September 22, 2006 in dry laboratory conference room from 11-12 am.

Present:
Maureen Purcell (IBC chair), Rusty Rodriguez (IBC member), Carl Ostberg (IBC member), Mike Canino (IBC member), and Jack Hotchkiss (Safety Officer)

Jim Winton (Observer)

Absent:
Evi Emmenegger (IBC member)

Agenda:

1. Linda Rhodes discussed how the IBC runs at the Northwest Fisheries Science Center.
2. Protocol 06-01 submitted by Jim Winton was reviewed.
3. Mike Canino, Linda Rhodes and Jack Hotchkiss performed a site inspection.
4. Protocol 06-01 was approved.

Minutes:

Jim Winton opened the meeting and discussed the need for federal agencies to become compliant with federal laws regarding recombinant DNA, pathogens and care of vertebrate animals. The WFRC requires an IBC at this time to obtain extramural funding from U.S. Department of Agriculture.

Linda Rhodes presented an overview of how the IBC functions at the Northwest Fisheries Science Center (NWFSC). Their committee holds a meeting once per year and handles most other business through email or phone. The NWFSC complies with the minimum legal standards set forth by NIH guidelines but sets the bar higher, particularly in regards to pathogens. When new projects are initiated, a one page questionnaire is filled out by the investigator and sent to the safety officer. The safety officer then determines if the project requires review by the IBC. The IBC application is sent to the investigator for completion. All members of the IBC will receive a copy of the application. One IBC member will do a more complete review of the protocol, potentially perform a site visit and report their findings to other IBC members. Approval requires signatures by the chair and by the members that performed the site visit. The committee also sends an annual survey to determine if any investigators have select agents. If laboratories have select agents, this would require enrollment in the Centers for Disease Control Select Agent Program (SAP).

Jim Winton verified that the WFRC does not possess select agents and that he has already formally reported to the SAP. Since the WFRC is a small center, the decision was made not to require annual select agent survey at this time. Jim excused himself from the remainder of the meeting.

Linda reported that the University of Washington uses the Institutional Animal Care and Use Committee (IACUC) as the point to determine if new applications require further screening by the IBC or by the occupational health department. Maureen mentioned that the WFRC is forming an IACUC and that we can consider this model.

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Jack is also revising many of the safety regulations at the WFRC and so these procedures may be changing.

The proposal by Jim Winton was reviewed (IBC # 06-01). Maureen provided an oral review of the proposal for the other members. Linda and Mike asked several questions regarding training, exposure of pathogens, disposal and treatment of effluent.

Mike, Linda and Jack performed the site inspection of Immunology, Virology and the wet laboratory facilities. Rob Jackson (maintenance) explained how the effluent is treated after leaving the BL3 and main wet laboratory.

Two concerns were raised during the inspection:

1. There is no current routine monitoring of the effluent treatment from the main wet laboratory. The question was raised whether we can be guaranteed that pathogens are non-viable when they enter the lake.
2. There were no iodine foot baths at the exits of the bays which contained live pathogens. The suggestion was made to have iodine foot baths or to provide disposal shoe covers which can be autoclaved after use.

Maureen agreed to raise those concerns with Jim Winton and Kyle Sato (the facilities manager).

Mike Canino and Jack Hotchkiss approved the site inspection. Linda Rhodes approved protocol 06-01 as acting chair of the IBC.

Minutes written by Maureen Purcell September 24, 2006

10-25-07
Meeting Notes: WFRC Institutional Biosafety Committee (IBC)

Attending: Mike Caiano from NOAA-Saindpoint, Maureen Purcell, Evi Emmenegger, Carl Ostberg, Jim Winton, Linda Rhodes (phone)

1. Meeting called to order by Maureen Purcell (out-going chairperson).

2. Discuss issues raised during last IBC meeting.
   - Footbaths are currently in place and in use.
   - Effluent monitoring: During the next 2 FY, the WFRC maintenance section hopes to have a monitoring program with redundant backups in place. We are working closely with maintenance staff to come up with a plan.
   - George Sanders, WFRC Veterinary officer, wants us to monitor the effectiveness of autoclave with the use of "pro-spore ampoules" (heat inactivated spores). Suggested monitoring is monthly. Maureen and Evi will design the protocol and present to the maintenance staff for implementation.

