTE: Some or all of the actual patent prosecution can be contracted out; however, the function still requires knowledgeable legal oversight. Contracting can be used to supplement in-house prosecution or for specialized patents.

Function: Legal Support for Agreements

Legal support may be more critical for ensuring compliance in using nontraditional mechanisms for transition in conjunction with traditional technology transfer mechanisms. This need can be met through an attorney who understands and advises on the use of OTs, grants, and acquisitions and assists in the proper crafting of such contracts. The patent attorney may provide this function.

	Implementation Preference		Relative Importance	Relative Priority	Relative Size
	In-house	Contract	High Medium Low	High Medium Low	≤1 2-4
Legal Support for Agreements	★		**H**	**M**	

Summary Qualifications: Experienced in federal acquisition and technology transition mechanisms, including OTs, grants, BAAs, licenses, and CRADAs. May be combined with patent attorney function above.

[11] As of the date of this publication, DHS has hired an attorney well-qualified to provide legal support for both patenting and agreements.

Function: IP Management

The degree to which agencies or laboratories engage in IP management is variable. All agencies must track and report on the generation of IP at a minimum; therefore, all have some sort of tracking system. Beyond tracking, there is a wide range of analysis and management that an agency can exercise. Of the agencies compared, HHS/NIH exercises the greatest degree of analysis, but they have the advantage of captured institutes with a common culture and objectives.

How much depth DHS will choose to exercise in IP management is unknown. However, DHS needs a robust system for IP tracking and management. This is more important for DHS than for other agencies because IP will be generated from many sources, with many applications and mission importance. In the spectrum of activities in IP management, there probably needs to be less IP analysis and more tracking to ensure that inventions generated using DHS funds from non-DHS laboratories are known and accessible.

	Implementation Preference		Relative Importance	Relative Priority	Relative Size
	In-house	Contract	High Medium Low	High Medium Low	≤1 2-4
IP Management & Reporting	★		**H**	**H**	

Summary Qualifications: Good sophisticated user of technology. Understanding of federal technology transition and the role of IP in technology transition. Able to produce accurate, detailed data reports.

Function: Strategy, Planning, and Coordination

Many technology transition organizations do not engage explicitly in developing commercialization strategies and plans because technology transition is not considered a primary mission. Therefore, it is carried out in an opportunistic manner. Commercialization may be the most important function for DHS to adopt because commercialization is important to its primary mission; employment and timing of the various tools and mechanisms require advanced thinking and deliberate preparation. Furthermore, this function would be applied to targeted technologies from all DHS R&D sources – universities, DOE national laboratories, and DHS laboratories.

An important question to consider is the following: will individual program managers (PMs) handle commercialization, or should DHS build a centralized capability to support these PMs and ensure a level of diligence and discipline? The problem with relying on existing PMs in S&T is that there isn't a single PM through the life of the program. Continuity of a PM through the life of the program would be ideal. Where that is not the case, careful attention should be paid to managing transitions to minimize discontinuity. A small staff with expertise in the tools of commercialization that can shepherd and track the technology along the commercialization path, identify the need for course corrections, and implement the plan through the life of the program would be a valuable service and provide continuity to the PMs.

	Implementation Preference		Relative Importance	Relative Priority	Relative Size
	In-house	Contract	High Medium Low	High Medium Low	 ≤1 2-4
Strategy Planning & Coordination	★		**H**	**H**	

Summary Qualifications: Knowledgeable and experienced in federal technology transition and/or acquisition mechanisms. Technical credentials to work on equal footing with PMs. Knowledge of business/industry sector. Proven experience developing commercialization strategy. Adept at process design.

Function: Business Intelligence

It is difficult to imagine doing strategy and planning for commercialization without knowledge of the technology application space, markets, and industry sectors. This is more significant for DHS than for HHS/NIH or USDA/ARS because the number of industry sectors is much greater than for the other agencies. This is more akin to the broad applications for DOE and DoD technologies.

However, the difficulty is in deciding how to approach this issue. The DOE laboratories have some expertise in-house, but not necessarily as intentionally focused as DHS needs. Another approach has been to contract with intermediaries to conduct market research or even to facilitate the process of small business creation to commercialize laboratory technologies. If a robust, centralized capability is to be developed, it should be done incrementally as the need is assessed with the intent of eventually supporting the DOE National Laboratories as well as the DHS-owned laboratories. One option would be to assign this function to the strategy and planning staff and support them with contracts to firms for market research and business intelligence.

	Implementation Preference		Relative Importance	Relative Priority	Relative Size
	In-house	Contract	High Medium Low	High Medium Low	 ≤1 2-4
Business Intelligence	★	★	**M**	**M**	**evolve as appropriate**

Summary Qualifications: Knowledgeable and experienced in market research and business intelligence. Adept at tools of market research, both primary and secondary, including other commercial sources of results. Proven ability not only to retrieve relevant information, but also to add value by analyzing and synthesizing information and insights into industry and business history and dynamics.

Function: Marketing and Competitive Process Management

Marketing and competitive process management includes both advertising and executing fair, competitive, and open processes when DHS owns the technology. DHS may also want to execute the process when extraordinary measures are being taken to provide incentives for and reduce barriers to commercialization when the technologies are not DHS-owned. This function accompanies the strategy, planning, market research, and business intelligence functions.

	Implementation Preference		Relative Importance	Relative Priority	Relative Size
	In-house	Contract	High Medium Low	High Medium Low	≤1 2-4
Marketing & Competitive Process Management	★		**M**	**L**	

Summary Qualifications: A single marketing lead from within the Office of Technology Transition, supported by excellent graphics and communication support would be advantageous to this team, which will need excellent communications—tactful, precise, and compelling. Adept at process design.

Function: Contract Negotiation (Licensing, CRADAs, OTs, etc.)

Expertise in negotiating and crafting agreements, especially licensing, is developed over years. Contract negotiations are normally led by ORTA staff, supported by the general counsel. For DHS laboratories, negotiations are likely to be infrequent because of the currently small IP portfolio. If additional business expertise is needed, DHS could reach out to other agencies for particular expertise.

The DOE laboratories already have experienced staff to negotiate traditional technology transfer agreements—CRADAs and licenses—where they own the technology and IP. In the case of OT contracting, experienced staff to craft and negotiate are probably hard to find, since DoD has previously been the only agency with authority to use this mechanism. If OTs are infrequent, DHS could use experienced DoD employees. If OTs are going to be a commonly used mechanism, DHS may want to hire or develop this expertise in-house. DHS will certainly want to build on DoD's experience in negotiating appropriate IP arrangements in such cost-shared agreements.

	Implementation Preference		Relative Importance	Relative Priority	Relative Size
	In-house	Contract	High Medium Low	High Medium Low	≤1 2-4
Contract Negotiation	★		**M**	**M**	

Summary Qualifications: Seasoned negotiator with experience in federal technology transition and/or acquisition mechanisms. Technical credentials to work on equal footing with program managers. Knowledge of business/industry sector.

Implications for DHS

The benchmark data and assessment of applicability of practices to DHS suggest the following:

- Leverage assets from other agencies.
- Centralize technology transition for its own GOGO laboratories by establishing expertise and resources within S&T and contracting out specific functions, at least initially.
- Rely on preexisting expertise and resources within the DOE national laboratories and other agencies for commercialization of their own technologies rather than duplicating functions centrally. The office must be large enough to enable the establishment of close, intense relationships with other laboratories and agencies. While leveraging assets from other agencies, DHS will discover and embrace its own approach to achieving technology commercialization.
- Establish a small Office of Technology Transition, emphasizing policy, process and management; IP management and tracking; strategy, planning, and coordination; and legal support for patenting and transactions. In-house resources for contracting are important, as well; however, they may be provided in the short term by other agencies.
- In question is the support required for business intelligence and marketing and competitive process management. It would be prudent to approach the acquisition of these functions incrementally. Resources can be conserved to the degree these can be provided by other staff in the ORTA, for example, by the staff members providing strategy, IP management, or contract negotiation.

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III. INFORMATION COLLECTING, TRACKING, AND REPORTING

DHS is subject to multiple requirements for information collection, tracking, dissemination, and reporting. Among the legislative requirements are the following:

- Transfer in a timely manner to the NTIS unclassified scientific, technical, and engineering information which results from federally funded research and development activities for dissemination to the private sector, academia, state and local governments, and federal agencies. [15 USC 3704 b-2 (a)]

  Note: Information dissemination requirements reach far beyond the traditional realm of technology transfer. For instance, the Atomic Energy Acts of 1946 and 1954, the Energy Reorganization Act of 1974, and the Department of Energy Act of 1977 all call for the dissemination of scientific and technical information (STI) to the public. These are specific to DOE and its predecessor agency, but similar requirements are in place for other agencies performing R&D.

- Provide and disseminate information on federally owned or originated products, processes, and services having potential application to state and local governments and to private industry. [15 USC 3710 (b) & (c)]

- Maintain all records of agreements entered into by agency laboratory directors with respect to the Stevenson Wydler Act. [15 USC 3710a (c)]

- Provide an annual report to DOC on the results of technology transfer. This report includes data on the number of invention disclosures, patent applications, patents, CRADAs, licenses, and revenue from licensing, as well as an explanation of the agency's technology transfer program, and progress made toward development of useful measures of the outcomes of the technology transfer programs. [15 USC 3710 (f)]

These requirements point to two distinct collections of information—technical information that results from research (STI), and IP information that results from research sponsored by DHS and performed at laboratories, both its own and those of other agencies. Both types must be actively collected and managed to record, disseminate, and preserve as critical assets.

Generally, these two sets of information are handled by discrete systems. By starting with a "clean slate" and a minimum of existing data, DHS may determine that both data sets could be coordinated within one system, resulting in a simpler and more efficient solution. The potential to accommodate STI was a consideration when examining IP systems.

Benchmarking

Every technology transition office interviewed has either developed their own or purchased and modified a commercial system for managing IP and technology transition contracts. DHS will need a computer information system to manage IP developed at its own laboratories, to monitor IP developed by partner laboratories, and perhaps to scout for existing technologies beyond the scope of its laboratories, partners, and centers of excellence.

To meet the STI obligation, agencies have developed systems for the collection, management, and tracking of such information. These systems serve many needs beyond the NTIS reporting requirement. They help to identify redundant or synergistic R&D, gaps in program development, and potential technical partners or resources. The NTIS dataset is a subset of much larger collections, which may include classified data, CRADA-protected information, and other items not approved for public release, which must also be managed.

The following chart shows how various agencies manage their technical data (STI):

Agency	Scientific and Technical Information Management System
DoD	Defense Technical Information Center (DTIC) ♦ Provides centralized operation of DoD services for the acquisition, storage, retrieval, and dissemination of STI to support DoD research, development, engineering, and studies programs. ♦ Systems have been developed by DoD, not purchased. ♦ Hosts approximately 100 Web sites for defense programs and manages 11 information analysis centers, which help customers locate, analyze, and use STI. DTIC strives to: ♦ Provide direct information support to the war fighter. ♦ Leverage the multibillion dollar investment in DoD scientific and technical research so that citizens at large can use it. ♦ Prevent unnecessary or redundant research from being performed at taxpayer expense.
DOE	Office of Science and Technical Information (OSTI) ♦ Makes the results of DOE's research available to scientists, researchers, and engineers in the DOE community and beyond, including academia, the international science community, and science-attentive citizens. ♦ Includes all DOE R&D accomplishments and project summaries, dating back to the Manhattan Project. ♦ Hosts a number of products that provide a vast array of information and resources pertaining to energy science and technology. Knowledge discovery is a key value in the accomplishment of the DOE mission. ♦ Coordinates the Scientific and Technical Information Program (STIP), a complex-wide collaboration program. ♦ Is supported and managed by Oak Ridge National Laboratory (ORNL).

Agency	Scientific and Technical Information Management System
USDA/ARS	♦ USDA R&D is managed and disseminated by the National Agricultural Library (NAL), which provides technical information on agricultural research and related subjects to scientists, educators, and farmers using computer databases. ♦ USDA R&D coordinates and is the primary resource for the national network of state land grant university and field libraries. ♦ USDA R&D serves as the U.S. center for the international agriculture information system. ♦ ARS also operates a system called CRIS, a documentation and reporting system for ongoing and recently completed research and education projects in agriculture, food and nutrition, and forestry. This encompasses sponsored research by universities, grant programs, the Small Business Innovation Research Program (SBIR), etc. ♦ USDA/ARS's policies for information dissemination seem to stem primarily from Title 7, Chapter 5 (not the technology transfer legislation). Title 7 defines ARS's responsibilities regarding public information and details on fees for searches, printing, and other library-related tasks. This may predate and essentially meet the technology transfer legislation requirements. ♦ NTIS handles invoicing and collection of fees for library services and printing. ♦ It is not apparent that USDA/ARS provides STI data to NTIS, but their Web site references NTIS as a source for printed documents. NTIS may be a provider of hard-copy documents only.
HHS/NIH	Like USDA/ARS, HHS/NIH's policies for information dissemination seem to stem not from technology transfer legislation, but from Title 45, Public Welfare, Subtitle A, Department of Health and Human Services, Part 5, Freedom of Information Regulations. This spells out in great detail the responsibilities of HHS/NIH to make the results of its research available to the public. HHS/NIH achieves this through four major information systems and Web portals: ♦ MEDLINE: This dataset of more than 12 million references to articles published in 4,600 biomedical journals is maintained by the National Library of Medicine (NLM) and may be accessed free of charge on the World Wide Web. Two Web-based products, PubMed and the NLM Gateway, provide this access. ♦ CRISP: The Officer of Extramural Research at HHS/NIH maintains this searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions. ♦ PubMed: A comprehensive database of article titles and abstracts. ♦ NLM Gateway: A portal that allows users to search in multiple retrieval systems at the NLM. ♦ HHS/NIH has a large staff to manage all Freedom of Information Act (FOIA) requests.

