

Biannual Compliance Monitor Report

United States of America v. Envigo RMS, LLC and Envigo Global Services, Inc.
Case No. 6:24CR16

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I. Introduction

The Compliance Monitor (“CM”) submits this biannual report (“Report”) pursuant to section 12(d)(1) of the Final Plea Agreement (“Plea Agreement”) between the United States, by and through the United States Attorney for the Western District of Virginia and the Environmental Crimes Section of the Department of Justice (collectively “DOJ”), and Envigo RMS, LLC and Envigo Global Services, Inc. (collectively “Envigo”), as entered into between the parties on June 3, 2024.

This is the first report provided since the CM commenced the monitorship on January 20, 2025. This Report reflects work performed and compliance activities observed by the CM during the first six months of the monitorship.

A. The Plea Agreement and the Resolution Agreement

The Plea Agreement and the related Resolution Agreement were entered into by the parties after Envigo pleaded guilty to conspiring to knowingly violate the Animal Welfare Act, 7 U.S.C. § 2131 *et seq.*, “by failing to provide adequate veterinary care, adequate staffing, and safe and sanitary living conditions for the dogs housed at [the Cumberland facility].” (§ 1). Further, Envigo pleaded guilty to conspiring to knowingly violate the Clean Water Act, 33 U.S.C. § 1251 *et seq.*, “by failing to properly operate and maintain the wastewater treatment plant at the Cumberland facility.” (*Id.*). The Resolution Agreement between DOJ and Envigo resolves the federal criminal investigation described in the Information to the Plea Agreement. (Plea Agreement, Attach. B, ¶ 1).

The Plea Agreement (§ 12(a)), among other things, requires that “a CM shall be appointed to ensure compliance with all Applicable Laws, the Plea Agreement, and the Resolution Agreement.”

The Plea Agreement (§ 5(c)) defines “Applicable Laws” as “all federal Animal Welfare Act and Clean Water Act laws, rules, and regulations, as well as all federal and applicable state and local animal welfare, animal cruelty, water, and sewage laws, rules, and regulations,” and it states that “ENVIGO recognizes it is the United States’ intent that [Envigo’s and Inotiv, Inc.’s (collectively the “Inotiv Entities”)] personnel and facilities shall exceed the minimum requirements under the Animal Welfare Act and Clean Water Act to ensure the health, safety, and well-being of animals under the care of the INOTIV ENTITIES.” (§ 5).

B. The Compliance Monitor

1. Duties, Powers, and Obligations of the CM under the Plea Agreement

The Plea Agreement (§ 12(b)) specifies that the scope of the CM is limited to review of (1) “the care of any ‘animal’ as defined by 9 C.F.R. § 1.1 by those components of the INOTIV ENTITIES that hold licenses pursuant to the United States Department of Agriculture [(“USDA”)] or conduct activities under those licenses,” and (2) “for purposes of ensuring compliance with the Clean Water Act laws, rules, and regulations, as well as all federal and applicable state and local water and sewage laws, rules, and regulations, those components of the INOTIV ENTITIES that hold permits regulated by the Clean Water Act, including, but not limited to, National Pollutant Discharge Elimination System (‘NPDES’) permits and indirect discharge permits and related activities, and any comparable permit issued through a delegated-state program.”

Within the scope of its review, the Plea Agreement (§ 12(b)) empowers the CM to:

- i. Freely review all records of the Inotiv Entities.
- ii. Freely communicate with all employees, contractors, and agents of the Inotiv Entities.
- iii. Take all steps necessary to determine if the Inotiv Entities are fully complying with all Applicable Laws.
- iv. Take all steps necessary to determine if the Inotiv Entities are fully complying with all (1) obligations set forth in the Plea Agreement and Resolution Agreement, (2) terms of probation, and (3) terms of the [Nationwide Compliance Plan].
- v. Report any matter to any Inotiv employee or any appropriate governmental or regulatory body, if the CM believes it to be in the interest of advancing the purposes of the Plea Agreement and the Resolution Agreement.
- vi. Promptly notify the Court and the United States if the CM is being denied access to information, resources, or employees or agents necessary to fulfill the CM's responsibilities.

In addition to a biannual reporting requirement, the Plea Agreement (§ 12(d)(ii)) requires the CM to provide, “[w]ithin 10 days of discovery by the CM, a report detailing any significant failure to comply with the Plea Agreement, Resolution Agreement, or a term of probation, unless the failure to comply is remedied within five days of such discovery.”

The Plea Agreement (§ 12(b)) also requires the CM to conduct on-site reviews of all the Inotiv Entities' facilities that are within the scope of the CM's review in three years. It limits the CM's on-site reviews to one-third of these facilities each year (rounded to the nearest whole number). Notwithstanding the foregoing limit, if the CM identifies a non-compliance during its on-site review of any facility, the CM may revisit such facility at any time to ensure corrective measures have been taken.

The Inotiv Entities identified six facilities that currently hold or conduct activities under USDA licenses or hold permits regulated by the Clean Water Act and thus are within the scope of the CM's on-site inspection authority. Accordingly, the CM intends to conduct on-site reviews of two facilities each year, beginning in 2025.

The Plea Agreement (§ 12(f)) directs that the CM's term shall expire after five years. However, if the Inotiv Entities are released from probation prior to completion of such five-year term, the monitorship “shall expire three years after the completion of the selection process for the CM, or two months after the completion of probation, whichever is later.”

2. The Compliance Monitor Team

John H. Fuson of Kleinfeld, Kaplan & Becker LLP (“KKB”) is the designated CM.

Mr. Fuson is supported by other attorneys at KKB, a veterinarian and a veterinary technician who are experts on the requirements of the Animal Welfare Act, and an expert on the

requirements of the Clean Water Act. Mr. Fuson, associated attorneys, and the subject matter experts comprise the Compliance Monitor Team.

The Compliance Monitor Team was notified of its appointment on December 12, 2024. Mr. Fuson entered into a retention agreement with the Inotiv Entities and commenced the monitorship on January 20, 2025.

