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Subject: **Docket Number 2004D-0343**
Submission of comments on
Draft Guidance for Industry and FDA Staff Hospital Bed System Dimensional Guidance to Reduce Entrapment

1) General comment: This draft Guidance represents an important step towards improved bed safety and reducing patient entrapment, which have been reported in countries around the world, including Canada and the United States. Health Canada believes this document will help address this widespread issue, but it must include test methods. Without these, manufacturers and users are free to measure bed system gaps in differing ways, and this will lead to marketplace confusion, with some products being labeled by different organizations as both compliant and non-compliant with the Guidance.

   If test methodology that is sound and recognized by all those (users, manufacturers, test houses, regulatory agencies) involved in the assessment of beds is incorporated into the Guidance and that the comments provided below are also considered and incorporated into the document, Health Canada believes the Guidance will be an excellent means to help reduce entrapments which has plagued this industry for many years.

2) Page 1: the first sentence mentions the Guidance provides recommendations for manufacturers. There is no mention of the Guidance's use for healthcare facilities until the end of the paragraph and in Appendix F. Consequently, healthcare facilities could be left with the impression, after reading the first sentence, that the Guidance applies only to manufacturers and stop reading at that point. The first sentence should indicate that the Guidance is a tool to be used by both manufacturers and facilities, to catch the attention of both immediately.

3) Page 3: “These entrapment events have occurred in openings between the bed rails, between the bed rail and mattress, under bed rails, between split rails, and between the bed rail and the head or foot boards.” It is not obvious from this sentence that this includes entrapments <u>within</u> bed rails; “openings between the bed rails” could be interpreted as openings between 2 separate and distinct rail assemblies. “Within the perimeter of the rail” is language used later in the Guidance; this wording could be used to be consistent.

4) Page 3: Reference to Health Canada should be as follows: “Health Canada’s Medical Devices Bureau”

5) Page 4: The following sentence: “Members of the HBSW are also developing procedures for measuring and assessing hospital bed systems and intend to make these available shortly.” begs the question what FDA will do with these procedures; will they be adopted by FDA as part of the Guidance, will they be published by HBSW without FDA acknowledging them, etc.? Where will they be made available? This should all be clarified.

6) Page 4: “products labeled as “powered hospital beds.”” should read as “products labeled as “electrically-operated hospital beds.””

7) Page 4: “The IEC standard is currently undergoing revision and will likely undergo significant change prior to its expected publication in 2006/2007.” should read as “The IEC standard is currently undergoing revision and will likely undergo significant change including possible inclusion of these other types of beds prior to its expected publication in 2006/2007.”

8) Page 5: Health Canada supports the view that stretchers should be included in the Guidance. Stretchers are becoming increasingly sophisticated, resulting in such devices often being used in place of beds. Additionally, in times of chronic bed shortages, constant supervision of someone placed in a stretcher is not guaranteed. Therefore, it is prudent to apply the Guidance’s entrapment reduction criteria to stretchers as well.

9) Page 7 Note: “NOTE: Bed systems using mattress overlays should comply with the dimensional guidance. The therapeutic benefit to the patient of a mattress overlay that has been applied to a noncompliant bed system should be assessed and should outweigh the risk of entrapment presented by use of such a system.”.

   Does the Guidance mean applied to a <u>compliant</u> or <u>non-compliant</u> bed system? Isn’t the concern that a mattress overlay that is added to a compliant bed could get it to go out of compliance and thus present a risk? And in such a case, you have to weigh the therapeutic benefit of the now non-compliant bed to determine whether the overlay should be used?

10) Request for Comments 1: Exclusions: Framed flotation therapy products and bed systems using powered air mattress replacements should not be exempted from the dimensional limits. The MAUDE database has several incidents of entrapment with these beds, many of which resulted in patient death[1]. It would be hard to argue in the case of these deaths that the benefits of these beds outweighed the risks. While the number of incidents, when compared to the total number of incidents for all types of beds may appear low, the number of these beds in use relative to all beds is also low. Consequently, the percentage of incidents for these specialty beds relative to the number of such beds in use may in fact be quite high. Health Canada is not convinced that the difficulties posed by making these beds compliant with the dimensional limits are insurmountable.

