

**FDA Guidance Document:
Hospital Bed System Dimensional and Assessment
Guidance to Reduce Entrapment**

A Message to ASHE and ASHES Members:

On March 10, 2006 the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) issued the document: *Guidance for Industry and FDA Staff – Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*. The document includes nonbinding recommendations intended to reduce life-threatening entrapments associated with hospital bed systems. It characterizes the body parts at risk for entrapment, identifies the locations of hospital bed openings that are potential entrapment areas, and recommends dimensional criteria for these devices. The Introduction states that “Manufacturers may use this guidance when designing new beds to ensure compliance with applicable FDA regulations...and to assist in ensuring that their devices are safe when used as labeled.” The document does not limit its scope to new beds only; as it states: “In addition, the recommendations in this guidance may be useful in evaluating and reducing the entrapment risk presented by hospital beds that have been placed in use, also known as legacy beds.”

The FDA *Dimensional Guidance* document is one more piece in the evolving body of knowledge on bed rail entrapment. In September 2002, the Joint Commission (JCAHO) issued Sentinel Event Alert #27 – *Bed Rail-Related Entrapment Deaths*. The alert reported that over a ten-year period JCAHO had received reports of seven deaths or injuries related to bed rails; three of these reports were from hospitals. This alert identified root causes from these reports and offered risk reduction strategies. As a result of this alert many hospitals have examined the issue of bed rail entrapment within their patient safety or risk management programs focusing on training of clinical staff to assess patients for the risk of entrapment and, for those patients vulnerable to entrapment, implementing appropriate changes to the beds using bed rail netting, clear padding, etc. to close gaps and reduce the risk of entrapment. Although JCAHO recommended re-evaluation of beds for entrapment potential, no guidance existed at that time regarding gap measurement or appropriate sizing of mattresses. With the release of the FDA *Dimensional Guidance* document, which has now established critical dimensions and a measurement procedure, healthcare providers’ focus on entrapment prevention may now inappropriately shift to proactive measurement of hospitals beds.

The FDA document does not suggest that measurement of each bed is necessary, rather a representative bed from each type of bed system, which includes the bed frame, side rails and mattress. However many hospitals may not be able to easily identify a limited number of bed systems given the interchange of components, particularly mattresses.

FDA points out that: “Not all patients are at risk for entrapment, and not all hospital beds pose a risk of entrapment” and that “Evaluating the dimensional limits of the gaps in hospital beds is one component of an overall assessment and mitigation strategy to reduce entrapment.” What it does not say is that new beds, manufactured in accordance to FDA *Dimensional Guidance*, are “safe” i.e. eliminate the potential for entrapment. FDA introduces the term “hospital bed system” to describe the bed frame and its components including the bed side rails, head and foot board, any accessories, and most notably – the mattress. To deem a “hospital bed system” as “safe” requires testing all of these components as a matched set.

In order to build a system based on bed measurement, rather than patient assessment, it is important to understand that any change in or replacement of a mattress or other component will require retesting of the entire bed system. This will necessitate a system of labeling, tracking, and recordkeeping to assure that a hospital bed system that was tested and deemed “safe” continues to have all of the same components intact or requires retesting before use - including any newly purchased beds designed to be compliant with FDA’s *Dimensional Guidance* document. Not to develop such a real-time tracking and recordkeeping system can lead to a false sense of security, believing a bed system is “safe” based on testing alone.

However, since the JCAHO Alert, hospitals have effectively managed the risk of entrapment without measuring beds. The policies and procedures that they developed in response to the alert, using a risk assessment process, should not be replaced by or rely primarily on bed measurement to protect the patient. **ASHE/ASHES members are encouraged work with** their patient safety committee to review the organizations’ policy and procedures regarding bed rail entrapment and determine if revisions are necessary. Many hospitals have standing task forces on patient restraint and prevention of patient falls that may also be addressing entrapment risks on an ongoing basis. In addressing entrapment, task force members should include nursing, risk management, facilities management, materials management, environmental services, physical therapy, infection control, and administration. Points for the task force to consider are:

- Creation of a purchasing specification requiring all new hospital beds meet the dimensional criteria of the FDA *Dimensional Guidance* document.
- Determination that clinical procedures are in place to assess patients for vulnerability to entrapment.
- Provision of current mitigation techniques (such as bumpers, pads, netting, etc) that are effective and available for all types of beds that may used for the care of patients vulnerable to entrapment.
- Reference materials to assist in completing the risk assessment:
 - JCAHO Sentinel Event Alert #27 – *Bed Rail-Related Entrapment Deaths* available at http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_27.htm
 - *Guidance for Industry and FDA Staff – Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment* available at <http://www.fda.gov/cdrh/beds/guidance/1537.html>
 - *Clinical Guidance for the Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities, and Home Care Settings*, available at: http://www.ute.kendal.org/learning/documents/clinicalguidance_SideRails.pdf

Of these documents, the FDA document (*Dimensional Guidance*) is the only one that has been or will be published in the *Federal Register*¹. Due to the lack of another standard mandating bed measurement, this guidance may be presented in court as a de facto standard and may also be adopted by states as law.