Implications for DHS

As a new agency, DHS has the opportunity to survey how other agencies manage this complex task and draw upon their experience and expertise. DHS is not hampered by vast amounts of legacy data, so a large, complex system is not needed at this point.

DHS S&T is committed to an integrated research, development, test, and evaluation (RDT&E) process, which will require access to technical data, generate new technical data, and benefit from access to IP data. Developing one integrated system to manage both STI and IP data sets may be an opportunity to conserve resources, meet requirements, and design a simpler solution than those used by older, larger agencies.

An overview of the RDT&E process reveals that the flow of information and access to technical data is important at every step, from early technology assessment through transition to manufacturers and end users. Most agencies (DoD, DOE, USDA/ARS, and HHS/NIH) have developed their own proprietary databases to manage technical information. All agencies we interacted with segregate STI from the specialized data related to IP.

Managing these two sets of information separately may not represent best practices for R&D technical program management, but rather a legacy solution addressing two requirements that evolved over time. DHS has the opportunity to determine if multiple systems are needed or if one system could be more effective in managing these related data sets.

IP Management as a System Solution

A system designed to track IP may provide the option to manage technical data as well, either within the same system, or by linking to other enterprise systems. This section summarizes an evaluation of three commercially available IP management systems used by other agencies and laboratories, comparing their performance in areas important to the successful management of IP portfolios. Consideration was also given to capabilities beyond IP management, such as the ability to warehouse technical information, interact with DHS's program management software, and provide subsets of data to other systems such as NTIS.

Evaluating IP Systems

In building a technology transition function, DHS will need a method to inventory and track IP that is developed at its laboratories. It may also benefit from knowledge of IP that exists at other research institutions it funds—both intramural laboratories of other agencies (e.g., DOE) and extramural institutions—where much of DHS's research is being conducted. Although that IP is likely to be owned by the laboratory or agency that developed it, DHS may have a vested interest in the disposition of that IP—whether patents are applied for, what fields of use (FOUs) are licensed, how the information is protected, etc.

This report's objective is to determine what IP management software packages are available, what is being used by the laboratory community, and what system can best meet the DHS's small but growing needs.

In examining the many agencies and laboratories involved in technology transition, it is apparent that there are two primary options: (1) build a custom system or (2) purchase an off-the-shelf solution and customize it to meet DHS needs. The agencies that have built their own systems tend to be large with significant resources to apply to such a project. DoD and USDA/ARS are two such agencies, but individual laboratories, such as SNL, have also chosen this path.

While DHS's current IP management needs are small, DHS may create or acquire new laboratories, and the potential for greater IP generation exists. This suggests an opportunity to purchase a modular system that can be customized and that can grow with DHS needs.

DHS has an advantage over more established agencies of being able to start with a clean slate, rather than needing to convert masses of data from legacy systems. Therefore, DHS should consider purchasing a system, rather than attempting to build something of its own. DHS's deputy chief information officer (CIO) has been apprised of this suggestion, and stated that DHS does not have the resources to build an in-house system. Note, however, that a significant amount of system customization seems to be required regardless of which commercial product is chosen.

This report examined three commercially available systems being used by various laboratories and agencies:

- Geowerx (formerly PartnerWorks) is a system that is undergoing a major overhaul after five years of relative inactivity. Programmers at Los Alamos National Laboratory (LANL) and SNL developed the original product, PartnerWorks. The developer spun off a company and provided PartnerWorks to LANL, SNL, Lawrence Livermore National Laboratory (LLNL), and ORNL, and perhaps others.
- IPMaster: This product has strong financial backing, as it has been adopted by the Thompson companies, which also owns Aureka, an excellent and widely used patent research tool. DOE uses this program to track inventions made by its national laboratories, and it is used by Idaho National Laboratory (INL) and Pacific Northwest National Laboratory (PNNL), who have teamed to build additional functionality into the system. The laboratories developed a disclosure module, which is now offered by IPMaster as part of their package.
- KSS TechTracS: This system is currently used by HHS/NIH, LLNL, NRL, and several universities.

iEdison is another system available free of cost from HHS/NIH, but this program is used only as a reporting mechanism for extramural inventions. For instance, when a federal agency funds research, the researcher must report the technical results and any IP generated. This Web-based program provides a portal for that information, but the data set is likely incomplete, as there is no "official" requirement to use this vehicle for reporting. Several agencies, including HHS/NIH, DoD, and DOE, are using the system, but many others simply collect and maintain their own data. DHS has entered into a memorandum of understanding (MOU) with HHS/NIH to use iEdison, but the interface between this and DHS's own system will need to be carefully designed to avoid duplicate input or reporting.

Over the past three years, several laboratories have chosen to either update their IP management systems or purchase or build new ones. These laboratories (NRL, ORNL, LANL, SNL) have shared their insights and, when available, formal benchmarking studies used to select a system. DHS will require many of the same functions that have been identified as critical by these laboratories, including the following:

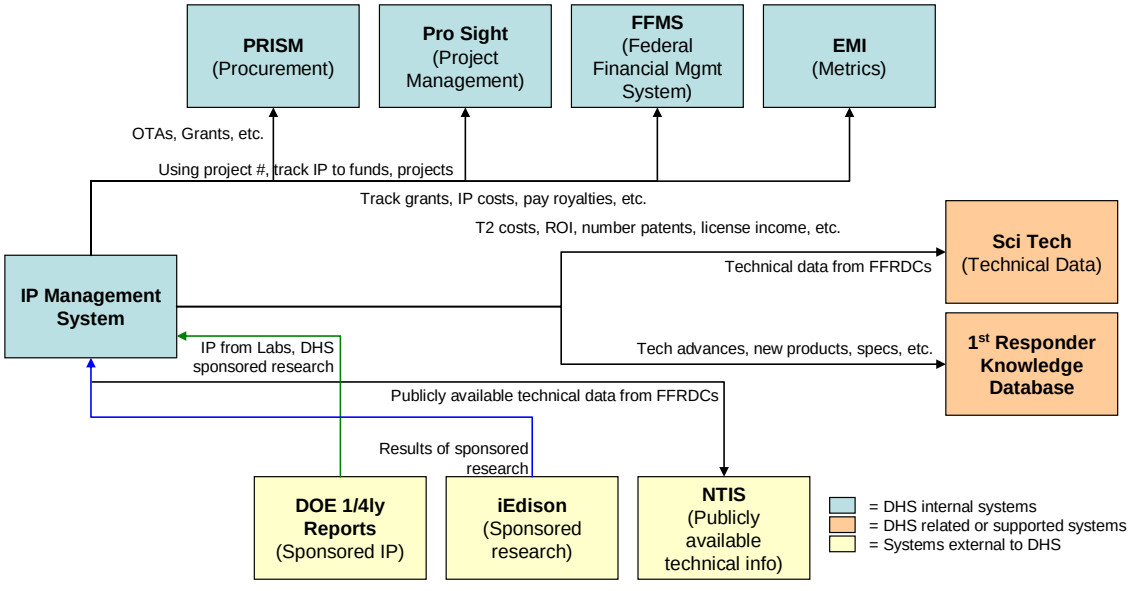
- Disclosure management.
- Copyright and trademark management.
- Patent application management, both for use by attorneys and by technology transition staff.
- License and encumbrance management.
- Royalty tracking and processing.
- Agreements tracking and processing: CRADAs, user facilities, or whatever contracts DHS decides to use.
- Contacts/opportunities.
- Robust reporting, both canned and user-defined.
- Robust search capabilities.
- Automatic reminders of events (bar dates, agreement closures, etc.).
- Document management.
- Approval routing.
- In addition, DHS may have broader needs than stand-alone laboratories, such as the following:
  - A need to understand what IP exists at its partner laboratories (e.g., DOE, DoD) that may play into their programs.
  - A need to develop and manage portfolios, not just individual pieces of IP. These may include IP not owned by DHS and may involve multiple laboratories and partners.
  - A need to mine IP in the early stages of program development.
  - Requirements to report to various agencies and organizations.

An IP management system that can provide expanded capabilities to meet requirements for information dissemination to NTIS would leverage DHS resources and provide a simpler solution than the legacy systems supported by larger agencies with vast quantities of data.

To meet the needs of both data dissemination and IP management, the system selected will need to interact with a variety of other systems, both within DHS and beyond (see Figure 8), such as the following:

- PRISM: This is the system used by procurement. If "procurement-type" contracts are used to effect technology transition, such as OTs and Title 3s, the activity should be tracked along with more traditional CRADAs and licenses in the IP management database.
- ProSight: This program is used across S&T to collect information for project management. It incorporates financial and technical data reported by laboratories doing sponsored research, that is, the DHS and DOE laboratories. Linking to the IP management database by project number would help to track where IP is generated and what organizations, projects, and managers get credit for development of IP, etc. Since technology transition needs to be incorporated into the entire RDT&E process, it seems appropriate to link the project management software with the IP software.
- Federal Financial Management System (FFMS): This DHS enterprise financial management system may be the vehicle for payment of royalties, so it would need to interact with the IP management system.
- EMI: This is a DHS system for collecting and developing metrics; it should be able to pull technology transition metrics directly from the IP system and may contribute additional data to the annual report to Congress.

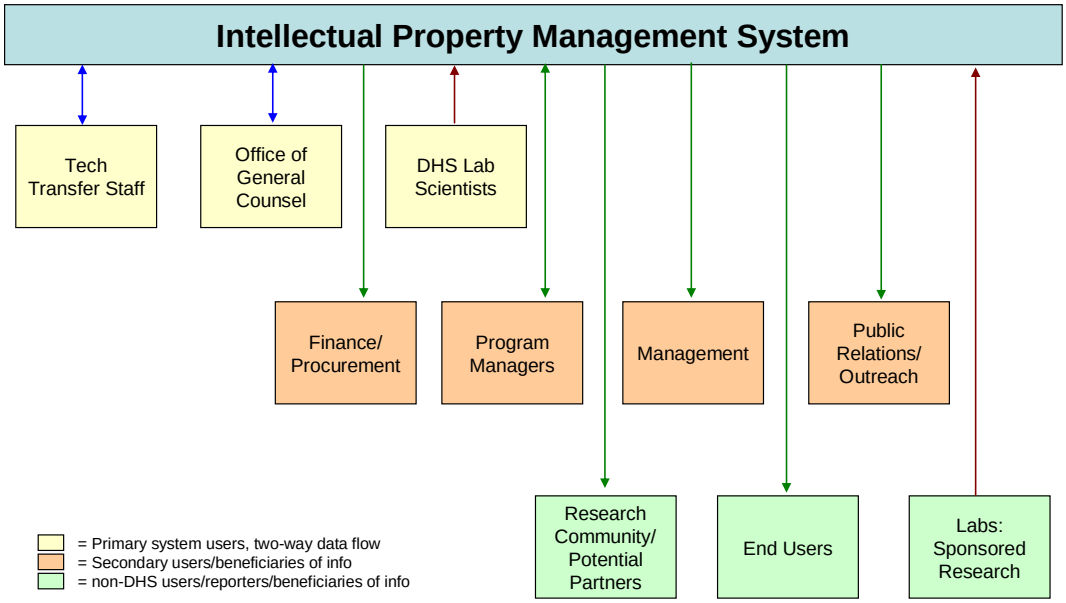
Figure 8: DHS Interactions with Other Databases



The DHS IP management system will need to interact with several other databases, both internal and external to DHS.

To serve the needs of all aspects of the RDT&E process, the system will need to accommodate data flow to and from several groups of users. Figure 9 highlights the many departments, functions, and organizations, both internal and external to DHS, which may potentially contribute data to or draw data from a DHS IP management system, particularly if the system is designed to support technical data collection and distribution. The success of this system is dependent on it being accepted by and useful to a broad spectrum of players across the S&T Directorate.

Figure 9: System Users



Data will flow both to and from the IP management system via several groups of users within DHS, as well as the external research community and end users.

Following is a list of potential users and contributors:

Primary users

- Technology transition staff will use the system to develop and manage IP portfolios, identify candidates for commercialization, monitor encumbrances, etc. This group primarily will maintain the IP portion of the database and will probably include the database administrator.
- OGC will use the docketing portion of the system to track patent applications, determine payment of fees, manage patent evaluation process, etc.
- DHS laboratory scientists will input disclosure information to the system via a Web interface, perhaps with assistance from ORTA or general counsel. There will be two-way data flow during the patent prosecution/docketing process.

