RFI Response: Federal Technology Transfer Authorities and Processes

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Submitted by: Sandia National Laboratories
Sandia National Laboratories is a multiprogram engineering and science lab and federally funded research and development center (FFRDC) operated by National Technology and Engineering Solutions of Sandia, LLC for DOE NNSA. Sandia's unique mission responsibilities in the nuclear weapons program create a foundation of capabilities that help the labs to solve complex national security problems. Sandia works with government agencies, industry, and academic institutions to accomplish its strategic missions, and conducts technology transfer to ensure the broader use and impact of federally funded innovations.

Sandia appreciates the opportunity to respond to NIST's request for information on federal technology transfer practices. Sandia supports efforts to maximize the impact of federally funded innovations and looks forward to working with NIST on this initiative.

(1) What are the core Federal technology transfer principles and practices that should be protected, and those which should be adapted or changed?

The core tech transfer principles that enable the laboratories to effectively work with non-federal entities are embodied and well-articulated in the Stevenson-Wydler and Bayh-Dole Acts. This legislation has led to a number of technology transfer mechanisms that allow the nation to benefit from federally funded research, including numerous innovations in energy, computing, safety, medicine, and a variety of other areas. However, these Acts were passed in 1980, when the economic and technological landscape was vastly different than today. Existing principles would benefit from updates and changes to better address current technology transfer needs.

For example, a principle to adapt is the Energy Policy Act of 2005. Changes should be made to broaden focus beyond energy technology areas and the funding source to additional offices at DOE and NNSA. Additionally, it would be beneficial to allow cost share instead of only matching funds to enable more small business participation. The adaptation of this and other principles can help to address current technology transfer limitations, making it easier to facilitate public benefit from federally funded R&D.

(2) What are the issues that pose systemic challenges to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D? Please consider those identified in the RFI as well as others that may have inhibited collaborations with Federal laboratories, access to other federally funded R&D, or commercialization of technologies resulting from Federal R&D.

Some systemic challenges are described below.

DOE Orders like 485.1 hinder the laboratories' ability to effectively work with a wide range of institutions. A large contributing factor to obstacles in the world of technology transfer are the steep **overheard costs** associated with providing funds-in to labs from partners for technology transfer projects (this goes for both small and large businesses).

Important **intellectual property aspects** that were not considered in 1980 are poorly handled in current laws and regulations for intellectual assets such as software and data. This is a challenge across all aspects of technology transfer. For example, the "Morella" rights to subject inventions from a CRADA do not apply to software written under a CRADA. In fact, the current CRADA structure does not address what rights, if any, are available to the CRADA partner with respect to software created during the CRADA. Furthermore, guidance and orders from both the White House and the various agencies have placed a strong emphasis on open source release of software funded with federal dollars. Because of this, it is possible to get into a situation where the DOE funding for a CRADA forces the software to be open source, thus taking away the CRADA partner's competitive advantage. Additionally, current laws and regulations do not permit licensing or simple means for transferring data generated by the labs.

Related to this are limitations with respect to protecting and licensing **trade secrets**. The only existing mechanism to protect such information is to treat it as Protected CRADA Information, but the five-year limit is likely insufficient for some technologies where the time to market is long.

Similarly, the **fairness requirements** for intellectual property (and technology transfer generally) from federal labs further hinder tech transfer. Because of uncertainty with respect to what "fairness" means and the need for uniform application across the federal labs system, there is a strong incentive to overcompensate to be fair, which slows down tech transfer. Universities can leverage existing relationships with companies to deploy technology, while a federal lab must treat each technology as a separate item and ensure fairness for each interaction.

