

INTERNAL AUDIT REPORT

Controlled Substances

May 5, 2023

Council Members

Mayor

Mattie Parker

Carlos Flores, District 2⁺⁺ Michael D. Crain, District 3 Alan Blaylock, District 4⁺⁺ Gyna Bivens, District 5 Jared Williams, District 6⁺⁺ Leonard Firestone, District 7⁺ Chris Nettles, District 8 Elizabeth M. Beck, District 9

> [†] Audit Committee Chair ^{††} Audit Committee Member

Audit Staff

5/5/2023 Date

5/5/2023

5-5-2023

David A. Medrano City Auditor

Date

Assistant City Auditor

Brian Burkland

Vanessa C. Martinez Audit Manager

Date

Kanizur Mazumdar Senior Auditor Date



Executive Summary

The Animal Care and Control Division (ACC) within the City of Fort Worth's Code Compliance Department administers two animal shelters (South and North) and one field office. Controlled substances are ordered, stored, and dispensed by shelter staff, and are stored and dispensed by field office personnel for activities including capturing stray animals, providing medical care, and euthanizing animals.

During on our audit procedures and audit tests, we observed opportunities for improvement in the design and operating effectiveness of internal controls, as described below, and in further detail in our <u>audit findings</u>.

Based on conversations with ACC staff, combinations to the safes in which controlled substances were stored at the South Shelter had not been changed in at least two years.

A lack of segregation of duties existed, as we identified one supervisor performing the ordering, receiving, recording, cycle count, issuance, and dispensing of controlled substances. In another instance, an employee performed the ordering, receiving, and transporting of controlled substances. According to ACC staff, the City's practice is to have at least two authorized employees present at the time of issuance of the Schedule II controlled substance (Fatal Plus), however, we identified 11 instances in which ACC employees issued Fatal Plus to themselves with no documented evidence of another employee being present.

Moreover, we observed that Schedule II, III, and IV controlled substances, as well as non-controlled substances, were being stored in the same safe at the North Shelter.

We observed a lack of documentation with respect to the inventory and related chain of custody in the transport of controlled substances from the South shelter to the North shelter; also, ACC did not perform an accounting of the full array of inventory of controlled substances on hand every two years as required by the Code of Federal Regulation (CFR), and there was no documented process or scheduled plan in place to complete this required inventory. Additionally, there was no evidence that a beginning inventory was performed at the North Shelter, which opened its doors in April 2021. Furthermore, there was no control activity in place to trace the quantity flow of controlled substances from the time of the purchase order to the point of its administration into the animal as recommended by the Drug Enforcement Agency (DEA).

§ 21 CFR 1301.12(a) indicates that a separate registration certificate is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person. The City did not have individual DEA certificates for either the North shelter or the field office.

The ACC's written Standard Operating Procedures (SOP) were considered incomplete and insufficient. For instance, they did not include a requirement to perform a full inventory every two years as required by Federal regulation, and it did not have a requirement for reconciliation or disposal processes.

§ 21 CFR 1305.05(a) indicates that a registrant may authorize one or more individuals to issue orders for Schedule I or II controlled substances on the registrant's behalf by executing a power of attorney. Internal Audit was not provided proof of the Power of Attorney for individuals who ordered controlled substances during the audit period.

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Background

The Animal Care and Control Division (ACC) within the City of Fort Worth's Code Compliance Department administers two animal shelters (the Chuck & Brenda Silcox Animal Care & Adoption Center "South" and the North Animal Campus "North") and one field office.

Title 21 of the Code of Federal Regulations (CFR) governs food and drugs within the U.S. for the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the Office of National Drug Control Policy (ONDCP).

The Federal Controlled Substances Act (CSA) classifies controlled substances into five Schedules, based upon the substance's medical use, the potential for abuse, and safety or dependence liability, as shown in the table below. The CSA also provides a mechanism for substances to be controlled (added to or transferred between Schedules) or decontrolled (removed from control).

