RLSS DEA Controlled Substance Inspection Checklist

|  |  |
| --- | --- |
| Approval Number |  |
| AH Name |  |
| ASC Name |  |
| Date |  |

Registration Status

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Y | N | N/A | Inspection Item | Comments |
| □ | □ | □ | Controlled Substance Registration Certificate current and all information valid |  |
| □ | □ | □ | Controlled Substance Registration Certificate contains the schedules for all controlled substance merchandise used in research |  |
| □ | □ | □ | If Controlled Substance Registration Certificate was modified to reflect a new address or schedules, the modified certificate is maintained until the next renewal date |  |
| □ | □ | □ | Registrant has a copy of DEA Form 224 or 225 Application for New Registration Under Controlled Substances Act of 1970 |  |
| □ | □ | □ | Registrant’s next renewal date is prior to the next chemical safety annual inspection |  |

Inventory Control

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Y | N | N/A | Inspection Item | Comments |
| □ | □ | □ | Each inventory contains a complete and accurate record of all controlled substances on hand on the date inventory is taken including any disposal or destruction of controlled substances |  |
| □ | □ | □ | Inventory records are retained for two years |  |
| □ | □ | □ | Inventory records of Schedule I and II are maintained separately from all records of the registrant |  |
| □ | □ | □ | Registrant has taken mandatory DEA initial inventory of all stocks of controlled substances when he/she first engages in controlled substance use |  |
| □ | □ | □ | Registrant has taken inventory within two years of mandatory DEA initial inventory and a minimum of every two years afterward; recommendation is for monthly inventory |  |
| □ | □ | □ | Inventory includes name of substance, each finished form of substance (i.e. 10 mg tablet or 10 mg concentration per fluid ounce or milliliter), number of units or volume (i.e. 100 tablet bottles or 3 mL vial), number of commercial containers of each finished form (i.e. four 100 tablet bottles or six 3mL vials), and time of use (i.e.  COB) |  |
| □ | □ | □ | Registrant has maintained an accurate, current and complete record of each substance received, date of receipt, date of distribution and/or dispensing |  |
| □ | □ | □ | Primary and secondary containers (including dilutions of controlled substances) are properly labeled |  |
| □ | □ | □ | Inventory accurately reflects date of disposition of controlled substances |  |

Record Keeping

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Y | N | N/A | Inspection Item | Comments |
| □ | □ | □ | All dispensed controlled substances taken from existing inventories are recorded in a logbook (paper or electronic) |  |
| □ | □ | □ | Records indicate controlled substance name, strength, quantity, date of dispensation, the name of person or animal ID administered the controlled substance, and initials of the registrant/agent who dispensed or administered the controlled substance |  |
| □ | □ | □ | ORCBS Internal Transfer Forms are current for controlled substances transferred to other UA registrants |  |
| □ | □ | □ | Registrant has used DEA Form 41 to document disposal procedures |  |

Dispensation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Y | N | N/A | Inspection Item | Comments |
| □ | □ | □ | Written instructions are provided to verified workers that are dispensed controlled substances |  |
| □ | □ | □ | If the dispenser is not the registrant, the registrant has provided protocol or agent-specific written authorization for the dispensation |  |
| □ | □ | □ | Dispensation is within limits (no more than 240 CC or 48 doses of opiates and no more than 120 CC or 24 doses of other controlled substances) |  |
| □ | □ | □ | All dispensers and workers who receive dispensed controlled substances are over the age of 18 |  |
| □ | □ | □ | Any unused dispensed controlled substances are destroyed or returned to the registrant/dispenser by the end of the day |  |

Order Forms

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Y | N | N/A | Inspection Item | Comments |
| □ | □ | □ | DEA Form 222 (Order Form) used to obtain or distribute a Schedule I or II controlled substance |  |
| □ | □ | □ | DEA Form 222 (Order Form) is maintained for at least 2 years |  |
| □ | □ | □ | Lost or stolen DEA Forms 222 are reported to the local Diversion Group at the DEA Office at 573-5500 |  |
| □ | □ | □ | All out-of-date DEA Form 222s (e.g. due to an address change) have been returned to the local DEA office; all unused DEA Form 222s are returned when a registrant inactivates their registration |  |
| □ | □ | □ | Power of attorney letters are on hand for each agent given permission to sign DEA Form 222s by the registrant |  |

Disposal of Expired Controlled Substances

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Y | N | N/A | Inspection Item | Comments |
| □ | □ | □ | Controlled substance distributors are contacted to request collection of expired controlled substances |  |
| □ | □ | □ | Risk Management Services is contacted for disposal of all controlled substance waste |  |

Security Requirements

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Y | N | N/A | Inspection Item | Comments |
| □ | □ | □ | Controlled substances, including dilutions, are stored behind at least 2 differently keyed locks at all times |  |
| □ | □ | □ | Controlled substances, including dilutions, listed in Schedule I or II are stored in a safe or locked, substantially constructed steel cabinet, mounted/secured if applicable (<750 lbs) |  |
| □ | □ | □ | Controlled substances, including dilutions, listed in Schedules III, IV and V are stored in a safe or securely locked, substantially constructed cabinet |  |
| □ | □ | □ | Dispensed controlled substances remain under surveillance until completely used, returned or disposed of appropriately |  |
| □ | □ | □ | Laboratory-specific training includes an acknowledgement that any drug-related felonies will be reported to the registrant |  |