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Webinar Features (con't)

- Resize the Whiteboard (where PowerPoint slides are shown): It can be resized using the drop down located in the Whiteboard area. (The default is "Fit Size").
- **Emotions:** Please refrain from using the emoticons, hand-raising and polling features during this session unless directed to do so by the presenter.



Presenter



Earlene Sesker

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Proposed Guidelines for Medical Diagnostic Equipment

Session Agenda

- Background
- Organization of Proposed Rule
- Proposed Technical Criteria
- Major Issues
- Next Steps

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Background

- Section 4203 of Patient Protection and Affordable Care Act (Public Law 111-148, 124 Stat. L. 119)
- Section 510 of the Rehabilitation Act of 1973

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Federal Partners







- U.S. Food and Drug Administration,
 Department of Health and Human Services
- Disability Rights Section, Department of Justice
- Department of Veterans Affairs

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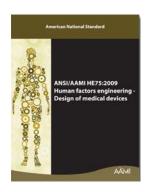
Barriers Affecting Accessibility and Usability of Medical Diagnostic Equipment

- 75% examination tables moderately difficult to impossible to use
- 68% radiology equipment moderately difficult to impossible to use
- 53% weight scales moderately difficult to impossible to use
- 50 % examination chairs moderately difficult to impossible to use

Rehabilitation Engineering Research Center on Accessible Medical Instrumentation 2004 national Survey

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Background



- ANSI/AAMI HE75 2009
 Human Factors
 Engineering Design of
 Medical Devices
- Chapter 16 Accessibility
 Considerations

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Background



ADA and ABA Accessibility Guidelines

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1.

How The Rule is Organized

- Preamble
- Regulatory Analysis
- Text of the Proposed Rule

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How The Rule is Organized

- M1 Application and Administration
- M2 Scoping Requirements
- M3 Technical Criteria
 - Supine, Prone, or Side Lying Position
 - Seated Position
 - Seated in Wheelchair
 - Standing Position
 - Communication
 - Operable Parts

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Definitions

Enforcing Authority – An agency that adopts the standards as mandatory requirements for entities subject to its jurisdiction.

Medical Diagnostic Equipment – Equipment used in or in conjunction with medical settings by health care providers for diagnostics purposes.

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Definitions

Operable Parts – A component of diagnostics equipment that is used by the patient to activate, deactivate, or adjust the equipment.

Transfer Surface – Part of diagnostic equipment onto which patients who use mobility devices or aids transfer when moving onto and off of the equipment.

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Supine, Prone, or Side-Lying Position

- Transfer Surface
- Supports
- Lift Compatibility

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Supine, Prone, or Side-Lying Position

Transfer Surface:

- Height
- Size
- Transfer Sides

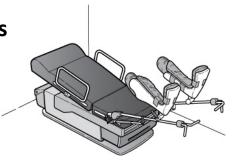


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Supine, Prone, or Side-Lying Position

Supports

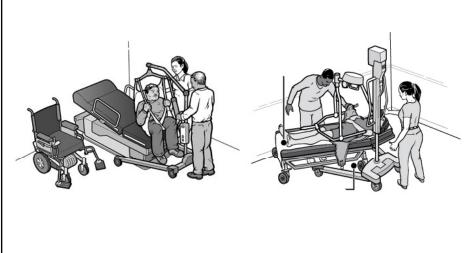
- Transfer Supports
- Stirrups
- Head and Back Support



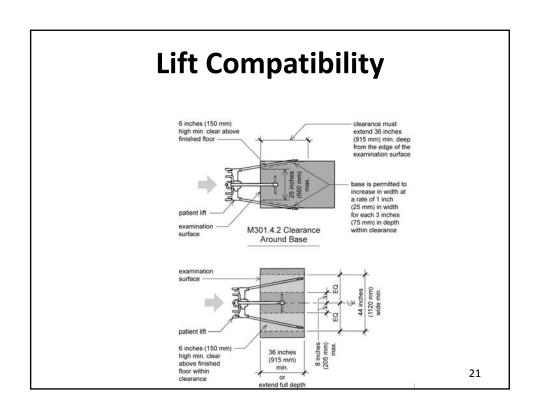
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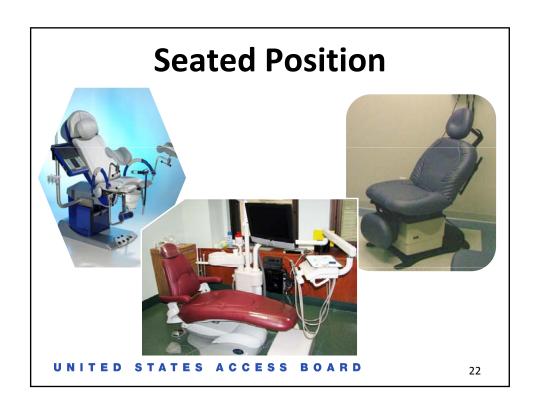
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Lift Compatibility



