2009 DRAFTING REQUEST

Assembly Amendment (AA-ASA1-AB578)

Received	d: 01/26/2010		Received By: chanaman								
Wanted:	As time perm	its	Identical to LRB:								
For: Gar	y Hebl (608)	266-7678	By/Representing: Tracy								
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Requester's email: Rep.Hebl@legis.wisconsin.gov											
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See response to #1 above; there does not appear to be a clear understanding of what resources within DHS or in support of the newly formed Council will be applied to the goal of determining standards for approved products and maintaining those standards over time as new research and products become available. State agencies would like to participate in that work and there does not appear to be any language addressing this concern.

5. There needs to be flexibility added to Chapter 16 bidding requirements to allow pilot testing to occur for these products. The UW-Madison (and many other agencies and campuses for that matter) is so large, that any pilot use of products will immediately push us into bidding thresholds (over \$5,000). Developing the best maintenance plan using these products is a very complex process. The true cost of cleaning products beyond the product cost includes: 1) Cost of labor as it relates to either the poor performance of a product or excelling performance. Testing of products is the only way to measure performance; 2) The amount of product used (not just recommended volumes by the manufacturer, but reality measures based on actual use); 3) ancillary costs, such as costs for application materials needed, and quantities used. We are asking to be relieved of bidding requirements for short term testing and pilot projects that would not exceed one year duration, without doing competitive bids. Without this flexibility, agencies will be unable to effectively find the products that truly work best for them in terms of cost and performance.

This should perhaps be the first concern listed. Chapter 16 is not impacted by the bill, and sets forth requirements for solicitation of state contracts. Ideally this legislation would waive bidding requirements under Ch. 16 in the short term for purchase and pilot testing of products covered by the legislation since there may not be 1) enough time $\overline{or 2}$ adequate competition within the market.

6. There are exceptions that we need to the bill: 1) Operations that require sterile environments such as medical facilities and "Clean Rooms" for research have a priority that the products and processes they use meet their objectives for a sterile environment; 2) some equipment that is in place by contract requires use of the equipment manufacturers' products. Existing contracts of this nature should be excepted until contracts expire. 3) in general, if there is not a product in the market-place that meets a performance need, there needs to be an exception.

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



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ASSEMBLY AMENDMENT,

TO ASSEMBLY SUBSTITUTE AMENDMENT 1, TO 2009 ASSEMBLY BILL 578

At the locations indicated, amend the substitute amendment as follows: 2 **1.** Page 4, line 5: after that line insert: 3 "Section 1e. 16.75 (6) (ag) of the statutes is created to read: 16.75 (6) (ag) Subsection (1) does not apply to a purchase that is made to comply 4 with rules promulgated under s. 254.565 (2) if the purchase is made to test the 5 6 performance of a product; to test the amount of a product needed; or to test materials for application of product, cleaning equipment, or instructions and if the amount purchased does not exceed the amount that would be required to test the product, materials, equipment, or instructions for a period of twelve months.". 9 10 (END)