

Questions (Batch #2) and Answers in response to RFI VA119-14-I-0101:

- 1) I have questions on MTR17 in the first section/MTR18 in the second section/MTR12 in the third section (only MTR17 is copied below).

Fluid handling capacity is  $\geq 20$  g/ 10cm<sup>2</sup>/24hrs: Reference: Must submit documentation referencing value using EN 13726 or Edana Method 442.1-99. (*Vendor must submit a certified document, which includes: 1. Testing method utilized 2. Name of laboratory utilized for testing 3. Testing results in g/10 sq. cm/24 hrs. [no other units are acceptable, conversions will not be performed by evaluators] 4. Name and signature of laboratory scientist/technician performing the test 5. Date testing was performed/completed* **\*Restatement of the value will be considered unacceptable.**)

**Question:** Is testing to BS EN 13726-1 acceptable?

**Government Response:** Yes

- 2) **Question:** Can you please explain why the measurement is in 10cm<sup>2</sup> rather than the standard of 100cm<sup>2</sup>? There are no dressing sizes that correspond to 10cm<sup>2</sup>.

**Government Responses:** This is the unit of measurement referenced on Surgical Materials Testing Laboratory (STML) data and is the unit of measurement found in clinical market research.

- 3) **Questions:** The following is referenced in all three sections: ***\*Restatement of the value will be considered unacceptable.*** Can you please advise what the “\*” is referencing? Can you please explain what is meant by “restatement of the value?”

**Government Response:** Only lab documented results will be accepted by the Wound Care Integrated Product Team (WCIPT). A restatement of the fluid-handling value on vendor letterhead will NOT be considered.

- 4) **Questions:** Can you please provide the published citation(s) for the values listed in these MTRs, i.e.  $\geq 20$  g/ 10cm<sup>2</sup>/24hrs and  $\geq 23$  g/ 10cm<sup>2</sup>/24hrs? If there is no published citation, can you please provide the rationale for these values?

**Government Response:** No. No market research was found for definite values. Values are based on published data from vendors. High fluid handling capacity in foam dressings is an essential component of efficacious use. Thus, WCIPT chose higher values consistent with this standard.