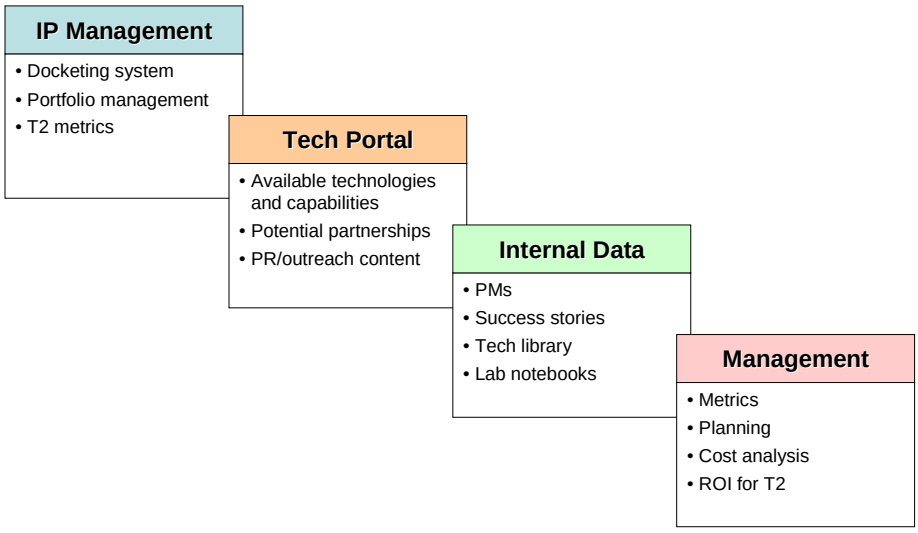
Secondary users/beneficiaries of information

- Finance and procurement will use the system to record payment of royalties and license compliance, and to track IP and technical data from procurement-type contracts like OTs, BAAs, etc.
- PMs will access system data to identify existing programs to avoid redundancy, locate synergistic programs, plan resources, etc. Since technology transition needs to be addressed early in the RDT&E process, knowledge of existing IP (i.e., patent applications) can be helpful in developing a transition plan, identifying potential partners, etc.
- Management will use system reports to track the cost of technology transition, return on investment (ROI), success of the activity, etc.
- Public relations/outreach will use the system to maintain a library of success stories, lessons learned, successful partnerships, etc. This would be very valuable to the public relations group in presenting a positive message to the public about how technologies are being developed for and applied to the nation's security.

Non-DHS users, reporters, and beneficiaries of information

- Research community and potential partners: A Web portal can be devised to give access to approved information to either the public or registered users, allowing users to search for projects, partners, technologies, or capabilities.
- End users: The same portal could help end users locate technical solutions to their most pressing problems or provide input and feedback on DHS systems and technologies.
- Lab-sponsored researchers: They could use the system to report technical information, disclosures, transitions, encumbrances, etc. as related to DHS-sponsored work. Laboratories could also post capabilities that support DHS for potential partners to access through the portal. This may occur through a feed from iEdison or by direct input.

Figure 10: System Functions



Types of data and functions that a mature, robust IP management system would support.

The advantage of a modular database system is that new functionality, beyond the original IP management goal, can be added over time as needed or desired. As shown in Figure 10, some examples of functionality include the following:

- IP Management. This is the primary function of the system, used by IP attorneys, technology transition staff, and management.
- Tech Portal. This function meets requirements for distribution of information to public and end users; creates access to DHS-funded research info for potential partners and laboratories; helps avoid redundancy; identifies synergy among research projects; identifies experts across large research complex.
- Internal data. This function provides one source for technical data and can feed to many places, both inside and outside the DHS organization.
- Management. This function allows for the development and analysis of metrics to determine the effectiveness of DHS technology transition activities. This function also assists in planning, cost analysis, and ROI for technology transition program, as well as for individual projects, programs, or technologies.

Summary

Below is a summary of considerations for DHS.

- Consider KSS TechTracS. It seems to be the most suited for DHS's needs because it is designed to meet the needs of portfolio managers and technology transition professionals rather than the needs of IP attorneys. IPMaster is primarily a docketing system serving large legal firms.
- Purchase a commercial system. Do not attempt to build from scratch.
- Purchase a modular system that can start small but that can also accommodate growth and change.
- Purchase a system that has been successfully adopted by organizations with similar requirements.
- Choose a program that addresses technology transition and portfolio management needs, not just a data warehouse for IP or a tool for IP attorneys.
- Stage implementation and deployment to meet immediate needs, followed by expanded capabilities.
- When populating with data, start with DHS-owned IP. Next expand to include first DOE IP resulting from DHS-sponsored research and then IP from other organizations, laboratories, and universities that may be of interest to DHS.
- Think broadly. Plan a system that interacts and supports other enterprise and external systems and serves the needs of many diverse user groups.

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IV. MECHANISMS ENABLING AGREEMENTS WITH NON-FEDERAL ENTITITES

The laws, orders, and regulations that have been written to implement federal technology transfer have created or encouraged the development of many tools to facilitate this activity. Methods of contracting with the private sector and mechanisms to develop and manage partnerships can take many forms. A full complement of contractual vehicles is essential to every organization engaged in technology transfer/transition.

In its future technology transition efforts, DHS will be targeting technologies and systems that will involve linking together a multitude of partners, including large corporations, small businesses, other federal agencies, national laboratories, and/or universities. Four types of contracts/agreements are particularly useful and are widely used throughout the entire technology transition process. They include NDAs, CRADAs, licenses, and OTs. Because these contracts/agreements are so important and pervasive as key elements of a vital technology transition process and because they each serve somewhat different purposes, each is described in separate sections that follow. In addition, Appendices D, E, and F detail the benchmark data for NDAs, CRADAs, and licenses summarized in this chapter.

Non-Disclosure Agreements

NDAs are frequently used during the "courting" phase of a partnership to ensure that proprietary information, be it financial, technical, or strategic, is protected. Execution of an NDA allows for an open exchange of information that can help qualify a potential partner's level of commitment, technical capabilities, and ability to carry a project through to a successful end. NDAs are the most frequently executed type of contract in most technology transition offices, so it is important and expedient that the "boilerplate" for these contracts be easy to use, understand, and implement.

Benchmarking

NDAs were compared and contrasted from six federal laboratories, representing four agencies. Details of this benchmarking are contained in Appendix A, including an article-by-article comparison. Surprisingly this agreement type had more divergent clauses and legal rigor than the other three contract types benchmarked. We had expected just the opposite since this is perhaps the simplest and lowest risk of the various contracts. We had also expected that this would be the agreement that was the most understandable to research staff, managers, and business staff alike. NDAs are likely to be the first legal introduction to a laboratory and the first in a chain of increasingly detailed contracts/agreements if the technology transition process proceeds successfully.

Cooperative Research and Development Agreements

CRADAs are one of the principal mechanisms used by federal laboratories to engage in collaborative efforts with non-federal partners. The CRADA, which is not an acquisition or procurement vehicle, is designed to be a relatively easy mechanism to implement, requiring less time and effort to initiate than standard government contracts—contracts based on Federal Acquisition Regulations (FARs). CRADAs are intended to take into account the needs and desires of private industry when commercializing a product, that is, the need for confidentiality and perhaps for exclusive rights to a technology.

The Federal Technology Transfer Act of 1986 created the CRADA mechanism. The stipulations and requirements for a CRADA are contained in U.S. Code 15, Section 3710a, which describes:

- The authority of laboratory directors to enter into CRADAs and to negotiate licensing agreements.
- The requirement that the federal laboratory may accept funds, personnel, services and property but may only provide personnel, services, and property—no "funds out" allowed.
- The provision for current and former government employees to benefit financially from the commercialization of inventions.
- The time requirements for approving CRADAs.
- The protection of trade secrets and confidential information.

Each agency and laboratory is free to develop its own CRADA model, but many provisions are common across agencies. An examination and analysis of the various models used will allow DHS to develop an agreement model that will provide the right level of flexibility and accountability to support successful partnerships.

Benchmarking

CRADAs were compared and contrasted from six federal laboratories, representing four agencies. Details of this benchmarking are contained in Appendix B, including an article-by-article comparison. While NDAs have a legal history that dates back many decades, CRADAs are a relatively new legal instrument, having been first chartered in 1986. As such, professional organizations such as the Technology Transfer Society and FLC had the opportunity for more extensive networking among federal agency policymakers, which has led to more uniformity in style, language, and legal rigor in model CRADAs used today. Differences in language and rigor result largely from differences among staff attorneys in perceived risk, program management oversight requirements, and varying approaches to legal sufficiency/necessity. Thousands of CRADAs have been executed by the federal laboratories in the last 20 years with few (if any) legal repercussions/disputes.

Licenses

A license is a contract between two parties (e.g., a laboratory licensor with a patent and an industry licensee) that ensures the licensee will not be sued for patent infringement. It is the federal government's policy to promote the utilization and commercialization of inventions that arise from agency-supported R&D through licenses. Patent license agreements may be incorporated into a CRADA or developed independently. Industry partners seeking to license government patents must satisfy a number of conditions:

- They must provide a satisfactory development or marketing plan and evidence of their ability to implement the plan.
- They must commercialize inventions within a specified period of time and continue to make the benefits of the invention reasonably accessible to the public.
- They must report utilization of the patent periodically to the agency holding the patent (assignee).
- They must generally agree that any products developed through the use of the invention will be manufactured substantially in the U.S.

In addition, the government always retains an irrevocable royalty-free right to practice the invention. Licenses take many forms and require careful negotiation and crafting of the contract language. DHS must take care to develop license templates that will efficiently lead to fruitful negotiations and valid contracts.

Benchmarking

Licenses were compared and contrasted from six federal laboratories, representing four agencies. Details of this benchmarking are contained in Appendix C, including an article-by-article comparison. Surprisingly, license terms and conditions are arguably the most uniform among the laboratories benchmarked. While licenses, as a contact vehicle, have been around since the early days of federal patent protection, one has to believe that this similarity is largely a result of the influence and networking opportunities afforded by the Licensing Executive Society.

Other Transactions

OTs are defined in the negative as transactions "other than contracts, grants, or cooperative agreements." They are not procurement contracts, as they are not subject to the FAR, but they have been traditionally administered by the procurement department.

Other transaction authority (OTA) was granted to DoD in 1989 (10 USC 2371) and has recently been extended to DHS and DOE. OTs are used extensively by DoD procurement officers to encourage the development of products that will ultimately be purchased by DoD to meet their mission.

OTs have not been used by ORTAs for several reasons:

- OTs require cost-sharing and are considered to be assistance instruments. Traditional technology transfer/transition agreements do not allow the government to provide payments to a research partner.
- OTs are intended to result in federal procurements, whereas technology transfer is intended to move technology to commercial markets.
- The stated function of ORTA is to identify technologies and ideas that have potential for application outside of the federal government (dual use). The DHS S&T mission is to move the technology into products that have a specific purpose beyond economic well-being, that is, products that meet a homeland security need and can be acquired through commercial products. This mission is new for an ORTA.

OTs have been traditionally used to "bring new technology in" to government agencies by streamlining processes and attracting companies that normally do not deal with the federal government. OTs may prove to be a valuable technology transfer tool that can be used to "push technology out" to homeland security end users by sharing development costs and market risks with industry partners.

OTs are a proven tool that may have new application in the realm of technology transition.

Benchmarking

While NDAs, CRADAs, and licenses have been used extensively for the past 15 years within the federal laboratories, the use of OTs have been limited by statute to only the DoD. Therefore, no extensive benchmarking with other agencies/laboratories has been performed. However, DoD has been using OTs successfully since they gained authority to do so in 1989. A 1999 study by the Potomac Institute for Public Studies followed 113 OT projects and found that 37 projects (33%) resulted in commercial products and another 69 were expected to result in commercial products. This is well above the study's adopted standard of 18%.

SNL has commissioned development of a report by LMI Government Consulting on how OTs can enhance DHS technology transition. This concept has not been tested, but it seems to offer a promising path toward the commercialization of homeland security products.

Implications for DHS

This section has examined four essential mechanisms as practiced across a variety of agencies and laboratories. The intended goal is to illuminate the differences between the entities' practices and allow DHS to select from among the best to develop mechanisms that are tailored to its technology transition mission. All of the agencies/laboratories have promulgated model agreements not only to apprise prospective partners of expectations for general terms and conditions, but also to reduce the time and cost for developing new agreements for each new partner. Perceived risks can be thought through ahead of time, and mitigating language can be included in model agreements. Even though there can be considerable advance work done, it does not reduce the need for experienced technology transition professionals (as described in Chapter II) who practice sound judgment in tailoring agreements to the specific needs of each individual situation. Therefore, in crafting a suite of technology transition contracts/agreements, DHS might consider the following list of questions in developing language that meets their mission needs:

- What is legally necessary to protect DHS's interests in technologies ready for transition?
- What is the perceived risk in transition interactions, and how much mitigating language is sufficient?
- How much program management oversight is required for wise stewardship of the federal investment in technology to ensure a successful transition?
- How easy is it to develop agreements by both DHS and partner staff?
- How long does DHS want to spend negotiating, processing, and closing a partnership agreement?
- How much does it cost in terms of ORTA manpower, partner costs, and, ultimately, the cost of delayed entry into the marketplace of advanced homeland security technologies?

