

FLC Educational Webinar Series

New T2 Regulations: What You Need to Know

May 22, 2018

Transcript

Slide 1:

Welcome to the FLC webinar, “New T2 Regulations: What You Need to Know.” My name is Courtney Silverthorn. I’m the deputy director of the Technology Partnerships Office at the National Institute of Standards and Technology. So today we have about 25 minutes of slides and then plenty of time for questions. We’ll be reading and answering those questions at the end.

There’s also a resource box on the right side of your screen that contains the final Bayh-Dole and personnel exchange rules, as well as some of the other resources I’ll be pointing out throughout the presentation.

Slide 2:

So, to set the stage for what we’ll be talking about today – the why, the when, and the what – we’ll go over some of the background of the lab-to-market initiative to tell you why we undertook the changes to these regulations. We’ll go over the timeline and implementation to give you a flavor of how long it took to put this into place, and important dates to know about; and then we’ll dive into the changes that you need to know about as a tech transfer professional.

Slide 3:

We’ll start with the why, some background on the lab-to-market initiative that sets the stage for how we got here.

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As many of you are already aware, the presidential memorandum on technology transfer in 2011 really kicked off all these lab-to-market activities. The Lab-to-Market Initiative was formalized as a cross-agency priority goal in 2014, and will continue on as a second cross-agency priority goal as announced in the President’s Management Agenda on March 20. Subsequent to the first Cross-Agency Priority Goal, a National Science and Technology Council subcommittee was chartered under the committee, and will be rechartered as the Lab-to-Market Subcommittee under the newly formed committee on science and technology enterprise. This will help efforts not only to do tech transfer but also on scientific collection, research infrastructure, and open data initiatives. The original CAP goal had 5 sub-goals: developing human capital, which were programs that encouraged entrepreneurship at federal agencies, as well as the foundations of the NIST partnership with the Minority Business Development Administration to encourage minority participation in federal T2 and the SBIR program; empowering effective collaborations, which focused on T2 authorities and best practices; opening R&D access, which is probably the most visible of the subgoals because this was the subgoal that led to the development of FLC Business 2.0; fueling small business innovations, which was led by SBA to improve the SBIR program; and evaluating impact, which focused on both tech transfer metrics and impact analysis of federal T2. The regulatory

activities that took place under lab-to-market both on Bayh-Dole and personnel exchanges were housed under the empowering effective collaborations subgoal, which focused on tech transfer authorities and best practices.

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While we'll mostly focus on the updates to the Bayh-Dole regulation today, there were actually 2 regulatory activities that took place under this empowering effective collaborations subgoal. The first was issued at the end of 2016 for personnel exchanges, and this was a goal to develop regulations to establish new and expanded mechanisms for the exchange of federal personnel with nonprofit and for-profit entities. While it's really easy for federal personnel to be exchanged out to, say, a university or a state and local government organization, it's been a little more challenging for agencies to send and receive personnel to and from private entities. This regulation created some clarifications with the CRADA statute that made personnel exchanges a little easier for agencies. These regulations can be found at 15 CFR 17. Then we focused on the Bayh-Dole Act after that, updating it to improve extramural funding partnerships, increase compliance by recipients of extramural funding, and improve agency access to data reported by extramural funding recipients. The data access was primarily through changes in the iEdison system, and the funding partnership and compliance we took through the regulatory pass.

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While there are a number of changes in the final Bayh-Dole regulation that was published in April, when we set out on this journey we had a couple of main goals. The first was that the 2011 America Invents Act created some timelines, definitions, and royalty payment requirements that were in conflict with provisions in the current regulation. We also identified certain scenarios, such as provisional applications, joint IP developed between a funding recipient and a federal lab employee, and CRADA background licenses that were not contemplated or adequately addressed in the original Bayh-Dole Act. We also decided to codify Executive Order 12591, which expanded the applicability of the Bayh-Dole Act to businesses of all sizes in the regulation. Previously, it had been only applied to small businesses in addition to nonprofits. And we discovered we'd numbered some of the sections in the original regulation wrong, so we worked with the Office of the Federal Register to renumber those in a way that was as least disruptive as possible. We identified additional goals and necessities in the update process as we went through the various stages of legal revision, agency review, and our public comment process.

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Next, we'll turn to timeline and implementation. This was a lot of work behind the scenes at NIST, and was an incredibly eye-opening process for me.

