
A Guide for Modifying Bed Systems and Using Accessories to Reduce the Risk of Entrapment

June 21, 2006



Developed by the
Hospital Bed Safety Workgroup

Table of Contents

Preface.....	ii
Introduction.....	1
Step 1: Assign Responsibility	2
Step 2: Determine High Risk Clinical Units, if appropriate	2
Step 3: Inventory Bed Systems	2
Step 4: Evaluate Bed Systems for Conformance to Bed System Entrapment Dimensional Guidance	3
Step 5: Initiate Corrective Actions.....	3
Step 6: Guidance for Purchasing Beds.....	5
Step 7: Implement Quality Monitoring.....	6
Attachment A: Algorithm for Making Decisions about Legacy Hospital Beds	7
Attachment B: Sample Format for Bed System Inventory.....	8
Attachment C: Summary of Seven Bed System Entrapment Zones, Recommended Dimensional Criteria, Hazard Score, and Possible Corrective Strategies.....	9
Attachment D: Accessories to Mitigate Entrapment Areas.....	10
Attachment E: Sample Monitoring Form for a Facility	11
Attachment F: Glossary	17
Attachment G: Selected References on Bed rail Reduction and Falls Prevention	18

In April 1999, the Food and Drug Administration (FDA) in partnership with representatives from the hospital bed industry, national healthcare organizations, patient advocacy groups and other federal agencies formed the Hospital Bed Safety Workgroup. The workgroup's goal is to improve the safety of hospital beds for patients in all health care settings who are most vulnerable to the risk of entrapment. The workgroup developed additional resources including dimensional guidelines, measurement tools, and educational materials to assist manufacturers, caregivers and consumers.

This Guide for Modifying Bed Systems is provided for discussion and educational purposes only and should not be used or in any way relied upon without consultation with and supervision of a qualified practitioner based on the case history and medical condition of a particular patient. The Hospital Bed Safety Workgroup, their heirs, executors, administrators, successors, and assigns hereby disclaim any and all liability for damages of whatever kind resulting from the use, negligent or otherwise, of this guide.

The contents of this publication may be reproduced without permission. Credit to the Hospital Bed Safety Workgroup as the source is appreciated but not required.

For information about the Hospital Bed Safety Workgroup, see the FDA's website at <http://www.fda.gov/cdrh/beds/>

A GUIDE FOR MODIFYING BED SYSTEMS AND USING ACCESSORIES TO REDUCE THE RISK OF ENTRAPMENT

Introduction

Entrapment is defined as an event in which a patient is caught, trapped or entangled in the spaces in or about the bed rail, mattress or hospital bed frame. Entrapment can result in serious injury or death. Solving the problem of patient chest, head or neck entrapment between bed frames, bed rails and mattresses is complex and should include conformance with the dimensional criteria for bed systems, quality improvement efforts, and patient, staff and family education. The purpose of this document is to assist in the reduction of risk for entrapment in existing (or “legacy”) hospital bed systems. A bed system is defined as a bed frame, mattress, bed rails, as well as other accessories that are compatible with each other.¹

This document is targeted for individuals in hospitals, nursing homes, home health, health care organizations, distributors of medical equipment and others who are responsible for implementing hospital bed safety programs. It focuses on modifying bed systems and using add-on or replacement equipment and accessories to reduce the openings in existing bed systems that can cause entrapment. Any modification is intended to be used in conjunction with a clinical patient assessment prior to an intervention. This document is intended to be a companion to the “Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings Clinical Guidance” (HBSW, 2003) which provides a uniform set of recommendations for caregivers in hospitals, long term care facilities and home care settings to use when assessing their patients’ need for, and possible use of, bed rails. The document is also a companion to the Food and Drug Administration’s (FDA) “Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment” (FDA, 2006) which provides dimensional limits and test methods for measuring gaps in hospital beds.

The guide that follows is intended to assist caregivers in making decisions about the care for their patients. Its components are not intended to serve as clinical standards or requirements for care. They are not intended to serve as applicable federal, state or local regulations or guidelines governing care in respective settings. Likewise the recommendations should not be interpreted as the best or only options, professional standards of care, or legal protection for the users.

The Mitigation Guide, along with Clinical Guidance and FDA guidance can be used as part of a facility’s bed safety program for beds in all healthcare settings. The HBSW recognizes that a hospital bed system that is initially or primarily intended for a particular care setting may be modified or moved to other care settings as part of routine equipment replacement. Therefore when evaluating the bed for patient entrapment within a risk management framework, manufacturers, suppliers and caregivers need to consider the diversity of healthcare settings recognizing the potential for the care setting or intended use of the bed to change over time. For a complete discussion of exempt products refer to pages 8-9 of the FDA Guidance, “Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment” (FDA, 2006).

¹ It is advised to check with the manufacturer for compatibility of bed system components.

To reduce the risk of patient entrapment in hospital bed systems, the HBSW suggests that the work of a hospital bed safety program should include the following steps to modify openings within existing hospital bed systems. (See **Attachment A** for algorithm):

Step 1:Assign Responsibility

Establish an interdisciplinary group that will accept responsibility for measuring existing bed systems and taking corrective actions when indicated. Membership can include representatives from engineering, nursing (including front-line staff), medicine, physical/occupational therapy, housekeeping, and quality management. To keep the number of persons who measure bed systems to a minimum and to maintain reliability of measurement, the responsible team could be a function of a quality improvement or a safety committee.

Step 2:Determine High Risk Clinical Units, if appropriate

If a facility has multiple clinical units serving different patient populations, determining clinical units that have patients who are high risk for entrapment will help to direct priorities for bed replacements and corrective strategies. High risk units are defined by a combination of patient, environment and monitoring factors.