3. Certain Deadlines Set by the Plea Agreement

Under the Plea Agreement, certain deadlines flow from the commencement of the monitorship, including:

- By February 19, 2025, the Inotiv Entities must report any deficiencies with respect to certain standards related to housing of nonhuman primates (“NHPs”) and, if necessary, a corrective action plan to be accomplished by June 3, 2025 (§ 5(b)(i));
- By February 19, 2025, the Inotiv Entities must report any deficiencies with respect to certain standards related to NHP enrichment, temperature, and lighting, and, if necessary, a corrective action plan to be accomplished by June 3, 2025 (§ 5(b)(i));
- By February 19, 2025, the Inotiv Entities must report any deficiencies with respect to certain standards related to species-appropriate housing of small animals and, if necessary, a corrective action plan to be accomplished by June 3, 2025 (§ 5(b)(ii));
- By April 21, 2025, the Inotiv Entities must submit to the DOJ and file with the Court a Nationwide Compliance Plan (“NCP”) (§ 13);
- By July 21, 2025, the CM must submit to the DOJ, the United States Probation Office, and file with the Court a report detailing the Inotiv Entities’ compliance record and efforts to improve their facilities (§ 12(d)(i)); and
- By January 19, 2026, and each year thereafter, the CM must conduct on-site reviews of one-third of the Inotiv Entities’ facilities that either hold licenses pursuant to the USDA or conduct activities under those licenses or hold permits regulated by the Clean Water Act (§ 12(b)).

Progress on these and other requirements under the Plea Agreement is described in this Report.

C. Facilities

As noted, the Inotiv Entities identified the following six facilities as within the scope of the CM’s on-site inspection authority pursuant to the Plea Agreement (§ 12(b)):

- Alice East (Texas)
USDA Class B License (74-B-0332) (licensed entity: Envigo Global Services Inc.)
- Inotiv LAMS/Alice West (Texas)
USDA Class B License (74-B-0773) (licensed entity: Inotiv LAMS West Inc.)

- Denver (Pennsylvania)
USDA Class A License (32-A-0774) (licensed entity: Envigo RMS LLC)
USDA Class B License (74-B-0332) (licensed entity: Envigo Global Services Inc.)
NPDES Permit (PA0084174) (permitted entity: Envigo Global Services Inc.)
- Indy East (Indiana)
USDA Class A License (32-A-0774) (licensed entity: Envigo RMS LLC)
- Greenfield (Indiana)
USDA Class A License (32-A-0774) (licensed entity: Envigo RMS LLC)
- Morrisville (RTP) (North Carolina)
Durham County Industrial User Permit (DCL-BSC009) (permitted entity: Integrated Laboratory Systems)

The CM reviewed documents provided by the Inotiv Entities and publicly available records. Based on that review, the CM is satisfied that the foregoing is a complete current list of facilities within the scope of the CM's on-site inspection authority.

II. Animal Welfare Compliance Obligations

A. Agreement Not to Sell Dogs

The Plea Agreement (§ 4) states Envigo's agreement that the Inotiv Entities will not breed or sell dogs and further that any dog under the care of or in the possession or control of the Inotiv Entities will be over the age of 90 days old.

On June 30, 2025, the Inotiv Entities confirmed in writing that they have not bred or sold dogs since entry of the Plea Agreement, and all dogs under their care are older than 90 days.

The CM will continue to monitor the Inotiv Entities' adherence to this commitment for the duration of the monitorship.

B. Agreement to Meet Certain Standards

1. Hiring

The Plea Agreement (§ 5(a)) requires that, in hiring veterinarians where applicants are equally qualified, the Inotiv Entities must give preference to applicants who are certified by the American Board of Veterinary Practitioners ("ABVP") and/or American College of Laboratory Animal Medicine ("ACLAM") in the relevant specialty. The NCP (p.19), discussed in detail below, affirms Inotiv's commitment to this requirement, and the CM understands that the Inotiv Entities are actively working to recruit qualified veterinarians.

The CM will review the Inotiv Entities' hiring practices and the qualifications of currently employed veterinary staff during its on-site visits and throughout the monitorship.

2. Training

The Plea Agreement (§ 5(b)) requires that all veterinarians employed by the Inotiv Entities complete at least 15 hours of continuing education per year. It further requires (§ 5(e)) that all

staff be trained to know and understand normal behaviors of the specific species of animals with which they are working. The NCP (p.19), discussed in detail below, affirms Inotiv's commitment to these requirements.

In a letter dated February 19, 2025, Inotiv notified the CM of certain "process enhancements" it was implementing to address gaps in training. These enhancements included formalizing "behavioral training for [staff working with] rodents at RMS facilities." Specifically, Inotiv explained that it created training for staff on relevant normal rodent behaviors. Once such training was approved, Inotiv intended to assign it to current and future small animal technicians. The letter anticipated a completion date of March 31, 2025.

The CM intends to review training records for staff, including veterinarians, and evaluate the Inotiv Entities' adherence to these requirements during its on-site visits and throughout the monitorship.

3. Rehoming

The Plea Agreement (§ 5(d)) requires the Inotiv Entities to "make reasonable efforts, and document such efforts, to find humane placement for dogs, cats, nonhuman primates, and exotics who are no longer used in research or breeding and are able to be retired." The NCP (p.12), discussed in detail below, affirms Inotiv's commitment to these requirements.

The CM reviewed two Inotiv policy documents outlining the Inotiv Entities' standards for rehoming NHPs and other animals: the *Non-Human Primate Rehoming Policy* and the *Animal Rehoming Policy*. Consistent with the Plea Agreement and the NCP, both policies express a commitment "to find humane placement for dogs, cats, nonhuman primates, and exotics that are retired from research or breeding." (*NHP Rehoming Policy* p.3; *Animal Rehoming Policy* p.3).

The *Non-Human Primate Rehoming Policy*, by its terms, applies to NHPs at facilities in North America only. The *Animal Rehoming Policy* specifically states that it only applies to dogs, cats, rabbits, pigs, sheep, goats, and cattle; rodents and NHPs are out of scope of this policy. (*Animal Rehoming Policy* p.3). The *Animal Rehoming Policy* does not apply to exotics, and the Inotiv Entities confirmed they do not hold such animals. If the CM later determines that the Inotiv Entities are holding animals for which they are obligated under the Plea Agreement to humanely rehome, but which are outside the scope of these policies, the CM will follow-up on such gap.

Under these rehoming policies, the Inotiv Animal Welfare Council oversees the adoption process for any animal to ensure it complies with the requirements set forth in each policy. (*NHP Rehoming Policy* p.3; *Animal Rehoming Policy* p.3).

NHP rehoming is also overseen by the NHP Rehoming Review Board ("Review Board"). The Review Board consists of an NHP Institutional Animal Care and Use Committee ("IACUC") chair, NHP attending veterinarian, NHP behaviorist, NHP quality assurance representative, and a finance team employee. (*NHP Rehoming Policy* pp.4-5). The *NHP Rehoming Policy* requires that the Review Board approve any prospective sanctuary and/or rescue facility before rehoming an NHP to the site. The prospective site must submit evidence that it is capable of caring for the species of animal, is financially stable, does not engage in breeding or experiments, provides adequate veterinary care, and is audited regularly for verification that it meets animal welfare standards, among other requirements. (*Id.*). The Review Board must consider this evidence before submitting a rehoming decision to the site, the applicable IACUC, and the Animal Welfare Council. (*Id.*).