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The very first email I can find identifying Bayh-Dole as a priority under the L2M initiative was Nov. 15, 2015, right at the end of 2015. We began the drafting process with assistance from our legal group as well as the interagency working group for Bayh-Dole. It took us until July 2016 to clear a draft through the working group and NIST, and send it over to the Office of Information and Regulatory Affairs (OIRA) to start the agency comment process. The agency comment process completed in October 2016, and it was finally cleared for publication in the *Federal Register* as a notice of proposed rulemaking. This was published on November 7, 2016, and had a 60-day comment period. As part of that comment process, we also held a public meeting and a webinar at NIST with about 35 attendees total. That pretty much took us up to the end of the first year of our timeline.

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Kicking off the second year of our timeline, our public comment period closed on December 9, 2016. We received 17 public comments through that. By March 2017 the rule had been revised at NIST, again, with assistance from our legal group and the Bayh-Dole working group. We received and addressed comments from the main Department of Commerce by August of 2017, and in September of 2017 OMB required us to revise the preamble language to include cost-savings information as required by the new Executive Order 13771. We finally cleared the rule through the Department of Commerce in October of 2017 and sent it off for a second round of agency review through the LRM process. By March of 2018 we had completed the final, final revision and published the rule on April 13, 2018—881 days from start to finish. The important thing to note here is that while the effective date of the rule is 30 days after publication, or May 13, 2018, the rule is only applicable to new funding agreements that are executed after the effective date or existing funding agreements that are modified at an agency's discretion to include the new rule applicability. So, you'll want to check with your contracts or grants group to check whether a particular invention is coming in under the old rule or the new rule.

Slide 10:

So now let's move on to the main topic—changes to the Bayh-Dole rule that will affect federal tech transfer offices. These changes are applicable to all agencies. I've identified five major changes that you should know about as a federal tech transfer professional. Then I'll also point out some more general changes that are pertinent to the extramural community, but might be interesting for you to be aware of as well.

Slide 11:

The first change is a new determination of exceptional circumstances, or DEC, in 401.3. In my past life I worked for a contractor that had a DEC, and it took me forever to realize that DEC was an abbreviation and not a “deck, d-e-c-k.” For those of you who don't already know, DEC is a determination that allows an agency to restrict or limit a contractor's Bayh-Dole rights due to the exceptional nature of the work that they're doing. There are already DEC's in place in the Bayh-Dole regulation that allow an agency to withhold Bayh-Dole rights for situations like foreign recipients of federal funding, contractors who work on nuclear programs, and contractors who work on behalf of the government under a Cooperative Research and Development Agreement. This change in 401.3 is to add a new DEC that states “If the contract provides for services and the contractor is not a nonprofit organization and does not promote the commercialization and public availability of subject inventions pursuant to 35 U.S.C. 200.”

What this is saying is that there are sometimes service-based support contractors who may occasionally have or contribute to a subject invention, but on the whole the service-based support contractor does not engage in commercialization activities that would ultimately advance an invention to the marketplace. Under the standard Bayh-Dole terms, the service-based support contractors would still have the full two-year period to decline to elect rights to an invention before that title would waive back to the funding agency. Under this DEC, the funding agency can determine upfront that the service-based support contractor would not be able to commercialize any inventions and then take title to inventions that happened to occur and manage them in accordance with the agency's mission and needs.

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The second issue I want to address is of priority order for co-inventions found in 401.10. I've used some stick figures to illustrate the scenarios here that can be a little complicated to follow along. You'll note that this is why I was not an art major in college. The typical scenario contemplated by Bayh-Dole is the figure on the left: The funding agency provides a contractor a grant to an extramural researcher, perhaps at a university, and that university researcher and his or her team work on a project. They invent something, and the Bayh-Dole Act states that the university researcher or his or her employer retains ownership of that invention. If they choose not to elect title to that invention, it reverts back to the funding agency, and everything is clean and simple. However, sometimes reality is not always so clean and simple. Sometimes we have the scenario on the right-hand side instead: A funding agency provides a contract or a grant to our university researcher, but now he or she needs some help from a different federal lab in order to carry out the work. For example, maybe NIH gives a grant to our university researcher and he comes to work at NIST at one of our user facilities and collaborates with one of our, say, nanotechnology experts, and that NIST employee and university employee jointly create an invention. There wasn't really a good understanding in the Bayh-Dole regulation of how to handle this type of co-invention, particularly after the extramural funding recipient waived title to the invention. An explicit reading of Bayh-Dole would say that it reverted back to the funding agency like any other invention. This fails to address the fact that another agency also has interest in the invention through its co-inventor.