- Risk factors related to patient characteristics include increasing age, cognitive impairment, functional dependency, and small body frame. Other contributing factors may include weakness, communication impairment, spasticity, or traumatic brain injury. Generally, the more risk factors present the greater the risk.
- Risk factors related to the physical environment include rooms with low visibility of the patients, patients who are in rooms not proximal to a nurses station, or configurations that include private rooms rather than open wards, large wards with long hallways, and bed systems that have unsafe openings or gaps, including incompatible rail/mattress/frame combinations, and/or accessories attached to the bed.
- Risk factors related to patient monitoring include low staffing levels, less staffing at night, care delivery processes that do not anticipate basic patient care needs such as toileting, feeding, and pain management, staff that has limited familiarity with the patients, staff working in an area with low visibility of patients, and limited use of technology such as cameras and bed exit alarms.

An evaluation of these risk factors, combined with existing quality improvement data, will assist in defining high risk units. Typically, residents in long term care units have the highest level of risk, followed by patients in medical surgical units.

Step 3:Inventory Bed Systems

The next step in assessing risk for entrapment in hospital beds is a systematic assessment of the type of bed systems used at a facility. An inventory of beds-in-use by unit, make and model will assist in identifying the need for replacement and specific corrective actions. Purchasing departments may have records of this information. If not, then an inventory can be developed through direct observation of all beds in a facility, starting with suspected highest risk units (See **Attachment B** for sample format). If make and model are not identified, an identification or a numbering system may need to be developed.

Step 4: Evaluate Bed Systems for Conformance to FDA's Bed System Entrapment Dimensional Guidance

Refer to FDA's Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment for information on how to measure and evaluate beds. Also see Appendix B in FDA Guidance to obtain information about obtaining the bed measurement tool and instructional video.

Based on an ergonomic evaluation of using a 15 pound test tool to evaluate a bed system, the most reasonable approach to protect against injury to the tool user is to limit its use to no more than 8 beds a day (at the rate of 4 per hour) per user. Any more frequent or prolonged use of the tool, such as in having one team measure 32 beds in 8 hours, may lead to work-related musculoskeletal injuries, followed by work absence for recovery. Using the WISHA Checklist, Work Related Musculoskeletal Injuries from Washington State, the limit for a caution job is lifting more than 10 pounds, more than 2 times a minute, for more than 2 hours. With a worst case scenario of 2 lifts a minute of a 15 pound device (30 measurements in 15 minutes), the evaluator is at the caution zone. Other suggestions are: (1) Have a height adjustable table to transport the tool to eliminate the lifting from the floor to the bed level and back to the floor. (2) Transport the measurement tool using a case on wheels with a handle that is long enough for comfortable use. (3) Make sure the height of the bed is elevated during the measurement procedure. Also, infection control procedures should be used to avoid cross-contamination of substances among beds.

Step 5: Initiate Corrective Actions

The corrective actions are based on: 1) the recommended dimensional criteria for four entrapment zones, 2) an analysis of risk by entrapment zone and 3) the use of bed accessories for each zone. Refer to **Attachment C** for a summary of the seven entrapment zones, risk and possible use of accessories. The use of any mitigation strategy or accessory should not increase the risk of other injury to patients or the health care provider.

While recognizing that there are seven potential entrapment zones, the HBSW chose to focus on the four entrapment zones that account for the majority of injuries and deaths from entrapments. Based on a review of FDA reported entrapment adverse events, zones 1, 2, 3, and 4 accounted for 80% of entrapment reports. Focusing on these high risk areas allows facilities to prioritize strategies for mitigating risks and for committing resources to mitigate risks. Test methods were developed for zones 1, 2, 3, 4.

Zone Specific Corrective Actions Suggestions

- Contact manufacturers, supply them with the inventory list of bed models and ask what equipment, accessories, adjustments or retrofits are available to correct entrapment in **Zone 1, the large opening within the rail**. If retrofit kits are not available, follow the manufacturers' recommendations to replace the bed rail with one that meets the recommended dimensions, or consider covering the rail with see-through covers. These are available from medical supply companies in a variety of types including clear plastics and netting. See through rail covers will close the openings in entrapment **Zones 1 and 5**,² and still permit the patient to see out and for staff to see the patient.

Application of manufacturer retrofits or bed rail replacement may reduce the risk of entrapment at **Zone 1**.

See through rail covers will close the openings in entrapment **Zones 1 and 5**, and still permit the patient to see out and for staff to see the patient.

- If **Zones 2, 3, and 4** do not meet the dimensional criteria, **and** Zone 7 is large², replace the mattress with one of a length, width and depth that closes the openings to meet the dimensional criteria. If the facility has multiple bed frames and multiple mattresses, consider color-coding beds and mattresses to easily match them. Alternately, use a “stuffer” to fill in the opening at Zones 4 and 7. Tighten loose rails.
- Although pressure reduction therapeutic products are excluded from FDA's dimensional Guidance except for Zone 1, air and water mattresses may pose unique issues if the mattress edges collapse under the weight of a person, pushing the individual into the rail and potentially increasing risk of entrapment in or around the rail or suffocation if the face is pushed against a mattress without air flow (Miles, 2002). When a mattress overlay is used, according to the FDA Guidance document, FDA recommends that it be used on a bed system that meets dimensional limits. FDA recommends that steps be taken to assess the therapeutic benefit to the patient when applying a mattress overlay to a bed system that does not meet the recommended dimensional limits. When using overlays, evaluate which of the available bed frames is most compatible with the mattress, and confer with the manufacturer to obtain their recommendations. When using pressure reduction products, the clinical benefit should outweigh the risk of entrapment presented by use of such systems.

Properly fitting mattresses taking into consideration the length, width, depth, compressibility, and characteristics of mattress surfaces will help to reduce openings in entrapment zones **2, 3 4, and 7**.²

² According to the FDA Guidance, FDA is recommending dimensional limits for zones 1 through 4 at this time because we believe the majority of the entrapments reported to FDA have occurred in these zones. FDA based these recommended limits upon the body parts entrapped in these individual zones identified through adverse event reports and entrapment scenarios described in the reports. For dimensional limits of Zones 1-4, refer to “Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment - Guidance for Industry and FDA Staff”. Dimensional limits for Zones 5-7 have not yet been specified.