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Seated Position

- Transfer Surface
- Supports
- Lift Compatibility



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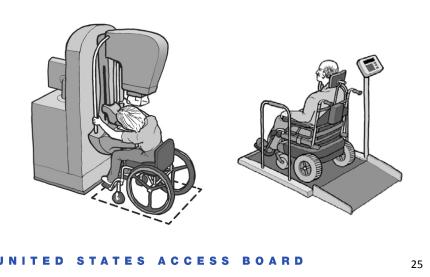
Lift Compatibility Exception

Where diagnostic equipment meets the requirements of M303 (seated in a wheelchair) and provides a folding seat, the equipment shall not be required to comply with the lift compatibility provisions.



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Seated in a Wheelchair



Seated in a Wheelchair

- Wheelchair Spaces
- Entry
- Components

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Seated in a Wheelchair

Wheelchair Spaces:

- Orientation
- Width
- Depth
- Knee Clearance
- Toe Clearance



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Seated in a Wheelchair

Entry:

- Vertical
- Beveled
- Ramped



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Seated in a Wheelchair Components

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Seated in a Wheelchair Components

Height of the breast platform = 30 inches minimum and 42 inches high maximum when in use by a patient seated in a wheelchair.



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Standing

- Standing Surface
- Standing Supports



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Supports

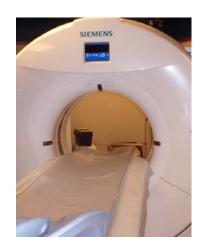
- Transfer
- Standing



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Technical Criteria Across Equipment Types

- Communication
- Operable Parts



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Example Application Document Output Output

Responses to NPRM

- 46 questions were posed in the preamble
- 51 commenters
- Range of comments

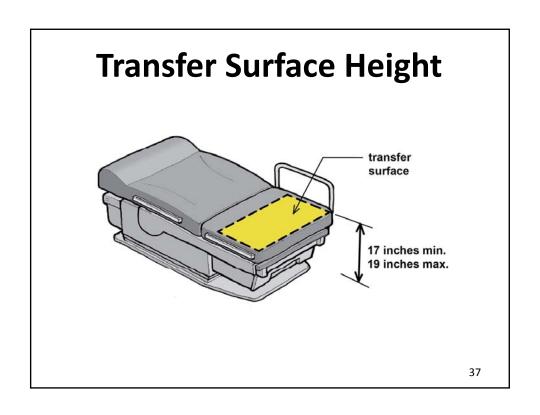
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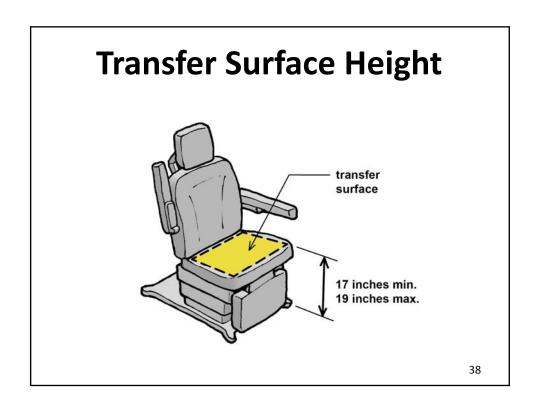
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Major Issues

- Transfer Surface Size and Height
- Transfer Surface Obstructions
- Transfer Support Location and Configuration
- Depth of Wheelchair Spaces

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Transfer Surface Height

Question 14

Adjustable Height

- a) Types of equipment currently height adjustable?
- b) Types of equipment not height adjustable?
- c) Equipment that can not be height adjustable?
- d) Intermediate heights?

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Transfer Surface Height

Patients

- Height is a major concern
- Range of users accommodated

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Transfer Surface Height

Manufacturers

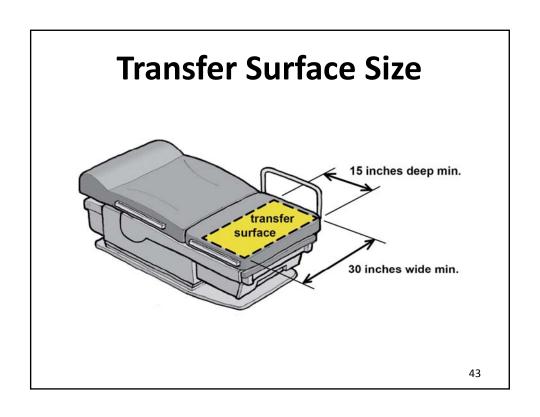
- Seat profile
- Components beneath transfer surface
- Span between the lowest transfer height and optimal caregiver height
- Cost and redesign