Under the Animal Rehoming Policy, prospective adopters may be: (1) Inotiv employees or first-degree family members of employees in the animal care and use program who have been employed by Inotiv for at least one year; or (2) approved third-party adoption agencies. In the case of the first category, non-employees may be permitted to adopt with approval by the Animal Welfare Council and/or the Chief Compliance Officer. (*Animal Rehoming Policy* pp.3-4). The policy clarifies that third-party adoption agencies may only be approved by the IACUC after a risk assessment is completed and an IACUC memorandum of understanding has been established; it identifies only one currently approved third-party adoption agency. (*Id.*).

Both policies include prerequisite and disqualifying criteria that must be considered before an animal can be rehomed. In the case of NHPs, animals must be healthy and exhibit appropriate species-specific behaviors. (*NHP Rehoming Policy* p.3). In the case of other animals, an animal is suitable for adoption if: (1) it is permissible under local law; (2) the animal has been adequately socialized; (3) appropriate measures have been taken to ensure the well-being of the animal after rehoming; and (4) there is no danger to the public, other animals, or the environment from the rehoming. (*Animal Rehoming Policy* p.3). Disqualifying criteria for all animals include, but are not limited to, the presence of infectious diseases, biohazards, immunosuppression, major surgeries, or chronic health conditions.

The adoption/rehoming process is the same under both policies. (*NHP Rehoming Policy* p.5; *Animal Rehoming Policy* p.4). First, the animal is prepared for adoption by the attending veterinarian, who will conduct a health exam, spay/neuter the animal, and compile a vaccination history. Second, the local IACUC institutional official reviews the rehoming request. Finally, if approved, the recipient of the animal receives a copy of the animal's vaccine and health history.

Based on its review of the rehoming policies, the CM believes that the processes described address the Plea Agreement's requirement for the Inotiv Entities to make reasonable efforts to find humane placement for retired animals. The CM will review rehoming placement data and documentation during its on-site visits and throughout the monitorship.

4. Care of Animals While Not Involved in Active Research

The Plea Agreement (§ 5(b)(i)) requires the Inotiv Entities to inform the CM within 30 days of the CM's appointment of any facility's deficiencies related to its compliance with the following certain standards for the care of NHPs while not involved in active research:

- Primary enclosures or housing and exercise must allow enclosure configurations that permit nonhuman primates: Vertical climbing opportunities with enough space to allow nonhuman primates to travel, feed, and rest in elevated space. Primary enclosures should also be spaces that allow for: access to a variety of substrates; avoidance of frightening stimuli and other individual animals; scent-retaining surfaces (with the exception of macaques); and address the needs of the nonhuman primates at a species, life-stage, and individual level, which must be addressed in individual environmental enrichment plans, including adaptations for nonhuman primates with physical impairments. As to any facility whose primary enclosures do not allow for outdoor access, the nonhuman primates will have alternative regular outdoor access, unless detrimental to the individual nonhuman primate as determined by the AV in writing, subject to quarantine, or prohibited by research protocol.
- Must allow nonhuman primates a level of control over their own enrichment including but not limited to toys that allow opening doors and peep holes (or other toys substantially

similar thereto), a primate nesting box or other similar space to provide the ability to remove themselves from stimuli, and the ability to avoid noxious stimuli, unless the health and well-being of the animal necessitates deviation, in which case the AV must record in writing the need for any modification. Animal care staff must provide for temperature and lighting in any nonhuman primate housing consistent with the nonhuman primate's diurnal cycles, unless the health and well-being of the animal necessitates deviation, in which case the AV must record in writing the need for any modification.

The Plea Agreement (§ 5(b)(ii)) further requires the Inotiv Entities to inform the CM within 30 days of the CM's appointment of any facility's deficiencies related to its compliance with the following certain standard for the care of small animals while not involved in active research:

- As species-appropriate, housing must provide: the space, ability, diversity, and complexity for freedom of movement, retreat, exercise, stimulation, and expression of natural behaviors (such as but not limited to denning, foraging, jumping, playing, running, digging, climbing, flying, swimming, swinging, nesting, retreating, or hiding); climate control and lighting; flooring to promote foot health and prevent sores; additional substrate or bedding; and use of diverse enrichment objects (such as but not limited to play structures, toys, chew objects, nesting materials, dig boxes, climbing structures).

On February 19, 2025, Inotiv's Chief Compliance Officer delivered a letter to the CM stating that "Inotiv presently does not have any deficiencies with respect to [such] requirements for nonhuman primate and small animal housing and/or enrichment."

The February 19 letter appears to satisfy the notification requirements in sections 5(b)(i) and (ii) of the Plea Agreement. Because the letter stated there were no deficiencies, it did not list any facility deficiencies or plans to correct such deficiencies by June 3, 2025, as would otherwise be required.

The CM will evaluate the Inotiv Entities' compliance with the certain standards for the care of NHPs and small animals listed in sections 5(b)(i) and (ii), including the three cited above, during its on-site visits and throughout the monitorship.

5. Staffing Study

The Plea Agreement (§§ 5(b)(i) and (ii)) requires the Inotiv Entities to complete a "staffing study" commissioned by an "outside, independent agency" within 60 days of June 3, 2024. The baseline requirement of the staffing study was to establish "necessary and sufficient" staffing levels to ensure that each NHP and small animal receives appropriate feeding, sanitation, health assessments, and enrichment. Per subsequent communications between Inotiv's counsel and the U.S. Attorney's Office for the Western District of Virginia, we understand that the Inotiv Entities provided a finalized staffing study to the United States on August 2, 2024 (60 days from June 3, 2024) (the *Report of Findings from Assessments of Adequacy of Staffing Levels at Inotiv/Envigo Animal Production Facilities*, dated July 26, 2024 ("*Staffing Study*")), indicating that the Inotiv Entities met the deadline to complete such study. Of note, Inotiv's counsel explained that the *Staffing Study* does not address those animal facilities that are not required to hold or operate under a USDA license (such as research facilities that only hold a USDA registration).