11) Page 8, HEAD: to be consistent with the description in NECK, this should state the "widest part of a small head"

12) Page 10, Table 2: The left column shows the body part. The right column is appropriately titled "Dimension" (of the body part) but its content inappropriately shows the requirements or recommendations for the gap, i.e. less than 60 mm, etc. The column should show the dimension of the body part, not the requirement, as the Guidance provides dimensional limits for the zone or gap, but not the body part.

13) Zone 1: "This takes into account any degree of play from loosened bars or rails which could increase the size of the space." should be reworded to "The test method should take into account any degree of play from loosened bars or rails which could increase the size of the space.". This comment applies to other Zones where the same sentence is used.

14) Zone 2: "This is a diagonal distance from the top of the compressed mattress to the bottom of the rail between rail supports." should be reworded to "This is a diagonal (shortest) distance from the top of the compressed mattress to the bottom of the rail between rail supports."

15) Zone 2: "Factors to consider are the mattress compressibility, lateral shift of the mattress or rail, and any degree of play from loosened rails." should be reworded to "Factors to consider are the mattress compressibility, lateral shift of the mattress or rail, and any degree of play from loosened rails or rail supports."

16) Zone 2: "It is thought that preventing the head from entering under the rail might prevent neck entrapment in this space.". This is certain, there is no doubt about it. If the head can't enter the space, the neck cannot.

17) Zone 2: "However, given the scenarios in the reports, some of these events may have occurred at the rail end, beyond the support (Zone 4). Incidents reported as neck entrapment between the rail supports might have occurred when the head entered under the rail first." should be reworded as follows: "However, given the scenarios in the reports, some of these events may have occurred at the rail end, beyond the

support (Zone 4). Incidents reported as neck entrapment between the rail supports might have been falsely assigned to between the rail supports and actually occurred when the ~~head~~ neck entered under the rail ~~first~~. at the rail's end"

18) Request for Comments: 2. More stringent dimensional limit of Zone 2: There is no need to make this requirement more stringent, however what is essential is that a well thought-out test method that accounts for mattress compressibility be developed and used. If such a method accounts for compressibility of the mattress under the weight of the patient, the 120 mm limit is appropriate. Some of the data in the retrospective study showed incidents having occurred with a gap of 76 mm as stated in the draft Guidance. However, as no head can fit in such a small space, the reported incident had to have happened at the end of the rail and not between the rail supports where a neck cannot get entrapped without first passage of the head. Recall that in the retrospective study, the manufacturers whom participated and provided data were asked to follow the following test procedure:

- "DIAGONAL: Push the mattress as far as it will go towards one side of the mattress deck. On the other side, have a person weighing a minimum of 150 lbs. lie on his/her side on the mattress, at the edge against the side rail. Measure the **maximum** space at an angle such that the measurement is taken from the closest lower inside corner of the side rail to the closest outside corner of the mattress when compressed by the person's weight; this measured space is where a person's head may get entrapment."

Thus, the method used accounted for mattress compressibility, and those manufacturers that reported small measurements at this zone, such as 76 mm, reported a measurement for an already compressed mattress. No head can fit in a space of only 76 mm, leading to the obvious conclusion that the reported incident had to have occurred at the end of the rail, with neck entrapment; as stated in the Guidance, the description of these incidents is often vague, with multiple possible interpretations of where (zone) the incident occurred.

While IEC may measure from the deck as opposed to the mattress, the IEC limit is the same as HBSW's and the draft FDA guidance. This is appropriate. What is key, is ensuring that mattress compressibility is factored into the measurement and that this space does not measurably increase with articulation (if it does, consideration should be given to testing at articulated positions as well, or at least those that seem to result in an increased gap). As the FDA Guidance does not at the present time incorporate test methodology, this is an area of concern. FDA is strongly encouraged to incorporate into its Guidance appropriate test methodology, for use by both manufacturers and users. This will allow users to evaluate the zone's gap for their beds as they age and the mattresses soften.