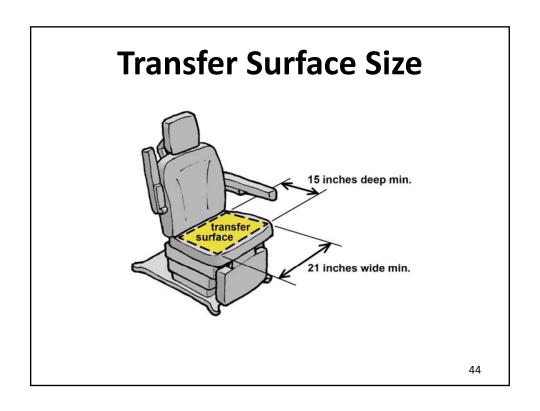
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Transfer Surface Height



Equipment Design Concerns





Transfer Surface Size

Question 15

Supine, Prone, or Side-Lying Position

- a) Is proposed size sufficient? (30" by 15")
- b) Support surface width > transfer surface?
- c) Alternate dimensions?
- d) Permit expandable surface (e.g., extendable platform)
- e) If required to be provided at more than one location where should transfer surface be located?

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Transfer Surface Size

Question 16

Seated Position:

- a) Is proposed size sufficient?
- b) Alternate dimensions? (21" wide and 15" deep)





Response to NPRM Questions

Patients

- Space for transfer
- Repositioning after transfers
- Range of body sizes
- Ergonomics

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Response to NPRM Questions

Manufacturers

- Use of supports
- Corner shape on transfer sides
- Relationship to base design
- Equipment proportions
- Redesign and costs
- Impact on exam room layouts

Transfer Surface Size



Equipment Design Concerns

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Transfer Surface Size

Diagnostic Equipment Used by Patients in Supine, Prone, or Side-Lying Position

- Width: increase to 35 to 36 inches decrease to 25 to 28 inches
- Same requirement for Equipment
 Used by Patients in Seated Position

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Transfer Surface Size

Diagnostic Equipment Used by Patients in in Seated Position

- Alternate dimensions 17 inches minimum depth
- Relationship to size requirement

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Permitted Obstructions to the Transfer Surface





Same issue for equipment used by patients in a supine, prone, or side-lying and equipment used in a seated position

Transfer Sides

Transfer Sides - Located to provide options to transfer from a mobility device onto one short side (depth) and one long side (width) of the surface. <u>Each transfer side</u> to provide unobstructed access to the transfer surface.

EXCEPTION: Temporary obstructions shall be permitted provided that they can be repositioned to permit transfer.

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Permitted Obstructions

Question 17

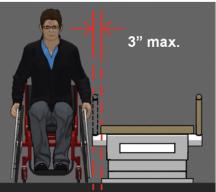
Transfer Sides:

- a) 3 inches maximum extension beyond the edge of the transfer sides
- b) Redesign requirements



Permitted Obstructions





Permit Up to 3 Inch Gap?

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Permitted Obstructions





Equipment Components That Extend Beyond Exam Surface



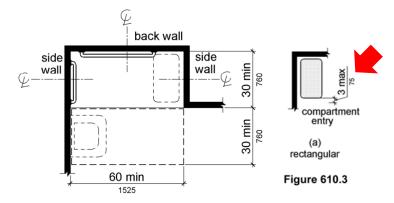


Figure 608.2.2

Shower seat edge is permitted to be 3 inches max. from shower entry

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Response to NPRM Questions

Patient Use - If Gap is Permitted

- Concerns about safety of transfers across a gap to exam surface
- Patient may not be in optimal health
- Equipment parts that extend beyond surface should not be permanently mounted

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Response to NPRM Questions

Equipment – If Gap is Not Permitted

- Need to add accessories
- Impact on certain equipment types –
 beds/stretchers and imaging
- Capacity of supports to bear weight loads if removable
- Redesign likely and associated cost

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Transfer Research



set up reflects amusement ride focus

Study: The Impact of Transfer Setup on the Performance of Independent Wheelchair Transfers

120 Subjects capable of independent transfer

Variety of configurations tested – including distance from seat

Transfer Research





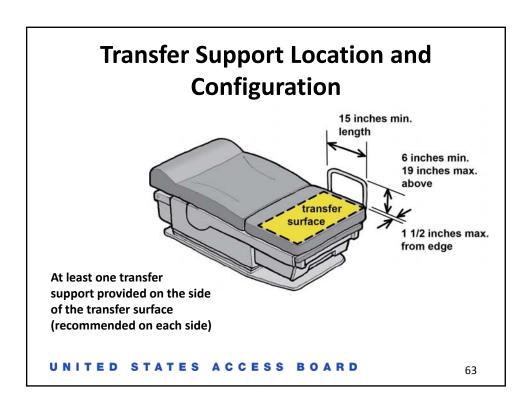
Height adjusted and spacers added at floor level

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Transfer Support Location and Configuration







Transfer Support Location and Configuration

Question 19

- a) Is proposed criteria sufficient?
- b) Can supports on different types of equipment meet proposed criteria?
- c) Redesign costs?
- d) Alternate technical criteria?
- e) Permit angled or vertical supports?