The Inotiv Entities engaged a third party to conduct staffing assessments at each of their USDA-licensed facilities. The individual charged with conducting the assessments (the "Staffing

Expert”) appears to be qualified, with 33 years of experience in lab animal facility operations and management. He visited five facilities: Indy East (Indiana), Greenfield (Indiana), Alice East (Texas), Inotiv LAMS/Alice West (Texas), and Denver (Pennsylvania). The *Staffing Study* notes that the charge issued by Inotiv “was simply to assess the adequacy of current staffing levels, and that if it was determined that staffing was inadequate, it is the responsibility of Inotiv management and veterinary staff to make final determinations as to the numbers of staff, by job description, required to provide animal husbandry and veterinary care in compliance with federal laws, regulations and guidelines.” (*Staffing Study* p.2).

As part of its review of staffing levels at each facility, the Staffing Expert reviewed current staffing levels by job title, required tasks, animal inventories, and other related details. It also reviewed USDA-APHIS-AC annual facility inspection reports to identify any areas of concern regarding Animal Welfare Act-regulated species. Within a span of 12 days in July 2024, the Staffing Expert visited the five USDA-licensed facilities, spending approximately 4-5 hours at each site. At each visit, the Staffing Expert reviewed SOPs and observed animals, supplies, equipment, husbandry logs/records, and staff traffic flow patterns. Additionally, the Staffing Expert interviewed supervisors, team leaders, and attending veterinarians.

The *Staffing Study* concluded that three sites (Indy East, Greenfield, and Denver) had staffing levels consistent with the workload.

The *Staffing Study* recommended changes to staffing levels at two sites (Alice East and Inotiv LAMS/Alice West) to support the given workload.

For Alice East, the *Staffing Study* recommended increasing staffing levels to supplement then-current staffing with two of each of the following: veterinarians, laboratory animal technicians, and veterinary technicians. As rationale, the *Staffing Study* explained that an increase in laboratory animal technicians would support additional responsibilities of that role; moreover, it could help address weather-related stresses and alleviate the need for staff to work every other weekend, which could lead to burnout and avoidable mistakes. The *Staffing Study* also concluded that the current veterinarian staff levels were insufficient to support the operation, noting that at the time of the visit, the veterinarians did not have sufficient time to address the needs of laboratory animal technician staff. As a result, the veterinarian from Inotiv LAMS/Alice West was borrowed from time to time.

For Inotiv LAMS/Alice West, the *Staffing Study* recommended increasing staffing levels to supplement then-current staffing with two laboratory animal technicians, one enrichment technician, and one veterinary technician. The *Staffing Study* found that the laboratory animal technician pool was not sufficiently staffed, specifically noting that staff work every other weekend, which reduces the available staff during the week and results in additional work that can lead to burnout and increased risks of mistakes or injuries. Furthermore, staff are often unable to utilize their paid time off and forfeit it at the end of the year. The *Staffing Study* presented identical observations concerning veterinary technician staff. The *Staffing Study* posited that the addition of an enrichment technician would better support the staff by covering an area of responsibility that exceeded what the staff were capable of covering. Finally, the *Staffing Study* indicated that at current levels, even if able to complete the assigned work, staff would not have adequate time for training, and the workload could become excessive during scheduled absences.

The CM is aware that on October 1, 2024, Inotiv’s counsel communicated via email with the U.S. Attorney’s Office of the Western District of Virginia, stating that the Inotiv Entities now

maintain staffing levels at Alice East and Inotiv LAMS/Alice West consistent with the recommendations in the *Staffing Study*. The email explained that the Inotiv Entities met and exceeded the recommendations of the *Staffing Study* regarding the hiring of full-time employees for non-veterinarian positions. Specifically, it explained that at Inotiv LAMS/Alice West, the Inotiv Entities hired an enrichment technician, two laboratory animal technicians, and two veterinary technicians. At Alice East, the Inotiv Entities hired two laboratory animal technicians and three veterinary technicians.

The email then proceeded to explain the challenges the Inotiv Entities experienced in attempting to hire veterinarians to the levels recommended by the *Staffing Study*. It explained that, at the time of writing, the Inotiv Entities had not yet been able to hire a full-time veterinarian; however, they had hired two contract veterinarians as an interim solution. As an additional temporary solution, the Inotiv Entities moved a clinical veterinarian from the Inotiv LAMS/Alice West facility to the Alice East facility to ensure adequate staffing; in tandem, they shifted the responsibilities of the other Inotiv LAMS/Alice West veterinarian to full-time clinical veterinary care (from 30%). This plan was discussed with the Staffing Expert to satisfy concerns highlighted in the *Staffing Study*. Finally, the Inotiv Entities reconfirmed that they were offering salaries to veterinarians at or above the market rate, along with other benefits such as relocation assistance and student loan forgiveness, and posited that the primary issue with recruitment was a lack of interest in the scope of work, single-animal species, and location.

The CM reviewed the *Staffing Study* and believes that the Inotiv Entities substantially complied with the Plea Agreement's requirement to complete the study. In a letter to Inotiv's Compliance Officer on February 18, 2025, the CM shared observations about some possible gaps in the study and encouraged the Inotiv Entities to consider these observations to ensure the highest level of health, safety, and well-being of animals under their care. The CM intends to further evaluate the sufficiency of staffing and whether the concerns raised by it and the *Staffing Study* are addressed during its on-site visits and throughout the monitorship.

C. Payments

The Plea Agreement (§ 7) requires Envigo to make certain payments. Per the representations described below, the CM understands that all payment obligations to date have been satisfied.

- The Plea Agreement (§ 7(a)) required Envigo to make a payment of \$5,000,000 by June 3, 2025, toward the total fine amount of \$22,000,000. Per an email from Inotiv's counsel dated June 3, 2025, we understand that, on June 2, 2025, the Inotiv Entities made two payments of \$2,500,000, totaling \$5,000,000 to the U.S. District Court of Western Virginia in satisfaction of this requirement.
- The Plea Agreement (§ 7(b)) required Envigo to pay \$1,143,991 to the Virginia Animal Fighting Task Force no later than 10:00 AM EDT on June 3, 2024. At a meeting with the CM on January 20, 2025, the Inotiv Entities reported they had made this payment on time.
- The Plea Agreement (§ 7(c)) required Envigo to pay \$1,856,009 to the Humane Society of the United States no later than 10:00 AM EDT on June 3, 2024. At a meeting with the CM on January 20, 2025, the Inotiv Entities reported that they made this payment on time.