- Consider lowering or removing bed rails, or fixing the bed rails in the lowest position when possible. Evaluate the use of full length and older rails and replace with newer shorter assist rails. Assist rails must be evaluated for the same risk as a side rail. These changes would need to be consistent with clinical needs, local practice patterns, and manufacturers' instruction for use.³ You may need to contact manufacturers for current instructions for use. Be aware that removing bed rails with bed controls and nurse controls could void the manufacturer's warranty. Refer to the "Clinical Guidance For The Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities and Home Care Settings Clinical Guidance Document" for details on how to safely reduce rail use through the use of clinical assessment and the use of alternatives.
- Bed rails should not be lowered or removed unless appropriate assessment and alternatives are implemented. The clinical guidance recommends that the process of reducing and/or eliminating the existing use of bed rails should be undertaken incrementally using an individualized, systematic and documented approach.

Placing the foot end rail in lowest position or removing foot end bed rails will reduce the risk of entrapment at **Zone 3** without placing undue burden on nursing staff.

Lowering or removing all bed rails will reduce risk of entrapment at **Zones 1, 2, 3, 4, 5 and 6²**.

Be aware that the uses of any mitigation strategy or accessory should not increase the risk of injury to patients or health care providers.

- Consider using accessories that would decrease the risk of entrapment (**Attachment D**). If accessories, such as mattress overlays or positioning poles, are added to beds, they should not alter conformance of the bed system to the recommended dimensions or create a new risk of entrapment or other injury. Accessories should be chosen that decrease entrapment

³ Rubenstein & Robbins (1984) described the use of bed rails as an example of "defensive medicine;" a standard of practice that is based on consensus rather than scientific evidence. However, several studies provide evidence to refute the routine use of bed rails. In a two group, non-controlled comparison design, Si, Neufeld, & Dunbar (1999) found that serious injuries were not associated with removal of bed rails. Using a retrospective, pre/post test, descriptive, Feinsod, Moore, & Levenson (1997) found that while patients in low beds fell more frequently, they had no greater injury rates compared to patients with half rails or no rails. Moreover, there was no significant difference in number of falls between residents sleeping with full length rails and those sleeping in beds with half-length rails. In this study, long term care residents were safest from injury when full rails were not used. In a prospective pre/post test, Hanger, Ball & Wood (1999) found that an educational and policy program on bed rail use, together with physically removing rails from beds, reduced full length rail use and was accompanied by a significant reduction in serious injuries to patients, mainly fewer head injuries. In this study full length bed rails were ineffective devices for keeping mobile and agitated older persons in bed. Hoffman, Powell-Cope, Rathvon & Bero (2003) conducted a quality improvement program to reduce the use of bed rails through the use of alternatives in long-term care. They found that compared to baseline, when rail usage was decreased, there was an 11% reduction in bed-related falls, and a slight decrease in the frequency of injuries due to falls from bed. As noted in a report by the Agency for Health Care Quality (Shojania, Duncan, McDonald, 2001) these study designs are weak, therefore there is no final conclusion in this area. More study on the impact of removing bed rails is therefore warranted. If side rails are used as physical restraints, it is important to note that this report concluded, "There is growing evidence that physical restraints have a limited role in medical care. Restraints limit mobility, a shared risk factor for a number of adverse geriatric outcomes, and increase the risk of iatrogenic events. They certainly do not eliminate falls, and decreasing their use can be accomplished without increasing fall rates. In some instances reducing the use of restraints may actually decrease the risk of falling."

risk regardless of the head and foot positions of the bed and whether the rail is in the low, intermediate or high position.

- Use monitoring systems such as video cameras, patient positioning monitors or bed exit alarms, and bed position devices. Increase monitoring of high risk patients by assigning them to “enhanced safety observation rooms,” if available, or to rooms close to the nursing station.
- Improve care delivery processes to anticipate patients’ needs and improve clinical decision making regarding the use of beds and bed rails, such as lowering bed rails. Other problems may surface when bed rails are removed such as staff, patient, and staff resistance, staff lack of knowledge of alternatives to bed rail use, a lack of a convenient place to hold urinals, bed controls, and call buttons. These problems may require creative solutions. Consider use of height-adjustable low beds and mats on the floor next to the bed. For a complete discussion of clinical interventions, refer to the “Clinical Guidance For The Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities and Home Care Settings Clinical Guidance Document” (HBSW, 2003)
- Use a continuous improvement approach. After a change is made to the bed system, reassess that change to make sure the bed system still meets the dimensional criteria and that the changes have not adversely affected any functioning of the bed system or caused an additional risk of injury.

Step 6: Guidance for Purchasing Beds

An integrated approach that considers the inventory of existing beds, options for corrective actions, and quality monitors will assist in long range planning for bed safety. Bed purchases will be most successful from a cost/benefit and safety perspective when purchasers, engineers, managers, and interdisciplinary staff work together to balance patient and environmental risk factors, patient and staff preferences, and cost.

- Develop a long range plan for bed replacement that considers all of the risk factors in hospital bed safety. Prioritize which units will benefit most from immediate new bed purchases. Trials of individual beds that include staff and patient evaluation will assist in making the right purchasing decisions. Height-adjustable, electric beds may be the best choice for staff and high risk patients. If your facility purchases refurbished beds, these should also meet the recommended dimensional criteria.
- Bed replacement plans should place a priority on addressing care units with the highest potential risk including long term care and medical/surgical areas, or other areas with high concentrations of patients who are at high risk.
- Mattress purchases pose a unique problem because they are replaced more frequently than bed frames. Therefore, new mattress purchases should consider the frame size for which they are purchased and any unique characteristics of the mattress type, particularly mattress overlays and specialty mattresses.

Step 7: Implement Quality Monitoring

Quality monitoring will allow for the evaluation of corrective actions taken to reduce entrapment. Although entrapment is a rare event in the general population of bed users, it is not a rare event in the population most at risk—the elderly, frail or confused.