If future incorporation of test methods into the FDA guidance is in doubt or if the adequacy of these test methods is in doubt, FDA may wish to consider adopting a limit of 120 mm between the rail and mattress deck (like IEC), to eliminate all

uncertainty about mattress compressibility. Doing so will result in a safer bed system as the IEC requirement is more stringent since the mattress thickness is not considered in the IEC requirements. Manufacturers wishing to sell internationally must meet the IEC requirements before their products can be certified as meeting UL standards.

19) Zone 3: "This area is the distance between the inside surface of the rail and the top edge of the compressed mattress." Comment: it's not really the top edge of the mattress we are concerned about, but rather the side edge of the mattress.

20) Zone 3: the term "loosened rails" is used throughout the Guidance. This implies rails that were once sturdy or tight, that might have loosened with time and use. This is of course a concern and regularly happens. However, the term implies that rails were once sturdy, when in fact the construction technique and design of some rails may be that the rails were never sturdy to begin with. Perhaps it would be best to say "loose or loosened rails"?

21) Zone 3: There is an extraneous hyphen at the end of "This space may change as the head or foot sections of the bed are raised and lowered-." Also, it is highly unlikely that this space would disappear, or even markedly change with deck articulation. Perhaps this sentence was mistakenly carried over from Zone 2? What may change with articulation is the vertical position of the rail wrt to the mattress (however, only if the rails are fixed to the frame and not the deck), but the horizontal gap between the rail and side of the mattress should not change with articulation.

22) Zone 3: "HBSW and IEC recommend a dimension of less than 4 ¾ inches (120 mm) because it is believed the head enters the space before the neck.". This is evident; the neck cannot enter this space before the head does.

23) Zone 3: "If the incidents identified as possibly occurring in Zones 2, 3 or 4 actually occurred in Zone 3, many of them still might have occurred despite the HBSW recommended dimensional limit for that Zone, greater than 4 ¾ inches (120mm)." This is not necessarily an argument for making the limit for this zone less. There are 2 reasons for this:

1) As pointed out, the entrapment described in the incidents could have occurred at a number of zones, and due to its accessibility, Zone 4 and not Zone 3 was probably the most common zone of entrapment,

2) Manufacturers were asked, in the retrospective study, to "Push the mattress as far as it will go towards one side of the mattress deck. On the other side, measure the **maximum horizontal** distance between the side of the mattress and the inside surface of the rail.". The method used by them did not involve compression of the mattress. Therefore, the distance they measured could have been (and was) very small, but with a bit of compression, could have led to a much larger space. The fact that they measured a small space does not necessarily indicate that the Guidance's 120 mm

limit is inappropriate IF a good test methodology that simulates mattress compression is adopted.

As in the previous Zone 2, if future incorporation of test methods into the FDA guidance is in doubt or if the adequacy of these test methods is in doubt, FDA may wish to consider reducing the dimensional limit from 120 mm to something smaller to eliminate all uncertainty about mattress compressibility. However, the draft revision to the IEC is currently proposing 120 mm for this zone (using compression of the mattress), and an effort should be made to remain harmonized with international requirements.

24) Request for Comments: 3. More stringent dimensional limit at Zone 3. See above point 23) which counters the first bullet in the draft Guidance's background information on this issue. Also note that if the mattress was changed by the user to a "non-recommended" mattress size (background bullet #2), this situation would likely lead to a worse situation than the one measured by the manufacturers participating in the retrospective study; thus this would not be an argument to tighten the dimensional limit as this situation should be easily identified in the testing methods. As for background bullet #4, the space should not change much with articulation, as described above, unless the rail does not articulate with the deck and mattress and that cone used in the test method ends up resting on a different part of the rail that could cause the cone to partially roll away from the mattress.

