

UNIVERSITY OF NOTRE DAME
JOINT LAB ASSESSMENT PRE-CHECKLIST

Lab Appropriate Documents to be reviewed at the time of the Joint Lab Assessment
These documents may be electronic or hard copies as appropriate.

Laboratory Safety (ALL laboratories.)

- Training Needs Assessment with list of all personnel working in the lab
- Training documentation for all lab personnel (as appropriate)
 - Laboratory Safety Parts 1, 2 and 3 or Lab Safety Refresher
 - Fire Extinguisher Training
 - Biosafety Training (required annually)
 - Bloodborne pathogen training (required annually for personnel working with human tissue, blood, cell lines or other bloodborne pathogens).
 - Radiation Safety or Refresher training
 - Laser Safety
 - Any Lab specific training (SOPs, emergency response and evacuation, etc.)
- PPE Assessment and signed Certification
- Standard Operating Procedures
- Eyewash monthly inspection
- Chemical Inventory
- PPE relaxation documentation (if a formal request for PPE relaxation requested, e.g. not wanting to wear safety glasses at desk)
- Blue emergency contact sign with current information.

Biohazard Safety

- List of all biohazards (blood, cells, tissues, bacteria, parasites, fungi, viruses or OPIM) stored or used in the lab.
- IBC and IRB Protocols (as appropriate)
- Lab Specific Biosafety Manual (if BSL-2) Must have emergency contact info, emergency procedures and copy of SOPs and approved IBC Protocols.
- Animal Use Protocols (If appropriate)

Radiation Safety

- List of sealed or non-sealed sources and/or radiation producing machines that are stored or used in the lab.
- Radiation Safety Manual
- Up to date log sheets (inventory forms) for all non-sealed materials
- Contamination survey forms, including lab diagrams, for at least one per month in which non-sealed material is used
- Waste forms from waste picked up in the past year
- Package receipt forms from orders delivered in the past year

Laser Safety (Class 3B and Class 4)

- Laser Safety Manual
- Manufacturer's Operating Manual for each unit
- Standard Operating Procedure for each unit (not the same as the Operating Manual). *This*

should include a list of the necessary eyewear for each unit, and each user must sign-off that he/she understands the contents of the manual.

Teaching/Research Shops

Shop safety coordinator is expected to attend training on: Lockout/Tagout, Hearing Conservation, Hazard Communication and have First Aid/CPR training. Provide training certificate.

- Any shop specific safety rules. These may be in a document or manual somewhere that they could provide before the inspection, but sometimes they are posted on a sign in the shop that we would see during inspection.
- A few shops have either forklifts or aerial lifts.

DEA Controlled Substance (CS) Records

**All documentation for substances in Schedules I and II must be kept separately from all other paperwork/records*

** Whiteout may not be used on any CS-related documents*

- Current Indiana Controlled Substance Registration card
 - Go to www.PLA.IN.gov to request/print a card
- Current DEA Controlled Substance Registration
- Complete Biennial Physical Inventory
 - Taken at least every 2 years, annually is recommended
 - For newer registrants, initial inventory may show quantity of zero
- A current list of individuals with access to the CS & their Notre Dame ID number

While **RMS will not ask to see copies of the following** during our LISP inspection, the registrant must maintain these documents and have them readily available for inspection (at the location where the CS are used/stored) by a state or federal agent. The registrant and PLC should easily be able to identify where these records are kept:

- Purchasing records for all CS received
- A CS Administered/Dispensed log for each CS on hand
 - Updated at least annually and each time CS is received or removed from its original container
- Those using cocktails must maintain a record of the formula(s) used and documentation of annual scale certification by the DEA
- A notarized memo indicating who may order and/or receive CS for the registrant (if applicable)
 - Memo must include registrant's DEA registration number and signature
- Those using Ketamine must maintain a record that the bottles are overfilled (if applicable)
- Disposal records, DEA Form 41 (if applicable)
- Theft/Loss records, DEA Form 106 (if applicable)