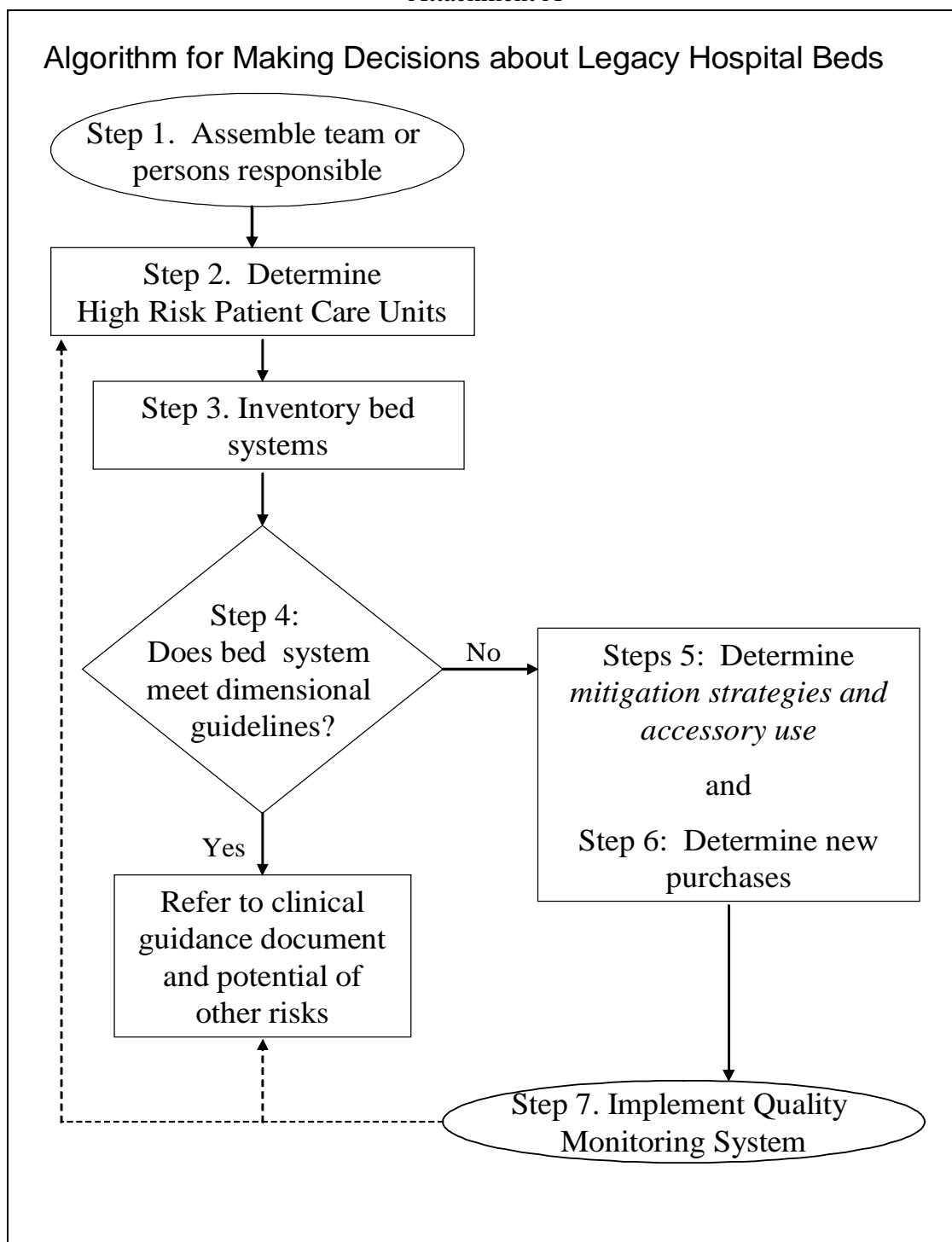
The FDA received approximately 691 entrapment reports over a period of 21 years from January 1, 1985, to January 1, 2006. In these reports, 413 people died, 120 were injured, and

158 were near-miss events with no serious injury as a result of intervention. These entrapment events have occurred in openings within the bed rails, between the bed rails and mattresses, under bed rails, between split rails, and between the bed rails and head or foot boards. The population most vulnerable to entrapment are elderly patients and residents, especially those who are frail, confused, restless, or who have uncontrolled body movement. Entrapments have occurred in a variety of patient care settings, including hospitals, nursing homes, and private homes. Long-term care facilities reported the majority of the entrapments.

Monitoring should continue on an ongoing basis to capture near miss and entrapment events in high-risk units and to ensure that the effects of corrective actions are implemented.

Recognizing that mitigation strategies for reducing entrapment risk could affect falls and fall-related incidents, monitoring bed-related falls is recommended. A *sample*-monitoring tool is included, and a facility is free to adapt it as needed to suit local needs (see **Attachment E**).

Attachment A



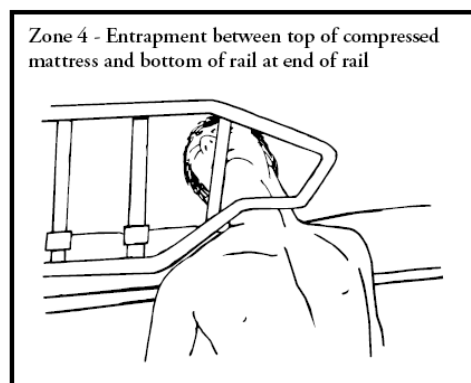
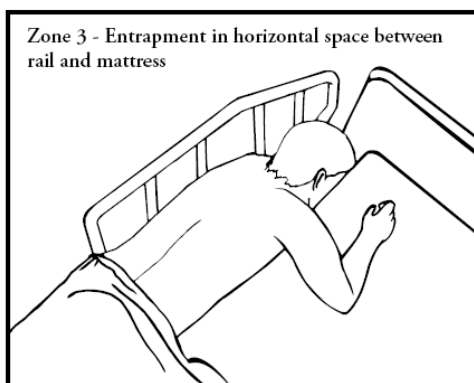
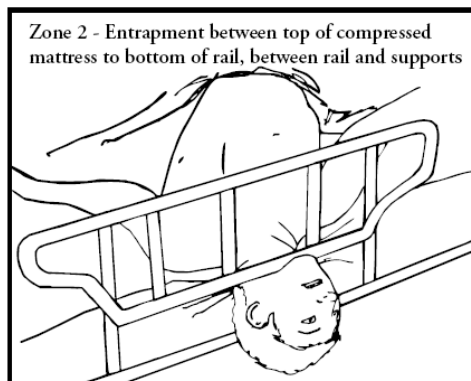
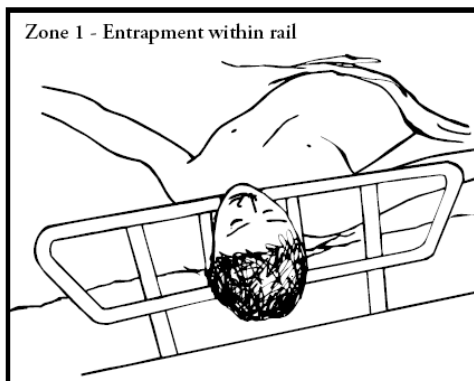
Attachment B
SAMPLE FORMAT FOR BED SYSTEM INVENTORY