The effective transfer of technologies from the national laboratories into the hands of those who can turn them into commercial successes is an essential element of the innovation ecosystem and critical to U.S. competitiveness in an increasingly demanding, technology-driven global market. Depending on the stage of development, technologies require different levels of support to make their transfer viable. Some may need additional years of focused research and development effort, but many need only small infusions of time and funding to be more attractive to partners who can successfully introduce them to the marketplace. **Technology maturation** funding can serve to increase the successful transfer of technologies licensed from the labs and often provides the necessary link between an innovative process or technology and a real-world application with powerful market potential. Unfortunately, sources of such early-stage funding are rare.

Startups are another aspect of tech transfer in which the federal labs are disadvantaged. There are no mechanisms or provisions in current federal law or regulations that permit support for startups using lab technology. While programs like Technology Commercialization Funds and Small Business Vouchers support startups, there are regulations such as conflict of interest and difficulties with CRADAs, Strategic Partner Projects (SPPs), and outside consulting that make it hard to foster startups by the federal labs. In particular, there are inconsistent and unclear regulations with respect to **conflict of interest** (COI), and this is a critical drag on tech transfer from federal labs. There is a need for clear guidance across the labs on how to apply COI requirements. To avoid COI issues within the current system, the labs must be exceptionally careful to not provide any support to a company started by one of its researchers, since such support could be perceived as COI. While universities are subject to a COI requirement, it is not at

the same scale. Universities often put forth exceptional effort to help companies started by a professor or a student, even allowing faculty to dedicate up to 50% of their time to a startup. Another concern with startups is that previous attempts at simplifying licensing to startups have been transactional focused (making executing a license option easier for lab patents) rather than systemically focused. Programs like the New Mexico Small Business Assistance (NMSBA) program should be replicated on a larger basis across all federal labs and a federal funding source should be identified.

Risk issues with respect to tech transfer from the federal labs are another major impediment. Management contractors have little incentive beyond the management fee to make a substantial investment in tech transfer. The way that GOCOs are contracted by the government does not encourage the management contractor to take risk associated with tech transfer since it cannot benefit from this activity, which is different from universities that can use the funds from tech transfer more flexibly. Excess funds from tech transfer at federal labs are returned to the U.S. Treasury, so a lab operator is not incentivized to take any tech transfer risk. This is reflected in the indemnification language in tech transfer agreements, the inability to protect IP, and the most conservative interpretation of federal regulations when undertaking tech transfer. As tech transfer is a small part of the federal labs mission, the management contractor is only incentivized to do the minimum necessary to support tech transfer, further limiting the risk the management contractor will assume. While some view Agreements for Commercializing Technology (ACT) and other such mechanisms as a potential cure—and in some cases, they may appropriately address these concerns—the high overhead costs cut into the amount of research conducted regardless of when or how funding is transferred.

Requirements for measurement of tech transfer results are very inconsistent and not clearly defined in laws or regulations. The metrics against which universities are measured—number of patents, number of licenses, revenue and startups (i.e. the factors in the Milliken Institute rating of university tech transfer)—do not align with the metrics against which federal labs are measured. In addition, neither may effectively measure impact on the economy. Impact of federal interactions under CRADAs isn't measured beyond funding or number of CRADAs, so there is no measure for impact by number of jobs, revenue increases, etc. For example, this is reflected in tech transfer benefits that occur when a company supplies products to the labs and creates new products to their specifications, which can then be sold more broadly. This type of tech transfer is not captured in any current metric.

(3) What is the proposed solution for each issue that poses a systemic challenge to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D? Please consider the approaches identified in the RFI.

Proposed solutions to the issues identified above include:

Culture – A culture conducive to the practice of transferring technology for the benefit of the U.S. economy should be an endemic element of each laboratory at a micro level. At a macro level, within the DOE Complex, NNSA, Science and Energy programs, along with the Office of Technology Transitions, has an opportunity from a headquarters perspective to work with lab directors and ingrain a more favorable disposition toward technology development and transfer.