3. Updates on laboratory exposure control plan.
   - Committee wants the Laboratory Exposure Control Plan to focus on recombinant DNA and infectious agents. Linda Rhodes will give us a copy of NOAA exposure plan.
   - Ann Buyers knows a lot about Chemical Hygiene Plan at NOAA and can be contact for further information
   - Jay Kennedy at NOAA Alaska Center has a Chemical Hazard Plan and Mike C. will forward the plan to us.
   - The committee members agreed that the WFRC IBC duties would be to oversee the use of recombinant DNA and infectious agents at the center. The Safety Officer or another committee will monitor hazardous chemicals.

4. Discussion of changes to the WFRC IBC operations

   a. Do we need to submit reports NIH?

Answer: Linda Rhodes: Not if we do not have a contract with NIH. However, once NIH funds any project, all projects at the facility are subject to review under NIH-IBC review.

b. Protocol expiration dates: Three year expiration date for protocols and PI required to submit an annual update indicating no new changes to protocol.

c. WFRC Occupational Health Questionnaire: Each PI would be required to review the list of tasks and material used in each research project and list the personnel working on the project. This would ensure that every person receives the appropriate safety training associated with each project. A prototype questionnaire presented at the meeting is attached.

5. New information from NIH on IBC operation: The National Science Advisory Board on Biosecurity (NSABB) has proposed a role for IBC in the review of "dual-use" research. NSABB will define specific duties in the future.

6. Approve new protocols.
    - No new protocols to review at this time.

7. Meeting is closed by Evi Emmenegger (incoming chairperson)

Meeting notes taken by substitute secretary, Dorothy Chase.

- meeting 11/1/2007 - Kyle, Jack, [illegible] & Eric

Jack - Full-time safety officer
Jack already - chemical hygiene Plan (COOK)
-pg-65-

Autoclave

Hazardous Waste Disposal -
- Autoclaves 12/15/07
- Waste Disposal
- 4-new autoclaves -
Pairing infectious waste -

Effluent - ~~Waste Disposal~~ Monitoring
2-year plan -
Stressing Environmental prospective vs facility
analyzing budget

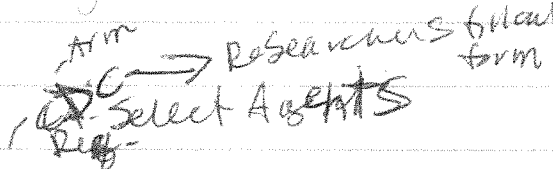
~~Waste~~ ~~Facilities~~ 3-year plan
UV-treatment
Effluent (Redundant)
monitoring

Meets the NPDS permitting requirements
National Pollution Discharge
from EPA requirements
We have a Permit
- Reviewing 2008 - Should be
received

Need files to update — Committee approval

Agenda- discuss IBC application triggered by Human/Industrial Safety questionnaire

Could we any research? not just wet lab work.



Where else can you get the Select agents list?
Need to check for any recent updates?
How does this relate to the risk groups?

It appears that the level of the risk group, generally defines your biosafety level

Autoclaving

- Effluent - Simpactix -

Foot baths (Iodine)

Efficacy
Autoclaving - Manufacturer
Protocol - BioSat

maureen SOP - Autoclave Efficacy
mntr

For Kyle

- Effluent System - Design 2.5 ppm monitoring -

2 ppm

- Redundant System -

- 1st chlorine (electrolytic) w/ alarm
- Back up chlorine gas - alarm shut-down
  Specific Head boxes - Shut-down

Assurances -

Proposal for effluent monitoring plan

Chip? → ~~N/A~~ ← Yes for secretary TBC

January 28, 2009

Institutional Biosafety Committee
Persons in attendance: Maureen Purcell, Evi Emmenegger, Carl Ostberg, Rusty Rodriguez, Mike Camino, Jim Winton, and Linda Rhodes
Notes taken by Dorothy Chase

1. Meeting called to order.
2. Discussion of changes to the WFRC IBC operations

a. Effluent Treatment: (Jim Winton: WRFC installed a sodium hypochlorite treatment system. System is setup into an alarm system incase of failure. We have 4 days of chlorine solution for treatment of effluent in case of system failure. WFRC is waiting for new regulations from NDPD before the purchase of testing system. We have applied for National Pollutant Discharge System permit. We are waiting for that permit to know what modifications we will need for the effluent monitoring.

b. Autoclave procedure: (Maureen Purcell: UW-IAUC has said that WFRC is not properly treating biohazards. So they have suggested that WFRC use a thermal log and biological test for validation of sufficient sterilization. We have added that to our Pathogen Exposure Plan. There is a new SOP for the autoclaves. There will be specific autoclaves designated for biohazard waste.