- The Plea Agreement (§ 7(d)) required Envigo to pay \$3,500,000 to the National Fish and Wildlife Foundation no later than 10:00 AM EDT on June 3, 2024. At a meeting with the CM on January 20, 2025, the Inotiv Entities reported that they made this payment on time.
- The Plea Agreement (§ 7(e)) required Envigo to pay \$525 to the “Clerk of Court” no later than June 3, 2024. At a meeting with the CM on January 20, 2025, the Inotiv Entities reported that they made this payment on time.
- The Plea Agreement (§ 7) further required Envigo to provide a lien to the United States against sufficient company assets to secure any unpaid deferred payments. At a meeting with the CM on January 20, 2025, the Inotiv Entities reported that it met its financial obligation of providing the lien to the United States for unsecured payments on June 3, 2024.

D. Improvements to Facilities

The Plea Agreement (§ 7(g)) requires Envigo to expend at least \$7 million on improvements to facilities and personnel to a standard *beyond* the minimum required to comply with the Animal Welfare Act and implementing regulations, including expenditures of not less than \$2,500,000 by June 3, 2025.

The Plea Agreement (§ 9) indicates that for an expenditure to be counted against the total dollar amounts required as listed in § 7(g), it must be “directly related to improving the welfare of animals at INOTIV ENTITIES.” (Emphasis added). Accordingly, only certain expenditures are qualifying expenditures under this paragraph. For instance, expenditures to improve facilities to ensure compliance with Clean Water Act standards would not count as qualifying expenditures if they are not directly related to improving the welfare of animals. The Plea Agreement further provides that the improvements must include, but are not limited to, certain mandatory targets for these expenditures in sections 9(a) and (b).

An email from Inotiv’s counsel dated June 3, 2025, represents that the Inotiv Entities have spent \$4,446,433.09 since June 3, 2024, towards improvements of its facilities and personnel. Inotiv further asserts that it will spend “at least another \$2,553,566.91 to fully satisfy its obligations under sections 7 and 9 of the Plea Agreement.”

The CM reviewed an appendix to the email containing details on the expenditures the Inotiv Entities have made towards improvements to their facilities and personnel. For each facility expenditure, the Inotiv Entities provided an explanation as to why such expenditure is qualifying. It appears that each of the provided facilities expenditures is germane to the welfare of animals.

The appendix also lists personnel expenditures, including salary, start date, and qualifying percentage (which we understand to be the expected proportion of work directly related to the welfare of animals, as opposed to other ancillary tasks).

The CM intends to review all such expenditures as part of its on-site review of the Inotiv Entities’ facilities and will evaluate whether they satisfy the terms of the Plea Agreement and improve the welfare of animals held at those sites.

E. Public Statement

The Plea Agreement (§ 10) required the Inotiv Entities to place a full-page public statement detailing their contrition for their conduct (a) in a nationally and widely distributed animal science journal, (b) in at least two national newspapers, (c) in two major Virginia newspapers (including one in Richmond), and (d) on the Inotiv Entities' publicly accessible company websites. The Plea Agreement required the Inotiv Entities to publish the public statement of contrition by June 13, 2024, and to maintain the statement on the websites for the duration of the probationary period.

At a meeting with the CM on January 20, 2025, the Inotiv Entities reported that on June 13, 2024, they published the public statement of contrition in the International Journal of Science (Nature). Inotiv provided the CM with a copy of the published statement on July 10, 2025. The CM believes this publication satisfies the requirement of section 10(a) of the Plea Agreement.

At a meeting with the CM on January 20, 2025, the Inotiv Entities reported that on June 10, 2024, they published the public statement of contrition in USA Today, the Financial Times (U.S. Edition), the Richmond Times-Dispatch, and The Virginian-Pilot, which is Virginia's largest daily newspaper. Inotiv provided the CM with copies of the published statements on July 10, 2025. The CM believes these publications satisfy the requirements of sections 10(b) and (c) of the Plea Agreement.

At a meeting with the CM on January 20, 2025, the Inotiv Entities reported that on June 3, 2024, Inotiv posted the public statement of contrition on its website. As required by the Plea Agreement, the statement of contrition remains posted on the site at <https://www.inotiv.com/news/a-statement-of-contrition-from-inotiv>. The CM believes this continued posting satisfies the requirement of section 10(d) of the Plea Agreement.

F. Nationwide Compliance Plan

The Plea Agreement (§ 13) requires Envigo to develop, adopt, implement, fund, and comply with a Nationwide Compliance Plan that governs compliance of all the Inotiv Entities' U.S. facilities with all Applicable Laws. The Plea Agreement directed Envigo to develop the NCP in coordination with the CM and file it with the Court and provide it to the United States by April 21, 2025.

Inotiv shared a draft of the NCP with the CM on March 16, 2025. The CM reviewed the draft and provided a markup to Inotiv. Subsequently, the CM met with Inotiv to discuss relevant aspects of the draft NCP. Inotiv and the CM continued to exchange drafts and confer until they reached a consensus on a final version, which Inotiv, through its counsel, filed with the Court on April 21, 2025.

The CM assessed whether the content of the NCP comports with the requirements in the Plea Agreement. As described below, the CM is satisfied that the NCP meets the content requirements and will assess the adequacy of its implementation during its on-site visits and throughout the monitorship.

1. Compliance Officer

The NCP, consistent with the requirements of the Plea Agreement (§ 13(a)), requires Inotiv to maintain a Compliance Officer who will be a member of Inotiv's senior management team,

reporting directly to the President and CEO, but that otherwise “shall not be subordinate to any other employee.” (NCP p.3).

The NCP assigns responsibilities to the Compliance Officer that mirror the responsibilities outlined in the Plea Agreement, namely, that the Compliance Officer shall be responsible for monitoring Inotiv’s day-to-day compliance activities as they relate to: the Animal Welfare Act and all federal and applicable state and local animal welfare and animal cruelty laws, rules, and regulations; the Clean Water Act and all federal and applicable state and local water and sewage laws, rules, and regulations; and any other obligations created under the NCP. (*Id.*).

At a meeting with the CM on January 20, 2025, the Inotiv Entities reported that Inotiv’s President and CEO, Robert Leasure, appointed Andrea Castetter to serve as Compliance Officer. They confirmed that Ms. Castetter reports directly to Mr. Leasure and is not subordinate to any other employee.