UNIT	TYPE OF UNIT	MAKE	MODEL	SERIAL OR TRACKING NUMBER	MATTRESS	RAILS (TYPE, CONFIGURATION)

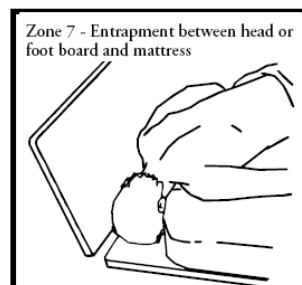
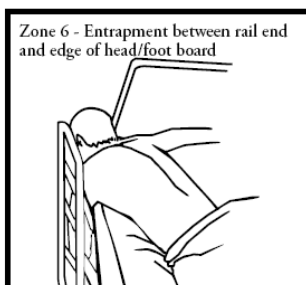
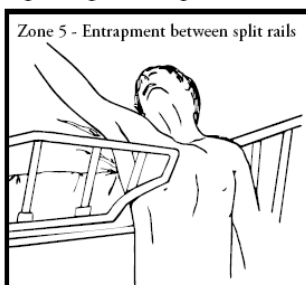
Attachment C

SUMMARY OF ENTRAPMENT ZONES

While recognizing that there are seven potential entrapment zones, entrapment zones 1-4 account for the majority of entrapments and deaths from entrapments. Focusing on these high risk areas allows facilities to prioritize strategies for mitigating risks and for committing resources to mitigate risks. For dimensional limits and test methods for zones 1, 2, 3, 4, refer to FDA Guidance, *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment* (Document issued on: March 10, 2006).



Zones 5, 6 and 7 are not measured zones. These are shown here only for reference for future reporting of entrapment incidents.



Attachment D

ACCESSORIES TO MITIGATE ENTRAPMENT AREAS

This list is provided for your convenience only and does not represent any endorsement by the Hospital Bed Safety Workgroup of the products listed, or the ability or effectiveness of any product to address any specific entrapment issue with beds and mattresses. Bed and mattress combinations may present differing levels of risk. Additionally, each combination must be examined in the context of the specific patient using the bed. Use appropriate clinical judgment when selecting or using any accessory device. Always monitor patients to ensure continued use of bed rails and accessories are warranted. Contact manufacturers and suppliers of beds, rails, mattresses, and bed system accessories for more information.

Accessories and Devices that Alter the Openings of Bed Systems	Potential Entrapment Zones Addressed
<u>Mattresses with optimal length, width and depth for bed deck, frame, and bed rails</u>	2, 3 4, 7
<u>Gap Fillers:</u> <ul style="list-style-type: none"> Bed rail inserts – rigid plastic that inserts into the bed rail openings to narrow the openings. Stuff pads – Plastic covered pads used to decrease open spaces between bed rails and mattresses, mattresses and head/foot boards. 	1 4, 7
<u>Pads & Wedges</u> <ul style="list-style-type: none"> Rail bumper wedges – elongated pads that address openings between the mattress and bed rail, and cover the openings in bed rails Rail pads – elongated pads that address openings between the mattress and bed rail, and cover the openings in bed rails 	1, 4, 5, 6 1, 4, 5, 6
<u>Drapes, Covers and Shields:</u> <ul style="list-style-type: none"> Rail covers – fabric devices or plastic that slip over the bed rails to close openings. Entrapment shields – rigid plastic device attached to a bed rail which occludes all openings along the side of the bed 	1, 5, 6 1, 2, 3, 4, 5, 6

For a complete discussion of creating a safe and comfortable bed and sleeping environment refer to “Clinical Guidance For the Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities and Home Care Settings Clinical Guidance” (HBSW, 2003). Reducing entrapment risk may necessitate the reduction or elimination of bed rail use in cases in which the bed rail is not in the best interests of the patient’s health and safety. The environmental changes listed below are suggestions for consideration. Whether they will be used for an individual patient depends on the patient’s assessment.

1. Use of low beds with an adjacent mat on the floor (with consideration given to using mechanical lifts and proper lift technique training for caregiver staff).
2. Use of low beds that can be elevated electronically for transfer and activities of daily living (ADL) care.
3. Placement of the patient’s call bell within easy reach and provision of visual and verbal reminders to use the call bell when necessary.

4. Use of bed alarms to warn of patients' attempts to exit from bed.
5. Use of "perimeter reminders" or "border definers" such as body pillow/cushions or mattresses with lipped/raised edges.
6. Use of a trapeze affixed to the bed to increase a patient's bed mobility. (For patients with shoulder conditions, trapeze use should be carefully scrutinized.)
7. Placement of inconspicuous signs, without patients' names, to inform caregivers of interdisciplinary care team recommendations.

