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| **Controlled Substance Licensing and Registration** |
| [**MI R 338.3132**](http://www7.dleg.state.mi.us/WebORRGSA/104_90_AdminCode.pdf) **and** [**21 C.F.R. 1301**](http://www.deadiversion.usdoj.gov/21cfr/cfr/2101cfrt.htm) | **Yes** | **No** | **Comments/Action** |
| Does a faculty member possess a current State of Michigan (SOM) controlled substance research license **or** SOM practitioner controlled substance license? |  |  |  |
| Is the SOM license present on site or readily retrievable? |  |  |  |
| Does the address on SOM license correspond with the laboratory address and room number where the controlled substances are stored? |  |  |  |
| Does a faculty member possess a current DEA 225 researcher registration **or** DEA 224 practitioner registration? |  |  |  |
| Is the DEA Certificate of Registration Form 223 present on site or readily retrievable? |  |  |  |
| Does the address on the DEA registration correspond with the laboratory address and room number where the controlled substances are stored? |  |  |  |
| Are research activities within the scope of SOM license and DEA registration? (E.g., substance schedule, manufacturing, analytical research, etc.) |  |  |  |
| Has SOM license and DEA registration information been entered into the University of Michigan [Controlled Substance in Research online (CSIR) database](https://www.umms.med.umich.edu/csir/logon.htm)? |  |  |  |
| **Inventory Records (Initial, Annual, Biennial, Closing)** |
| [**MI R 338.3151- 338.3152**](http://www7.dleg.state.mi.us/WebORRGSA/104_90_AdminCode.pdf) **and** [**21 C.F.R. 1304**](http://www.deadiversion.usdoj.gov/21cfr/cfr/2104cfrt.htm) | **Yes** | **No** | **Comments/Action** |
| Was an initial inventory performed (new DEA registrations or address change)? |  |  |  |
| Are the initial, SOM annual, and DEA biennial inventory records for the last two years on site? |  |  |  |
| Are the inventory records readily retrievable? |  |  |  |
| Was an SOM annual inventory performed and mailed to the SOM Bureau of Health Professions during 4/1 - 6/30 of the previous or current year? |  |  |  |
| Was a DEA biennial inventory performed and retained on site?  |  |  |  |
| Are schedule I - II inventory records kept separate from schedule III - V inventory records? |  |  |  |
| Were exact inventory quantities and amounts reported for schedule I - II controlled substances? |  |  |  |
| Was a closing inventory performed (moving, transferring, retiring)? |  |  |  |

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| **Usage Records (General Inventory, Multi-dose, Diluted Solution)** |
| [**MI R 338.3151- 338.3152**](http://www7.dleg.state.mi.us/WebORRGSA/104_90_AdminCode.pdf) **and** [**21 C.F.R. 1304**](http://www.deadiversion.usdoj.gov/21cfr/cfr/2104cfrt.htm) | **Yes** | **No** | **Comments/Action** |
| Are the usage records (logs, general inventory) for the last two years retained on site? |  |  |  |
| Are the usage records readily retrievable? |  |  |  |
| Are the usage records for schedule I - II substances kept separate from the usage records for schedule III –V substances? |  |  |  |
| Were the general inventory and usage records recently reconciled for accuracy? |  |  |  |
| Are waste amounts signed by both the DEA registrant (or authorized agent) and a witness? |  |  |  |
| Are individual containers or packages labeled with a unique identifier to assist in usage record tracking? |  |  |  |
| Do multi-dose vials have their own usage log? |  |  |  |
| Do diluted solutions of controlled substances have their own usage log? |  |  |  |
| Does the general inventory document transfers of expired or unneeded controlled substances to a reverse distributor for disposal or destruction? |  |  |  |
| **Invoice and Purchase Records** |
| [**MI R 338.3153**](http://www7.dleg.state.mi.us/WebORRGSA/104_90_AdminCode.pdf) **and** [**21 C.F.R. 1305**](http://www.deadiversion.usdoj.gov/21cfr/cfr/2105cfrt.htm) | **Yes** | **No** | **Comments** |
| Are supplier invoices for controlled substances readily retrievable? |  |  |  |
| Are supplier invoices for schedule I - II controlled substances kept separately from supplier invoices for schedule III - V controlled substances?  |  |  |  |
| Do all invoices contain the following: Name, address, DEA registration numbers of supplier and purchaser, order date, drug names, strengths, container forms, and quantities received? |  |  |  |
| Are all invoices signed and dated upon receipt or delivery? |  |  |  |

