

indicated in the preamble to the July 2005 final rule, the bioavailability of these pigments and/or their individual components when ingested is expected to be low.

This submission did not provide any factual information to modify FDA's conclusion that the subject pearlescent pigments present no toxic potential when ingested at levels estimated by the agency, based on their proposed use in coloring ingested drugs. Namely, this submission did not provide specifically identified reliable evidence that can lead to resolution of a factual issue in dispute (§ 12.24(b)(2)). A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions (§ 12.24(b)(2)). Therefore, FDA is denying this objection.

#### V. Summary and Conclusions

The agency is denying the objections to the final rule in the two submissions received on the following bases. The objection to the use of pearlescent pigments in food is outside the scope of the July 2005 final rule, which amended the color additive regulations to provide for the safe use of mica-based pearlescent pigments to color ingested drugs. The objections in the second submission that the subject pearlescent pigments would contain iron contaminants, that the iron contaminants would cause stability issues for active ingredients in drugs, and that the use of the pigments to color ingested drugs will limit availability of medications for the persons who must monitor their iron intake, are not supported by any factual information.

The filing of the objections served to stay automatically the effectiveness of § 73.1128. Section 701(e)(2) of the act states: "Until final action upon such objections is taken by the Secretary \* \* \*, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made." Section 701(e)(3) of the act further stipulates that "As soon as practicable \* \* \*, the Secretary shall by order act upon such objections and make such order public."

The agency has completed its evaluation of the objections and concludes that a continuation of the stay of this regulation is not warranted.

In the absence of any other objections and requests for a hearing, the agency, therefore, further concludes that this document constitutes final action on the objections received in response to the regulation as prescribed in section 701(e)(2) of the act. Therefore, the agency is acting to end the stay of the

regulation by establishing a new effective date of July 20, 2006 for this regulation listing mica-based pearlescent pigments prepared from synthetic iron oxide, mica, and titanium dioxide to color ingested drugs. As announced in the July 22, 2005, final rule, the previous effective date of the regulation was August 23, 2005.

Therefore, under sections 701 and 721 of the act, notice is given that the objections filed in response to the July 2005 final rule do not form the basis for further stay of this final rule or require amendment of the regulations. Accordingly, the stay of § 73.1128 that FDA is announcing in this document is removed effective July 20, 2006.

#### List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (section 1410.10 of the FDA Staff Manual Guide), notice is given that objections and a request for a hearing were filed in response to the July 22, 2005, final rule. Notice is also given that the agency is denying these objections. Accordingly, the amendments issued thereby are effective July 20, 2006.

Dated: July 14, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-11536 Filed 7-19-06; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

#### 29 CFR Parts 1926 and 1928

[Docket No. S-270-A]

RIN 1218-AC15

#### Roll-Over Protective Structures

**AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.

**ACTION:** Final rule; corrections and technical amendments.

**SUMMARY:** On December 29, 2005, OSHA published a direct final rule in the **Federal Register** reinstating its original construction and agriculture standards that regulate the testing of roll-over protective structures ("ROPS") used to protect employees who operate wheel-type tractors. OSHA received one

comment to the direct final rule; this comment recommended a number of clarifications to the original ROPS standards published in the direct final rule. In the present notice, the Agency is making corrections and technical amendments to the ROPS standards in response to this comment, as a result of editorial errors found in the ROPS standards published in the direct final rule, and to improve consistency among the figures generated for these standards. The Agency finds that these corrections and technical amendments do not change the substantive requirements of the ROPS standards.

**DATES:** The corrections and technical amendments specified by this rulemaking become effective on July 20, 2006.

#### FOR FURTHER INFORMATION CONTACT:

*Press inquiries:* Kevin Ropp, OSHA Office of Communications, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693-1999.

*General and technical information:* Matthew Chibbaro, Acting Director, Office of Safety Systems, Directorate of Standards and Guidance, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-2255.