ASHE/ASHES believes that measuring beds for the potential of bed rail entrapment will be a labor-intensive process with little or no actual gain in patient safety and may inappropriately divert attention from other high-risk issues diluting already scarce patient safety resources. Clinical evaluation identifying a vulnerable patient should result in appropriate mitigation strategies to provide a safe bed environment.

To better understand the issue of bed-rail entrapment and how this draft guidance document will affect your healthcare organization, please refer to the attached discussion questions and the section: A Common Sense Approach to this issue (updated from the November 2004 ASHE Regulatory Advisory urging ASHE members to comment on the draft *Dimensional Guidance*). For questions or comments contact Dale Woodin at dwoodin@aha.org or 312-422-3812

¹ In September, 2004, the FDA held a 90-day comments period for the draft document. ASHE sent a Regulatory Advisory to all members urging them to provide comments to the FDA. In addition, ASHE and ASHES submitted comments to the FDA disagreeing with the intent to enact new standards on existing equipment and encouraging the FDA to clearly identify the critical role of clinical assessment to identify patients that may be vulnerable to entrapment.



Assessing the Risk of Bed Rail-Related Entrapment: Discussion Q&A for a **Common Sense Approach**

1. Won't measuring existing beds improve safety?

A safe environment for patient care is a fundamental patient right, and preventing harm from reaching any patient, is the duty of all hospitals. A single patient death from bed rail related entrapment is one death too many. Greater awareness to this safety risk is needed, and ASHE applauds the work of the Joint Commission (JCAHO), the Veterans Administration (VA), and others in helping to alert and educate the healthcare community to this tragic issue. But routine usage of hospital beds does not typically pose a patient safety risk. In fact, the statistical occurrence of bed rail entrapments per hospital admission² has already achieved six-sigma³; considered the “gold standard” for performance improvement within the safety community. There continues to be a need for improvement – but that improvement will not be achieved through measurement of existing beds to assess their gaps. **Measuring each bed for the potential of bed rail entrapment will be a labor-intensive process with little or no actual gain in patient safety and may inappropriately divert attention from other high-risk issues diluting already scarce patient safety resources.**

The goal of measuring a bed to determine if it is “safe” from entrapment risk is neither practical nor realistic. If that were true; a hospital that purchased all new beds, which met the FDA *Dimensional Guidance* criteria, would be completely “safe” from entrapment risk. But if the mattress is shifted or compressed, a gap may be created which could result in an entrapment in a bed that was determined to be “safe”. The reality is hospitals typically do not replace all of their beds in a single purchase order and therefore have different models and styles of beds purchased at different times throughout the facility. Measuring each of these beds for compliance to the *Dimensional Guidance* will be a difficult task to accomplish, but due to the frequent movement of beds from location to location, tracking their location post-testing will be even more difficult.

2. Why not simply retrofit all beds that fail the *Dimensional Guidance* criteria?

The field trials leading up to the release of the *Dimensional Guidance* showed that most existing (legacy) beds will fail one or more part of the measurement procedure. This is not surprising as they were not designed to this criteria – it did not exist when many of these beds were designed and manufactured. Assuming that most legacy beds will fail the measurement test – should they simply be altered with retrofit kits supplied by the original manufacturer of the bed? Before taking this course of action, ASHE members should consider the following points

- Retrofit kits may not be available from the original bed manufacturer for each type and model of bed still in service. If a third party kit is available for that bed model, it

² According to the FDA, in the 21-year period between 1985 and 2006, there have been 691 entrapment reports. This roughly equates to 1 entrapment per every 3.4 million admissions.

³ Six-sigma is a quality measurement program that strives for elimination of defects or errors. Commonly used in clinical quality assurance programs, its name is derived from 6 standard deviations from the mean.

should be carefully evaluated to assure it does not inadvertently introduce a new set of risks by altering the original design of the bed

- Retrofit kits, regardless if from the original manufacture or third party, must be designed as to not promote the proliferation of micro-organisms. Each kit should be examined to determine if the bumpers, wedges, netting, etc. can be cleaned and disinfected without their removal from the bed. If they can be cleaned without removal, it is likely that any crease, fold, joint, or other variation in the bed surface will increase the time spent by environmental services professionals in cleaning and properly disinfecting the patient room. If they must be removed, additional training will be required to properly remove, clean, disinfect, dry, and then exactly reinstall the various components to the bed.
- Because a product recall is not part of the FDA actions on entrapment, hospitals will need to purchase and install these kits for each affected bed.