Schedule	Potential for Abuse	Accepted Medical Use	Potential for Addiction in Humans	Did the City purchase and/or utilize during the Audit Period?	
Schedule I	High	No	The drug is not safe to use,	No	
			even with medical supervision.		
Schedule II	High	Yes, sometimes allowed	Abusing the drug can cause severe	Yes	
Schedule II	nigii	with restrictions	physical and mental addiction.	Tes	
Schedule III	e III Medium	m Yes	Abusing the drug can cause severe mental	Yes	
	weatum		addiction; or moderate physical addiction.		
			Abusing the drug may lead to mild	N	
Schedule IV	IV Low	Yes	mental or physical addiction.	Yes	
Schedule V	1		Abusing the drug may lead to mild	N -	
	Lowest	Yes	mental or physical addiction.	No	

Controlled Substances Schedules

Source: DEA guidelines, CFW DEA license, and ACC records

The ACC uses Pet Health's PetPoint data management system to track operational data including but not limited to animal intakes and impounds, medical and behavior notes, administered medications (including euthanasia), customer information, and citation history.



The objectives of this audit were to:

- determine whether the Animal Services Division complied with City, State, and Federal regulations; and,
- evaluate the effectiveness by which controlled substances are managed within the Animal Services Division.

Scope

Review of records for the period of October 1, 2019 through September 30, 2021. Activity beyond this period was reviewed as deemed necessary.

Methodology

To achieve the audit objectives, the Department of Internal Audit performed the following:

- interviewed ACC staff and management;
- reviewed applicable City, State, and Federal laws and regulations, as well as related industry best practices;
- reviewed departmental policies and procedures;
- compared ACC practices to City, State, and Federal requirements;
- performed physical observations of the storage and safeguarding of controlled substances;
- performed inventory counts of controlled substances;
- conducted a review of data from badge access to the designated drug room at the South shelter (North shelter uses key to access);
- observed security camera feed;
- reviewed and attempted reconciliation of records including paper logs and electronic PetPoint records;
- reviewed the continuing professional education training records; and
- evaluated internal controls related to controlled substances.

This Controlled Substances Audit was authorized, as part of the Department of Internal Audit Fiscal Year 2022 Annual Audit Plan, by the Audit Committee of the City of Fort Worth. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.



Based on our audit procedures and audit tests, opportunities for improvement exist in the design and operating effectiveness of internal controls in the administration of controlled substances.

The Department of Internal Audit would like to thank the Code Compliance Department for their cooperation and assistance during this audit.

Overall Risk Evaluation

High	Medium	Low
Inadequate segregation of duties		
Inadequate physical security controls and chain of custody controls		
No biennial inventory or trace of flow of the quantity of controlled substances		
No registration certificate for North Animal shelter or field office		
	Records were incomplete, incorrect, inconsistent, and/or not in compliance with regulations and guidelines.	
	Deficient SOPs	
	No record of required power of attorney	



Detailed Audit Findings

1. Inadequate segregation of duties related to the handling of controlled substances.

§V.B of the City's Internal Controls Financial Management Policy states that "...job duties will be adequately separated to reduce, to an acceptable level, the opportunities for any person to be in a position to both perpetrate and conceal errors or irregularities in the normal course of assigned duties."

Based on our review of purchasing records and interviews with South shelter staff, we observed a lack of segregation of duties related to the City's handling of Schedule II, III, and IV controlled substances.

In one instance, we observed a Supervisor performing the ordering, receiving, recording, cycle count, issuance, and dispensing of controlled substances.

In another instance, audit procedures identified an employee at the South shelter performing the ordering, receiving, transporting, and safekeeping of controlled substances.

