Human Pathogens and Toxins Act (HPTA)& Regulations (HPTR) and the Canadian Biosafety Standards (CBS) 2nd Edition

The final versions of the Human Pathogens and Toxins Regulation and the Canadian Biosafety Standards, 2nd Edition which come into effect December 2015 have now been released. The early release of the final versions is allowing institutions to familiarize themselves with the requirements and initiate any required changes.

Human Pathogens and Toxins Regulation (HPTR)
For more information on the Regulatory framework of the HPTA/HPTR, click here. For more information on how this may impact your work with biological agents at the U of M go to page 2-4 of the December 2014 Biosafety Newsletter.

Canadian Biosafety Standards 2nd Edition (CBS)
The Standards originally published as Part I of the CBSG, 1st Edition, have been updated and published as the Canadian Biosafety Standard (CBS), 2nd Edition. The CBS will be the cornerstone of the new HPTA and regulatory framework when the HPTR comes into force. At that time the CBS 2nd Edition will come into effect and supersede the CBSG. The PHAC and the CFIA will use the CBS starting December 1st, 2015, to verify the ongoing compliance of regulated facilities. Risk Group 1 biological agents are not regulated by the HPTA/R and CBS but are still subject to institutional policies. For a list of other biological material exempt from the regulations click here.

The Guidelines originally published as Part II of the CBSG, 1st Edition, are currently being updated and will be published as the Canadian Biosafety Handbook (CBH), 2nd Edition and a series of supporting Biosafety and Biosecurity Guidelines. The CBH is a companion document to the CBS that provides guidance on how to achieve the biosafety and biosecurity requirements outlined in the CBS.

PHAC has reported that printed copies of the CBS and CBH will be available in the fall.

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Biosecurity Risk Assessment and Plan

One of the new HPTR license components for research institutions has been reported to be the submission of a ‘Administrative Oversight Plan’ for Biosafety and Biosecurity. The current Biosafety Policy, Procedure and accompanying Permit and Project Approval process form a major part of the U of M oversight plan for Biosafety.

The CBS indicates that the Biosecurity Plan is to include strategies for the risks associated with physical security, personal suitability and reliability, pathogen accountability and inventory, incident and emergency response, and information management and is to be based on a documented Biosecurity Risk Assessment.

The Biosafety Program, in consultation with the Office of Risk Management, is using the well-established Enterprise Risk Management model for establishing a prioritized list of vulnerabilities related to biosecurity. To that end a Biosafety Risk Assessment Committee (BRAC) was struck comprising the major stakeholders for the plan elements. The committee has met twice and a third meeting is scheduled to vote to prioritize the identified items. After the list is defined, EHSO will work with the stakeholders to develop strategies to mitigate the vulnerabilities and develop an Institutional Biosecurity Plan.

We thank Shannon Boychuk from the Office of Risk Management for her expertise and leadership in this undertaking with us.

Consultations with Departments on the HPTA, HPTR and CBS 2nd Ed.

Starting this summer, ahead of the December 2015 deadline, Biosafety Program personnel are engaging in compliance promotion visits with Department Heads to familiarize them with the key components of the new regulations and the potential impact on their facilities, researchers and the U of M license.

As shared in an earlier newsletter, the regulators have promised to visit each of the license holders once during the term of the license (five year terms for a Risk Group 2 license, shorter for a Risk Group 3 license). No schedule has been released for these visits and indications are that a schedule may be based on the information provided in license submissions.

Biological Safety Officers from other universities who have been visited as part of a pilot inspection project indicate that while the expectations have been reasonable, the time lines for administrative updates can be as short as two months and as short as six months for facility upgrades.