**SUPPLEMENTARY INFORMATION:** On December 29, 2005, OSHA published a direct final rule in the **Federal Register** reinstating its original construction and agriculture standards that regulate the testing of roll-over protective structures ("ROPS") used to protect employees who operate wheel-type tractors (see 70 FR 76979). The Agency received only one public comment (Ex. 3-1) on the direct final rule, which it determined was not a significant adverse comment. The commenter recommended several clarifications to the ROPS standards published in the direct final rule.

The table below describes the clarifications recommended by the commenter who responded to the direct final rule, and OSHA's response to these recommendations. This response provides the Agency's rationale for accepting a recommendation or excluding it from further consideration. Accordingly, OSHA is making a number of corrections and technical amendments to the ROPS standards for construction (§ 1926.1002) and agriculture (§§ 1928.52 and 1928.53) based on the commenter's recommendations.

Recommendation	OSHA's response
<p><b>Figure W-15:</b></p> <ul style="list-style-type: none"> <li>• 05T needs to be 0.5T and 09T needs to be 0.9T</li> <li>• (50 DEG <math>\pm</math> 5 DEG) (1270 plus/minus 127 mm) needs to be (50 inches plus/minus 5 inches) (1270 plus/minus 127 mm).</li> <li>• Path of travel should also state center of tractor</li> </ul>	<p>OSHA added the decimal points as recommended. However, instead of revising "DEG" to "INCHES," OSHA is replacing the entire caption with "45 in. min. (1143 mm)" to make this figure consistent with Figure C-10. Regarding the third recommendation, OSHA is adding a caption to the figure indicating the center of the tractor on the path of travel. For consistency, OSHA added this caption as well to Figure C-10. However, this caption applies only to the linear center of the tractor, which does not necessarily represent the tractor's center of gravity.</p>
<p><b>Figure W-16:</b></p> <p>Under 1926.1002(i)(1)(i), Dimension D equals 2 inches (51 mm) inside of the frame upright to the vertical centerline of the seat. However, because Dimension G is 24 inches (610 mm), Dimension D should be 12 inches (305 mm).</p>	<p>OSHA is not making a change in response to this comment. Dimension D represents the minimum deflection from the true horizontal permitted during side-load testing, which must be at least 2 inches (51 mm). Dimension G is the minimum design limit for the width of a ROPS (i.e., the ROPS must have a width of at least 24 inches). Therefore, the dimensions in Figure W-16 are correct.</p>
<p><b>Figure W-17:</b></p> <p>Under 1926.1002(i)(1)(i), Dimension F equals not less than 0 inches (0 mm) and not more than 12 inches (305 mm) measured at the centerline of the seat backrest to the crossbar along the line of load application. Clarify whether the distance between the seat backrest and the frame cannot be more than 12 inches after impact.</p>	<p>OSHA is not making a change in response to this comment. Dimension F represents two values: 12 inches is the pre-load design dimension and 0 is the maximum deflection permitted during rear-load testing (i.e., the distance between the two lines circumscribed by Dimension F can be no greater than 12 inches during testing). Therefore, the dimensions in Figure W-17 are correct and clear.</p>
<p><b>Figure W-18:</b></p> <p>Figure W-18 does not have any dimension specifications or an explanation of what it is and what it does.</p>	<p>OSHA is not making a change in response to this comment. The figure legend states that the figure represents a method for measuring instantaneous deflection, which is explained in § 1926.1002(g)(1)(ii) and (g)(2)(v).</p>