Duties	Employee 1	Employee 2
Ordered schedule III and IV drugs for South Shelter	<u>×</u>	
Ordered schedule III and IV drugs for North Shelter		<u>X</u>
Completed DEA 222 Form (Schedule II) for North and South Shelters		X
Received Schedule II drugs		<u>x</u>
Received Schedule III and IV drugs	X	<u>x</u>
Responsible for organizing and storing (shelving) schedule III and IV	X	
drugs at the South shelter		
Transported drugs from South shelter to North shelter		<u>X</u>
Performed cycle counts at South shelter	X	
Had key/combination code to the North shelter safe		<u>X</u>
Had keys/combination code to the South shelter safe	X	

Segregation of Duties Issues Observed

Source: Staff interviews, and ACC records

In one of our earlier interviews during this engagement, ACC staff indicated that some of the above duties were not segregated due to staff vacancies and shortages. ACC staff indicated that a former supervisor was in charge of ordering for North shelter, however, when that employee left the City, these responsibilities were temporarily reassigned to South shelter staff. In a later interview, ACC staff indicated that purchasing tasks for the North shelter once again resided with staff at that location.

According to ACC staff, the City's practice is to have at least two authorized employees present at the time of issuance of the Schedule II controlled substance (Fatal Plus), however, we identified 11 instances in which ACC employees issued Fatal Plus to themselves with no documented evidence of another employee being present.

Lack of segregation of duties places the City at risk as there is higher potential for unnoticed misuse, abuse, or illegal distribution of controlled substances.

Recommendation 1A: The Code Compliance Department Director should establish proper segregation of duties regarding the ordering, receiving, storing, dispensing, inventorying, and transporting of all controlled substances.

Auditee's Response: Partially Concur. With operational and staffing requirements, I do not concur that "ordering, receiving, storing, dispensing, inventorying, and transporting of all controlled substances" can



be separate duties. To reduce risk of theft or misappropriation, it is agreed that ordering and receiving should be separate tasks and not performed by the same person. In this response, the task of "receiving" entails ensuring that what is received is the amount ordered. This will be verified using the original Purchase Order that lists names and quantities ordered and the packing slip provided with the shipments (orders). All other duties listed above can be performed by the same person. For example, whomever orders can also store, dispense, inventory and transport and whomever receives can also store, dispense, inventory and transport.

Further, we are unable to locate a DEA CFR that requires segregation of these duties, only the requirement that the registrant or power of attorney orders the controlled substances based on the individual schedule requirements.

While the Department does not concur with this exact finding, we are amendable to the differentiation of the first two steps in the process listed above; specifically ordering and receiving. This process update will be provided to staff and implemented **immediately**. Additionally, this will be included in the written Standard Operating Procedure; Target Date 6/1/2023.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

Recommendation 1B: The Code Compliance Department Director should ensure that the ACC's practice of having two witnesses present when Schedule II controlled substances are issued, is enforced, and that the requirement is documented in the ACC's written SOPs.

Auditee's Response: Concur. In 11 of 68 (16%) instances, an employee issued Fatal Plus (Sch. 2) to themselves. This was an employee error and was immediately addressed and corrected for all future issuance.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

2. Inadequate physical security controls and chain of custody controls for controlled substances.

§ 21 CFR 1301.72(3)(II)(b) indicates that "...in the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination." Additionally, §5.D of the City's Internal Controls Financial Management Policy states that "...procedures shall be designed and maintained to ensure that adequate safeguards exist over the access to and use of financial assets and records."



Based on our audit results, the transportation of controlled substances from the South shelter to the North shelter is not documented to ensure chain of custody controls; also, we observed inadequate physical security controls.

Transportation

Beginning in March 2022, a South shelter employee had been accountable for transporting controlled substances from the South shelter to the North shelter. The employee had a key to the safe at the North shelter and was responsible for delivering and placing the controlled substances in the safe. Upon inquiry, we were informed that neither the employee nor the manager documented the quantity of controlled substances being transported and delivered, and staff at the North shelter did not date stamp or sign to confirm the quantity received. Upon inquiry, the employee indicated that documentation or signatures were not required when transporting controlled substances from one location to another.