Additional products and devices that may be helpful when bed rails are not used include:

- Patient Positioning Monitors to detect when an individual moves out of the center of the bed near the edge where entrapment could occur;
- Positioning Aids such as (a) Assist Bars attached to the side of a bed to help patients reposition their bodies, and (b) Folding grip rails, hinged rail devices to provide stability to patient's transferring in and out of bed. These can provide some of the benefits of bed rails without introducing the disadvantages, but assist bars must be assessed like a side rail.
- Bed Control Options, such as pendant controls, provide access to bed controls other than controls that are built into the bed rail; and
- Net Enclosures, made of fabric or net which completely enclose an area over the bed and prevent a patient from being able to exit the bed in any direction. In special circumstances and based on clinical assessment, net enclosures may be used to prevent bed exit. Most of these devices could potentially mitigate entrapment in Zones 1, 2, and 4, however, without proper mattress edge and bed rail gap controls, Zone 3 entrapment mitigation might not be provided.

Attachment E

SAMPLE MONITORING FORM FOR A FACILITY BED-RELATED ENTRAPMENT AND FALL REPORT

For the next several weeks ----our facility is tracking bed-related entrapment and falls from bed. Please use this form to record all events whether they result in injuries or not.

An entrapment is defined as a patient being caught, trapped or entangled in the spaces in or about the bed rail, mattress or hospital bed frame.

A bed-related fall is defined as a fall that occurs from bed when a patient is getting out of bed, into bed or when a patient accidentally falls from the bed to the floor.

Date of incident

Time of incident (military)

1. Facility _____

2. Unit _____

3. Room/Bed Number -

4. Bed Barcode number

5. Bed Make _____

6. Bed Model _____

7. Patient Name _____
Last Name
First Name

8. Patient Age (in years)

9. Mental Status at time of incidence

Alert & Oriented

Mildly Confused

Severely
Confused

Comatose/Veget
ative State

Baseline
Intellectual
Disability

☐
☐
☐
☐
☐

10. Does patient have a seizure or movement disorder?

Yes

No

☐☐

11. Gender

Male

Female

☐☐

12. Height _____

13. Weight _____

14. Patient's admitting diagnosis:

15. Date of admission

15. Description of Incident, including events leading up to the incident:

16. Type of incident

Entrapment ☐Bed-related
fall ☐

17. Was the patient injured?

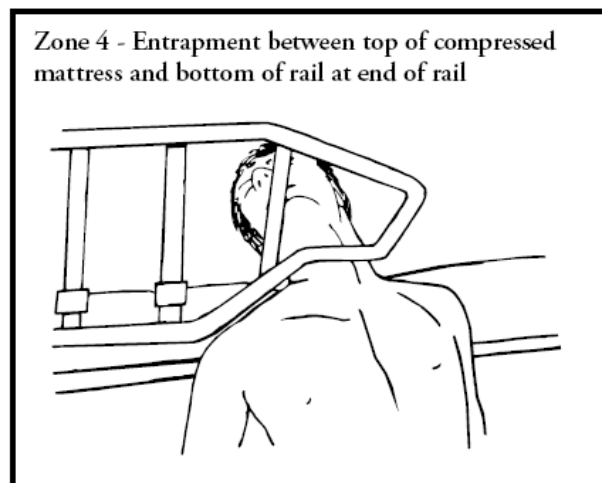
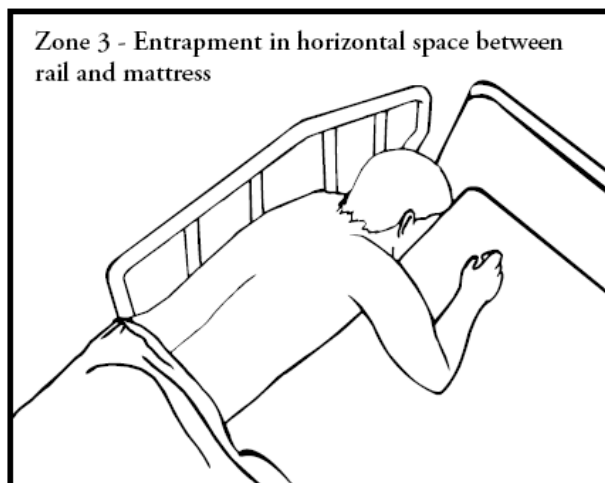
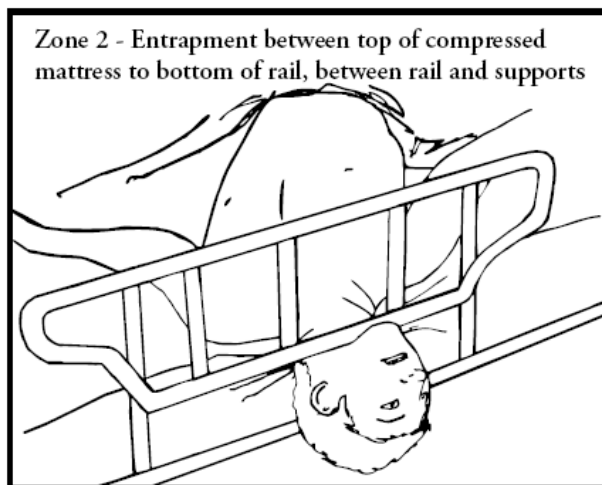
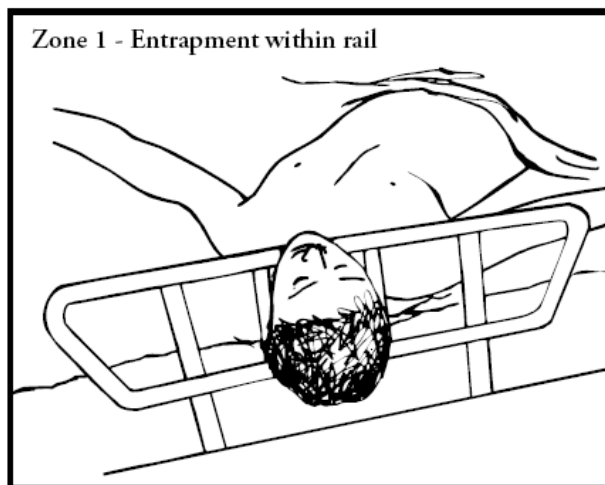
Yes ☐No ☐18. What treatment was
provided?None ☐First Aid ☐Medical/Surgical
Intervention ☐Other ☐