Based on the results of this benchmarking study and careful consideration of questions like those enumerated above, the DHS S&T Technology Transition Process Development (TTPD) team can consider several options in developing their own NDA, CRADA, licensing, and OT agreements:

- Option 1: Use simpler, less stringent agreements (e.g., USDA/ARS and HHS/NIH). Note that this option does not apply to licensing, only to CRADAs and NDAs.
- Option 2: Use middle-of-the-road style of agreements (e.g., AFRL and ARL).
- Option 3: Use more stringent and complex agreements (e.g., SNL and NRL).

For an embryonic organization, Option 1 is attractive because there would be less to learn to get started. On the other hand, Options 2 and 3 appear to be the most appropriate because of the complexity and diversity of the technology, industry sectors, and potential partners. However, because of the dissimilarities between some license clauses, it would be worth spending some time reviewing all the clauses to determine if they are worth including in a DHS license agreement.

Summary

Two steps will allow DHS to establish mechanisms that enable technology transfer agreements: (1) decide on the appropriate approach among the three options (above) for each type of mechanism and (2) develop a model agreement for each type of mechanism. Accomplishment of these two steps is enabled by detailed backup tables comparing each template for each mechanism. OGC is responsible for developing legal agreements and templates for each mechanism. These templates will be developed with business and policy input from the ORTA staff.

V. ROYALTY SHARING (EMPLOYEE REWARDS AND INCENTIVES)

U.S. Code §3710c, Distribution of Royalties Received by Federal Agencies, provides the framework for mandatory royalty sharing policies administered by laboratories as an incentive to innovate. Although the code provides general guidance and mandatory minimums and maximums for government agencies, royalty distribution policies and their implementation are generally left to the individual laboratories, and there is some variance among laboratories, even within a particular agency. Policies tend to fall into two main categories:

GOGO laboratories develop their policies within the guidelines established by §3710c, which requires the following:

- The first $2,000 of royalties received for an invention is paid to the inventors and co-inventors if their rights have been assigned to the U.S. government.
- Thereafter, at least 15% of the royalties received per invention are to be distributed to inventors and co-inventors, after the payment of other costs delineated in a license or assignment agreement, such as patent costs.
- An agency or laboratory may provide incentives from royalties to laboratory employees who are not inventors but who substantially increased the value of the inventions.
- The balance of payments is to be transferred by the agency to the laboratories (with the majority share going to the laboratory where the invention occurred). These transferred funds may be used in the following five ways:
  - Reward scientific, engineering, and technical employees, regardless of whether the technology has commercial applications.
  - Further scientific exchange among laboratories of the agency.
  - Educate and train employees consistent with the R&D missions and objectives of the agency or laboratory and other activities that promote transition of the technology.
  - Pay expenses incidental to IP administration and licensing.
  - Use for scientific R&D consistent with the R&D missions and objectives of the laboratory.

GOCO laboratories generally adopt the royalty sharing policies of their contractor sponsors.

In either case, each inventor shall not receive more than $150,000 per year in royalties, and 75% of royalties or payments to any agency that exceed 5% of that agency's budget shall be paid to the U.S. Treasury. As can be seen from the benchmarking table that follows, most of the GOCOs have implemented policies fairly consistent with the GOGO guidance.

Benchmarking

GOGO Royalty Policies

The agencies with GOGO facilities surveyed for this study include the following:

- DoD
- USDA/ARS
- HHS/NIH

All distributed at least 20 to 25% of the royalties to the inventors—at least 5% more than required. There was some difference in interpretation/implementation of the rule about the first $2,000 going to inventors. Most distribute $2,000 per inventor, but USDA/ARS split the $2,000 among the inventors. After the inventors are awarded their share, the remaining 75% to 80% was distributed somewhat differently.

DOD's policy is very broad and distributes the remaining 80% to the laboratories, which may spend the funds consistent with the five uses outlined above.

USDA/ARS's policy closely follows the federal guidelines, but after distributing 25% to the inventors, the remaining 75% goes to the technology transfer office to supplement its budget.

HHS/NIH's policy is scaled after the $2,000 per inventor is distributed. Inventors receive 15% of royalties between $2,001–$50,000 and an additional 25% of royalties greater than $50,000. The distribution of the balance is left to the individual institutes. Each royalty check that HHS/NIH collects is matched to the institute or institutes where the invention occurred. After the inventor payout, the remaining balance of this check is placed in a royalty account at each institute, where further disbursements tend to be handled somewhat differently. Some use the funds to pay their patent prosecution bills or their share of the technology transfer office operations budget. Others use the funds to pay for new equipment or other R&D projects not funded under the regular budget. The institute scientific director or a "Royalty Committee" sometimes makes these decisions. Some institutes also guarantee that the laboratory where the invention took place receives 25% of these funds.

In addition to the other agencies, this report examined the policies of the agencies formerly holding the laboratories that are now part of DHS. The study found that intellectual property and technology transfer activities were scarce or non-existent among those R&D facilities, reducing concerns of imposing technology transition policies in conflict with standing practices.

GOCO Royalty Policies

GOCOs surveyed for this report include:

- LLNL [contractor: University of California (UC)]
- LANL (contractor: UC)
- SNL (contractor: Lockheed Martin Corporation)
- ORNL (contractor: Battelle)
- PNNL (contractor: Battelle)

GOCO facilities, which tend to adopt the royalty policies of their sponsoring contractors, have more latitude in the way they distribute royalties; however, they remain close to the federally mandated regulations, with the exception of the initial award to inventors of the first $2,000 received from royalties.

The UC-operated laboratories follow UC's overarching policy. Both UC-operated laboratories, LLNL and LANL, distribute 35% of the *net* royalties to the inventors. (Net royalties are those remaining after deducting patenting and licensing costs.) This approach is primarily due to the fact that these laboratories are affiliated with an academic institution where it is common to use royalties from inventions to not only recruit and retain top talent but also to raise the visibility and stature of the institution. Other salient aspects of the UC policy include the following:

- 15% of net royalties and fees per invention shall be allocated for research-related purposes on the inventor's campus or laboratory.
- When there are two or more inventors, each inventor shall share equally in the inventor's share of royalties, unless all inventors previously have agreed in writing to a different distribution of such share.
- Equity received by UC in licensing transactions, whether in the form of stock or any other instrument conveying ownership interest in a corporation, shall be distributed in accordance with the Policy on Accepting Equity When Licensing University Technology.
- In the disposition of any net income accruing to the university from patents, first consideration shall be given to the support of research.

Royalty policies of the other GOCOs, (SNL, PNNL, and ORNL) award the bulk of the remaining royalty funds to the laboratory as discretionary research dollars. This is considered a major incentive to inventors since this money often goes back to the department where the inventors work. This allows them to practice mission-related, high-risk science in the areas that interest them most. While it is a powerful incentive to receive royalty payments as individuals, the ability to do interesting science is an equally powerful incentive.

Benchmarking Data

	Inventor Awards			Distribution of Remaining Royalties			
	Inventors of licensed technologies[12]	Rewards for inventing	Classified inventors	Overhead to promote technology transfer	Reinvest in technical orgs	Patent funding	Other Contributors
Government-Owned, Government-Operated Laboratories (GOGOs)[12]							
DoD	1st $2,000 of royalties per inventor/ at least 20%	Up to 80% to the service or laboratory that generated invention. They exercise discretion consistent with the law.					Up to the laboratory, but can't exceed the amounts to the inventors
USDA/ARS	1st $2,000 of royalties split amongst inventors + 25%			75%		Part of the 75% share to technology transfer[13]	
HHS/NIH	$2,000 per inventor + 15% of $2001–$50,000 + 25% >$50,000			Balance of funds distributed to institutes generating inventions. Institutes exercise discretion consistent with the law.			
Government-Owned, Contractor-Operated Laboratories (GOCOs)							
LLNL and LANL (Contractor: UC)	35%[14] Net / 35% Net			50% Net	15% Net / 65% Net		
ORNL (Contractor: Battelle)	15% AGR[15]				81% AGR		4% AGR of prior year's royalties as a one-time award.
PNNL (Contractor: Battelle)	15% Gross			85%			Part of the 15% that goes to inventors
SNL (Contractor: Lockheed Martin)	20%	2%	4%	5%	65%		4%

[12] GOGO laboratories required to provide $2,000 per inventor (or split evenly if total annual royalty income is less than $2,000 per inventor) plus at least 15%.

[13] Written into the license is a reimbursement for patenting, especially foreign patent filings.

[14] Patent fees and other administrative fees are taken off the gross royalties received.

[15] Adjusted gross royalty (AGR) is the gross royalty less amounts paid under inter-institutional agreements or other special royalty sharing agreements.

Implications for DHS

Since DHS may have oversight for both GOGO and GOCO laboratories, it can either have one overarching policy in line with the federal regulations for GOGOs or have two separate policies: one in line with GOGOs and one in line with GOCOs. It makes sense to delay this decision until there is a GOCO. A decision would be based on an agreement between DHS and the contractor operator and would depend on whether royalty administration will be managed in a centralized or decentralized fashion.

Given the consistency among agencies with respect to sharing royalties with inventors and the likelihood that licensing will be modest in both volume and royalty amounts, decisions with respect to inventor distribution are focused on the following:

- Whether to restrict inventors to $2,000 to be shared among the inventors or to allow $2,000 per inventor (the trend is to allow each inventor $2,000).
- Whether to set the rate at 15%, 20%, or 25%. (Most agencies have 20% or 25% for GOGOs. This is a question of whether DHS wants to be more generous by going to 25%.)
- Whether to maintain license increases at a constant rate or to scale as royalty income (scaling is more difficult to administer).

The method of remaining amounts must also be decided. The major decision is whether to administer the bulk of funds centrally or to distribute to the laboratories that have generated the investment and give them discretion in how to distribute.

Option 1: Distribution of Royalty Balances and Spending Discretion to Laboratories

The norm, supported by legislative language, is to distribute remaining balances to the inventing laboratory and give discretion for spending funds within the legal guidelines.[16] USDA/ARS was the only exception found to the practice of allowing the laboratories a high degree of discretion for the entire balance of funds after distributing to inventors. However, there are reasons for DHS to consider the alternative of central administration.

Option 2: Central Administration of Royalty Balances

Given the small number and size of DHS laboratories, the agency may choose to administer the remaining 75% or 80% royalty balances centrally. In considering this decision, DHS may want to avoid two things. First, it may be inappropriate financial management to set up a situation where a windfall for one laboratory could occur. Likewise, it may also be a poor use of funds to distribute insignificant amounts in a way that won't have impact. It might be more useful to keep the funds centralized, at least initially, as a pool and identify significant uses. However, there are still some key decisions required for implementing such a practice.

[16] U.S. Code 3710c(a)(1)(B) states, "The balance of the royalties or other payments shall be transferred by the agency to its laboratories, with the majority share of the royalties or other payments from any invention going to the laboratory where the invention occurred."

Distribution to Laboratories

Under central agency administration, to what extent should laboratories get funds returned for discretionary use within federal guidelines? This builds goodwill and incentives for continued invention, invention disclosure, and IP protection. The legislation also states that the majority of funds should go to the inventing laboratories after distributing the inventors' awards.

If there is a lucrative license, does it make sense to have the entire balance or even a fixed percentage going to a small operation? For example, one vaccine might generate substantial funds and present a windfall for PIADC. There are three ways to mitigate this:

- Set aside a percentage with a floor and a cap.
- Set aside a percentage that declines with increasing revenue (this still allows for a cap).
- Don't set aside a specific percentage, but make decisions each year based upon the circumstances that year. Meanwhile, a practice of distributing royalty income that exceeds some specified minimum to the inventing laboratory each year can still be used to provide the laboratories with incentives.

  Note: Another reason to keep funds centralized initially is that it becomes very difficult to change a policy once it is in place because the policy becomes viewed as an entitlement for recipients. Given the evolving nature of DHS, it might be best to start with a general royalty policy that gives discretion each year to a board that reports to the ORTA manager. Broad guidelines could help establish practices for sending funds to the laboratories. This would allow some experience to develop before committing to specific percentages or spending targets.

Funding for ORTA Operations

USDA/ARS is unique in using its royalty funds in this manner. However, they have some similarities with DHS. Both have small agency-managed laboratories. Using the royalty funds to help fund ORTA functions is one way of realizing impact by maintaining a critical mass. Such uses include the following:

- Funding for patent prosecution
- Funding for staff and other operations

  Note: TSL is the one exception to the general rule that DHS laboratories are small. Within the last few years, the Department of Transportation's Federal Aviation Administration (DOT/FAA) has begun to develop and implement technology transition activities. The impact on TSL needs to be considered in establishing a policy of central administration, especially in deciding whether, and how much, to send to the laboratory.