3. Review protocols and manuals:

Chemical Hygiene Plan: Evi Emmenegger has prepared a Chemical Hygiene Plan for the WFRC. The protocol was reviewed by the panel and minor edits were suggested.

Comments from Linda Rhodes about the Hygiene Plan
Linda Rhodes suggests that "secondary container" be clarified.
See page 6 of the Chemical Hygiene Plan.
On page 9, clarify "the container shall not be de-faced.....".
Page 11, a physician must train the user how to use a respirator.

Page 12 Chemical water disposable....LR understands that chemical waste storage is not allowed to be stored in lab. Change "waste storage" to "waste containment".
Page 14 "IBC chair" why are they contacted? E.E. Because we do not have an onsite safety officer we are contacting IBC officer to keep tract of accidents and incidents
Page 15 Add a statement about Questions about Biological Safety Cabinets.
Page 17 Change "section" to each "laboratory has access to the MSDS
Comments from Carl Ostberg
Page 6 Please clarify why each section should develop procedures. Change the wording to each laboratory should develop.....

a. Pathogen Exposure Plan:
Evi Emmenegger has developed a Pathogen Exposure Plan. The protocol was reviewed by the panel and minor edits were suggested.

Comments from Linda Rhodes
Blood question. The protocols go beyond what we need at the lab for fish blood exposure so the procedures are developed for exposure to human blood standards. Legal description is "human blood". E.E. & J.W. response: We're taking a conservative approach to safety, if we maintain high safety standards we reduce the risk to our employees. Further there is a risk of being exposed to human blood, via a safety incident (e.g. a fellow employee has an open bleeding wound and another employee is exposed while administering first aid). In addition, the WFRC could house and work with mice (i.e. to generate monoclonal antibodies) in the future.

Appendix B Does this get filled out before job titles
Page 4 Change hazardous waste to biohazardous waste.
Page 6 Surfaces should be water resistance and not water impervious.
JW Yes, some surfaces should be water resistant and some like the floors should be water impervious.
Page 13 Point 2. Change wipe surfaces with 70% ethanol to wipe with bleach solution.
4. If the spill is large.....
5. Page 14 Point 4. Question about vaccination. JW response that this

Page 23 make edits to definition of pathogen.

Rusty Rodriguez Comments
Page 4 Rusty Rodriguez had questions about this sentence " employees can be reasonably be expected to blood ..... E.E. response is that this is exact verbiage from OSHA
Should volunteer be added to the Job Classifications? JW suggests using "official volunteer".

4. The manuals and protocols were approved with the suggested edits.

5. Meeting called to a close.

WFRC Action items determined from the Biosafety & Biosecurity Training
(Evi attended July 2016 in Fort Collins, CO)

Future biosafety action items to consider:

*When OSHA becomes involved with personnel safety at labs working with any infectious agents then may need to address this issue. Baseline Serum for people working with animals/pathogens. Occupational hazard of personnel exposed to pathogens (the ones we work with unlikely to cause disease), however detrimental immune response and development of allergies is possible. However baseline serum long-term storage is typically an issue. This option include in pathogen exposure plan if requested. An alternative is to offer serum response procedure. Sample at time of exposure to obtain a profile and then screen again 2-weeks later (this option not as applicable for WFRC since not working with zoonotics). OSHA may want us to emphasis the options to new employees working with animals and pathogens.

*Have we done a confirmatory test of pathogen destruction for the autoclaved samples? Especially autoclaving of denser/larger whole fish carcasses in order to confirm that the pathogen is non-viable. Some facilities have a two-tier system (e.g. autoclaving, then incineration or tissue shredder with high heat) for final disposition of research animals. This two-tier system would likely be needed if a regulatory agency places aquatic pathogens in higher agriculture risk groups.

*Screening of an individual for work in the ABSL-3 (esp. w/new agents or Tier 1) Referrred to as "institutional suitability assessment requirement", "assurity clearance", or personnel suitability evaluation. People clearance has been revoked for bad credit/traffic violations. Essentially a psychological assessment by biosafety officer, HR, occupational health officer, and lead BSL-3 scientist, etc. In some cases, they use a category "recommend with reservation" and then the person has a probationary period.