19. Was the incident reported?Yes ☐No ☐**20. Would this incident have normally been reported?**Yes ☐No ☐**21. What was the patient's level of mobility at time of incident?**Up ad lib ☐Ambulate with assistance ☐Ambulate with walker ☐Wheelchair/chair bound ☐Bed bound ☐Missing limbs ☐**22. What was the patient's communication ability at time of incident?**Verbal ☐Nonverbal only ☐Sign language ☐Foreign language ☐**22. Accessories and Treatments in Use**

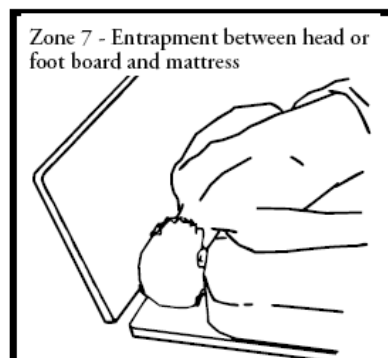
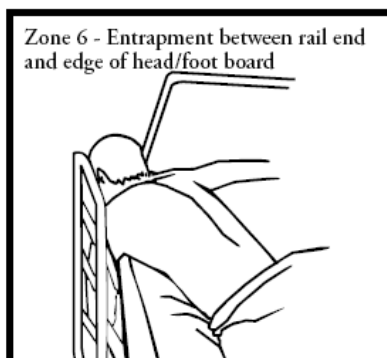
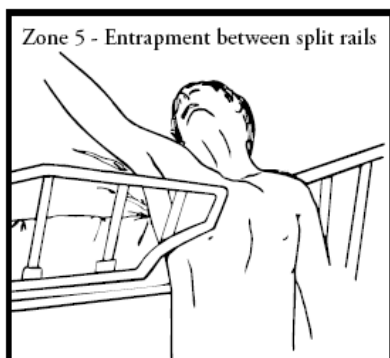
Rail bumper wedges	<input type="checkbox"/>	Rail pads	<input type="checkbox"/>	Rail covers	<input type="checkbox"/>	Entrapment shields	<input type="checkbox"/>
"Stuffer pads"	<input type="checkbox"/>	Bed rail extenders	<input type="checkbox"/>	Bed rail inserts	<input type="checkbox"/>	Positioning monitors	<input type="checkbox"/>
Bed exit alarm	<input type="checkbox"/>	Raised perimeter mattress	<input type="checkbox"/>	Positioning aid	<input type="checkbox"/>	Net enclosure	<input type="checkbox"/>
Nasal oxygen	<input type="checkbox"/>	IVs	<input type="checkbox"/>	Overbed table	<input type="checkbox"/>		
Other	<input type="checkbox"/>	Other	<input type="checkbox"/>	Other	<input type="checkbox"/>	Other	<input type="checkbox"/>

23. If an entrapment event occurs, indicate the location of entrapment by circling the appropriate Zone number.

Potential Entrapment (Zones 1, 2, 3 and 4 are the only zones assessed.)



Zones 5, 6 and 7 are not measured zones. These are shown here only for reference for future reporting of entrapment incidents.



23. What body part was entrapped? Neck ☐ Head ☐ Chest ☐ Other _____

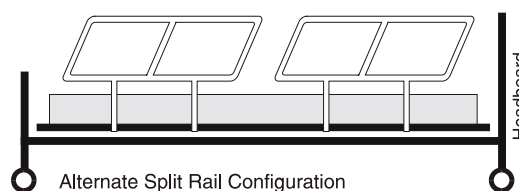
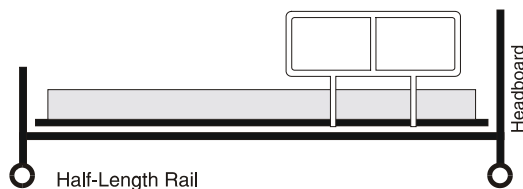
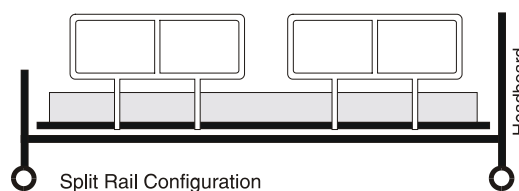
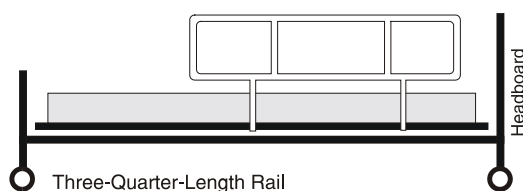
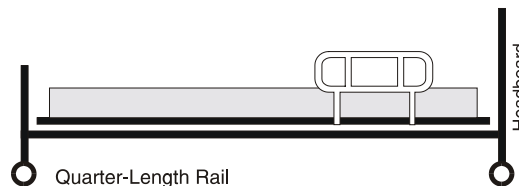
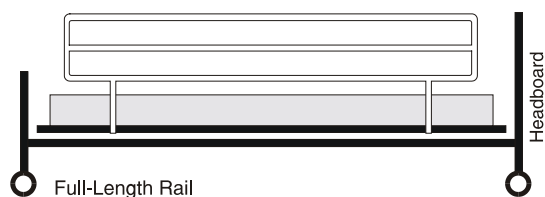
Yes No

24. Was patient in restraints? ☐ Yes ☐ No

If yes, indicate type. Check all that apply.