Overhead costs – A solution to the liquidity issue raised is to amend the Stevenson-Wydler Act to allow for substantial Congressional appropriations (for example, $200 million annually). The funds could be used as the in kind resources of the laboratories and would be awarded pursuant to strict guidelines. The Small Business Vouchers pilot and other such programs that have since proliferated provide a good incubator, but the programs are missing scale.

Software protection – The underlying legislation and regulations should be modified to enable appropriate technology transfer of software separate from data rights, since the transfer mechanisms and economic value are very different. This would result in changes in commercial licensing of laboratory-developed software. Additions to CRADA regulations with Morella-like terms for software would be helpful. Furthermore, the federal government should develop a unified message with respect to the most effective way to transfer software from the laboratories. For example, there is guidance from the White House and from DOE NNSA programs pushing the release of most software from the labs as open source. While providing the most access, open source is not always the optimal deployment mechanism for software if the intent is to see utilization in commerce, since certain open source licenses are not commercial friendly.

Data and Trade Secrets – The protections of CRADA Protected Information need to be expanded, especially for fully funds-in CRADAs. The agencies should each develop public data access plans and licensing terms for data. This would need to be managed at the agency level, rather than at each individual lab.

Startups – Rather than transactional approaches, a comprehensive approach should be taken with startups, such as combining the various programs in a more seamless process. For example, a startup that has licensed IP from a federal lab could have an easier path into Innovation Corps (I-Corps) or there could be a simplified process for NMSBA-like programs.

Conflict of Interest – Improved guidance should be provided uniformly across all federal labs, including standardized mechanisms and criteria of what constitutes conflict of interest, especially with respect to tech transfer. Clarifications could be added to remove some of the difficulties associated with former federal lab employees who leave to start a company. This would also need to be expanded to support federal lab employees providing consulting assistance to companies trying to deploy technology from the labs. Right now, the current mechanisms (CRADA and SPP) are likely too expensive for many startups which would benefit from help by the inventors. One solution might be for federal lab employees to be able to provide a certain amount of consulting with limited prior approval (for example, 100 hours) before more rigorous COI rules are applied.

Risk – There are a number of ways to reduce the risk associated with tech transfer for the federal labs management contractors. One option is legislation specifically limiting the liability of the labs in suits arising from tech transfer activities to some cap based on either the lab's budget or the management fee. This would make it easier for the management contractors to assume risk.

Metrics – The Department of Commerce should provide updated standard requirements for metrics across all tech transfer efforts from federal funding, both from federal labs as well as universities. The

best path for this may require more specificity in federal acquisition regulations and in federal grant requirements to align the data coming back to the government.

Funded Mission Objective – Reforming technology transfer legislation would support tech transfer as a funded mission objective. Technology transfer and commercialization should be a core mission objective that is integrated with the other missions of each lab, funded appropriately, and include accountability. Currently, technology transfer and commercialization are managed largely as relatively unfunded mandates, with a focus on adapting technologies developed for a mission assignment to commercial applications. If commercialization is truly important, it should be assigned and funded as a mission objective that is integrated with the other assigned missions of each lab and managed throughout the full R&D lifecycle.

(4) What are other ways to significantly improve the transfer of technology, knowledge, and capabilities resulting from Federal R&D to benefit U.S. innovation and the economy? What changes would these proposed improvements require to Federal technology transfer practices, policies, regulations, and legislation?

Homogeneity in tech transfer practices across the broad spectrum of national laboratories will be difficult to achieve. While there is a tendency to want to create a unified approach through modifications to legislation, the sacrifice will be innovation at the lab level. Some laboratories are more effective than others at technology transfer from a process and impact standpoint; lessons should be shared as to how success is achieved and then leveraged by peers.

Additional recommendations to improve this transfer include the following efforts.