25) Zone 4: This, or any other Zone in the Guidance does not take into account the possibility that the space between the mattress and the rail could start quite small at the very end of the rail (thus meeting Zone 4 limits), then increase if the rail's underside curves upward before reaching the first rail support. This enlarged space, after the initial small Zone 4 opening could present an area large enough for the head to get entrapped in. The head would be caught between 4 surfaces, names the rail support on one side, the small opening at the end of the rail on the other side, the rail above, and the mattress below. This space would be similar to the Zone 2 area. The draft IEC standard is presently addressing this issue, and so should the FDA Guidance; in IEC it is defined as "Partially enclosed opening defined by the lowest point of a SIDE RAIL, the adjacent side rail support, and MATTRESS SUPPORT PLATFORM, to the outside of the rail supports" with a dimensional limit of 120 mm when the cone end of the tool is brought to bear on the opening of interest and a 50N force is applied to the end of the cylinder in the most disadvantageous direction.

26) Zone 4: "Consistent with HBSW's recommendations, FDA is recommending a diagonal dimensional limit of less than 2 1/3 inches (60 mm) from the inside bottom edge of the rail at the end of the rail, to the top of a compressed mattress, and greater than a 60 degree angle at the end of the rail for Zone 4." There was much discussion at IEC about where to measure the angle that is meant to be greater than 60 degrees. An adequate solution to this was to specify that the angle between the rail and the mattress deck should be measured at the range of the mattress height defined by the manufacturer ± 2

cm. The same should be applied to the FDA Guidance where it could be stated that the angle between the mattress (compressed) and the rail be greater than 60 degrees at a range of ± 2 cm from the surface of the compressed mattress.

27) Zones 5-7: "Additionally, IEC intends to set dimensional limits for areas comparable to HBSW's zones 1-6 in IEC's proposed international standard for hospital beds**."** This is incorrect. IEC <u>currently</u> sets limits for Zones 1, 2, 4, 5, 6 only. It is important to say so since the revised IEC standard will not be published in final form for probably another 2 years and that we do not want readers of the FDA Guidance to think that until then, IEC does not address Zones 5 and 6.

28) Zone 5: There is no mention of the need for these limits to be maintained for intermediate side rail positions. It only states "These spaces may vary in size and angle when the hospital bed system is articulated through the various ranges of motion."

29) <u>Request for Comments: 4. Recommendation for a dimensional limit for Zone 5</u>. It is wise to address Zone 5 in the Guidance since the revised IEC standard will not be published for another 2 years and the current version of the standard has limits inconsistent (e.g. 235 mm) with current thinking on this issue. The 60 mm and 318 mm limits set out in the FDA guidance are consistent with the draft of the revision to the IEC standard. The 60 degree limit mentioned in the FDA Guidance is not included in the revision to IEC at this time and should have been. To be consistent with Zone 4, FDA should probably specify the location where the angle between the split rails must be greater than 60 degrees.

30) Zone 6 intro: "Zone 6 is the space between the end of the rail and the side edge of the headboard or footboard. The space at its narrowest point should be small enough to prevent neck entrapment or large enough to prevent chest entrapment." This is contradicted by a later statement that says "Therefore, FDA believes that a dimensional limit of less than 2 1/3 inches (60 mm) and an angle of greater than 60 degrees between the end of the upper (head) side rail and the side edge of the headboard for Zone 6 would reduce entrapment.". The latter statement is correct, the former is not since the former makes no distinction between limits at the head end of the bed and limits at the foot end of the bed.

31) Zone 6: as in zone 5, there is no mention of intermediate rail positions and the effect of these on the gaps.

32) Zone 6: This sentence is confusing: "Additionally, FDA believes a dimensional limit at the foot end (of what? The bed?, the rail?) of either less than 2 1/3 inches (60 mm) and (use "with" instead of "and"?) an angle of greater than 60 degrees, or greater than 12 ½ inches (318 mm), between the end of the lower (foot) side rail and the side edge of the footboard would reduce entrapment in this Zone"

33) Request for Comments: 5. Recommendation for dimensional limits for Zone 6. It is our belief that limiting the gap between the head board and rail to 60 mm (with 60 degree limit as well) is appropriate. As well, doing so at the footboard is also appropriate but since the space at the foot of the bed may be used for egress / ingress by patients, it is appropriate to alternatively allow a large gap of 318 mm to allow for egress / ingress.