We understand that Ms. Castetter is serving in this role in addition to her roles as General Counsel and Corporate Secretary to the company. The NCP directs that “any job responsibilities the Compliance Officer may have unrelated to compliance must not interfere with his/her ability to perform the duties outlined in the NCP.” (NCP pp.3-4). Despite the significant burdens of these positions, to date, the CM has not observed any interference in Ms. Castetter’s ability to perform her duties as Compliance Officer. We note, for example, that Ms. Castetter was an active participant in the development of the NCP; based on meeting minutes, she attends Compliance Committee meetings; she signs off on critical, company-wide compliance policies; she signs incident reports Inotiv has filed pursuant to section 13(i) of the Plea Agreement; and has been a regular attendee of other meetings between the Inotiv Entities and the CM. She also makes periodic reports directly to Inotiv’s President and CEO regarding compliance matters, as directed by the NCP and the Plea Agreement.

The NCP further requires that the Compliance Officer have the “necessary funding to oversee compliance.” (NCP p.3). The CM will evaluate the adequacy of resources at upcoming site visits and throughout the course of the monitorship.

2. Compliance Committee

The NCP, consistent with the Plea Agreement (§ 13(b)), directs Inotiv to form and maintain a Compliance Committee. Inotiv had established a Compliance Committee before the CM’s appointment. The NCP describes the responsibilities of the Compliance Committee, which, like the Compliance Officer, is charged with overseeing compliance with animal welfare, environmental, and other requirements provided for in the NCP. (NCP p.4).

Additionally, Inotiv represents that the Compliance Committee oversees “Global Policies, Procedures, SOPs, and Reporting” functions, including ESG, “Risk Management, Training, Audits/Assessment, DOJ Resolution, and Reporting functions.”

The Plea Agreement requires the Compliance Committee to include the Compliance Officer and “other members of Senior Management necessary to meet the requirements of the NCP (e.g., senior executives of relevant departments, such as legal, regulatory, audit, human resources, and operations).” (§ 13(b)). Thus, to ensure it has the authority, experience, and resources necessary to fulfill its obligations, the NCP directs that the Compliance Committee will include the Compliance Officer, at least one institutional official, and “senior leadership” of 11 functions: Compliance; Human Resources; Legal; Operations, Research Models and Services (“RMS”);

Operations, Discovery and Safety Assessment (“DSA”), Global Lab Animal Resources, Scientific Services, Environmental, Health, and Safety (“EHS”); Operations, Non-Human Primates; Global Facilities; and Quality Assurance. (NCP p.4).

In a June 18, 2024, email to Inotiv Entity employees, Mr. Leasure announced that the composition of the Compliance Committee, which included company leadership from the following functions: Legal, Human Resources, the Animal Welfare Council, Global Lab Animal Resources, Quality Assurance, Non-human Primates, RMS, Scientific Services, DSA, and EHS. The makeup of the Compliance Committee was restated during a meeting between Inotiv and the CM on January 21, 2025, with the only change being the addition of two additional committee members representing Corporate Compliance and RMS. Further, we understand that Inotiv has added four adjunct members to the Compliance Committee representing Facilities/Engineering, Communications, Finance, and Quality Assurance. Based on the foregoing, it appears the Compliance Committee is reasonably staffed to perform the functions ascribed to it under the NCP.

Pursuant to the NCP, the Compliance Committee receives reports of any potential non-compliances within 24 hours, along with the results of any investigation. (NCP p.22). It further requires that the Committee receive reports from the Compliance Officer regarding investigations on animal welfare, including proposed corrective action plans. (NCP p.23).

According to its meeting minutes, the Compliance Committee met at least monthly (sometimes twice a month) from July 11, 2024, through February 26, 2025. Further, as required by the Plea Agreement (§ 13(b)) and the quarterly meeting schedule set by the NCP, the Compliance Committee held meetings on February 26, 2025, and June 11, 2025, which the CM attended.

The Plea Agreement and the NCP specify that the Compliance Committee shall report quarterly to Inotiv’s President, CEO, and Board of Directors regarding “the status of the NCP.” The CM intends to request and review such reports.

Based on the foregoing, it appears that the Compliance Committee is receiving and reviewing compliance information and fulfilling its obligation to support the Compliance Officer in fulfilling her responsibilities. The CM will continue to assess the effectiveness of the Compliance Committee during its on-site visits and throughout the monitorship.

3. Board of Directors’ Compliance Obligations

On April 21, 2025, the Inotiv Board of Directors (the “Board”) formally approved the NCP prior to its submission to the Court. Going forward, the Plea Agreement (§ 13(c)) obligates the Board to oversee compliance with and evaluate the effectiveness of the NCP. The NCP explains that the Board oversees corporate governance and compliance policies via its Nominating and Governance Committee, which is in turn supported by the Compliance Committee. (NCP p.13). Based on publicly available materials, we understand that the Nominating and Governance Committee is composed of Board Members Michael J. Harrington, Nigel Brown, Ph.D., Terry Coelho, and R. Matthew Neff.

The NCP identifies multiple avenues by which the Board receives information about compliance matters. For example, it directs the Compliance Officer to report on compliance matters to the Board at any time. (NCP p.3). It requires the Compliance Committee to report at least quarterly on the state of compliance with animal welfare, environmental, and other requirements set forth in the NCP. (NCP p.4). The CEO and the Compliance Officer both report directly to the Board

on the effectiveness of the NCP. (NCP p.13). Furthermore, Board members are subject to the same Code of Conduct as all Inotiv employees, and Inotiv employees are encouraged to report compliance concerns directly to the Board, among other reporting options, under the company's *Speak Up Policy*. (NCP p.22).

Based on the foregoing, it appears that the Board is aware of the company's compliance obligations, that appropriate channels are in place for management and other employees to bring compliance matters to the attention of the Board, and that the Board can respond in a timely and appropriate manner to any concerns.

4. Compliance with Applicable Laws

The Plea Agreement (§ 13(d)) requires the Inotiv Entities to "evaluate their current business to ensure they are not currently violating the Applicable Laws." If they identify any violations of such laws, they "must report the violations to the CM and take necessary steps to remediate any such conduct." The obligation to continuously evaluate compliance is also included in the NCP. (See e.g., NCP pp.14, 26).

On November 26, 2024, Inotiv's President and CEO, Robert Leasure, signed a statement, pursuant to section 13(h), discussed below, certifying "to the best of my knowledge after diligent inquiry that the Inotiv Entities fully complied with all Applicable Laws from October 1, 2023 through September 30, 2024," excepting three matters specified in an appendix to that document, which the company addressed.

5. Training Programs

The Plea Agreement (§ 13(e)) requires the Inotiv Entities to "maintain, and, if necessary, enhance their training programs to ensure that pertinent employees are familiar with the requirements of the Applicable Laws, as well as the required standards set forth under [§ 5 of the Plea Agreement], and how those requirements apply to the INOTIV ENTITIES' conduct."