Slide 13:

What we've done here in 401.10 is created an explicit order of operation for how to handle these joint inventions between extramural funding recipients and federal lab researchers. Obviously, because this is the Bayh-Dole regulation, the contractor has the first right to elect title—because it's the Bayh-Dole regulation. Where we looked next was if the contractor waives that first right, the inventing agency will have second right to elect title. The reason we took the stance was because the Constitution grants inventors ownership of their invention, so we thought that it followed that the federal lab researcher and their laboratory would have second right to elect title to a joint invention. If both the contractor and the inventing agency waive title to the invention, it would then default to the funding agency, just like under the normal Bayh-Dole processes.

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Again, this change to 401.10 creates an explicit priority order for ownership of inventions jointly created between an extramural funding recipient and a non-funding agency: first the contractor, second the inventing agency, and third the funding agency. It does require the funding agency to notify the inventing agency if a contractor waives title to a joint invention. This is because only the funding agency would have access to that invention's record in the iEdison system. It also requires the funding agency to provide administrative assistance (but not any financial assistance) to the inventing agency if the inventing agency decides to secure title to the invention. It also requires the inventing agency to consult with the funding agency on the management of the invention to ensure that the invention is managed in a way that is consistent with the original goal of the funding that resulted in the invention.

Slide 15:

Next, we've addressed the definition of initial patent applications in a couple of sections: 401.2, 401.10, and 401.14. We've included provisional applications as well as PCT applications and plant variety protection

certificates in the definition of “initial patent application” in 401.2. Additionally, we’ve permitted co-inventing agencies in the scenario that I just laid out to file initial patent applications in order to protect subject inventions; this could be a provisional application. The only caveat is that they should not be doing anything in that filing that would prevent the contractor from waiving rights. But they do have the ability to secure those rights if they know that there's an imminent disclosure.

Slide 16:

The next change I'll note is in 404, which deals with management and licensing of federally owned inventions. We have broadened the newness requirements for announcing a prospective exclusive or co-exclusive license for a federal invention to be published in the *Federal Register* or other appropriate manner. This could be an agency website, could be a printed publication, or some other manner appropriate for announcing information to the public. The guidance we've received at NIST and want to make sure you're aware of is that if your agency or lab does choose to use alternate means to announce exclusive licenses outside of the *Federal Register*, they do need to let the public know in—you guessed it!—the *Federal Register*, where those alternate places are so they can find information about exclusive license notifications from that agency.

Slide 17:

Finally, we’ve streamlined the process for CRADA collaborators to access background inventions. “An executed CRADA which provides for the use for research and development purposes by the CRADA collaborator under that CRADA of a federally owned invention in the federal laboratory’s custody and which addresses the required information”—this is all laid out in 404.8—“may be treated by the federal laboratory as an application for a license.” What this does is if you have a background invention that's about to be used in a CRADA, at NIST and a couple of other agencies the extramural partner would have to execute the CRADA and also execute a license for the research. What we've done is eliminated the license application in that scenario, provided the CRADA collects and displays all the information that would normally be collected under a license application.

Slide 18:

Finally, just some other general changes that you might want to be aware of. As I mentioned previously, the new Bayh-Dole regulation codifies Executive Order 12591 to make the Bayh-Dole Act applicable to all businesses regardless of size, large, small, and everything in between. It complies with the America Invents Act to create updates into the reporting timelines and definitions and statutory period. It requires contractors to have their employees explicitly assign rights to the contractor. This is a result of the *Stanford v. Roche* decision. It requires contractors to file nonprovisional applications within 10 months of provisional filing. Contractors can request waivers, and to reduce the burden on agencies, we’ve stated that these will be automatically granted unless otherwise notified by the funding agency. It requires contractors to notify agencies 60 days before the end of the statutory period if a decision is made to not continue patent prosecution. This is an increase from the previous 30 days under the old Bayh-Dole rule. It eliminates the time limit for an agency to request to elect title as a result of the contractor’s failure to adhere to Bayh-Dole reporting requirements. Previously, if a contractor failed to disclose an invention or failed to elect title within the required timeline, an agency only had 60 days to request to elect title as a response to that noncompliance. Under the new Bayh-Dole rule, an agency can request title indefinitely any time after they become aware of a contractor's failure to either disclose an invention or to elect title to an invention in a timely manner.

