2009 DRAFTING REQUEST

Assembly Amendment (AA-ASA1-AB578)

Received: **01/26/2010**

Received By: **btradewe**

Wanted: **01/27/2010**

Identical to LRB:

For: **Gary Hebl (608) 266-7678**

By/Representing:

This file may be shown to any legislator: **NO**

Drafter: **btradewe**

May Contact: **Don Nelson, UW**

Addl. Drafters:

Subject: **Health - miscellaneous**
Environment - other

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Hebl@legis.wisconsin.gov**

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Exception for certain labs

Instructions:

See attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?							
/1	btradewe 01/26/2010	jdyer 01/27/2010	phenry 01/27/2010	_____ _____	sbasford 01/27/2010	sbasford 01/27/2010	

FE Sent For:

<END>

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/?	btradewe	1/27 jld	1/27 ph	1/27 ph			

FE Sent For:

<END>

Standards for general purpose are not applicable to research, clinical environments. This is also a very critical concern and Hartley has expanded upon 1) as follows:

7. We have concern here regarding how this affects our ability to manage labs and clean rooms on campus. Example: Waisman Clinical BioManufacturing Facility must remain compliant with established Good Laboratory Practice (GLP) and Good Manufacturing Practices (cGMPs). All products, their deployment, and use within the clean room must be tested, operators must be trained, and the whole process verified and certified. The certification process is lengthy, time consuming, and costly in its own right. Typical cleaning products may not work in this application and we definitely need some sort of research/laboratory use exemption.

The only exceptions allowed are not automatic, and require approval of the Council. They are also only available based on a cost analysis (negative financial impact). The University absolutely requires exceptions for those facilities with certifications based on the products and practices in place at the date as of the date those certifications were issued.

Tradewell, Becky

From: Don Nelson [dnelson@wisc.edu]
Sent: Tuesday, January 26, 2010 4:36 PM
To: Tradewell, Becky
Subject: Fwd: Green Cleaning bill detail on GMP

Becky

Here are the sources of those standards. I hope this helps.

Sent from my iPhone

Begin forwarded message:

> **From:** "Murray, Hartley" <hmurray@bussvc.wisc.edu>
> **Date:** January 26, 2010 4:30:47 PM CST
> **To:** Don Nelson <dnelson@wisc.edu>
> **Cc:** "Voss, Lori" <lvoss@bussvc.wisc.edu>, "Miner, Don" <dminer@bussvc.wisc.edu>, "Hardiman, Mike" <mhardiman@bussvc.wisc.edu>, Ruth Anderson <randerson@uwsa.edu>, Grant Huber <ghuber@uwsa.edu>, KACKERBAUER@fpm.wisc.edu, jharrod@fpm.wisc.edu, paul.evans@housing.wisc.edu, "Bazzell, Darrell" <DBAZZELL@VC.WISC.EDU>
> **Subject: Green Cleaning bill detail on GMP**
>
> All:
> cGMPs are the FDA's regulations for producing therapeutics for human use as codified in 21 CFR (chapter 21 code of federal regulations) sections 210, 211, 600, 610, and 1271. The attached guidance document gives an overview of the cGMPs for early stage human clinical trials.
> Regards
> Hartley Murray, C.P.M.
> Purchasing Services,
> University of Wisconsin-Madison
> 21 N. Park St., Suite 6101
> Madison, WI. 53715-1218
> 608-262-4562
> 608-262-4467 (fax
> hmurray@bussvc.wisc.edu
> Visit our website at: http://www.bussvc.wisc.edu/purch/purch.html

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> **From:** Don Nelson [mailto:dnelson@wisc.edu]
> **Sent:** Tuesday, January 26, 2010 3:33 PM
> **To:** Don Nelson
> **Cc:** Voss, Lori; Miner, Don; Murray, Hartley; Hardiman, Mike; Ruth Anderson; Grant Huber; KACKERBAUER@fpm.wisc.edu; jharrod@fpm.wisc.edu; paul.evans@housing.wisc.edu; Bazzell, Darrell
> **Subject:** Re: Green Cleaning bill Update

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A--GENERAL

PART 58 GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

Subpart A--General Provisions

Sec. 58.1 Scope.

(a) This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 510, 512-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987; 64 FR 399, Jan. 5, 1999]

State of Wisconsin
2009 - 2010 LEGISLATURE

8:30 Wed

LRBa1384/1
RCT:...

ASSEMBLY AMENDMENT ,

TO ASSEMBLY SUBSTITUTE AMENDMENT 1,

TO 2009 ASSEMBLY BILL 578

At the locations indicated, amend the substitute amendment as follows:

1. Page 10, line 3: after that line insert:

"(cm) Rules promulgated under sub. (2) do not apply to the cleaning of a laboratory or other facility if the regulations of the federal food and drug administration requiring the use of good laboratory practices or current good manufacturing practices apply to the laboratory or other facility.".

(END)