*Pathogen inventory control, select agents have to chain of custody and tight inventory control. CSU adopted "a 90-day rule" for experiment samples;
<90 days samples are "in experiment inventory"
>90 days samples are considered semi-permanent are in the select-agent inventory
In the future could adopt a similar system for the "high risk pathogens". That way any samples stored indefinitely would be added to the WFRC high-risk inventory database. Also have commercially available "freezer management" computer programs available if we no longer want to use our in-house FileMaker Pro high-risk pathogen database. BMBL also has some guidance on short-term and long-term storage of pathogens. Currently WFRC doesn't have a strict timeline on making a decision on a pathogen being categorized for short or long term storage. We focus on receipt of requested pathogens. Also need to consider destruction of detected

pathogens in diagnostic samples/mystery pathogens or retention and placed in inventory control.

*Future facility action items

-Pre-filter exchanges; BSL-3 HVAC systems are doing pre- pre-filters into the ventilation system to reduce exchange of expensive pre-filters & HEPA filters.

-Effluent discharge pipes (drain to treatment/kill tank). We need to be able to do inspection of these pipes to confirm that there no leaks. We don't have sight line to the discharge pipes below aquatic BSL-3? Purchase a sewer line camera (invisible length)? FMDV 2005/2006 had an effluent discharge pipe break before the kill tank.

-Now new BSL-3 labs are required to have redundant air-handler exhaust systems. For older BSL-3 labs it was suggested that an air trap needs to be put in place, if the system goes static so no air-borne release.
Since we do not have a redundant HEPA exhaust for the BSL-3 ventilation system, some labs have retro-fitted a "fast inter-locking seal" in case the air goes static. ANSI BSL-3 ventilation standards, released in 2014. I downloaded some of the references associated with the new standards. Also compare with the USDA APHIS and ARS standards. They will be updating, the new dual exhaust requirement and suggestion of the reverse air seal retrofit for older BSL-3 labs is the result of this ANSI 2014 ventilation standard. Inform maintenance or already know?

Action Items that need to be done soon:

1. Occupational Health Officer (Chris/Jill inform Brian Rebo?)
The occupational health officer serves on the IBC and IACUC. The OH officer is then familiar with procedures that the staff perform and then can better respond to safety requests/concerns. Add Brian to the IACUC and tell him about the upcoming IACUC meeting in August 23rd. Brian escorted the USGS occupational health representative during their recent visit (7/20/2016) into the BSL-3 labs. They asked who has training for shipping dangerous goods. I told them that Jima and I had completed the training, and Brian stated he was going to complete the training soon.

2. Biosafety Lab self-inspections (Jill present to IBC?)
Recommended that IBC do a biosafety lab self-inspection at least annually (e.g. dry labs). WFRC performs IACUC self-inspections, to catch discrepancies, but no biosafety perspective inspections of the laboratories. This could also qualify for WFRC identifying biosafety risk gaps and develop corrective action plans (CAPs). This demonstrates our pro-active approach to biosafety and maintaining compliance. Include in pathogen exposure plan if agreed upon (see below).

3. Biosafety Annual Training (biosafety officer - Maureen)

If doing on-line/power point training, need to have follow-up to confirm that individuals understood the training and "not just flipping through the slides". Remember training must be documented. Since we are deficient for 2 years of annual biosafety training (noted in USDA inspection), really need to have this done soon. If USDA does one of their unannounced inspections, it will be cited as a "willful violation" since it wasn't corrected. Status on 2016 training?

4. Pathogen Exposure Plan Update (Evi present to IBC)
-Change Plan name (Pathogen Control Plan, Infection Prevention & Biosafety)

-Include the fit test for the N-95 mask for the "respiratory protection program". Kyle already has something in place. Need to clarify in manual.

-We don't re-use needles, but our filling of syringes, testing needle seal and re-capping prior to injection challenge poses a hazard. Suggest one handed re-capping needle method and/or to use extreme caution to avoid needle sticks.