Technology Maturation – Create and gain approval for a DOE guidance (or policy) statement that clearly describes permissible activities by the DOE national laboratories in post-research scale-up and/or demonstration of lab-developed concepts, technologies and inventions for making market benefits obvious to industry partners, that lead to privately financed product development and market deployment. Additionally, it would be helpful to expand technology transfer related programs (i.e. tech maturation) from Energy to other parts of DOE (NNSA, Science). Another idea is to provide for a tech maturation position for postdocs or grad students on a temporary limited term basis. The position would work in labs with inventors to move technology to prototype stage. The Office of Technology Transitions could provide I-Corps-type mentorship to produce a well-developed business plan.

The national laboratory technology maturation program would allow small businesses that have licensed technology from a national laboratory to apply for assistance from national laboratory scientists and engineers to mature the technology and further develop products and services until they are market-ready or sufficiently developed to attract private investment. This would require sufficient funding and time to generate a return on investment, which could include increased licenses and start-ups catalyzed by this program, jobs created or retained, increased sales, higher average salaries, and subsequent funding attracted or leveraged.

Expand Programs/Funding – Expand all technology transfer-related programs (in addition to technology maturation) to other parts of DOE (NNSA, Science). Explore opportunities to allow labs to accept gifts of

funding for research (e.g. foundation, industry collaboration). Lab technology research programs are another option, where funds are provided to labs to work with the private sector to get to the result. Finally, CRADA language could be modified to allow funds to be sent to non-federal parties.

Foreign Approval – Reform DOE's review of lab foreign engagements and internal lab agreement processing procedures. DOE Order 485.1 could be modified to limit approval to the initial interaction with the company, or a list of acceptable countries or acceptable technologies exempt from this order could be created. For U.S. manufacture, develop a more defined process for the approval of net benefits statements on CRADA/licensing to foreign companies regarding global manufacturers.

Entrepreneurial Separation or Leave – Current regulations (the Atomic Energy Act) require employees to terminate for entrepreneurial separation primarily due to U.S. government ownership of the inventions generated by lab employees. Negotiating something with DOE/NNSA (such as a waiver) for inventions ownership generated by lab employee while on a leave for entrepreneurial separation could mean entrepreneurs wouldn't have to do a full termination, making this option more feasible and attractive.

Process Improvements and Clarification – Helpful improvements include:

- Issuing a clear DOE policy on technology transfer and industrial engagement from the Secretary of Energy.
- Reforming technology transfer legislation to support tech transfer as a funded mission objective.
- Maintaining entrepreneurial spirit by adjusting policies (e.g. conflict of interest, fairness of opportunity) that currently inhibit DOE labs from fully engaging with startups and entrepreneurial communities.
- Modifying indemnity requirements for domestic sponsors (DOE Regulatory Reform Decision Memo #2) including: increase indemnification flexibility for specific partner types (e.g. state and local governments, state universities); provide DOE blanket policy approval to remove the general and IP indemnity clauses for all federally-funded sponsors and state/local governments; approve indemnification clauses for sponsors not under a blanket DOE policy.
- Clarifying potential discrepancy in Stevenson-Wydler between the CRADA definition and the authority in this act. The potential discrepancy is that the general authority statement allows for collaboration with GOGO laboratories, but the CRADA definition states that a non-federal party is required for every CRADA.
- Granting laboratory directors the ability to enter into agreements without transactional approvals of agreements or work statements by DOE.
- Creating easier exception processes for U.S. competitiveness clause.
- Waiving the federal administrative fee (FAC) for ACT/FedACT.
- Authorizing know-how for trade secret licensing.
- Examining U.S. Patent and Trademark Office's fees for micro entities.
- Modifying Morella rights that currently prevent labs from working with multiple partners in similar research areas; Morella rights should not attach for in kind CRADAs, only to non-federal funded CRADAs.
- Eliminating DOE, source, or other approvals in the copyright assertion process.
- Ensuring lawsuits against infringers are pursued and checking for infringing items at the border.

- Modifying how title is handled for inventions made by universities under laboratory funded research in a CRADA (currently causes title separation).
- Clarifying Government Use Rights purpose.

Thank you for the opportunity to comment on this initiative.