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| **DEA Form 222 (Schedule I and II Order Forms)** |
| [**MI R 338.3153**](http://www7.dleg.state.mi.us/WebORRGSA/104_90_AdminCode.pdf) **and** [**21 C.F.R. 1305**](http://www.deadiversion.usdoj.gov/21cfr/cfr/2105cfrt.htm) | **Yes** | **No** | **Comments** |
| Are unused and executed DEA Form 222s stored in a locked and secure location? |  |  |  |
| Are unused or executed DEA Form 222s readily retrievable? |  |  |  |
| Are there any missing DEA Form 222s? If so, have missing forms been reported to the Detroit DEA office? |  |  |  |
| Do unused DEA Form 222s with mistakes or those returned from supplier have "VOID" marked across the form? |  |  |  |
| Are all executed DEA Form 222s signed by the DEA registrant? |  |  |  |
| Do all schedule I or II shipments have a corresponding DEA Form 222? |  |  |  |
| Are all copy 3 (Purchaser) sections of executed DEA Form 222s complete and accurate? |  |  |  |
| **Disposal** |
| [**21 C.F.R. 1317**](http://www.deadiversion.usdoj.gov/21cfr/cfr/2117cfrt.htm) | **Yes** | **No** | **Comments** |
| Are expired or unneeded controlled substances kept in a substantially constructed cabinet until pick up by an OSEH Hazardous Materials contracted reverse distributor? |  |  |  |
| Are all disposal forms and DEA Form 222s associated with a reverse distributor transfer kept on site? |  |  |  |
| Were non-recoverable waste amounts properly disposed of? |  |  |  |
| Are non-recoverable waste amounts documented in the inventory or usage record with two signatures (DEA registrant or authorized agent and one witness)? |  |  |  |
| **Loss or Theft** |
| [**MI R 338.3414**](http://www7.dleg.state.mi.us/WebORRGSA/104_90_AdminCode.pdf) **and** [**21 C.F.R. 1301.76**](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_76.htm) | **Yes** | **No** | **Comments** |
| Have all actual or suspected cases of theft or significant loss been reported to the U-M Department of Public Safety, MI Bureau of Health Professions, and DEA? |  |  |  |
| Was a DEA Form 106 submitted for actual or suspected cases of theft or significant loss? |  |  |  |
| Have losses incurred during shipment been reported to the supplier? |  |  |  |
| Are non-recoverable losses documented in inventory or usage record with two signatures (authorized agent and witness)? |  |  |  |

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| **Security** |
| [**MI R 338.3141-338.3145**](http://www7.dleg.state.mi.us/WebORRGSA/104_90_AdminCode.pdf) **and** [**21 C.F.R. 1301.71**](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_71.htm) **–** [**1301.93**](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_90.htm) | **Yes** | **No** | **Comments** |
| Have policies or standard operating procedures been developed by the laboratory with respect to storage, administering, and record keeping of controlled substances? |  |  |  |
| Are the controlled substances stored in a securely locked, substantially constructed cabinet or safe that is anchored to a wall or the floor? |  |  |  |
| Is the storage cabinet located at the address (building and room) as identified on the DEA registration? |  |  |  |
| Does the controlled substance storage location have minimal traffic flow? |  |  |  |
| Is the lab or room with the storage cabinet locked when the registrants or authorized agents are not present? |  |  |  |
| Are controlled substances requiring refrigeration securely stored or locked in a refrigerator? |  |  |  |

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| Is access to controlled substances kept to a minimal number of authorized agents? |  |  |  |
| Are keys to the controlled substance storage cabinet locked up or secured when not in use? |  |  |  |
| Do the locks on the storage room and cabinet have the capability to be reset or rekeyed if an authorized agent resigns, is terminated, or a loss or theft is suspected? |  |  |  |
| Is an authorized personnel log kept on site?  |  |  |  |
| Is the authorized personnel log updated frequently? |  |  |  |
| Have background checks been performed on authorized agents and authorized personnel? |  |  |  |
| If a formal background check was not performed, have all authorized agents read and signed an "Authorized Agent Screening Statement? Are screening statements kept on file. |  |  |  |
| Are all screening statements complete and kept on site?  |  |  |  |
| Are controlled substances delivered directly to a receiving individual in the laboratory? |  |  |  |