Summary

Although royalty policies vary somewhat among agencies and laboratories, most have fairly similar features. The great majority of the DHS laboratories will be GOGOs, so adopting a policy that meets the federal requirements for FFRDCs and varies little from what the laboratories were accustomed to under their prior agencies (before being moved to DHS) would seem to be the most prudent course of action.

If DHS opts to have a few externally managed laboratories (GOCOs), the royalty policy for those laboratories would ideally be the same as for the GOGOs, at least in the allocation to inventors, to avoid complaints from employees about inequities. However, if the contractor/sponsor insists on a different policy and is responsible for administering it, any reasonable policy with approval from DHS should be acceptable.

Keeping the distribution policy easy for headquarters to administer is another consideration. The more complicated the formula, the more resources are needed for administration, and the easier it is to lose track of what has been done from one year to the next.

The major decision that needs to be made is whether to administer royalty balances centrally or automatically distribute them to the inventing laboratories. If administering balances centrally, then a decision needs to be made about whether or not to allocate some funds to the inventing laboratories. Other questions will eventually need to be addressed, for example, the distribution to inventors after retirement (or other separation?) and the disposition of undistributed inventor royalties.

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VI. INVENTION OWNERSHIP AND OBLIGATIONS

15 USC 3710d requires government agencies to promote employee rights and obligations regarding inventions made, and to provide training for employee-inventors. DHS is subject to these requirements.

U.S. government agencies typically meet requirements for promotion of employee invention rights and obligations through implementation of technology transfer mechanisms such as the following: (1) invention disclosure and protection processes, (2) royalty sharing and rewards programs, and (3) training programs. The first two mechanisms have been addressed in previous chapters. This chapter addresses the third mechanism, training, to educate, communicate, and promote employee invention rights and obligations.

Benchmarking

Several excellent examples of compliance mechanisms exist within the federal agencies surveyed, and there is a willingness to share experience and expertise with DHS. This generosity can make implementation of such a system expedient and simple, drawing on the good work of others. For instance, HHS/NIH has an excellent Web-based training system for their scientists, while USDA/ARS's technology transfer organization brings "road shows" to each district office at least biannually, combining this material with broader technology transfer information and training. These "best practices" can be borrowed and tailored to fit the specific needs of DHS, keeping development costs low and allowing for rapid implementation with high confidence in the quality of the materials.

Implications for DHS

Adoption of three different vehicles for education and training would serve to fit different circumstances.

- A Web-based training program. This type of training can be administered at any time and from any computer, whether at DHS or other locations. This course could be offered to inventors at key points in the technology transition process, such as upon being assigned to an IP-rich program, when initial interactions with a potential industry partner commence, prior to attending technical seminars and trade shows, and when an invention is made. HHS/NIH has an excellent Web-based program and has offered to work with DHS and help with needs-based modifications. This would be quick to implement and complies with legislative mandates. Implementation would require the following:
    - A project facilitator with a technology transition background and the ability to rework the HHS/NIH program, tailoring it to meet DHS requirements. Skills needed: writing, editing, knowledge of technology transition and legislative requirements, and perhaps interaction with human resources (HR).
    - DHS Web development support.
    - Interaction and assistance between the S&T CIO's group, the project facilitator, and HHS/NIH's developers to work information technology (IT) issues (servers, tracking, support, etc.).
    - An unknown cost. The program would be available free from HHS/NIH, but funds may be needed for DHS internal resources.

- Developed materials. These can be presented and delivered (paper copies) one-on-one with inventors as the need arises and can be delivered at new-employee training sessions. These materials would match the information provided in the training program (above), but they would be formatted as a brochure, booklet, or packet. These materials would probably also include HR forms regarding employee rights to inventions.
- Seminars. USDA/ARS offers two-day seminars focused on technology transfer. These include in-depth presentations on the legal aspects of patenting and IP, available agreement contract options and how to implement them, how to license a technology, etc. These seminars are planned to coincide with other meetings of interest to the research community in order to leverage travel dollars and gain a wider audience. These are given at each of USDA/ARS's regional centers at least biannually. Another advantage of these events is the benefit that flows from the face-to-face interaction between the technology transfer staff and the technical line. Seminars are probably the best venue for educating and connecting with the scientists, but they are also the most expensive and hardest to deliver.

DHS should consider implementing all three of these delivery mechanisms (perhaps sequentially, beginning with the Web-based training program), followed by the one-on-one materials. The seminars could be designed and delivered once the DHS ORTA is fully established and would serve the dual purpose of introducing that function and its members to the scientific staff.

To meet these requirements, a collection of education delivery options could be developed to address the appropriate level of information for different points in the career of an employee–inventor, such as:

- When hired
- When an invention is made or a partnership with industry is in the development stage
- Periodic refresher courses

Important considerations in the development of such a program would include the following:

- Multiple, flexible delivery options
- Consistency of message across all delivery mechanisms
- A method to track delivery to all employees, including follow-up and refresher courses

Topics that need to be addressed include the following:

- Every inventor's obligation to transition technology
- An inventor's rights in DHS-developed IP
- Proper use and control of laboratory notebooks
- An inventor's obligation to disclose inventions in a timely manner
- How and when to file an invention disclosure
- Available mechanisms for engaging in partnerships with industry and when they are appropriate
- Support and resources for the inventor (legal, technology transition, etc.)

Summary

A training program consisting of three vehicles, adopted from other agencies and tailored to DHS needs by the DHS ORTA staff would flesh out the requirements for promoting employee invention ownership rights and obligations.

VII. SUMMARY AND NEXT STEPS

This study has surveyed a number of agencies/laboratories and compared/contrasted their individual approaches in meeting the requirements of federal technology transfer legislation. We have provided information on how the agencies' varying missions, end users, and structure have all combined to make each approach somewhat different. Based on this information and analysis, DHS can now make decisions about how they can best meet their mission-driven commercialization goals. They can pick and choose from practices and experience already in place in other federal agencies, or they may invent new processes and mechanisms that suit their organization better. The following sections summarize salient points discussed previously and further refine them into suggested next steps for DHS's consideration.

Establishing an Office of Research and Technology Applications (ORTA)

Based on the benchmarking study of existing ORTAs, there are several key functions that reside within ORTAs and that DHS should consider for its own ORTA. These functions are defined as follows:

- Policy and process management
- Patenting
- Legal support for agreements
- IP management
- Strategy, planning, and coordination
- Business intelligence
- Marketing and competitive process management
- Contract negotiation

The key functions have been examined to determine relative importance and priority, as well as ideal staffing levels and qualifications. ORTAs are generally managed in one of two ways: as a centralized office that actively administers these critical functions for a collection of laboratories or as a decentralized activity, which provides oversight and guidance to satellite laboratories that administer the functions locally.

Using the benchmark report as guidance, DHS can make decisions and take actions to establish an ORTA. Suggested next steps include the following:

- Determine the organizational placement of the ORTA within S&T.
- Assign management responsibility and leadership for the ORTA (hire or appoint from within). The ORTA director should lead remaining steps.
- Determine initial configuration of ORTA, balancing the need for dedicated staff, the potential to outsource activities, and available funding.
    - Develop staffing/hiring plan (perhaps develop both interim and longer-term plans).
    - Implement hiring plan.
- Roll out new ORTA to S&T and partner laboratories.
    - Introduce ORTA staff and functions/services—establish POCs.
    - Educate S&T and laboratory staff by Web-based training/visiting/presenting.

Information Collecting, Tracking, and Reporting

Information systems play a foundational role in ORTAs, facilitating the management of IP, metrics of success, and reporting responsibilities. This report provides insight into how this task is accomplished by different agencies and what software tools they use.

Using this report as guidance, DHS can make decisions and take actions to purchase and develop a data management system to provide for current and future needs. Suggested next steps include the following:

- Hire or appoint staff to implement purchase and configuration of data system and to provide long-term support and administration.
- Select and purchase one of the products reviewed in this report. Most systems are modular and can be configured initially to meet current needs and can be supplemented as new requirements arise.
- Install a core system and modules to meet current needs (disclosure, CRADA, license, and docketing modules to start).
- Work with supplier to customize system to DHS needs:
    - Build fields, Web screens, reports, portfolio taxonomy.
- Populate database with existing data.
    - Work interfaces with DOE, DHS laboratories, and other DHS enterprise systems.
- Define reporting requirements; assign responsibility for generating, writing, and submitting reports (e.g., annual report to DOC, regular reports to NTIS, etc.)
- Roll system out to the following:
    - OGC staff, who will use the system to track patent applications.
    - ORTA staff, who will use the system to monitor partnerships.
    - DHS laboratory staff, who will use the system to report inventions.
    - DOE and other agencies providing research support, who will report inventions and technical data resulting from DHS-sponsored research.

Mechanisms for Enabling Agreements with Non-Federal Entities

Technology transition is realized through various types of contracts, which define the rights and obligations of the parties, the goals of the partnership, and the tasks to be performed. Three types of contracts form the basis of most federal technology transfer/transition: NDAs, CRADAs, and licenses. A fourth contract, known as OTs, has not been used by traditional ORTAs, but it may be an excellent tool within the context of DHS's unique technology transition mission.

These four contract types have been analyzed in this report, providing a comparison of contract language across several agencies. Although there are several other contract types that may be of use to DHS, these form the core for most technology transition and should be developed first.

Using this comparison of language as guidance, DHS can make decisions and take actions to develop model agreements for use by the ORTA and DHS laboratories to implement partnerships for technology transition. Suggested next steps include the following:

- Assign responsibility for creation of model agreements.
- Establish priority based on current needs (CRADA and NDA forms are needed now).
- Roll out model agreements.
- Inform and educate legal staff, ORTA staff, and laboratory staff.

Royalty Sharing

Federal agencies are required by law to share royalties with their inventors as an incentive to innovate. This report has benchmarked the royalty-sharing policies of several laboratories and agencies.

Using this comparison of royalty-sharing provisions as guidance, DHS can make decisions and take actions to develop a royalty-sharing policy that will apply to royalties generated by inventions from the DHS laboratories. Suggested next steps include the following:

- Assign responsibility for development of a royalty-sharing policy (probably should be done by the ORTA manager and a member of OGC).
- Determine who needs to review and approve the policy.
- Determine what DHS would like to achieve with its royalty-sharing policy.
  - Status quo or standardization for DHS laboratories that have been moved from other agencies?
  - Same or different policies for new DHS laboratories negotiated for GOCO DHS laboratories?
  - Central or distributed administration?
  - What to do with royalties in excess of inventor awards?
- Draft the royalty policy.
- Develop a plan to implement and administer royalty payments.
- Roll out policy to ORTA, OGC, and laboratory staff (introduce and educate).

Invention Ownership and Obligations

Federal agencies are required by law provide employee–inventors training on their rights and obligations with regard to their inventions. This includes such things as how to use and maintain a laboratory notebook, inventor rights to inventions, and inventor obligations to disclose discoveries.

This report examines how various agencies provide this training, the forms the training may take, when it is delivered, and the possible venues for delivery.

Using this examination of training programs as guidance, DHS can make decisions and take actions to develop a set of training vehicles. Suggested next steps include the following:

- Assign responsibility for training program development and implementation.
- Determine delivery options, audience, and content.
- Develop (or adopt) an integrated training program.
  - Many elements can be borrowed from other agencies – for example, HHS/NIH has an excellent online program that it is willing to share.
- Roll out training program.
  - Rollout of the training program may provide an opportunity to introduce the new ORTA and its staff and services.

APPENDIX A: NDA COMPARISON

NDA Terms Benchmarking

This study was performed as a survey of terms and conditions within generic NDA templates from six federal laboratories. It was not intended to identify all legal requirements for NDAs developed for use by the DHS S&T TTPD team. Although it was not within the scope of this project, a review of all legal requirements for DHS in terms of NDAs is highly recommended. Further, the reasons for the differences between the NDAs were not resolved or researched with laboratory representatives.

Template or model NDAs from six federal laboratories were compiled for this comparative analysis. The NDAs were either retrieved from the laboratories' partnerships or technology transition Web sites, where possible, or requested from contacts working in these laboratories. The laboratories whose documents were reviewed included the following:

- SNL, a DOE laboratory
- Air Force Research Laboratory (AFRL), a DoD laboratory
- ARL, a DoD laboratory
- NRL, a DoD laboratory
- USDA/ARS
- HHS/NIH

To facilitate the comparative analysis, a table was compiled summarizing each article or clause in the NDA agreements across these six laboratories. The articles or clauses in SNL's NDA were used as a reference to compare the other five NDAs against. However, articles or clauses that were in the other laboratories' agreements, but not in SNL's were also considered. More than fifteen different articles and numerous other clauses were reviewed for the NDA analysis. The summarized results of this analysis are outlined in the articles that follow.

Agreement between Parties

All six laboratories have an Agreement between Parties statement in their NDAs. Required in any contract to identify parties to the agreement.