Vest/chest	<input type="checkbox"/>	Wrist soft--bilateral	<input type="checkbox"/>	Ankle soft--bilateral	<input type="checkbox"/>	Mitt--bilateral	<input type="checkbox"/>
Pelvic/crotch	<input type="checkbox"/>	Wrist soft--one	<input type="checkbox"/>	Ankle soft--one side	<input type="checkbox"/>	Mitt--one	<input type="checkbox"/>
Combination chest/pelvic	<input type="checkbox"/>	Wrist leather--bilateral	<input type="checkbox"/>	Ankle leather--bilateral	<input type="checkbox"/>	Other	<input type="checkbox"/>
Waist/Belt/roll belt	<input type="checkbox"/>	Wrist leather--one	<input type="checkbox"/>	Ankle leather--one side	<input type="checkbox"/>	_____	

25. Circle the diagram that best indicates the Rail Configuration on the bed involved in the entrapment.



Other, describe _____

26. Were bed rails:

All up

All down

1 up

Top half up

Bottom half up

(Patient's Left ☐,
Patient's Right ☐)(Patient's Left ☐,
Patient's Right ☐)(Patient's Left ☐,
Patient's Right ☐)☐☐☐☐☐**27. What was the upper bed deck articulation?**☐

Flat

☐

46 to 89 degrees

☐

15 to 30 degrees

☐

90 degrees

☐

31 to 45 degrees

28. What was the lower deck articulation?☐

Flat

☐

46 to 89 degrees

☐

15 to 30 degrees

☐

90 degrees

☐

31 to 45 degrees

27. Type of Mattress☐

Standard (Foam)

☐

Other, specify

☐

Water-filled

☐

Air-filled

27. Mattress size: _____length _____width _____depth**28. Mattress age (or production date)** _____**28. List medications patient took within the 24 hours prior to the incident.**

1.

8.

2.

9.

3.

10.

4.	11.
5.	12.
6.	13.
7.	14.

Attachment F

SELECTED REFERENCES ON BED RAIL REDUCTION AND FALLS PREVENTION

American Geriatrics Society (2001). Clinical Practice Guidelines – The Prevention of Falls in Older Persons, Presented at AGS 2001 Annual Scientific Meeting, Chicago, Illinois.

Clinical Practice Guidelines, (1998), Falls and Fall Risk, American Medical Directors Association & American Health Care Association.

Feinsod, F. M., Moore, M., & Levenson, S. A. (1997). Eliminating full-length bed side rails from long-term care facilities. *Nursing Home Medicine*, 5(8), 257-263.

Food and Drug Administration, Center for Devices and Radiological Health. (2006). Guidance for Industry and FDA Staff: Hospital Bed System Dimensional Guidance to Reduce Entrapment Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment - Issued on: March 10, 2006

Fuller, G.F. (2000). *American Academy of Family Physicians*,
www.aafp.org/afp/20000401/2159.html.

Hanger H.C., Ball, M.C., & Wood, L.A. (1999). An Analysis of Falls in the Hospital: Can We Do Without Bedrails? *Journal of the American Geriatrics Society*, 47, 529-31.

Hendrich, A. (1996). *Falls: Immobility and restraints*. St. Louis: Mosby.

Hendrich, A., Nyhuis, A., Kippenbrock, T., & Soja, M.E. (1995). Hospital falls: development of a predictive model for clinical practice. *Applied Nursing Research*, 8(3), 129-139.

Hoffman, S., Powell-Cope, G., Rathvon, L., & Bero, K. (2003). BedSAFE: Evaluating a Program of Bed Safety Alternatives for Frail Elders. *Journal of Gerontological Nursing*, 29(11), 34-42.

Hospital Bed Safety Workgroup [HBSW] (2003). Clinical guidance for the assessment and implementation of bed rails in hospitals, long tem care facilities, and home care settings. Retrieved

March 20, 2006 from <http://www.fda.gov/cdrh/beds/>. Also available as part of The Hospital Bed Safety Workgroup (HBSW) Bed Safety Entrapment Kit.

Joint Commission for the Accreditation of Health Care Organizations [JCAHO] (2002). Sentinel Event Alert, Issue 27 - September 6, 2002. ()

Ledford, L. (1996). *Research protocol: Prevention of falls*. University of Iowa Gerontological Nursing Interventions Research Center. Unpublished report.

Miles, S. (2002). Deaths between bedrails and air pressure mattresses. *Journal of the American Geriatrics Society*, 50(6), 1124-1125.

Morse, J .M. (1993). Nursing Research on Patient Falls in Health Care Institutions. *Annual Review of Nursing Research*, 13, 299-326.

Morse, J.M. (1986). Computerized evaluation of a scale to identify the fall-prone patient. *Canadian Journal of Public Health*, 767(Suppl.), 21-25.

Morse, J.M. (1994). Strategies for Preventing Resident Falls, *PADONA Journal*, Jan-Feb. 1994, 15-22.

Morse, J.M., Black, C., Oberle, K., & Donahue, P. (1989). A prospective study to identify the fall-prone patient. *Social Sciences & Medicine*, 28, 81-86.

Morse, J.M., Prowse, M., Morrow, N., & Federspeil, G. (1985). A retrospective analysis of patient falls. *Canadian Journal of Public Health*, 76, 116-118.

Morse, J.M., Tylko, S.J., & Dixon, H.A. (1987). Characteristics of the fall-prone patient. *Gerontologist*, 27, 516-522.

Morse, JM. (1997). *Preventing Patient Falls*, Sage Publications, Thousand Oaks, London.

Rothschild, J.M., Leape, L.L., (2000, September). *The nature and extent of medical injury in older patients—Executive summary*. AARP Publication ID: 2000-17.

Rubenstein, L. & Robbins, A. (1984). Falls in the elderly: a clinical perspective. *Geriatrics*, 39(4), 67-71, 75-6, 78.

Shojania KG, Duncan BW, McDonald KM, et al., eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43 (Prepared by the University of California at San Francisco–Stanford Evidence-based Practice Center under Contract No. 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.

Si, M., Neufeld, R. R., & Dunbar, J. (1999). Removal of bedrails on a short-term nursing home rehabilitation unit. *The Gerontologist*, 39(5), 611-614.

Tideiksaar, R., (2001, June). Fall risk management – A guideline for fall risk management *PS/RS Newsletter, June 2001—Vol. 1, Number 3*.

Tinetti, M.E. & Williams, C.S. (1997). Falls, Injuries due to falls, and the risk of admissions to a nursing home. *Massachusetts Medical Society*, 337(18), 1279-1284.

Weiss, C.A., (2000). Fall Prevention Among the Elderly, *Nursing Spectrum-Career Fitness Online*, www.nsweb.nursingspectrum.com/ce/cel51.htm.