Not documenting the transportation of controlled substances properly and in detail poses a risk for both the employee and the City in that controlled substances can be lost or damaged without a proper trail to determine accountability.

Storage

We observed a bottle of Fatal Plus in the safe at the field office. Based on processes described by ACC management, Fatal Plus should be stored only at the South and North shelters. A field office manager confirmed to Internal Audit that the bottle observed should not have been in their safe.

During interviews, staff indicated that the combinations on the three safes at the South shelter where controlled substances are maintained, had not been changed in at least two years. There is an increased risk of diversion or theft of controlled substances by not changing the safe combinations periodically. This could impact the ACC's daily operations, could mean a loss of resources, negative publicity and pose a danger to residents.

§ 21 CFR 1301.72(3) states "... safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed...." Internal Audit Department observed that the safe at the North shelter was not bolted to the ground.

Moreover, we observed that Schedule II, III and IV controlled substances as well as non-controlled substances were being stored in the same safe at the North Shelter. § 21 CFR 1304.04 (h)(1) states that "...inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records...." Additionally, § 21 CFR 1301.72(8) allows non-controlled substances to be stored alongside Schedule III and IV controlled substances, provided authorization is obtained in advance and in writing, from the Special Agent in Charge of DEA for the area in which such storage is situated.

Recommendation 2A: The Code Compliance Department Director should establish and implement proper chain of custody controls for transporting controlled substances, including a transportation form or log to be completed by the issuer, the transporter, and the receiver.

Auditee's Response: Concur. Staff were unaware of the requirement to have a separate registration for each facility (Staff believed that the registration at Chuck and Brenda Silcox covered both the North Shelter and transport). This was immediately addressed and corrected for all future transports.



Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

Recommendation 2B: The Code Compliance Department Director should ensure that safe combinations are more frequently changed and that only select employees get access to the safe combination or keys.

Auditee's Response: Concur. Employees believed that having a safe behind a card accessed (limited access with separated employee's losing access at time of separation) and locked door with infrequent combination changes was sufficient. Combinations have been changed and will be changed on an annual basis or when employees with the combination separate from the City.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

Recommendation 2C: The Code Compliance Department Director should ensure that the North Shelter complies with Federal Regulation regarding appropriate separation protocols for controlled and non-controlled substances.

Auditee's Response: Concur. All non-controlled substances have been removed from safes containing schedule II, III, IV, and V controlled substances. Staff were unaware that this was prohibited.

Target Implementation Date: Completed – Pending Follow-Up Verification

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

3. ACC did not perform a biennial inventory or trace the flow of the quantity of controlled substances.

Inventories

ACC did not perform an accounting of the full array of inventory of controlled substances on hand every two years as required by § 21 CFR 1304.11(c), and there was no documented process or scheduled plan in place to complete this required inventory. A beginning inventory count is required per § 21 CFR 1304.11(b), however, there was no evidence that a beginning inventory was performed at the North Shelter, which opened its doors in April 2021.



A lack of accounting for the full array of inventory of controlled substances could lead to misappropriation of inventory, falsification of records, or unintentional errors that would be difficult to detect.

Tracing

Per the Drugs of Abuse Resource Guide provided by the DEA, "...trace the flow of any drug from the time *it is first imported or manufactured, through the distribution level* ... then to the actual patient...." Additionally, the Texas Department of State Health Services Zoonosis Control, recommends that euthanasia logs contain the supervisor's reconciliation of the amount of drug used with the drug remaining in stock. ACC staff indicated that there was no formal reconciliation process.

According to the GAO best business practices, "...approval of adjustments by management ... helps ensure reliable counts and research." Our audit procedures indicated potential deficiencies in the accuracy of transaction records, as we observed that at the field office, the dart log contained 1) calculation errors and 2) adjusting entries which had no documented justification or management approval.

Recommendation 3A: The Code Compliance Department Director should ensure that a full array of inventory of controlled substances is performed biennially as required by the CFR. The Code Compliance Department Director should also consider performing inventories more often for stronger controls.