Type of Information Protected

All six laboratories define the type of information protected in their NDAs. Required to determine the subject of the agreement—what set of information will be exchanged?

Purpose of NDA Delineated

All six laboratories delineate a purpose for the NDA. Required to define scope of the agreement—why do the parties want to exchange information?

Article I—Identification and Marking of Protected Information

Optional. Four of six laboratories (SNL, AFRL, ARL, and NRL) have comparable Identification and Marking of Protected Information sections in their NDAs. The only exception is that ARL does not specifically require oral disclosures to be noted as protected information and/or followed up with a written notice accordingly. Allows parties to clearly identify information subject to nondisclosure.

Article II—Nondisclosure Obligations

All six laboratories have Nondisclosure Obligations sections in their NDAs. The nondisclosure clauses are generally comparable, but there are some differences. For example, SNL does not allow disclosure of information to a third party, whereas, NRL, USDA/ARS, and HHS/NIH do allow disclosure of information to a third party without prior written permission. Required to define obligations of each party to the agreement.

Article III—Exclusions to Nondisclosure Obligations

All six laboratories have comparable Exclusions to Nondisclosure Obligations sections in their NDAs. These exclusions are fairly standard in all NDAs, whether from government or private industry.

Article IV—DOE Audit and Inspection Rights

Optional. Only SNL has a DOE Audit and Inspection Rights clause in its NDA. This government-only clause may be unacceptable to industry partners.

Article V—No Implied Rights/No Warranty

All laboratories, except USDA/ARS, have a No Implied Rights/No Warranty section in their NDAs. However, NDA templates for AFRL, NRL, and HHS/NIH are lacking the no warranty clause.

Article VI—No Promise to Purchase Products or Services

Optional. Only SNL and NRL have comparable termination clauses relating to No Promise to Purchase Products or Services in their NDAs.

Article VII—Return or Destruction of Proprietary Information

Optional. Four of the six laboratories (SNL, AFRL, ARL, and NRL) have comparable Return or Destruction of Proprietary Information clauses in their NDAs.

Article VIII—Termination

Only SNL and NRL have comparable Termination clauses in their NDAs.

Article IX—Exclusion of Express or Implied Warranties

Only SNL and NRL have comparable Exclusion of Express or Implied Warranties clauses in their NDAs.

Article X—Term of Agreement

Only two laboratories, SNL and NRL, have a Term of Agreement clause in their NDAS, with terms of three years each. This should be included so that the contract and the obligation to protect information does not exist in perpetuity

Article XI—Right to Disclose Information

Only SNL has a Right to Disclose Information clause in its NDA.

Article XII—Effective Period of Nondisclosure Obligations

All six laboratories have an Effective Period of Nondisclosure Obligations clause in their NDAs, with terms ranging from two to ten years. This is separate from the contract termination date and establishes the maximum length of time that the information must be protected. Clock starts on the date of disclosure, not the date of the contract.

Article XIII—Choice of Law

Four of the six laboratories (SNL, AFRL, ARL, and NRL) include a Choice of Law clause in their NDAs. Recommended that boilerplate exerts DHS's choice, but generally any non-foreign domain is acceptable.

Article XIV—Export Control

Three of the six laboratories (SNL, ARL, and NRL) and have comparable Export Control clauses in their NDAs, with the exception that ARL does not require written consent before requesting authority to export protected information from the United States.

Article XV—Notices/Contact Information

All six laboratories have a Notices/Contact Information section in their NDAs.

Entire Agreement

Only SNL and NRL have an Entire Agreement section in their NDAs.

Signature Block

All six laboratories have a Signature Block section in their NDAs. Required.

Other NDA Articles

Several other articles are included in the NDAs from DoD services, USDA/ARS, and HHS/NIH. These articles and the laboratories that use them are listed below:

- Amendments (AFRL, NRL)
- Assignment of Rights (AFRL, ARL, NRL)
- Effective Date (ARL, USDA/ARS)
- Reverse Engineering (AFRL, NRL)
- Discussions Considered Proprietary (ARL)

Conclusion

In general, the NDAs are not very similar among the laboratories: only 4 of 15 (or 26%) of the articles listed above are included in all six laboratories' agreements. However, some broad conclusions can be made based on this comparative analysis of NDAs used by DOE, DoD, USDA/ARS, and HHS/NIH. The DOE and DoD laboratories' NDAs are relatively close in content, compared to USDA/ARS and HHS/NIH. Only one DOE laboratory (SNL) was reviewed, so it is not known how its NDA template compares to other DOE laboratories. Not surprisingly, the DoD services' NDAs (AFRL, ARL, and NRL) contain more comparable clauses among them, but even NRL's NDA stands out as being more comprehensive than the other two services.

As far as the rigor of the NDA agreements, USDA/ARS and HHS/NIH use simpler, less stringent NDA agreements. AFRL and ARL use NDAs that are somewhat more detailed than USDA/ARS and HHS/NIH, so they represent a middle-of-the-road style of agreement. SNL and NRL appear to use more stringent and complex NDAs. Overall, NRL's NDA stands out as being more comprehensive than all the other laboratories.

Unlike CRADAs, NDAs are a common instrument familiar to industry. It is normal for one partner to insist on the use of its NDA or to require modification of the contract language to comply with its internal standards. Therefore, an NDA form that includes familiar terms and excludes government-specific clauses is more likely to be readily accepted by industry partners, thus avoiding time-consuming legal review and negotiations.

APPENDIX B: CRADA COMPARISON

CRADA Benchmarking Study

This study was performed as a survey of terms and conditions within generic CRADA templates from six federal laboratories. It was not intended to identify all legal requirements for CRADAs developed for use by the DHS S&T TTPD team. Although it was not within the scope of this project, a review of all legal requirements for DHS in terms of CRADA agreements is highly recommended. Further, the reasons for the differences between the CRADA agreements were not resolved or researched with laboratory representatives.

Template or model CRADAs from six federal laboratories were compiled for this comparative analysis. The CRADAs were either retrieved from the laboratories' partnerships or technology transition Web sites, where possible, or requested from contacts working in these laboratories. The laboratories whose documents were reviewed included:

- SNL, a DOE laboratory
- AFRL, a DoD laboratory
- ARL, a DoD laboratory
- NRL, a DoD laboratory
- USDA/ARS
- HHS/NIH

To facilitate the comparative analysis, a table was compiled summarizing each article, term or clause in the CRADA agreements across these six laboratories. The articles, terms, and clauses in SNL's CRADA were used as a reference with which compare the other five CRADAs. However, articles, terms, and clauses that were in the other laboratories' agreements, but were not in SNL's were also considered. More than 30 different articles, and numerous other terms, and/or clauses were reviewed for the CRADA analysis. The summarized results of this analysis are outlined in the articles that follow.

Agreement between Parties

Five of the six laboratories have an Agreement between Parties statement in their CRADAs. USDA/ARS does not include this statement in its CRADA.

Article I—Definitions

All six laboratories have a Definitions section in their CRADAs. Some CRADA definitions are relatively common between laboratories (e.g., proprietary or confidential information and subject invention). However, some terms are not in common use at all (e.g., generated information, protected CRADA information, background IP, non-subject data, and non-subject invention). Other laboratories use different terminology for the same concept, which leads to some initial confusion (e.g., generated information = subject data, special purpose license = government rights, restricted access information = protected CRADA information, subject data = generated information, research plan = statement of work).

Article II—Statement of Work

Five of the six laboratories have a Statement of Work section in their CRADAs, and all six referenced a detailed statement of work in Appendix A. USDA/ARS does not include this section in its CRADA. HHS/NIH refers to its statement of work as a "Research Plan." USDA/ARS includes a clause (in a different article) about requiring changes in scope to be incorporated into the CRADA by written amendment.

Article III—Term, Funding, and Costs

All six laboratories have a Term, Funding, and Costs (or equivalent) section in their CRADAs. This article in the SNL CRADA includes clauses such as effective date, term, extension of term, funding summary, no obligation to continue performing in excess of contribution, notification of cost increase, and payment terms. All six laboratories' CRADAs have term and funding summary clauses; four of six have effective date and no obligation to continue performing in excess of contribution clauses; three of six had extension of term clauses; and one of six had notification of cost increase and payment terms clauses. USDA/ARS includes a funding summary in "Schedule 3 - Estimated Budget" of its CRADA. HHS/NIH includes a funding summary in Appendix B of its CRADA: "Financial and Staffing Contributions of the Parties." Two other clauses not included in the SNL CRADA, but included in other laboratory CRADAs are accounting records (ARL, NRL, HHS/NIH) and financial liability (ARL).

Article IV—Personal Property

Five of the six laboratories have a Personal Property section in their CRADAs. SNL's CRADA includes personal property ownership and return or disposition of property clauses, as do three other laboratories. Three clauses in other laboratory CRADAs, but not in SNL's are property warranty and liability (AFRL, ARL, HHS/NIH); costs of maintenance, removal, storage, repair, disposal, and shipping of all tangible property (NRL); and inspection and repair of property (AFRL).

Article V—Disclaimer

Five of the six laboratories have comparable Disclaimer statements in their CRADAs. USDA/ARS does not include this statement in its CRADA.

Article VI—Product Liability (Indemnification)

All six laboratories have comparable Product Liability (Indemnification) clauses in their CRADAs.

Article VII—Obligations as to Proprietary Information

All six laboratories have Obligations as to Proprietary (or Confidential) Information sections in their CRADAs. SNL's CRADA contains clauses pertaining to nondisclosure of proprietary information, identification and marking of oral disclosure, return or destruction of proprietary information, and terms (and conditions) of protection and release of obligation from protection of proprietary information. All six laboratories have nondisclosure of proprietary information sections, although the specific content of the clauses within this section vary widely. Every CRADA except AFRL's contains a clause on identification and marking of oral disclosure. Three laboratories' (SNL, USDA/ARS, and HHS/NIH) CRADAs have terms (and conditions) of protection and release of obligation from protection of proprietary information. Only SNL includes a clause on return or destruction of proprietary information. Five clauses included in other laboratory CRADAs but not in SNL's are protecting third-party proprietary information (ARL); ownership of proprietary data (AFRL, ARL, NRL); no implied license (NRL); marking of data (NRL); and designation of subject data as proprietary/confidential information (HHS/NIH).

Article VIII—Obligations as to Protected CRADA Information

Only two laboratories, SNL and NRL, have a section on Obligations as to Protected CRADA Information in their CRADAs. Both contain comparable clauses on designation and marking of protected CRADA information, nondisclosure of protected CRADA information, and term of protection and release of obligation for protected CRADA information. It is not known why the other four laboratories do not appear to use the designation "protected CRADA information."

Article IX—Rights in (Nondisclosure of and Accessing) Generated Information

Four of the six laboratories have a CRADA clause describing Rights in (Nondisclosure of and Accessing) Generated Information (ARL and USDA/ARS do not). The terminology in this clause is comparable, except HHS/NIH does not contain a government rights statement, and AFRL does not explicitly agree to exchange generated information statement.

Article X—Export Control

Five of the six laboratories have an Export Control clause in their CRADAs (HHS/NIH does not). ARL includes a clause that reserves their right to review the transfer of information in conjunction with export control requirements. NRL includes two clauses concerning the responsibility for export licenses and the marking of export-controlled data. Only SNL includes a clause on International Traffic in Arms Regulation (ITAR), and only SNL and NRL include a clause that requires notification regarding change in foreign ownership and control.

Article XI—Reports and Abstracts

Four of six laboratories have comparable sections on reports and abstracts outlining deliverables to be produced by both parties. In addition, SNL has three clauses that are specific to DOE/NNSA, which don't apply to the other five laboratories. Three clauses included in other laboratory CRADAs but not in SNL's are classified information (NRL), meetings (USDA/ARS), and records (USDA/ARS).

Article XII—Pre-Publication Review

All six laboratories have Pre-Publication Review sections in their CRADAs. All have clauses on approval and endorsement of products or services. One clause that is included only in NRL's CRADA relates to objection to public disclosure.

Article XIII—Copyrights

Four of the six laboratories have a Copyrights section in their CRADAs (SNL, AFRL, ARL, and NRL). SNL's CRADA has the following clauses under this section: assertion of copyright; rights in copyright assertion; government rights in licensing copyrights; and designation and marking of copyright material. (SNL also includes two clauses that are specific to DOE/NNSA, which don't apply to the other five laboratories.) Only SNL has an assertion of copyright clause. All four laboratories have comparable rights in copyright assertion and government rights in licensing copyrights clauses. Only SNL, AFRL, and NRL have designation and marking of copyright material clauses, which are similar in content. Two clauses are included in other laboratory CRADAs: provide three copies of works (AFRL) and software liability (ARL).

Article XIV—Reporting Subject Inventions

All six laboratories have Reporting Subject Inventions sections in their CRADAs. SNL's CRADA has three clauses in this section: disclosure of subject inventions, completeness of disclosures, and reporting of bars and marking of disclosures. The six laboratories all have comparable disclosure of subject invention clauses in their CRADAs. Only three laboratories (ANL, ARL, and HHS/NIH) include clauses on completeness of disclosures, which are similar in content. Two laboratories have a reporting of bars clause (SNL, ARL), and three have a marking of disclosures clause (SNL, USDA/ARS, HHS/NIH). Four additional clauses are included in other laboratory CRADAs: obligation to report subject invention (NRL), determination of subject inventions (NRL), subject inventions (USDA/ARS), and plant variety protection certificate applications (USDA/ARS).

