



Utilization Reporting

Changes coming in 2023

February 9, 2023

About Utilization Reporting



What is it? How does it currently work?

Utilization Reporting in the Regulations

- 37 CFR 401.14(h)
- “The Contractor agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify. ... As required by 35 U.S.C. 202(c)(5), the agency agrees it will not disclose such information to persons outside the government without permission of the contractor.”



Why is Utilization Reporting Important

- Utilization Information can be useful for a number of different purposes
 - Identifying outputs of programs
 - Calculating return on taxpayer investment
 - Providing success stories
 - Determining overall economic impact
 - Establishing compliance with requirements
 - Etc.
- Increased interest in utilization reporting
 - On July 9, 2021, the President issued Executive Order 14036 stating that NIST should consider a rulemaking requiring the agencies to annual report the utilization information they have received from their awardees



How Utilization Reporting Currently Works

- Some but not agencies require utilization reporting
 - NIH and DOE require annual utilization reporting in iEdison
 - Other agencies ask for utilization on an ad hoc basis
- In iEdison, you receive notifications annually for NIH or DOE funded inventions that a utilization report is due:
 - For each invention to which you have elected to retain title (or for NIH “Elect to Retain Title” or selected “Designated as an Unpatented Biological Material or Research Tool”)
 - All due at the end of your fiscal year (notification will post on the first day of your new FY)
 - For example, if your 2020 FY runs July 1st 2019 – June 30th 2020, then your 2020 utilization notifications would have posted on July 1st 2020.

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How Utilization Reporting Currently Works (cont.)

- In iEdison, a list of questions are populated and you answer all that apply before saving the utilization report
- These questions were pulled over from the NIH system and include basic questions with certain supplemental questions if the invention is FDA approved or has DOE funding

Submit Utilization Report

Invention Report #: 07654321-22-0003 Invention Docket #: 22-0003 Institution: DAN'S INSTITUTION (7654321) Primary Agency: NIST

Invention/Patent/Utilization Tree +

Invention Details -

Invention Report Number *	07654321-22-0003		Institution	DAN'S INSTITUTION (7654321)
Invention Title	Talking Avocado			
Primary Agency	Invention Report Date	Title Elect Date		
NIST	02/15/2022	02/15/2022		

Utilization Details -

Reporting Year (YYYY) *

Indicate the latest stage of development of any product arising from this invention, according to the following categories: *

If any product arising from this invention has reached the market, what was the calendar year of the first commercial sale? (YYYY)

In the designated reporting period, what was the total income received as a result of license or option agreements? Do not include specific patent costs reimbursement. \$0.00

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Current iEdison Utilization Questions Include

- Stage of Development (not licensed, licensed, commercialized)
- Date of first commercial sale
- Total income received from licenses/options
- Whether domestic manufacturing waiver(s) were requested?
 - If so, how many granted?
- Number of exclusive licenses
- Number of non-exclusive licenses
- Number of licenses to small businesses (less than 500 employees)
- *IF product is FDA approved:*
 - Product name
 - FDA approval number
 - Product type
 - Approval status
- *DOE funded only*
 - Approximate number of US based jobs created because of commercialization efforts
 - Number of US companies created because of commercialization efforts
 - How the development and commercialization of the subject invention comply with any required U.S. manufacturing requirements
 - Unique commercial product names
 - NAICS code for products
 - Manufacturing locations of products
 - First date of manufacturing

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New Utilization Changes



What is changing? How will it work in the future?

Changes Are Underway

- Based on increased interest in utilization reporting, many changes are underway and coming, including
 - Who is asking for utilization reporting
 - When utilization reporting is due
 - What questions are being asked
 - How utilization questions are asked in iEdison

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Who is Asking for Utilization Reporting

- Starting on October 1, 2023, **ALL AGENCIES** utilizing iEdison will begin requesting utilization reports
- This will happen automatically, and you will be notified via notifications that they are due
- These reports will 2023 and forward. iEdison will not generate notifications for past years for agencies that did not previous request utilization reports
 - NOTE: your previously due utilization reporting will remain UNCHANGED (such as the previously due reports for NIH and DOE – those will still be due)

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When Utilization Reporting is Due

- Moving forward– ALL utilization reporting will be due on October 1st of each year
- To align with the regulations, iEdison has not generated utilization notifications with due dates after October 2, 2022
 - Previously due (overdue) utilization reporting remains unchanged
- Notifications for new utilization reporting will resume on October 1, 2023

What questions are being asked

- The interagency working group for Bayh-Dole has been working for months to develop a common set of questions that will be asked by each funding agency
- Certain agencies have also developed a few supplemental questions that will be asked ONLY when they are listed as a funding agency for that specific invention
- These questions are still being finalized and will be announced in the coming weeks
 - However, they are largely based on the previous utilization questions
 - You can expect questions about stage of development, revenue, license agreements, products, and manufacturing locations

How utilization questions are asked in iEdison

- THE NEW FORMAT IS CURRENTLY BEING DEVELOPED; OUR PLAN INCLUDES:
 - You will be asked a Stage of Development question (similar to the current utilization reporting)
 - Your response will dictate what question(s) you are asked next
 - So if you select “Licensed”, you will be asked about your licenses but not date of first sale or products
 - If you select “Commercialized”, you will be asked questions about licenses and products
 - Your most recent report for each invention will auto-populate from the previous year’s answers (like it does now in the new system) and you can edit auto-populated information if it needs updating

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Preparing for the changes



What we are doing & what you can do

What are we doing

- **Questions will be finalized** in the coming weeks and will be announced and posted on the iEdison homepage
- We will be developing an interagency **guide document** with definitions and examples from the agencies to aid in answering the standard questions
 - For supplemental, agency-specific questions, you will need to ask that agency
- Development in iEdison is already starting
- As soon as development is completed, we will **update API documentation** and provide to database provided and those on our API list
- We also plan to update the **bulk upload** capability

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What you can do

- Make sure you know the status of your inventions
- Track what inventions are licensed
- Ensure your licenses include domestic manufacturing requirements
 - Ensure your licensees are compliant with those requirements
- Know where your products are being manufactured
- Clean up old files and cases that are still active in iEdison

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Questions?



More information will be coming soon, so please check the iEdison homepage regularly