

BIOSAFETY COMMITTEE MEETING

MINUTES

The Watertown Special BioSafety Committee has scheduled a REMOTE ZOOM meeting on Thursday May 20, 2021 at 7:00 pm

PRESENT: Heather McManus PhD, Chairperson, Bradford M. Parsons Committee Member, Deborah L. Mc Ewan PhD Committee Member, Larry Ramdin, Director of Public Health

Staff: Maureen Foley, Head Clerk,
In attendance Morris Trichon, Corey Martin, Rae Moore

CALL TO ORDER: Dr. McManus called the meeting to order 7:11 pm

Public Comment

No Public comments

Overview for the Biosafety Special Meeting

Dr McManus stated she called this meeting to discuss what Life Science work in the Town of Watertown falls within the Watertown Biotechnology Regulation. WBSC is tasked within the Biotechnology regulation with creating procedures for the implementation of the regulation. WBSC recommendations for amendments to the Biotechnology Regulation have to be presented to and voted on by the Board of Health.

Dr. McManus referred to the draft discussion document posted with the agenda Dr. McManus stated that this document is a draft to guide discussion and is subject to correction and change. Dr. McManus outlined the existing exemptions within the Watertown regulation.

- a) Patient samples that are being tested with established, commercially available clinical diagnostic products and procedures for diagnostic purposes, i.e. CLIA certified labs (Section 7D of Watertown Biotechnology Regulation)
 - o Dr. McManus offered the example of Quest diagnostics as a BSL-2 facility that is exempt from the Watertown Regulation.
- b) Testing kits and products utilized by medical device and manufacturing companies for quality control (QC) proposes (Section 1 of Watertown Biotechnology Regulation)

Dr. McManus explained the areas where the possible exempt status of a company is unclear and therefore the Biosafety committee needs to provide clarity for applicants/companies:

- established cell lines purchased from commercial vendors used without introduction of new rDNA, that are assumed to be non-infectious
- commercially-sourced tissue, blood, or bodily fluid samples used without introduction of new rDNA, that are assumed to be non-infectious

- patient samples for research purposes fall?
- Where does BSL-2 work that falls in this section and also falls in Section 3 (requiring registration) fall?

Dr. McEwan stated a BSL1 uses exempt materials and requires no training. Deb asked are we regulating too much.

Brad stated currently chemical labs with highly toxic materials are virtually unregulated. There is equally dangerous work being done at these facilities. Brad mentioned that chem. labs may not fall under biosafety committee but there should be an oversight by the town. [SEP] Larry stated in the past, there was a hazardous material permit with no fees attached. Brad stated he can see issues on the horizon, a water enabled chemical on a third floor mixed use building vs a garage on ground level with the same or similar chemicals. The Town needs to have a committee to address these issues.

Corey stated there is a large range of work being done at BSL2 labs. Labs could be working with human cell lines, modified viruses, commercially derived tissues and cell lines. WBSC needs to capture the work that falls through the cracks.

Brad stated the BSL1 application is short. This application does not include a safety protocol and EAP. The low risk should be expanded to be more of a lab registration. Deb would like a floor plan, security plan and storage of chemicals. BLS2 should require screening document (screened not to be infectious) in the FAQ.

Resident Morris Trichon thinks the language leaves much latitude. The nanotechnology field of quantum biology is growing. McManus stated unless rDNA is used with the nano particles then the lab is exempt.

Dr. McManus moved onto the agendas action item #1:

Action Item 1: Craft a recommendation for applicants as to what BSL-2 and/or rDNA work is not subject to the Watertown Biotechnology Regulation.

Dr. McEwan made motion that based on the regulations and operations the following are exempt from the Watertown Biotechnology regulation, [SEP]

- Commercially procured human cell lines that have been screened to be negative for [SEP] known human pathogens
- Commercially procured animal cell lines, tissues, and products, excluding non-human primate material, that have been screened to be negative for known zoonotic pathogens [SEP]
- Primary human cells or tissues from clinical sources are not exempt from the Watertown Biotechnology regulation"

Motions granted (McEwan, Ramdin) 4-0. All in favor [SEP] Roll Call

Dr. McManus asked if the recommendation for action item #1 provides the clarity needed for the proposed Action Item #2 (Craft a recommendation for applicants as to what is required for

exempt rDNA work utilizing BSL-2 materials that are not otherwise subject to the Watertown Biotechnology Regulation). The WBSC and the safety consultants present agreed that it is now clear that work with rDNA listed as exempt in the NIH Guidelines conducted in BSL-2 materials exempt from the Watertown Biotechnology regulation requires a “low risk facility” registration.

Further discussion:

When should the WBSC start inspecting labs now that COVID restrictions have been lifted.

Heather stated WBSC does not have procedures in place when there is a change in a IBC meeting. New protocols should be added and an SOP be put in place. Deb stated the WBSC only does an initial review of IBC minutes. How do we capture changes in protocol? There may be a possibility of hiring a consultant.

Adjourn: Ramdin recommended Adjourn, McEwan 2nd 9:30 PM

All in favor. ^[L]_[SEP] Respectfully submitted: Larry Ramdin, Director of Public Health