Slide 19:

What are our next steps? First, we can finally move forward with the new publication of the FLC “Green Book.” If anyone doesn’t already know, the “Green Book” is the collection of relevant technology transfer legislation, regulations, and a few policies and executive orders that is published by the Federal Laboratory Consortium. It’s a little bit overdue for republication; we have been holding the publication of the “Green Book” so that we could include the most up-to-date Bayh-Dole regulations that just came out. Now that that’s published we can move forward and get those copies into your hands as soon as possible. Separately, under a separate initiative, NIST and the National Institutes of Health will be undertaking an effort to rebuild the iEdison invention reporting for extramural recipients beginning in FY19. We’ve already talked to participating agencies to find out what their needs are for the new system, and will be going out to the public with a request for information in the next several months. We appreciate your help in making sure that we get a good response to that, so if you could forward the link when you see it to your funding recipients and/or your extramural colleagues, that would be greatly appreciated. While this effort to update Bayh-Dole regulations was not explicitly connected to the Return on Investment Initiative that NIST started up this year or the Unleashing American Innovation Symposium that took place on April 19th, they certainly are interconnected. I put the link to the NIST ROI website up on screen so you can find out more information about that initiative, the request for information that’s currently out, the public forums that we are in the process of holding, and what our next steps will be from that stakeholder engagement process.

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Finally, I’ve listed some of the resources. Under the Bayh-Dole regulation, you can look at the docket information, the original notice of proposed rulemaking that was released in the *Federal Register* back in November of 2016; you can see the regulations.gov docket information with all the public comments; and the final rule, which was published on April 13, 2018.

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Since I mentioned the personnel exchanges regulation that’s part of the Lab-to-Market Initiative as well, the docket information for personnel exchanges, the NPRM publication, and the final rule are also linked here.

Slide 22:

I want to thank all of you for attending this FLC webinar today to learn about the changes to tech transfer regulations that might affect your office. My contact information is on the screen. Please feel free to reach out to me if you have any questions about the applicability of the changes in the Bayh-Dole rule or its implementation, or anything to do with personnel exchanges or lab-to-market. I’ll be turning now to the chat box to take your questions and answer them.

Q&A:

Alright, so moving over to some of the questions that have come in during the slides.

There was a question about the priority order changes in 401.10—Aren’t both the inventing agency and the funding agency the federal government? Yes, that is true, but we do respect that there are differences in how

agencies undertake patent management, so this just provides an opportunity to very clearly lay out who's responsible at what point in the process, whether it's the inventing agency taking the lead on that patent prosecution because they have a co-inventor, or if they defer to the funding agency as would be typical under a standard Bayh-Dole situation.

A question came in—How will this impact standard CRADA forms?

There should be no changes that come out of the Bayh-Dole rule explicitly to the CRADA form. The only thing that we've changed in this regulation that touches on the CRADA aspect is that background license, which would have been a separate document outside of the CRADA form anyway. So, no changes should be needed to any standard CRADA forms at any agency.

One question—How will the new T2 aspects help with biomedical T2, where multiple stakeholders are involved in the long development pipeline and regulatory hurdles have to be overcome?

This issue was not addressed in the Bayh-Dole rule update or the personnel exchange update, but it sounds like a great topic for the Return on Investment Initiative. We are taking a very broad look at tech transfer in that space, where this was very specifically looking at extramural reporting and extramural management of inventions that are funded by the federal government.

Similarly, there was a question about Wilbur Ross's news announcement regarding tech transfer.

That is a very recent initiative, the ROI initiative. As I pointed out earlier in the slides, the Bayh-Dole regulatory update timeline started over 2 years ago and just coincidentally happened to take effect the same week that we are rolling out the ROI initiative. So, I'm hopeful that Secretary Ross's news announcement will result in action. We're in the process of that stakeholder feedback process and looking forward to the results of that down the road.

How does this impact the Department of Defense tech transfer community, if at all?

Both regulations, as I mentioned in the slide presentation, are equally applicable to all agencies, so you are in the same boat as everyone else on this one.

A question about how new regulation will affect government contract terms. Government contract terms are found in the Federal Acquisition Regulations, or the FAR, and those are managed by a section of GSA. We did coordinate throughout the process of implementation with GSA. They will need to do an update to the FAR to have the provisions in the FAR match the provisions in the Bayh-Dole rule. There are actually a couple of places where we took language from the FAR and incorporated it into the Bayh-Dole regulations. A great example of this was that the FAR already required contractors to file nonprovisional applications within 10 months of filing provisional applications, so we took that language verbatim and replicated it in 401.14 when we made the Bayh-Dole update. A couple of other things like the timelines and the requirement for contractors to assign the rights to their inventions to the employer will need to be in the FAR update. Once that language is updated, that'll be the standard language for government contracts.