Auditee's Response: Concur. The Department has completed an inventory of all controlled substances and started new log books for each. The Department has also set policy for quarterly and annual inventories.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

Recommendation 3B: The Code Compliance Department Director should ensure that when inventories are performed, they are documented appropriately as required and recommended by Federal and State regulations (i.e. including address, DEA registration number, date/time, a signature of the person who is taking inventory, drug name, strength, form of drug, number of units, unit volume, and total quantity in stock, etc.).

Auditee's Response: Concur. The Department has completed an inventory of all controlled substances and started new logbooks for each. A schedule for quarterly and annual inventories meeting the requirements of Federal and State regulations has been set.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director



Recommendation 3C: The Code Compliance Department Director should establish a reconciliation process for all locations, appropriate management sign-offs, and proper documentation of adjustments and corrections.

Auditee's Response: Concur. At each quarterly or random surprise count of controlled substances on hand, a reconciliation process has been established to ensure appropriate sign-offs, adjustments documentation and corrections are compliant with Federal and State regulations.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

Recommendation 3D: The Code Compliance Department Director should consider establishing a process to perform random surprise counts of controlled substances on hand.

Auditee's Response: Concur. The Administrative Division, a separate Division from Animal Care and Control, will perform random surprise count of controlled substances on hand and report findings to the Code Compliance Director and the Assistant Director of Animal Care and Control.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

4. Neither the North shelter nor the field office were in possession of the required controlled substance registration certificate, as issued by the DEA.

§ 21 CFR 1301.12(a) indicates that "...a separate registration certificate is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person." The City did not possess the required controlled substance registration certificates for either the North shelter or the field office.

During the audit period, the City was in possession of the following controlled substance registration certificates issued by the DEA:

- "MLP-Animal Shelter," in the name of "Fort Worth Animal Control," with address 4900 Martin Street (i.e. South shelter); and
- > "Practitioner," in the name of the City's head Veterinary, with address 4900 Martin Street.

The DEA has the authority to suspend or revoke a registration from any entity in violation of the CFR, which could adversely impact the continuity of ACC's operations.



Recommendation 4: The Code Compliance Department Director should consult with the City Attorney's Office and ensure that each separate physical location handling controlled substances in the City is properly registered with the DEA, as required by Title 21 of the Code of Federal Regulation.

Auditee's Response: Partially concur. Staff believed the current license for the Silcox shelter covered both locations. We spoke with the DEA and they stated that based on the operations, a DEA registration was not required for the Field offices. The shelters (which have DEA registrations) dispense to the Field office and a separate registration is not needed.

Target Implementation Date: Completed in 2022

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

5. Controlled substances records were incomplete, incorrect, inconsistent, and/or not in compliance with regulations and guidelines.

The ACC had a process in place consisting of keeping a paper log of controlled substances purchased and issued to shelter and field office staff, and an electronic record within PetPoint of dosages given to individual animals. § 21 CFR 1304.22 (c) indicates that "...*records shall be maintained ... the name and address of the person to whom it was dispensed... and the name or initials of the individual who dispensed...."* However, with the exception of Fatal Plus, controlled substance logs did not include the name of the person to whom the controlled substance was dispensed (the recipient), nor did it include the dispenser's initials, only the recipient's initials were recorded. Additionally, neither the paper logs nor the PetPoint records include the finished form (e.g. 10-mL tablet or 10-mL concentration per fluid ounce) nor the number of units or volume of finished form in each commercial container (e.g. 100-tablet bottle or 3-mL vial) of each controlled substance, as required.

§ 21 CFR 1304.21(a) indicates that "Every registrant required to keep records pursuant to § 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory."

Additionally, the Texas Department of State Health Services Zoonosis Control recommends record keeping of daily use in the shelter, including recording the animal's weight within euthanasia logs.

Moreover, the ACC's Euthanasia SOP indicates that staff should enter the weight of the animal for each euthanasia performed.

