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A collaborative program between the ADA National Network and the U.S. Access Board



The Session is Scheduled to begin at 2:30pm Eastern Time  
We will be testing sound quality periodically

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## Webinar Features

- **Closed captioning** – click **CC** icon (located in the Audio/Video Panel) or control-F8 (command-F8) and adjust your screen.
- **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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## Webinar Features (con't)

- **Customize your view** – You can change the size and location of any of the panels (Chat, etc.) by hovering your mouse over the ☰ icon at the right of each panel and select “Detach Panel”. Each panel can be repositioned and resized.

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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.

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## 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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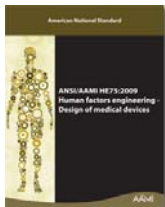
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## Background



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

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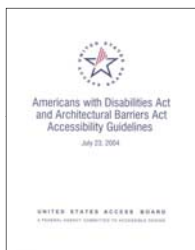
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## Background



### ADA and ABA Accessibility Guidelines

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## How The Rule is Organized

- **Preamble**
- **Regulatory Analysis**
- **Text of the Proposed Rule**

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## How The Rule is Organized

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- 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

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**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

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**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



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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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## Lift Compatibility



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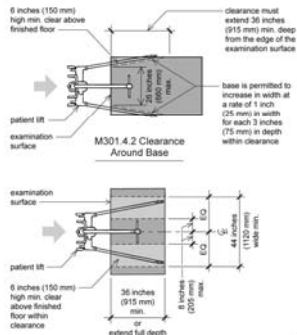
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## Lift Compatibility



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## Seated Position



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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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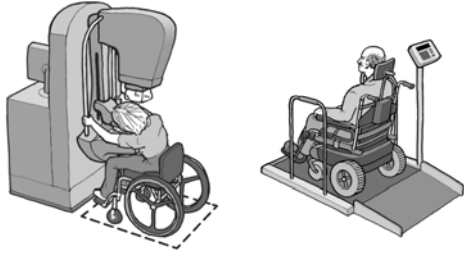
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## Seated in a Wheelchair



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## 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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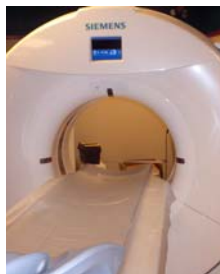
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## Technical Criteria Across Equipment Types

- Communication
- Operable Parts



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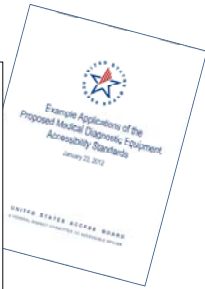
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## Example Application Document



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## Responses to NPRM

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

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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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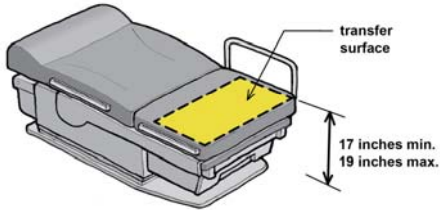
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## Transfer Surface Height



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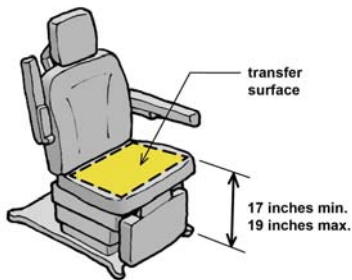
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## Transfer Surface Height



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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

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### Patients

- Height is a major concern
- Range of users accommodated

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## Transfer Surface Height

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### 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

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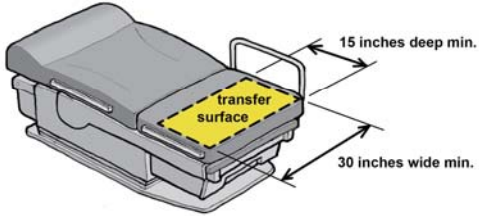
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## Transfer Surface Size



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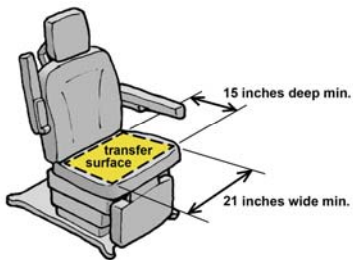
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## Transfer Surface Size



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## Transfer Surface Size

### Question 15

#### Supine, Prone, or Side-Lying Position

- a) Is proposed size sufficient? (30" by 15")
- b) Support surface width  $\geq$  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**


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**Question 16**

**Seated Position:**

a) Is proposed size sufficient?

b) Alternate dimensions? (21" wide and 15" deep)



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**Response to NPRM Questions**

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**Patients**

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

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**Response to NPRM Questions**

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**Manufacturers**

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

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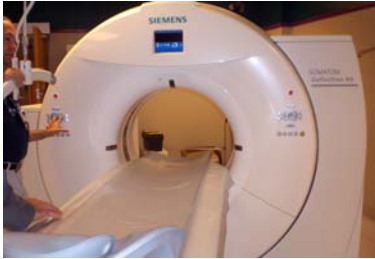
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## Transfer Surface Size



### 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

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## 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. Each transfer side 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



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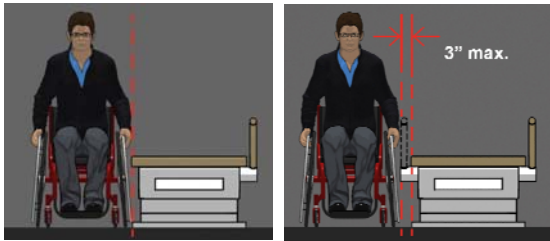
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## Permitted Obstructions



Permit Up to 3 Inch Gap?