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Transfer Support Location and Configuration

Question 20

Height:

- a) Considering 6 min. and 19 max. above surface. Is height this range usable?
- b) Can supports on different types of equipment meet proposed criteria?
- c) Alternate criteria?

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Proposed Gripping Surface Cross Section 4-4.8 perimeter 100-120 1 11/4"-2" Non-circular Cross Section UNITED STATES ACCESS BOARD 66

Armrest on Exam Chairs



Transfer Support Location and Configuration

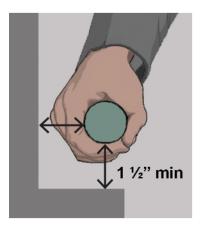
Question 21

Cross Section of Gripping Surface:

- a) Can transfer support meet grab bar specifications in ADA Standard?
- b) Can handholds meeting cross section be integrated in cushioned armrest?
- c) Alternate designs?

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Proposed Gripping Surface Clearance



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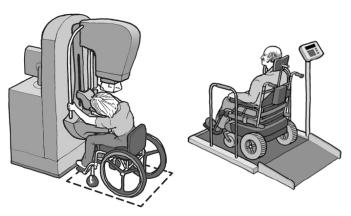
Transfer Support Location and Configuration

Question 22

Clearance Around Gripping Surfaces:

Can transfer supports on different types of equipment provide 1 ½ inches minimum clearance around the gripping surfaces?

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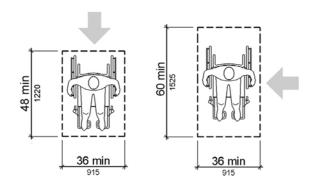


M303 Diagnostic Equipment Used by Patients Seated in a Wheelchair

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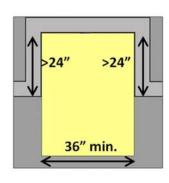
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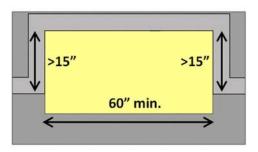
Depth of Wheelchair Spaces



front or rear sideWheelchair Spaces – Width and Depth

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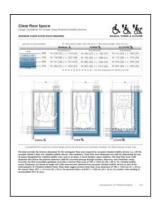


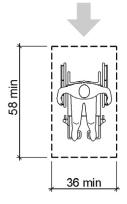
Based on 305.7 Maneuvering Clearances where space confined on 3 sides (and more than half of space depth confined)

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Depth of Wheelchair Spaces





data from wheeled mobility anthropometry project indicates a 58 inch width minimum for front or rear entry

Question 29

- a) What would be the incremental costs for the design or redesign and manufacture of the equipment to provide a wheelchair space that is 58 inches deep minimum?
- b) Are there types of equipment that cannot provide a wheelchair space that is 58 inches deep min. because of the structural or operational characteristics of the equipment?

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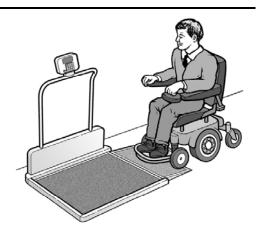
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Depth of Wheelchair Spaces

edge protection – some curbs permit wheelchair footrests to extend beyond the raised platform

Exceptions Considered if edge protection permits:

- 32"width minimum, 36" would be needed for arms and elbows
- 48" depth minimum



Wheelchair Spaces on Raised Platform

Question 31

- a) How much of 48 min. depth of wheelchair space should be permitted to extend beyond raised platform edge and over edge protection?
- b) Maximum height of edge protection to allow extension beyond platform over edge protection?
- c) Should supports be prohibited from obstructing wheelchair space outside the perimeter of the raised platform above any edge protection?

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Depth of Wheelchair Spaces

Question 32

- a) Raised platforms usable by patients who use scooters?
- b) Should width and depth be changed to accommodate scooters?
- c) Should folding seats be required on raised platforms?
- d) If folding seat provided should platform be able to accommodate scooters?



Next Steps

- Comment Analysis
- Advisory Committee
- Final Rule

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Questions?

Highlight "GreatLakes" in the participant list and "right click" on your mouse to send a private message. Type your message into the chat area that appears. The question will be viewed by all moderators. (Keyboard - F6, Arrow up or down to locate "GreatLakes" and select to send a message)



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Thank you for participating in today's webinar





Next scheduled session: "Accessible Amusement Rides" **January 3, 2013**

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