DEA/DHHS INSPECTIONS

PERFORMANCE STANDARD: DEA/DHHS inspections are managed in a manner that assures the integrity of the institution, the accuracy of the findings, and the clarity of communication.

BACKGROUND/PURPOSE: NC Department of Health and Human Services (DHHS) and the federal Drug Enforcement Agency (DEA) enforce the regulations for use of Controlled Substances. Individuals choosing to use Controlled Substances must apply for and receive registrations from both agencies. Both agencies often perform inspections on the individuals holding such registrations. Failure to comply with the regulations around the use of Controlled Substances may result in revocation of the registration, fines and incarceration, depending upon the severity of the non-compliance.

DEFINITIONS:
- **Controlled Substance**: Any substance listed in the Controlled Substances Act, Code of Federal or Substance Regulations (21 CFR, part 1300 to end), the North Carolina Controlled Substances Statue (Chapter 90, Article 5) or the North Carolina Administrative Code (10A; Sections 26E and 26F).
- **DEA**: U.S Drug Enforcement Administration, established in 1973 under the US Department of Justice, is responsible for the enforcement of the Controlled Substances Act (Controlled Substances Act, Code of Federal or Substance Regulations-21 CFR, part 1300 to end).
- **DHHS**: North Carolina Department of Health and Human Services is responsible for the regulation of Controlled Substances at the state level (North Carolina Controlled Substances Statue (Chapter 90, Article 5), North Carolina Administrative Code (10A; Sections 26E & 26F)).
- **Registrant**: Individual listed on both DEA and DHHS registrations as responsible for oversight of Controlled Substances
- **Site Inspection**: Typically the inspection performed by either DHHS and/or DEA to determine if the storage site for the Controlled Substances is suitable prior to issuing the registration
- **Inspection**: DEA and DHHS may audit/inspect any registrant at any given time to determine if the Registrant is compliant with the regulations regarding Controlled Substances. This inspection occurs typically after the issuance of a registration.
MANAGEMENT PROCESS: When the DHHS and/or the DEA contacts the Duke registrant in order to schedule an inspection, the Duke registrant is encouraged to contact OAWA and arrange for an OAWA representative to be present during the DEA or DHHS inspection. It is highly recommended that the OAWA representative meet with the registrant to review the CS program prior to the inspection as a pre-review activity.

PRIOR TO THE INSPECTION: The Duke registrant applicant should contact OAWA for a pre-inspection assessment. OAWA will review and confirm the acceptability of the following:

1. A secured two-lock storage system for Controlled Substances. NOTE: See the description in “CONTROLLED SUBSTANCE USE AND MANAGEMENT PROCEDURES” for appropriate storage devices and mechanisms.

2. A three-ring binder containing the following:
   a. Copy of the application for the DHHS Registration or the current DHHS registration.
   b. Authorized user list: This template is available on the Duke web at: http://vetmed.duhs.duke.edu/PDF/Forms\%20\%20Reports/Controlled\%20Substance/2008_01_authorized_users_list.pdf

3. A completed and signed ‘Physical Inventory’ form showing that there are NO Controlled Substances on site. All the information pertaining to the registrant should be completed.

4. A ‘Purchase Log’ that will be empty. This record will NOT be completed as there should be NO Controlled Substances purchased. However, all the information pertaining to the registrant should be completed.

5. A ‘Use Log’ that will be empty. This record will NOT be completed as there should be NO Controlled Substances purchased. However, all the information pertaining to the registrant should be completed.

Note: OAWA staff (e.g. Drs. Bill Wilkison, Ron Banks, or Anna Hampton) will perform the OAWA Pre-Inspection by assessing the conditions of storage and providing information or answering questions prior to the Site Inspection.

DURING THE INSPECTION:

1. The Registrant must be present. Additional staff may attend as well.
2. At least one OAWA staff member should be invited to attend the inspection. The primary duties of the OAWA staff member will be to answer questions and address issues identified up by the Agent.

AFTER THE INSPECTION: OAWA and the Registrant will:

1. Discuss any concern(s) identified, and
2. Develop a corrective action plan for the concern(s)