Article XV—Title to Subject Inventions

All six laboratories have Title to Subject Inventions sections in their CRADAs. SNL's CRADA has three clauses in this section: ownership of subject inventions, government rights (government use) in subject inventions, and licensing subject inventions. (SNL also includes one clause that is specific to DOE/NNSA and one that is specific to SNL.) All six laboratories have comparable ownership of subject inventions, government rights (government use) in subject inventions, and licensing subject inventions clauses, although the specific content of the clauses within these sections vary widely. A non-subject inventions clause is included in NRL's CRADA.

Article XVI—Filing Patent Applications

All six laboratories have Filing Patent Applications sections in their CRADAs. SNL's CRADA has two clauses in this section: rights in patent applications and designation and marking of patent applications. (SNL also includes one clause that is specific to DOE/NNSA.) All six laboratories have comparable rights in patent applications clauses, although the specific content of the clauses within these sections vary widely. Only SNL and AFRL have designation and marking of patent applications clauses, which are similar in content. Three additional clauses are included in other laboratory CRADAs: preserving IP rights (NRL), filing deadlines (NRL), and patents and plant variety protection certificate applications (USDA/ARS).

Article XVII—Trademarks

Two of the six laboratories (SNL and NRL) have a Trademarks clause in their CRADAs, and the terms are comparable.

Article XVIII—Mask Works

SNL has a Mask Works clause in its CRADA, which may be reserved.

Article XIX—Cost of Intellectual Property Protection

Only SNL has a Cost of IP Protection clause in its CRADA.

Article XX—Reports of Intellectual Property Use

Only SNL has a Reports of IP Use clause in its CRADA.

Article XXI—DOE/NNSA March-In Rights

Only SNL has a DOE/NNSA March-In Rights clause in its CRADA, which does not apply to the other laboratories.

Article XXII—U.S. Competitiveness

Four of the six laboratories have a U.S. Competitiveness clause in their CRADAs (SNL, ARL, NRL, and USDA/ARS), and the terms are comparable.

Article XXIII—Assignment of Personnel

Only SNL has an Assignment of Personnel clause in its CRADA.

Article XXIV—Force Majeure

All six laboratories have comparable force majeure statements in their CRADAs.

Article XXV—Administration of the CRADA

All six laboratories have terms that are included in SNL's Administration of the CRADA section. SNL's CRADA has three clauses in this section: authority to enter into this CRADA; assignment, delegation, or transfer of CRADA administration; and inure to heirs, assigns, or successors. All laboratories except USDA/ARS have comparable clauses that delineate authority to enter into this CRADA.

SNL and USDA/ARS have assignment, delegation, or transfer of CRADA administration clauses that are similar. Only SNL has a clause addressing inure to heirs, assigns, or successors.

Article XXVI—Records and Accounting for Government Property

SNL has a Records and Accounting for Government Property clause in its CRADA.

Article XXVII—Notices

All six laboratories have comparable Notices sections in their CRADAs.

Article XXVIII—Disputes

All six laboratories have comparable Disputes sections in their CRADAs. However, the forms of dispute resolution vary range from arbitration to negotiation, or referral to an authority for decision. SNL also has a business relations with others term in this article.

Article XXIX—Entire CRADA and Modifications

All six laboratories have terms that are included in SNL's Entire CRADA and Modifications section. SNL's CRADA has two clauses in this section: entire CRADA (entire agreement) and modifications. All laboratories except AFRL have comparable entire CRADA (entire agreement) clauses. All six laboratories have similar modifications clauses.

Article XXX—Termination

All six laboratories have Termination sections, although the specific content of the clauses within this section varies.

Other CRADA Articles

Many other articles are included in the CRADAs from DoD services, USDA/ARS, and HHS/NIH. These articles and the laboratories that use them are listed below:

- Representations and Warranties (AFRL, ARL, NRL, HHS/NIH)
- Cooperative Research (ARL, NRL, HHS/NIH)
- Research Exclusion (USDA/ARS)
- Regulatory Compliance with Government Rules & Regulations (USDA/ARS)
- Objective (NRL)
- Equal Opportunity (ARL)
- Covenant against Contingent Fees (ARL)
- Final Review/Approval by ARL (ARL)
- Rights in Non-Subject Data (ARL)

Other General Provisions

Many other general provisions are included in the CRADAs from DoD services, USDA/ARS, and HHS/NIH. These provisions and the laboratories that use them are listed below:

- Governing Law (AFRL, ARL, NRL, USDA/ARS, HHS/NIH)
- Severability (AFRL, ARL, NRL, USDA/ARS, HHS/NIH)
- Assignment (AFRL, ARL, NRL, USDA/ARS, HHS/NIH)
- Relationship of Parties (AFRL, ARL, NRL, USDA/ARS, HHS/NIH)
- Officials not to Benefit (AFRL, ARL, USDA/ARS)
- Waiver of Rights (AFRL, ARL, NRL, HHS/NIH)
- Publicity (AFRL)
- Disposal of Toxic or Other Waste (AFRL, NRL)
- Availability of Appropriations (USDA/ARS)
- Ambiguities (USDA/ARS)
- Subcontracting Approval (USDA/ARS)
- Amendment (USDA/ARS)
- Reasonable Consent (HHS/NIH)
- Survivability (NRL, HHS/NIH)
- Headings (ARL, NRL, HHS/NIH)
- Exceptions to this CRADA (HHS/NIH)
- Facsimile Transmissions (ARL)
- Public Release (NRL)

Signature Block

Five of the six laboratories have a Signature Block section in their CRADAs (USDA/ARS does not).

Appendices

SNL's CRADA has four appendices: Appendix A—Statement of Work, Appendix B—Abstract Format Description, Appendix C—Background IP, and Appendix D—Confirmatory License Form. All six laboratories have an Appendix A—Statement of Work or equivalent. (HHS/NIH's "Research Plan" is equivalent to a Statement of Work.) Both SNL and NRL have a Confirmatory License Form Appendix. Several other appendices (or equivalent) are included in the CRADAs from DoD services, USDA/ARS, and HHS/NIH. These appendices and the laboratories that use them are listed below:

- Certifications (ARL)
- Estimated Budget (ARL)
- Financial and Staffing Contributions of the Parties (HHS/NIH)
- Exceptions or Modifications to this CRADA (HHS/NIH)

Conclusion

These CRADAs are all generally comparable: all six laboratories contain 13 of 30 (or 43%) of the articles listed above. However, some general conclusions can be made based on this comparative analysis of CRADAs used by DOE, DoD, USDA/ARS, and HHS/NIH.

The DOE and DoD laboratories' CRADAs are relatively close in content, compared to those used by USDA/ARS and HHS/NIH. Even so, SNL's CRADA is lacking some general provisions, articles, and clauses that the other laboratories' CRADAs have that are probably worth including. (It should be noted that DOE dictates the terms of its laboratories' CRADAs.) Only one DOE laboratory (SNL) was reviewed, so it is not known how SNL's CRADA template compares to other DOE laboratories. Not surprisingly, the DoD Services' CRADAs (AFRL, ARL, and NRL) contain more comparable clauses between them, but NRL's CRADA stands out as being more comprehensive than the other two services. USDA/ARS and HHS/NIH contain specialized clauses due to the nature of their research.

As far as the rigor of the CRADA agreements, USDA/ARS and HHS/NIH use simpler, less stringent CRADA agreements. AFRL and ARL use CRADAs that are somewhat more detailed than USDA/ARS and HHS/NIH, so they represent a middle-of-the-road style of agreement. SNL and NRL appear to use more stringent and complex CRADAs. Overall, NRL's CRADA stands out as being the most comprehensive.

It is debatable what kind of template would best suit DHS's needs or be faster and easier to implement. While a more comprehensive, stringent CRADA may provide more protection for federal government interests, it can also create obstacles for industry partners. A CRADA with highly specific and rigid terms might result in quicker negotiations. Or such a CRADA may contain so many standard terms and conditions, that educating the industry partner as to what is and isn't negotiable could be very time-consuming.

APPENDIX C: LICENSING COMPARISON

Licensing Terms Benchmarking

This study was performed as a survey of terms and conditions within generic license templates from six federal laboratories. It was not intended to identify all legal requirements for licenses developed for use by the DHS S&T TTPD team. Although it was not within the scope of this project, a review of all legal requirements for DHS in terms of license agreements is highly recommended. Further, the differences between the license agreements were not resolved or researched with laboratory representatives since it was not within the scope of this project.

Template or model licenses from six federal laboratories were compiled for this comparative analysis. The licenses were either retrieved from the laboratories' partnerships or technology transition Web sites, where possible, or requested from contacts working in these laboratories. The laboratories whose documents were reviewed included:

- SNL, a DOE laboratory
- AFRL, a DoD laboratory
- ARL, a DoD laboratory
- NRL, a DoD laboratory
- USDA/ARS
- HHS/NIH

To facilitate the comparative analysis, a table was compiled summarizing each article or clause in the license agreements across these six laboratories. The articles or clauses in SNL's license were used as a reference to compare the other five licenses against. However, articles or clauses that were in the other laboratories' agreements, but were not in SNL's were also considered. More than seventeen different articles and numerous other clauses were reviewed for the license analysis. The summarized results of this analysis are outlined in the articles that follow.

Agreement between Parties

All six laboratories have an Agreement between Parties statement in their licenses.

Article I—Background

All six laboratories have a Background (or equivalent) section in their licenses. SNL's license has three key clauses in this article: U.S. competitiveness, liability, and DOE waiver. Only SNL has clauses addressing liability and DOE waiver, but NRL has a similar U.S. competitiveness clause. Three clauses included in other laboratory licenses but not in SNL's are: point of practical application (AFRL, ARL, NRL, USDA/ARS), development/marketing plan or commercial development plan (AFRL, ARL, NRL), and public use and benefit (USDA/ARS, HHS/NIH).

Article II—Definitions

All six laboratories have a Definitions section in their licenses. In general, the set of definitions included in the licenses are distinct between the laboratories. Surprisingly, however, terms common to the SNL license do not appear in some other laboratories' licenses (i.e., FOU, disclosure, net selling price). AFRL and ARL reserve the right to restrict license to the FOUs or geographic areas after the fifth license year. Conversely, the other laboratories included definitions that SNL does not: commercial development plan or development plan (AFRL, NRL, HHS/NIH), effective date (AFRL, ARL, NRL, USDA/ARS), licensed patent (ARL, NRL, USDA/ARS), net sales (NRL, USDA/ARS, HHS/NIH), practice the licensed invention (AFRL, NRL), and practical application (AFRL, ARL, NRL, HHS/NIH).

Article III—License (or Grant)

All six laboratories have a License (or Grant) section or equivalent in their licenses. SNL has four clauses in this article: grant, allow extension of rights to licensee's affiliates, allow licensees to sublicense, and exclude implied rights and licenses. All six laboratories have a grant clause. Three laboratories have a clause to allow extension of rights to licensee's affiliates (SNL, ARL, NRL). Five laboratories contain a clause that allows licensees to sublicense (SNL, AFRL, NRL, USDA/ARS, HHS/NIH). It is not known why ARL's license template does not allow licensees to sublicense, or whether the laboratory allows sublicensing in some circumstances. Four of six laboratories have an exclude implied rights and licenses clause (SNL, AFRL, NRL, HHS/NIH).

Article IV—Duties of the Parties

All six laboratories have a Duties of the Parties section or equivalent in their licenses. SNL has three clauses in this article: nondisclosure, commercial milestones (or performance), and use of technical assistance. Only SNL and HHS/NIH have nondisclosure clauses—although HHS/NIH's nondisclosure relates to licenses, whereas SNL's refers to SNL patent applications or information relating to or contained in SNL disclosures. All six laboratories have a commercial milestones (or performance) clause. Commercial milestones are distinct between the laboratories; however, five laboratories list carrying out a development and marketing plan to bring the licensed patents to the point of practical application. Other commonly used commercial milestones in the other laboratories' licenses include the following:

- Make the benefits of the licensed invention readily accessible to the public.
- Products will be manufactured substantially in the United States.
- Licensee agrees to promptly report to licensor any changes in mailing address, name, or company affiliation.

Use of technical assistance is specifically cited in two laboratories' licenses: SNL and USDA/ARS. It is not known why the other laboratories' license templates do not allow technical assistance, or whether the laboratories allow technical assistance in some circumstances.