34) Request for Comments: 6. Recommendation for dimensional limits for Zone 7. Health Canada is not aware of reported incidents in Canada at this Zone; that is not to say however that none have ever occurred, they may just be unreported or the incident description too vague to be identified as a Zone 7 entrapment. In any case, the possibility for entrapment at that location exists and Health Canada believes it is wise and prudent to recommend a limit. This would be consistent with the attempt in the other parts of the Guidance to limit entrapment at other locations in the bed system. It does not make sense to limit gap sizes at all other locations and leave a wide gap at Zone 7.

As far as the recommended dimensional limit is concerned, 120 mm would initially appear to be an appropriate limit as it would prevent head entrapment (as in the case of Zone 3). However, since this gap will increase as the deck articulates (the head or foot boards do not move with the end of the mattress deck), it would be wise to reduce this limit to below 120 mm. To avoid adding a new dimension in the Guidance, 60 mm would be an appropriate choice. Manufacturers should be encouraged to make the gap as small as possible, leaving only enough room for unimpeded articulation and installation of bed linen. The test tools being considered by HBSW do not allow for compressive forces being applied to the 60 mm cylinder part of the tool. The 120 mm part of the tool allows for compressive force to be applied, due to the weight of the cone. Thus 2 tests could be considered for this zone, and a bed would need to pass both. One would be where the distance between the board and end of the mattress is measured as being less than 60 mm, the other being where the cone is placed in the space much in the same way as the test method HBSW is considering for Zone 3, and the cone must not sink by more than ½ its diameter. This last test would ensure that a soft mattress that initially appears to meet the 60 mm diameter would not easily “open up” under compression.

One issue that needs to be considered though is whether requiring a limit on the space at the footboard will eliminate the possibility of the foot drop feature on some beds. The use of this feature may require or result in an increase of the gap between the board and mattress end. The clinical benefits of this feature need to be weighed against the potential for entrapment, which statistically appears to be remote.

35) Request for Comments: 7. Articulated bed positions Health Canada agrees that patient care can occur in various deck articulations and that as such, testing for entrapment and specifying dimensional limits for only the flat deck position is an oversimplification which may result in undetermined hazards (gaps) at articulated deck positions. Health Canada, like FDA, has limited information about the position of the deck when incidents are reported. However, Health Canada has received

concerns from users about the size of gaps between split rails when both rails on one side of the bed are in differing positions, such as intermediate and fully raised. Thus, it seems to be recognized among users that articulation can lead to problems.

Health Canada believes that there is certainly potential for entrapment at articulated positions as beds are often used in articulated positions and that to assume entrapment incidents occur only in the flat deck position is inappropriate and unreasonable.

With respect to the background information in the Guidance on this point, the size of the gap at Zone 3 is likely to be unchanged when measured to the vertical plane of the side rail. However, it is recognized that depending on where the cone in this test will lie with respect to the rail, it may move in or away from the mattress if the height of the mattress relative to the rail changes (since the cone may either rest directly against a side rail bar, or between 2 bars for example).

36) <u>Request for Comments: 8. Application of this guidance to all health care settings</u>
The Guidance should definitely apply to all health care settings. No health care setting is immune to entrapment issues, incident statistics support this, and while it can be argued that some settings have continuous monitoring that would prevent injury to result from entrapment, accidents happen quickly and there is no guarantee that a bed used in a highly monitored patient care area will not some day be used in an area with limited or no monitoring at all.

37) Table 3: This table needs to emphasize the point, as discussed above, that the exact entrapment location could often not be determined from the incident descriptions. As discussed above, a gap as small as 76 mm at Zone 2 was measured by the manufacturers participating in the retrospective study. However, no head can fit such a small gap, leading to the conclusion that the entrapment had to have occurred elsewhere, such as at Zone 4. Without this explanation, Table 3 can lead readers to conclude that the suggested dimensional limits are too lax.

38) Table 3: Above comments apply to Table 3's last 2 columns.

Notes:

1: To Dec 31, 2002. MAUDE entrapment incidents are as follows:
Flotation Therapy - Report numbers: 57085, 1045510-1997-00001, 1045510-1997-00004, 91831, 1045510-1997-00006, 176946, 1045510-1998-00010, 268087, 1824206-2000-00007, 1824206-2000-00015).