2. Can the risk of entrapment be managed through clinical assessment and mitigation?

In May 2003 the Hospital Bed Safety Workgroup of the FDA released the document *Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities, and Home Care Settings*⁴. This FDA guidance document provides a detailed look at many of the issues raised in the September 2002 JCAHO Sentinel Event Alert #27 titled *Bed Rail-Related Entrapment Deaths*. This alert identified root causes, risk reduction strategies and provided recommended precautions to prevent entrapment death. Taken together, these documents compel healthcare organizations to:

1. First - Address the issue of assessing patients for potential fall and entrapment hazards and then;
2. Appropriately match equipment with the patient needs.

These steps are consistent with other strategies to manage the patient risk through proper equipment selection such as assessing the potential risk of pressure ulcers and then determining the proper equipment to meet clinical needs, such as an air fluidized bed. In this case the appropriate equipment may be the existing patient bed with a retrofit kit applied to the bed based the outcome of the patient assessment. This would reduce the use of retrofit kits to an “as-needed” supply on hand for application to beds used in the care of patients assessed to be vulnerable to entrapment. As an alternative, entrapment “safe” beds may be kept on hand for application when needed (again, similar to air fluidized beds).

4. Will the FDA *Dimensional Guidance* document lead to proactive testing of all hospital beds?

While the FDA is clear on its position that the *Dimensional Guidance* Document is guidance and not a regulation or an enforceable document, there is the potential for these requirements to be mandated by other entities and held in court to be a de facto standard. Additionally, at least one state has already expressed interest in establishing regulations based on the FDA document. ASHE members should remain vigilant in monitoring activity proposed state legislation or revision of agency rules to require retroactive measurement of beds.

⁴ www.fda.gov/cdrh/beds/

During the early pilot testing of a cone-and-cylinder tool, its size and weight based to simulate a small individual, 351 existing hospital beds were measured by a two-person crew at a rate of 23 beds per day. The assessment consumed nearly 245 man-hours and resulted in workers compensation injuries to 3 of the 4 workers assigned to measure beds. And, nearly all of the bed systems failed the measurement standards. Since that early prototype, the tools have been refined and retesting conducted. The tools are available for purchase from a private source but the real cost is in the labor to measure all types of beds and bed/mattress combinations.

A Common Sense Approach

Healthcare organizations should first consider the patient population that is served and their risk for bed rail entrapment, and then, if appropriate, focus on the bed rail dimensions to determine if mitigation is needed. Bypassing the patient assessment and simply focusing on the measurement of bed rail gaps will lead organizations directly into a solution and miss the critical first step of clinical assessment. Assessing the needs of the patient and, if indicated, re-evaluating the bed for entrapment potential, is a realistic way to manage this risk.

If your facility utilizes beds that were not specifically manufactured to the new criteria in the FDA *Dimensional Guidance* document, it is highly likely they will fail at least one of the steps within the measurement procedure. If that is true, than measuring the bed will only verify what you already suspect leading to a solution of mitigating the entrapment risk through use of a retrofit kit. Under the three step scenario suggested in the FDA document (patient assessment, bed measurement, and risk mitigation) the second step of bed measurement becomes an unnecessary extra step if the strategy is refined to patient assessment and than risk mitigation. This alternative strategy no longer relies on the bed measurement as a factor in determining the need for risk mitigation. Rather it distills down to a concept of:

If the patient is at risk, go right to risk mitigation.

This alternate strategy may offer a more reliable and quicker path to assuring that the patients' entrapment vulnerability is effectively addressed then proactively testing each bed or mitigating based on a beds failure when tested.

With a multitude of types of beds, and bed/mattress combinations, in each healthcare facility, testing all beds at one time is neither an effective solution nor proper use of resources. Conducting a periodic sample of your hospital beds to verify that they are in good repair and the mattresses properly fit the bed is a good starting point toward assuring that your hospital beds perform their designed patient care function. In addition, work with your patient safety committee and/or risk manager to identify your support role in assuring that proper equipment is available for patients identified as "at risk" for bed rail entrapment.

(NOTE – this discussion is updated from ASHE's November 2004 Regulatory Alert regarding the call for comments on the FDA draft *Dimensional Guidance* document)