-Employees having fish tanks in their offices. During last USDA APHIS inspection this was a new question. Since at the time I knew that Rachel and Gael's fish tanks weren't operational I could answer honestly that we did not. My recommendation would be not have them. Otherwise it would open up an inquiry of why we have potentially vulnerable animals in non-lab areas. One alternative is to list criteria of which staff could have tanks. Personnel that don't work with pathogens or high-risk pathogens, or animals, etc. would be allowed to have aquaria? Though this poses a risk gap that again would like be frowned upon by USDA APHIS and likely in the future OSHA. Include text in pathogen control plan after a decision is made.

5. ABSL-2 wet laboratory effluent treatment monitoring (present to IBC)
In terms of risk assessment, this is our biggest risk gap. Most facilities treating effluent with chlorine either have a real-time monitoring system (input and output) or frequently monitor the post-treatment effluent concentrations to ensure that the pathogens were treated at sustained high concentrations of chlorine to ensure the majority pathogens are non-viable at the end of treatment. Testing the chlorine level output levels every two weeks was purposed, but monitoring once every 3 months was implemented. I believe monitoring the post-treatment chlorine levels every 3-months is not enough and puts us at a greater risk for having an accidental environmental/pathogen release that could directly impact the adjacent wetlands that receives our de-chlorinated treated effluent. Altered monitoring time frame?

6. BSL-3 manual/BSL-3 signature forms (Evi updates)
-For inspections, especially if an unannounced/spot check occurs ask for the inspectors credentials and ID. Change training signature form for visitor entry, inspection, repair person, etc. Visitors need to be briefed on biocontaminant/biosafety etc. especially if entering during an experiment. Signature of person and space for affliation. Also record if any equipment was

decontaminated. Follow SOP outline for inspector/regulator entry to BSL-3 lab presented by USDA ARS Biosafety Policy person. See attached SOP draft.

-Also need to be aware if emergency personnel ever have to enter the BSL-3 laboratory (i.e. inform them that not zoonotic risk, but environmental containment).

-Limited entry/security already discussed in manual, but need to clarify that access between experiments is discontinued and then re-instated for the next experiment. Also include on signature form. Also state in manual the WFRC security barriers that we already have in place (e.g. only one door open during business hours, visitors log in and state affliation, day visitors must have escorts. Outside gate secured during non-business hours, etc.

-State that any pathogen liquid samples transferred to the BSL-2 for analysis needs to be transported in a secondary containment container with a lid.

-If sending someone an inactivated sample, need to include documentation stating the method of inactivation.

-Need to include in BSL-3 manual who we report to if there is an incident (e.g. accidental release). We already summarized in the USGS plan in response to the GAO audit, but this information now needs to be included in our "procedural manual".

-Include Baulin tubes as a visual check for negative airflow or BSL-3 labs.
Include an airflow direction map for BSL-3 labs/antechamber (clean to dirty)
Include an encouragement for staff to wear prescription eyeglasses instead of contacts.

-List Jim or Jill as the alternate responsibilities official (ARO). Be sure to state "alternate", not assistant or substitute. USDA permits don't allow ARO on the permit, but we can list in the manual. Then can be back-up if they come for an unannounced inspection.

-BSL-3 operational manual designated as "secured documents" for biosecurity. Knowing our operations is a possible biosecurity intrusion risk. Many are declaring their BSL-3 operation manuals as secure documents.

7. BSL-3 checklist (Evi updates)
-Check that automated light cycle is operating properly (i.e. on/off cycle) at the start of the experiment.

-Include a space for checking-off each item. Some facilities have documentation, signed by investigator that check list was completed. Probably should do this, since

I do it anyway, as does Gael. This would provide further documentation to outside agency regulators and internal federal oversight groups.

8. Maintenance BSL-3 items
Record/Log of HVAC system pre-filter and HEPA filter exchanges. This is already in the BSL-3 SOP, but unsure if this is being performed. If a copy of the maintenance log is archived in the BSL-3 records this would meet documentation needs and I would have them in hand during a regulatory visit or USGS/GAO audit, etc. The upgraded air handler (#3) system appears to have rectified the previous air flow failures and worker health issues, we just need to ensure that the proper airflow is maintained to be in compliance with BSL-3 HVAC standards and maintain worker safety. Need documentation for BSL-3 ventilation upkeep. (Jill request from Kyle).

Need documentation of work requests, both unscheduled during experiments and scheduled during down-time etc. Print out and keep a log of repairs and upgrades, etc. (Evi start a maintenance repair/upgrade log).