Schedule II (Fatal Plus)

Through our audit procedures, we identified that 66.5% of all Fatal Plus dosage records within FY2020 and FY2021, did not record the animal's weight. The risk to the City in not including the animal's weight, at the time Fatal Plus was administered, is that it would preclude management from being able to 1) determine if the amounts given to the animal were proper based on their weight, 2) detect and investigate any potentially questionable drug usage, 3) detect improper use of the controlled substance, falsified records, etc., and 4) promptly identify the errors.



Our review of PetPoint records revealed the following discrepancies:

- There were 25 bottles, each with a 250 mL per bottle volumetric capacity, that were reportedly "returned empty" per the paper log. However, amounts dispensed per PetPoint records, do not support the complete usage of the 250 mL volume. Variances observed ranged from 2 mL to 81 mL, with an average variance of 12.56 mL. Upon inquiry, ACC management indicated that it is most likely due to data entry errors, including extracting an incorrect dosage from the bottle or not recording the correct dosage administered in the PetPoint records;
- In five instances, PetPoint records indicated that more than the capacity of a bottle was used (i.e. 259 vs. 250 mL), with variances ranging from 0.5 mL to 9 mL. Upon inquiry, ACC management indicated that these were potentially data entry errors; and,
- In three instances, amounts of controlled substances dispensed per the paper logs, were not supported by the PetPoint records, with variances from 10 mL to 174 mL.

Our review of paper log records provided to Internal Audit revealed inadequate controls regarding the release and accountability of Fatal Plus bottles, as follows:

- <u>Initial issuance of full bottles:</u> We observed that 22 of the 68 bottles of Fatal Plus used during the audit period (per PetPoint records) were not recorded in paper logs, as required. Paper logs are used by authorized staff to record the release of controlled substance bottles to a human recipient prior to the subsequent administration of the controlled substance into the animal; and
- <u>Subsequent return of empty bottles:</u> PetPoint records support that in at least three instances, bottles of Fatal Plus had been used completely. However, there was no documentation that any of these three bottles had been returned to a supervisor prior to a staff member being issued another bottle, as is normal department practice.
- We observed several instances when writing was illegible or information had been scratched, for instance, there were nine bottles issued for which we were unable to read the names of the individuals who received the bottles. Without legible records, it is impossible to determine if the bottle was issued by the authorized personnel.
- In all instances of the issuance of Fatal Plus, there was no protocol which required or subsequently indicated in which City facility the bottle was to be stored and its contents used for the subsequent euthanasia of an animal.

Schedules III and IV

- Per our review of FY2020 and FY2021 PetPoint records, there were 109 of 445 dosages of "lab tranquilizer" (which includes Ketamine) recorded without the animal's weight. Additionally, in all PetPoint medical procedures, other than "lab tranquilizer" and "euthanasia," the animal's weight was not recorded.
- There was no paper log for Buprenorphine (Schedule III controlled substance), even though PetPoint reports show that 28.31 mLs of this drug were administered between November 2020 and May 2021. Without the paper logs, a reviewer would be unable to determine who received the bottles or when.
- We noted various instances when the controlled substances running balance noted by staff on paper logs contained math errors (i.e. amount dispensed minus prior balance), and the wrong balance was then carried forward. We also noted out-of-sequence data entries, instances in which data entries were overwritten, and instances where data was illegible.



The Veterinary Association provides standardized guidelines intended to be used as reference material by individuals and agencies when combining controlled substances with non-scheduled drugs to create various commonly used combination (combo) drugs (i.e., TTDex et al). When combo drugs that include Schedule III and IV controlled substances are used, the Veterinary Association recommends that the amount of each controlled substance is documented separately upon administration of that drug. The ACC's practice is to document the amount of each ingredient that is used to make the combo drug, and PetPoint is used to log the amount of the combo drug that was dispensed to each animal. However, our review of the paper log and PetPoint records, did not reference the individual amounts of each ingredient in the combo drug administered into the animal.