The NCP affirms Inotiv's commitment that "[t]raining shall ensure that pertinent employees are familiar with the Animal Welfare Requirements, Environmental Requirements, and the other requirements" set forth in the NCP. (NCP p.20). Ensuring that employees receive relevant training is crucial for those with duties related to maintaining Inotiv's compliance. This objective is repeated in the Inotiv *Animal Welfare Policy* (p.3): "Inotiv is committed to all members of the animal care and technical staff receiving education and training commensurate with their positions and responsibilities."

The NCP defines several categories of employees for the purposes of training requirements. For example:

- New employees, who must undergo orientation covering facility protocols and compliance requirements (NCP p.20);
- All personnel involved in animal care, who must complete "initial and ongoing training programs" concerning general policies and specific roles (NCP p.20);
- Pertinent employees, who must undergo the above-mentioned training (NCP p.19);

- IACUC members, who will receive training to “understand their responsibilities and duties” as well as “ongoing relevant IACUC training” (NCP p.20); and
- All staff, who must be trained “to know and understand normal behaviors for the specific species of animals with which they are working.” (NCP p.19).

In addition, the NCP details numerous requirements applicable to “all employees,” including “certain mandatory annual training.” (NCP p.20).

The NCP expresses Inotiv’s intent to centralize the review and dissemination of training materials, such as by mandating that the Compliance Officer (or a designee) oversee training programs and the Compliance Committee “review, update, and enhance training programs at least annually to reflect changes in regulations, industry best practices, and facility needs.” The CM also reviewed the Compliance Committee’s meeting minutes, which indicate that the Committee has considered utilizing Inotiv’s current training platforms to roll out compliance training. (See, e.g., Compliance Committee Meeting Minutes for Nov. 13, 2025, p.3 (“Completing required Compliance training on-time via learning and development platforms.”)).

The CM intends to review individual employee training records during its on-site visits and throughout the monitorship to confirm continuous adherence to these training obligations and commitments.

6. Non-Compliance Reporting

The Plea Agreement (§ 13(f)) requires the Inotiv Entities to “ensure they have, and maintain, processes to (a) encourage employees to report suspected non-compliant activities by the INOTIV ENTITIES, customers, or others, and to (b) acknowledge or otherwise recognize employees for reporting confirmed non-compliant activity.”

The NCP affirms this commitment, which Inotiv asserts is central to its core value to “Always Do the Right Thing.” (NCP p.3). This is reflected in the Board-adopted *Speak Up Policy*, which is made available to all employees on Inotiv’s intranet and is intended to “facilitate the reporting and investigation of alleged misconduct.” (NCP p.13).

The *Speak Up Policy* considers the following categories of incidents to be within its ambit: (1) violations of federal or state criminal law; (2) failure(s) to comply with any other legal obligation; (3) concern over any aspect of animal welfare; (4) breach of Inotiv’s Code of Conduct, policies, procedures, protocols, controls, or work instructions; (5) breach of Inotiv’s Confidentiality Agreement; (6) any threat to the health and safety of any individual or the environment; (7) any concern over a security breach or threat to physical security; and (8) any other potentially improper or unethical conduct. (*Speak Up Policy* pp.3-4). The CM believes the above-listed categories are sufficiently broad to encompass the types of reporting anticipated by the Plea Agreement.

The efficacy of the *Speak Up Policy* depends on the expertise, experience, and knowledge of Inotiv employees, which in turn depend on training (as required by section 13(e) of the Plea Agreement) and hiring practices at Inotiv. An employee who is unfamiliar with a particular requirement, including the certain standards set forth in the Plea Agreement, cannot be expected to report a violation of it.

Moreover, the *Speak Up Policy* imposes a “good faith” requirement on individuals making reports of suspected non-compliance, stating that “[a] person who submits a report has a responsibility to act in good faith...[a] report made is made in good faith when a reasonable person would believe the report is valid.” (*Speak Up Policy* p.4). The *Policy* further states that “[a]ll persons who submit a report in good faith, disclose information related to a report, or otherwise participate in an investigation are entitled to protection from retaliation.” (*Id.*).

The NCP emphasizes that “Inotiv is committed to creating a ‘Speak Up’ culture where everyone feels safe and comfortable reporting concerns about animal welfare, environmental compliance, employee safety, and other potential legal or ethical concerns.” (*Id.*). The *Speak Up Policy* states that Inotiv is committed to creating a culture “in which everyone feels safe and comfortable reporting...potential breaches of legal or ethical standards.” These stated objectives appear to align with the overall spirit of the Plea Agreement requirement.

The CM intends to further evaluate the effectiveness of the *Speak Up Policy* during its on-site visits and throughout the monitorship.

7. Adequate Investigation of Complaints

The Plea Agreement (§ 13(g)) requires the Inotiv Entities to:

[M]aintain, and, if necessary, enhance, policies and procedures designed to ensure effective investigation of any complaints and/or potential deficiencies relating to compliance with the Applicable Laws. Such policies and procedures shall include, but are not limited to:

- i. Training and providing guidance to all pertinent employees as to the requirement to report all information regarding potential non-compliance with the Applicable Laws to the Compliance Officer, who in turn, in consultation with the CM, will review and determine whether corrective actions are required.
- ii. Tracking allegations and remediation action plans regarding potential noncompliance with the Applicable Laws to identify issues that may require corrective actions.

To satisfy the terms of this provision, the NCP states that “Inotiv’s *Investigation Policy* is designed to ensure that it will effectively investigate any complaints and/or potential deficiencies relating to compliance with laws, regulations, and Company policies, including the Animal Welfare Requirements, Environmental Requirements, and the other requirements set forth in [the NCP].” (NCP p.12). The CM reviewed a copy of the *Investigation Policy* and considers its adoption to be a tangible step towards enhancing Inotiv’s extant policies and procedures for effective investigations of complaints and deficiencies.

The *Investigation Policy* applies to “all Inotiv employees...as well as third parties, such as contractors, suppliers, consultants and services providers.” (*Investigation Policy* p.3). It is intended to cover “reported allegations of misconduct that could have significant impact on Inotiv, such as actions by [Inotiv], its directors, officers, employees, or agents...” (*Id.*). The document then provides specific examples of alleged misconduct that could have a “significant impact,” including incorrect financial reporting, violations of applicable laws, Inotiv’s policies, or actions that “may otherwise amount to improper conduct.”

The CM interprets these circumstances to be those that would cause a “significant impact” on Inotiv. There may, then, be complaints or reports to which the *Investigation Policy* would not apply. During its on-site visits and throughout the monitorship, the CM intends to review Inotiv’s investigation practices and assess the extent to which this *Investigation Policy* has been applied.