Article V—License Fees and Royalties

All six laboratories have a License Fees and Royalties section or equivalent in their licenses. SNL has two clauses in this article: nonrefundable license fees and royalties, and government sales. All six laboratories have similar nonrefundable license fees and royalties clauses, although the terminology used between laboratories is dissimilar. Some terms are not in common use at all (e.g., benchmark royalties/milestone payments). Other laboratories use different terminology for the same concept that leads to some initial confusion (e.g., license execution fee = license issue fee = license execution fee = license issue royalty; annual minimum royalty = annual guaranteed minimum license fee = annual license maintenance fee = nonrefundable minimum annual royalty; sublicense fees = sublicense royalties; and earned royalties = royalties = running royalties). Only SNL, AFRL, and NRL have government sales clauses. It is not known why the other laboratories' licenses do not appear to include this clause. Several related clauses that are included in other laboratories' licenses are cessation of royalty payments, royalties paid to escrow during lawsuit, foreign license costs, no multiple royalties, and sales made to sublicensees.

Article VI—Statements, Reports, and Payments

All six laboratories have a Statements, Reports, and Payments section, or equivalent, in their licenses. SNL has seven clauses in this article: conveyance of licensed product; statements and payments due; record-keeping, audits, and retention; any taxes, assessments or charges assessed or imposed by an entity or government, other than U.S.; rate of exchange in calculating royalties; interest rate for past due fees or royalties; and assistance with DOE reporting. Only SNL's license contains a conveyance of licensed product clause and an assistance with DOE reporting clause. All six laboratories have comparable statements and payments due clauses, and record-keeping, audits, and retention clauses in their licenses. Only SNL and HHS/NIH have comparable clauses that addresses any taxes, assessments, or charges assessed or imposed by an entity or government, other than U.S. Four of six laboratories (i.e., SNL, NRL, USDA/ARS, and HHS/NIH) have a comparable rate of exchange in calculating royalties clause and a comparable interest rate for past due fees or royalties clause in their licenses. Several related clauses that are included in other laboratories' licenses are sublicensees royalty reports, all plans marked confidential, benchmark reports due per Benchmarks and Performance Plan, Commercial Development Plan due prior to signing license, and annual reports due per Commercial Development Plan.

Article VII—Duration and Termination

All six laboratories have a license Duration and Termination section, or equivalent, in their licenses. SNL has three clauses in this article: continuance of rights and licenses, cause for termination of rights and licenses granted, and bankruptcy cause for termination of rights and licenses granted. All laboratories, with the exception of NRL, have a comparable continuance of rights and licenses clause. All laboratories' licenses contain a comparable clause for termination of rights and licenses granted, but the DoD services, USDA/ARS, and HHS/NIH licenses contain a more comprehensive list of causes for termination, such as lack of performance and when such action is necessary to meet requirements for public use specified by federal regulations. All laboratories, with the exception of NRL, have a bankruptcy cause for termination of rights and licenses granted clause. The bankruptcy cause for termination clauses are comparable except for ARL's, which states that the license agreement shall immediately and automatically terminate at the occurrence of bankruptcy. In addition, HHS/NIH requires that in the event that licensee becomes insolvent or files a petition in bankruptcy, the licensee shall immediately notify HHS/NIH in writing.

There are many related clauses that are included in the DoD services, USDA/ARS, and HHS/NIH licenses, but not in SNL's license. The clauses and the laboratories that use them are listed below:

- Termination by licensee (AFRL, ARL, NRL, USDA/ARS, HHS/NIH)
- Written notice of termination given to licensee (AFRL, ARL, NRL, HHS/NIH)
- Licensee appeal of termination (AFRL, ARL, NRL, HHS/NIH)
- Disposition of sublicense after termination (USDA/ARS, HHS/NIH)
- No release of obligations or liability with termination (ARL)
- Termination if marketing/development plan not met (ARL)
- Written determination about termination to licensee (NRL)
- All payables due immediately upon termination (USDA/ARS)
- Termination for public use (HHS/NIH)
- Final report due after termination (HHS/NIH)
- All payables due immediately upon termination (HHS/NIH)
- Return or destroy materials after termination (HHS/NIH)

Article VIII—Warranty, Infringement, Liability, and Litigation

All six laboratories have a Warranty, Infringement, Liability, and Litigation section, or equivalent, in their licenses. SNL has six clauses in this article: exclusion of express or implied warranties, right to grant rights and licenses warranty, no warranty of patent rights or that they will not infringe, warranty that patent rights do not infringe, liability/hold harmless, and right to litigate for infringement. All laboratories except for NRL have a comparable exclusion of express or implied warranties clause in their licenses. All six laboratories' licenses contain a comparable right to grant rights and licenses warranty clause in their licenses. All six laboratories' licenses contain a comparable no warranty of patent rights or that they will not infringe clause in their licenses, except for NRL's license which is lacking the will not infringe portion of the clause. Only SNL has a warranty that patent rights do not infringe in its license as an optional clause. Five of six laboratories (SNL, AFRL, ARL, NRL, and HHS/NIH) have liability/hold harmless clauses in their licenses. However, the ARL and NRL licenses do not include the hold harmless portion of this clause, and both the AFRL and HHS/NIH license do not include the liability portion of this clause. All laboratories, except for NRL, contain a right to litigate for infringement clause, but there are distinct differences in the terms. In SNL's license, the licensor has sole right to litigate. As licensors, ARL and HHS/NIH reserve the first right to litigate, but they also give the licensee the right to litigate. USDA/ARS's licensee has the first option to litigate, and AFRL's licensee also has the right to litigate. HHS/NIH, USDA/ARS, and AFRL state that they have no obligation to enforce against infringers.

There are many related clauses that are included in the DoD services, USDA/ARS, and HHS/NIH licenses, but not in SNL's license. The clauses and the laboratories that use them are listed below:

- Obligation to enforce against infringers (AFRL, USDA/ARS, HHS/NIH)
- No immunity from or defense under antitrust laws (AFRL, NRL, USDA/ARS, HHS/NIH)
- Obligation to notify about infringement (AFRL, ARL, HHS/NIH)
- Cooperation of licensor in litigation (AFRL, HHS/NIH)
- Know-how (AFRL)
- Conditions for enforcement actions (USDA/ARS)
- No waiver of rights with infringing party (USDA/ARS)
- Right to litigate for invalidity or non-infringement judgments (HHS/NIH)
- Litigation fee responsibility (HHS/NIH)

Article IX—General Provisions

All six laboratories' license templates contain a General Provisions or equivalent section. The general provisions listed in SNL's license and the laboratories that use them are listed below:

- Endorsement of product/use of trademark (SNL, AFRL, ARL, USDA/ARS, HHS/NIH)
- Notices (SNL, AFRL, ARL, NRL, USDA/ARS, HHS/NIH)
- Waiver of a breach of this license agreement (SNL, USDA/ARS, HHS/NIH)
- Patent markings affixed to licensed product (SNL, AFRL, ARL, NRL, USDA/ARS, HHS/NIH)
- Index and headings of license agreement (SNL, ARL, NRL)

Many other general provisions are included in the DoD services, USDA/ARS, and HHS/NIH licenses, but not in SNL's license. These provisions and the laboratories that use them are listed below:

- Patent maintenance responsibility (ARL, NRL, HHS/NIH)
- Patent maintenance expenses (AFRL, USDA/ARS, HHS/NIH)
- Independence of the parties (ARL, NRL)
- Dispute resolution/amicable settlement (USDA/ARS, HHS/NIH)
- Officials not to benefit (ARL)
- Notice relating to patent prosecution (NRL)
- Notification of patent maintenance issues (HHS/NIH)
- Human studies (HHS/NIH)

Article X—Assignment

All six laboratories have an Assignment section or equivalent in their licenses. SNL has two clauses in this article: sublicensing and assign, delegate, or transfer rights. Only SNL's license contains a sublicensing clause in this article. All six laboratories' licenses have an assign, delegate, or transfer rights clause. This clause in SNL's license states that it may assign, delegate, or otherwise transfer any rights or duties under this license to any assignee or transferee. In the DoD services, USDA/ARS, and HHS/NIH licenses, this same clause states that the license is unassignable without prior written approval except to the successor or assignee of licensee's entire business interest relating to the licensed patents. Two laboratories warn against foreign ownership in such a transaction (NRL, USDA/ARS), and HHS/NIH requires an additional one percent (1%) royalty on the fair market value of any consideration received for any assignment of the license.

Article XI—U.S. Competitiveness

Five of six laboratories have a U.S. Competitiveness clause in their licenses (only AFRL does not). It is not known why AFRL's license template does not contain this clause. Only USDA/ARS includes a related clause in this article that requires the licensee to keep products reasonably available to the U.S. public.

Article XII—Government Rights and Sponsorship

All six laboratories have a Government Rights and Sponsorship section or equivalent in their licenses. SNL's license has three clauses in this article: government rights; warranty and liability; and march-in rights for exclusive licenses. All six laboratories contain a comparable government rights clause and march-in rights for exclusive licenses clause. Two other laboratories besides SNL (AFRL and NRL) have a comparable warranty and liability clause. Several related clauses that are included in other laboratories' licenses are: right to restrict to FOU, right to manufacture for internal purposes, provide quantities of licensed products for research use, future licenses/research license, right to grant research licenses, and license subject IP (SIP) march-in rights.

Article XIII—Export Control

Five of six laboratories have an Export Control clause in their licenses (USDA/ARS does not). It is not known why USDA/ARS's license template does not contain this clause.

Article XIV—Controlling Law

All six laboratories have a Controlling Law clause in their licenses.

Article XV—Severability

Five of six laboratories have a Severability clause in their licenses (AFRL does not). It is not known why AFRL's license template does not contain this clause.

Article XVI—Force Majeure

Only two laboratories' licenses, SNL and ARL, contain a Force Majeure clause. It is not known why the other laboratories' license templates do not contain this clause.

Article XVII—Entire Agreement

All six laboratories have an Entire Agreement section or equivalent in their licenses. SNL's license contains three clauses in this article: entire agreement, warrants, and supercedes; modifications; and inure to heirs, assigns, or successors. All the other laboratories, except AFRL, contain a clause similar to SNL's entire agreement, warrants, and supercedes. However, only SNL contains the warrant portion of this clause, and USDA/ARS is lacking the supercedes portion of this clause. Five of the six laboratories have a modifications clause with only minor differences between them. The outlier, USDA/ARS, has a modifications clause that indicates it will give the licensee advance written notice of intent to modify or terminate the license and allows the licensee thirty (30) days after the date of such notice to remedy any breach or show cause why the license should not be modified or terminated. Only SNL has an inure to heirs, assigns, or successors clause.

Effective Date

All six laboratories have an Effective Date section or equivalent in their licenses. Four of the six laboratories address this term in their definitions rather than as a separate section in the license.

Signature Block

All six laboratories have a Signature Block section in their licenses.

Exhibits/Appendices

SNL's license has four Exhibits/Appendices: Exhibit A—List of Patents, Patent Applications, and Disclosures; Exhibit B—Technical Assistance Terms; Exhibit C—Nonrefundable Fees and Royalties; and Exhibit D—Commercial Milestones. Only HHS/NIH has an Exhibit A similar to SNL's, titled "Appendix A—Patent(s) or Patent Application(s)." None of the other five laboratories have an Exhibit B similar to SNL's. HHS/NIH, again, has an Exhibit C similar to SNL's, titled "Appendix C—Royalties." HHS/NIH also has an Exhibit D similar to SNL's, titled "Appendix E—Benchmarks and Performance." AFRL, ARL, and USDA/ARS do not include exhibits/appendices in their license templates.

Several other exhibits/appendices are included in the NRL and HHS/NIH licenses. These exhibits/appendices and the laboratories that use them are listed below:

- Commercial Development Plan (NRL, HHS/NIH)
- Licensed FOUs and Territory (NRL, HHS/NIH)
- Modifications (HHS/NIH)

Conclusion

These licenses are all very comparable: all six laboratories contain 13 of 17 (or 76%) of the articles listed above. However, some general conclusions can be made based on this comparative analysis of licenses used by DOE, DoD, USDA/ARS, and HHS/NIH. The DOE and DoD laboratories' licenses are relatively close in content, compared to USDA/ARS and HHS/NIH. SNL probably has a slightly more detailed license; however, its license is lacking some clauses that the other laboratories' licenses have that are probably worth including. SNL's license also has many more distinct clauses within each article, but many are DOE-specific and don't apply to the other laboratories. (It should be noted that DOE takes a more hands-off approach in terms of its laboratories' licensing processes.) Only one DOE laboratory (SNL) was reviewed, so it is not known how SNL's license template compares to other DOE laboratories. The DoD services' licenses (AFRL, ARL, and NRL) contain more comparable clauses between them. But inexplicably, there are many cases where a basic clause that is in one DoD laboratories' license is not in the other two laboratories' licenses. USDA/ARS and HHS/NIH licenses are similar to each other, but between them, HHS/NIH has a more detailed license. As with the CRADAs, USDA/ARS and HHS/NIH contain more specialized clauses due to the nature of their research.

As far as the rigor of the license agreements, they are all very comparable in terms of content. No one license, not even NRL's, stands out as being more comprehensive or stringent than the other laboratories. If required to distinguish between them, USDA/ARS's and HHS/NIH's licenses would be moderately stringent, and the DOE and DoD laboratories' licenses would be somewhat more stringent and complex.

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