Somebody is very excited to get their new copy of the Green Book! I believe that those should be available sometime this fall, certainly in time for you to get your physical copies at the next FLC meeting in April of 2019. Before that, it will be available as a PDF online as soon as the updates are made by the FLC Legal Issues Committee. I'm sure there will be a big announcement as soon as they're ready. We've been waiting for almost a year to get that Green Book update out, so we will get it through as soon as we can.

One question about the new DEC that we added in 401.3—Will the new DEC be an option for all agencies to use? Yes, every agency has the ability to use that DEC.

Also asking about the DEC—Will the DEC here replace existing agency decks or supplement the DEC?

Each agency that has a contractor DEC has undergone that review process to determine what the appropriate DEC is for that particular contractor. We would expect that any agency using the new DEC for service-based contractors that don't have a business model of commercializing interventions to also review and make a determination that that DEC was the most appropriate DEC for that particular contract.

A question came in about the co-invention—If a contractor improperly notifies the co-inventing agency of an invention, does the funding agency retain its right to reclaim the title to the invention? What if the co-inventing agency has proceeded to file a patent?

If there was not a proper invention report to the funding agency, that speaks to the change that we made in 401.14(d)(1), which eliminated the 60-day deadline for agencies to claim title to inventions if a contractor does not disclose. My assumption is that if it was a co-invention that was also not reported properly, then it would also be applicable to that change in 401.14 where a funding agency could retain its right to reclaim the title. If the co-inventing agency has proceeded to file a patent, at that point we would expect the co-inventing agency and the funding agency to work in cooperation in that instance.

Question—When an awarding agency contracts with a university and the university partners with another federal agency, what agreement is in place between the university and federal partner? A CRADA? A subaward or subcontract?

It probably would not be a subaward or subcontract to another federal agency, but it could be a CRADA or it could be perhaps a Cooperative Agreement. But most likely a CRADA, in that they would need to come to access the expertise of that federal agency. Another great example might be a user facility agreement, so if they came in to access a user facility and worked with a scientist during that time, that could also result in a co-invention.

Can parties agree to an arrangement for co-ownership that differs from the statute?

Yes, we've explicitly said in 401.10 that the provisions of that regulation addressing co-ownership do not supersede any other institutional agreements, so if the parties agree to manage the invention in a different way, then that is certainly acceptable.

Which change do you think will affect the day-to-day of a federal tech transfer officer the most?

At least at NIST, I know that not having to execute a separate license for a CRADA background invention will be the most impactful here. I know that not every agency has that requirement to do a separate license, but for the agencies that do, that should save quite a bit of time and effort on both the federal tech transfer professional's part as well as the collaborator's part because they don't have to fill out two separate documents.

Can you elaborate on a user facility agreement? What authority?

I would have to look up the specific authority for user facilities. I don't have that available right in front of me. But a user facility agreement is how outside entities can access expertise and facilities at a government agency. For example, NIST has two user facilities. We have a nanofab facility and neutron research facility; those are things that are not readily available to the general public for their own development and use. So, they can come to NIST

under our facility agreement and access the facilities for a research project. I can get back to you through the FLC on what the specific authority for that is.

Who determines that the contractor cannot commercialize the technology and does this exclude the contractor's ability to license out the technology?

We're looking at what we've colloquially called service-based contractors. These are not researchers. These are contractors that provide off- and on-site services and are not able to take an invention through commercialization efforts because that's not their business model. Their business model is that they provide onsite services. We would expect that the agency would make that determination. It is, of course, subject to review at the contractor's request as all DEC's are. If a contractor feels the DEC has been applied improperly, they can certainly avail themselves of the review process. In that case, yes, it would exclude the contractor's ability to license out the technology because it's been determined that they are not able to commercialize it and therefore the government agency would have title to that. Just like any other DEC, they could request greater rights for a specific invention if they could show that in that case they would be able to license and commercialize that particular piece of technology. All other DEC rules still apply in this instance.

Was any consideration given to how the regulations apply to FFRDCs as an entity rather than the parent organization's legal status?

FFRDCs are subject to Bayh-Dole, as they are contractors to parent agencies, and they would have Bayh-Dole regulations apply to them just like any other contractor.

Okay, so my chat box window is empty! I really want to thank you all again for participating today. Feel free to reach out to me with additional questions. If I can't answer them, I will forward them to our wonderful legal counsel here, who will get you an answer to your question. Thanks again; I really appreciate you taking the time out of your day.