The *Investigation Policy* addresses several key features of effective investigations, including prompt timing, designation of an appropriate function to conduct the investigation, and an expectation that investigations will be carried out “thoroughly, with integrity and independence.” (*Id.*).

As adopted, the *Investigation Policy* broadly states that “appropriate investigative steps may vary depending on the specific facts, nature, and complexity of the misconduct,” and provides a list of elements that should generally be included in an investigation. (*Id.* p.4).

The CM has reviewed reports of potential or actual violations submitted to us pursuant to section 13(i) of the Plea Agreement. Some of these reports refer to or discuss investigations conducted by Inotiv following a potential non-compliance, albeit in insufficient detail to determine whether and to what extent the *Investigation Policy* was applicable and/or followed. The CM intends to review documentation concerning investigations during its on-site visits and throughout the monitorship.

8. CEO Certification

The Plea Agreement (§ 13(h)) requires Inotiv’s President and CEO, for the duration of the probationary period, to certify under oath that, “to the best of their knowledge after a diligent inquiry, (1) the INOTIV ENTITIES fully complied with all Applicable Laws in the preceding year, or in the alternative, (2) the INOTIV ENTITIES fully complied with all Applicable Laws in the preceding year, with the exception of attached detailed non-compliant activity and the steps taken to remedy such non-compliant activity.”

The NCP incorporates this requirement, stating that “[t]he CEO will certify annually Inotiv’s compliance with Animal Welfare Requirements and Environmental Requirements, excepting and detailing any instances of noncompliance.” (NCP p.16).

As noted above, on November 26, 2024, Inotiv’s President and CEO, Robert Leasure, signed a statement, pursuant to section 13(h), discussed below, certifying “to the best of my knowledge after diligent inquiry that the Inotiv Entities fully complied with all Applicable Laws from October 1, 2023 through September 30, 2024,” excepting three matters specified in an appendix to that document, which the company addressed.

The CEO Certification appears to satisfy this requirement for the fiscal year ending on September 30, 2024.

9. Notification of Potential or Actual Violations

The Plea Agreement (§ 13(i)) requires Envigo, “within 60 days of receiving notice of a potential or actual violation of the Applicable Laws, any federal criminal law, or a term of the Plea Agreement at any of the INOTIV ENTITIES,” to “notify the CM, the United States, and the United States Probation Office of such violation, ENVIGO’s findings, and corrective action taken, if any.” This requirement is included in the NCP. (NCP p.26).

During the previous six months, Inotiv provided 15 reports to the CM pursuant to section 13(i). The CM reviewed each report and relevant underlying documentation. The CM has also discussed certain reports with Inotiv's Compliance Officer, members of the Compliance Committee, and veterinary staff.

In each case, the CM determined that, based on the information provided, the Inotiv Entities appeared to respond appropriately to the incidents. The CM intends to follow up and observe relevant facilities, enclosures, and equipment, review affected procedures, and speak with relevant personnel during its on-site visits.

G. Notice to Personnel of Inotiv Entities

The Plea Agreement (§ 14) requires all Inotiv Entities to require each full-time and part-time employee equivalent to read the Plea Agreement, the Information (Attachment C to the Plea Agreement), and the Resolution Agreement (Attachment B to the Plea Agreement) within 30 days of entry of the guilty plea. Further, it requires all new full-time and part-time equivalent employees to read the Information, Plea Agreement, and Resolution Agreement, within 30 days of the start of their employment with one of the Inotiv Entities.

The CM intends to review records documenting satisfaction of these requirements during on-site inspections.

H. Public Access to Information

The Plea Agreement (§ 15) required the Inotiv Entities to “facilitate, for the period of probation, the posting of copies of final [USDA] inspection reports of INOTIV ENTITIES’ facilities, the certifications submitted by Inotiv Inc.’s President and CEO ..., and reports prepare by the CM, on the INOTIV ENTITIES’ free and publicly accessible company websites, within fourteen days of receipt of each document.”

Inotiv maintains on its website a page (located at <https://www.inotiv.com/about/inspection-reports>) where it posts copies of final USDA inspection reports. The earliest dated reports for sites in Fort Collins, CO, and Indianapolis, IN, are from June 4, 2024.

Inotiv also maintains on its website a page (located at <https://www.inotiv.com/about/certification-reports>) where it posts copies of certifications submitted by Inotiv’s President and CEO. It includes the certification dated November 26, 2024, for the Fiscal Year dated October 1, 2023, through September 30, 2024.

These postings appear to satisfy the requirements of section 15 of the Plea Agreement.

To date, no reports have been prepared by the CM for the Inotiv Entities to post.

III. Environmental Compliance Obligations

The Plea Agreement (§ 12(b)) directs the CM to ensure compliance with the Clean Water Act laws, rules, and regulations, as well as all federal and applicable state and local water and sewage laws, rules, and regulations at “those components of the INOTIV ENTITIES that hold permits regulated by the Clean Water Act, including, but not limited to, National Pollutant Discharge Elimination System (“NPDES”) permits and indirect discharge permits and related activities, and any comparable permit issued through a state delegated program.”

The CM understands that the Inotiv Entities' facility in Denver, PA, is the only facility that holds an NPDES permit. The CM also understands that the Inotiv Entities' facility in Morrisville, NC, holds a county-issued industrial user permit. Additionally, based on documents provided by the Inotiv Entities and Appendix A of the CEO Certification Inotiv filed pursuant to section 13(h) of the Plea Agreement, the CM understands that the facilities at Alice East and Inotiv LAMS/Alice West engage in activities regulated by the Texas Commission on Environmental Quality ("TCEQ"). Specifically, we understand that the facility at Alice East holds a Wastewater Evaporation Pond General Permit, an Industrial Reclaimed Water Use Authorization, and is subject to a Public Water System Monitoring Plan, all of which are approved, authorized, or instituted by TCEQ. The CM also understands that the facility at Inotiv LAMS/Alice West holds a General Permit to Dispose of Wastewater and is preparing documents related to its reverse osmosis treatment system for submission to TCEQ.

The CM will evaluate the Inotiv Entities' compliance with these permits, the Clean Water Act laws, rules, and regulations, as well as all federal and applicable state and local water and sewage laws, rules, and regulations at these facilities as directed by the Plea Agreement during its planned on-site visits.

Prepared By:

Dated: July 21, 2025



John H. Fuson
Compliance Monitor
*United States v. Envigo RMS, LLC and
Envigo Global Services, Inc.*