Separately, the City's field officers use combo drugs, which include the controlled substances Ketamine and Telazol, to make 1cc or 3cc darts, to aid in the capture of animals. The usage and tracking of darts are recorded in the "Dart Check out Log," the "Darting Drug Log" and the "Chemical Captures" report within PetPoint. Per management, the "Dart Check out Log" is updated daily with the number of darts issued to each officer and whether the darts were returned full or empty. We randomly selected 6 months of activity to review, we compared all three sets of records and observed that:

- 26.47% (170 entries) of dart entries in the "Dart Check out Log" did not reconcile to either the "Darting Drug Log" or the PetPoint "Chemical Captures" report;
- Sometimes entries in either the "Dart Check out Log" or the "Darting Drug Log" were illegible; and,
- PetPoint "Chemical Captures" reports do not include the amount (i.e., 1cc, 3cc, etc.) of the controlled substance administered into the captured animal.

Inadequate internal controls in the record keeping that serves to document and support the authorized administration of controlled substances, could prevent ACC management from identifying and resolving theft, misuse, or diversion of controlled substances, and could result in the City's inability to provide records to the DEA if ever requested, potentially, adversely impacting the future, ongoing viability of its operations.

Recommendation 5A: The Code Compliance Department Director should consider changing and/or consolidating the current record-keeping steps and templates, while ensuring that records contain fields required by CFR and recommended by the State.

Auditee's Response: Concur. When staff converted from an all-manual to a dual-record keeping process utilizing computer software, it created an unexpected gap. The Department will maintain separate AHAA DEA approved log books for each Schedule II, III, IV & V controlled substances.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

Recommendation 5B: The Code Compliance Department Director should ensure that records are complete and accurate, including being legible, free of math errors, and that the weight is recorded, as required by CFR and recommended by the State.



Auditee's Response: Concur. This was due to employee errors and not system or systemic issues. Management and medical staff have been directed to make immediate corrections to internal processes to ensure compliance with state and federal requirements and to hold employees accountable.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

Recommendation 5C: The Code Compliance Department Director should ensure that ACC staff record combination drug dosages as recommended by the Veterinary Association.

Auditee's Response: Concur. Management and medical staff implemented immediate corrections to internal processes to ensure compliance with state and federal requirements.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

6. Standard Operating Procedures (SOP) are deficient.

According to the ACC's two-page SOP dated March 2022 "Shelter Standards for Clinic Inventory", "It is the Fort Worth Animal Control Divisions' policy that all medical supplies, medication and controlled substances are accounted for and any loss be reported to a Supervisor immediately." Moreover, the purpose of the SOP is to "Establish appropriate clinic inventory standards, while providing consistency and direction."

In our review of the SOP, we considered its content to be insufficient, as it failed to provide adequate direction to staff, in that it did not specifically provide practical standards for designing, implementing, or administering any, but not limited to the following, each of which serves as an important element in supporting the purpose of the policy:

- segregation of duties with respect to ordering, receiving, and dispensing controlled substances;
- procedures for ordering controlled substances from vendor(s) websites;
- process for documenting the receipt of controlled substances from vendor(s);
- biennial inventory and related documentation;
- special documentation, ordering, and handling processes for Schedule II controlled substances (e.g. Fatal Plus); including the proper completion of form DEA 222, as noted in § 21 CFR 1305.12 and § 1305.13;
- City-defined threshold for reportable theft or significant loss of controlled substances, nor the DEA form to be used to report such theft or loss;
- City-defined threshold for incidental losses that could trigger further investigation;



- process and documentation requirements for transferring controlled substances from one City location to another;
- process and documentation for the destruction of controlled substances (when applicable);
- proper safeguarding of controlled substances, including frequency for modifying combinations to safes; and,
- reference to the department's euthanasia policy (Shelter Standards for Lab/Euthanasia Operations), including procedures for the handling of Fatal Plus.