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## Permitted Obstructions



Equipment Components That Extend Beyond Exam Surface

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## Permitted Obstructions

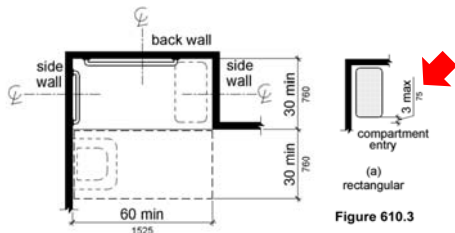


Figure 608.2.2

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

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## Transfer Research



Height adjusted and spacers added at floor level

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## Transfer Support Location and Configuration



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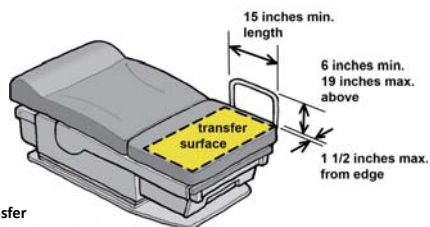
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## Transfer Support Location and Configuration



At least one transfer support provided on the side of the transfer surface (recommended on each side)

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## 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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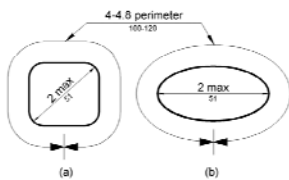
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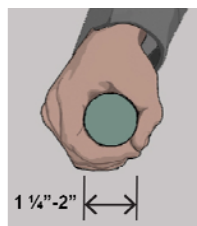
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## Proposed Gripping Surface Cross Section



Non-circular Cross Section



Circular Cross Section

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## Armrest on Exam Chairs



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## 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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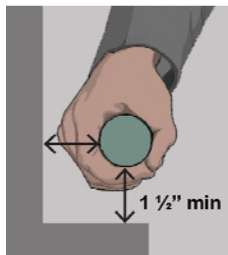
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## Proposed Gripping Surface Clearance



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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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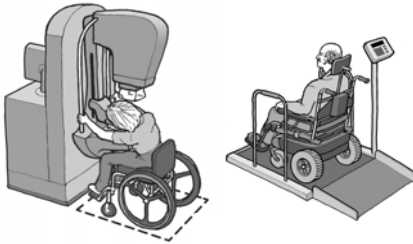
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## Depth of Wheelchair Spaces



M303 Diagnostic Equipment Used by Patients Seated in a Wheelchair

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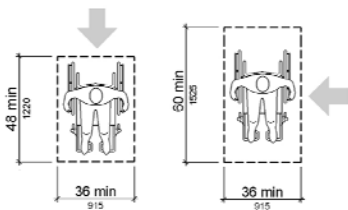
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## Depth of Wheelchair Spaces



**front or rear**      **side**  
Wheelchair Spaces – Width and Depth

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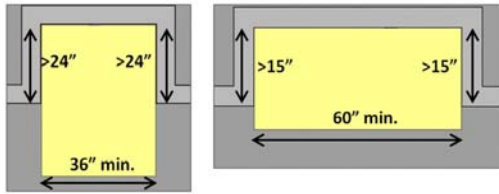
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### Depth of Wheelchair Spaces



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

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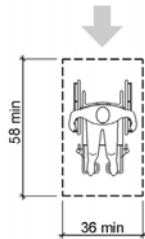
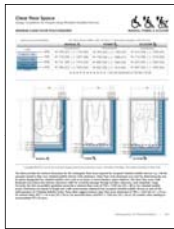
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### Depth of Wheelchair Spaces



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

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### Depth of Wheelchair Spaces

#### 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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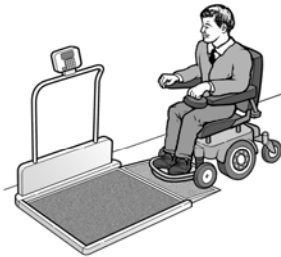
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## Depth of Wheelchair Spaces

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

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## Depth of Wheelchair Spaces

### Question 31

- How much of 48 min. depth of wheelchair space should be permitted to extend beyond raised platform edge and over edge protection?
- Maximum height of edge protection to allow extension beyond platform over edge protection?
- 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

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



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## 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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