Per § D. of the ACC's Shelter Standards for Lab/Euthanasia Operations, staffing in the euthanasia lab must include all of the following, concurrently:

- Lead One (1) Senior Code Compliance Officer,
- Puller One (1) Animal Control Officer or Shelter Technician, and,
- Euthanasia Technician One (1) Animal Control Officer or Shelter Technician (either of which must be a Certified Euthanasia Technician or have completed certification within 120 days of employment).

Additionally, within § H.1 "...Any employee performing euthanasia MUST be a Certified Euthanasia Technician (or obtain certification within 120 days of employment)."

However, PetPoint records include a field called "performed by" which includes titles other than Animal Control Officer or Shelter Technician, which may not identify the appropriate person actually required to be certified. Based on our review of PetPoint and training records and we were unable to identify the designated Euthanasia Technician and whether they were a Certified Euthanasia Technician.

Clearly written guidelines serve as the standard for an organization's operations. Without updated and clearly documented SOPs, there could be confusion about how to handle and manage controlled substances, the potential for inaccurate recording or reporting, and frustration among employees, especially during periods of turnover. Furthermore, there is a potential that practices differ from CFR requirements, which could result in fines and penalties up to the loss of a DEA license.

Recommendation 6A: The Code Compliance Department Director should ensure that SOPs are updated to include relevant Federal and State requirements and recommendations including but not limited to ordering, record keeping, training, dispensing, disposal process, segregation of duties, specific requirements for handling Schedule II controlled substances, and other processes for controlled substances.

Auditee's Response: Concur. Staff are currently reviewing all state and federal requirements and ensuring compliance.

Target Implementation Date: NLT 6/1/2023

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director



Recommendation 6B: The Code Compliance Department Director should ensure that a reportable significant loss threshold, and a threshold for incidental losses are defined.

Auditee's Response: Concur. As required by law, The Department has reported significant losses to the DEA. The Department has not found guiding principles from any source, including the DEA, to set minor loss thresholds. We are surveying other municipalities and private organizations to determine if there are best practices.

Target Implementation Date: NLT 6/1/2023

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

Recommendation 6C: The Code Compliance Department Director should establish a clear path of record related to who performed the euthanasia and whether that staff member is properly certified as a Certified Euthanasia Technician.

Auditee's Response: Concur. This was an employee record-keeping and reporting error.

Target Implementation Date: June 1, 2023

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director

Applicable Assistant City Manager: Valerie Washington

Recommendation 6D: The Code Compliance Department Director should establish a schedule for periodic review and update of SOPs to ensure ongoing compliance with Federal and State regulation changes.

Auditee's Response: Concur. The Department has set a directive establishing a Standard Operating Procedure for periodic review and update of all legal and policy changes.

Target Implementation Date: Completed

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director



7. The ACC did not have record of the power of attorney required to order controlled substances.

§ 21 CFR 1305.05(a) indicates that "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."

Internal Audit identified at least one individual ordering Schedule II controlled substances using Form 222 for whom there was no documentary evidence of a power of attorney having been obtained. By not obtaining the proper powers of attorney for individuals ordering Schedule II controlled substances, the City is at risk of being fined and up to losing the DEA issued registration certificates.

We have been informed that the Code Compliance Department has begun the process to obtain the proper powers of attorney.

Recommendation 7: The Code Compliance Department Director should ensure that a power of attorney is executed for each of the individuals authorized to order Schedule II controlled substances, and should ensure that the documents are maintained at the applicable location (i.e. South or North shelters, or field offices), and are available for review.

Auditee's Response: Concur. In 2022, Power of Attorneys (POAs) for the Silcox shelter DEA registration were obtained. Currently working on the POAs for the North shelter registration.

Target Implementation Date: May 1, 2023 [Completed]

Responsibility: Chris McAllister, Assistant Director, Animal Care & Control

Applicable Department Head: Brandon Bennett, Code Compliance Department Director