<p><b>Figure W-19:</b></p> <ul style="list-style-type: none"> <li>• <math>0.8L_{max}</math> needs to be <math>0.8L_{max}</math>.</li> <li>• Load L, lb (kg) – Define as L = static load, lb (kg)</li> <li>• Deflection D, in. (mm) – Define as D = deflection under L, in. (mm)</li> </ul>	<p>OSHA added the decimal point as recommended. However, OSHA is not revising "Load L, lb (kg)" or "Deflection D, in. (mm)" because these terms are defined in the regulatory text at § 1926.1002(j)(3).</p>
<p><b>Figure W-20:</b></p> <ul style="list-style-type: none"> <li>• EU = OQD/12 ft-lb – Add an explanation that dividing by 12 converts [to] in-lb.</li> <li>• Load L, lb (kg) – Define L = static load, lb (kg)</li> <li>• Deflection D, in. (mm) – Define D = deflection under L, in. (mm)</li> </ul>	<p>OSHA is not making a change in response to this comment. OSHA does not believe it is necessary to specifically explain that dividing by 12 converts ft-lbs to in-lbs. See OSHA's response above for Figure W-19 regarding the comment on defining "Load L, lb (kg)" and "Deflection D, in. (mm)."</p>
<p><b>Figure W-21:</b></p> <p>Add the weight of the pendulum (4,410 lbs (2,000 kg)) and the height of the pendulum (18–22 ft (5.5–6.7 m)) on the drawing.</p>	<p>OSHA is not making a change in response to this comment because the information in the figure is provided in § 1926.1002(h)(1)(ii).</p>
<p><b>Figure W-24:</b></p> <ul style="list-style-type: none"> <li>• Correct the first notation to read: <math>H = 4.92 + 0.00190 W</math> or <math>H' = 125 + 0.107 W'</math>.</li> <li>• Correct the second notation to read: W = tractor weight as specified by 29 CFR 1926.1002(e)(1) and (e)(3), in lb. (<math>W'</math>, kg).</li> </ul>	<p>OSHA is adding the decimal points in the notation "<math>H = 4.92 + 0.00190W</math> or <math>H' = 125 + 0.107W'</math>," as well as correcting the second notation to read "W = tractor weight as specified by 29 CFR 1926.1002(e)(1) and (e)(3) in pounds (<math>W'</math> in kg)."</p>
<p><b>Figures C-2, C-3, C-8, C-9, C-13, C-14, C-15, C-16:</b></p> <p>Define SRP as "Seat Reference Point."</p>	<p>OSHA is not making a change in response to this comment. Both 1928.52(d)(iv) and 1928.53(d)(iv) define this term, and OSHA believes these definitions are sufficient.</p>
<p><b>Figure C-4:</b></p> <p>This drawing does not have any dimension specifications or an explanation of what it is and what it does.</p>	<p>See OSHA's response above for Figure W-18. In this case, the method is explained in §§ 1928.52(d)(3)(i)(E) and 1928.53(d)(3)(i)(E).</p>
<p><b>Figure C-5:</b></p> <ul style="list-style-type: none"> <li>• Load L, lb (kg) – Define as L = static load, lb (kg)</li> <li>• Deflection D, in. (mm) – Define as D = deflection under L, in. (mm)</li> </ul>	<p>See OSHA's response above for Figure W-19. In this case, the terms are defined in §§ 1928(d)(2)(ii) and 1928(d)(2)(ii).</p>
<p><b>Figure C-6:</b></p> <p>Add the weight of the pendulum (4,410 lbs (2,000 kg)) and the height of the pendulum (18–22 ft (5.5–6.7 m)) on the drawing.</p>	<p>See OSHA's response above for Figure W-21. In this case, the information is provided in §§ 1928.52(d)(3)(i)(B) and 1928.53(d)(3)(i)(B).</p>

Recommendation	OSHA's response
<p><b>Figure C-7:</b></p> <ul style="list-style-type: none"> <li>The second notation should read: W = tractor weight (see 29 CFR 1928.51(a) in lb. (W', kg).</li> <li>Clarify whether impact energy is in ft-lbs × 1000 instead of lb × 1000</li> </ul>	<p>OSHA is substituting Figure W-24 for this figure, but is correcting the notation in the new figure to read "W = tractor weight as specified by 29 CFR 1928.51(a) in pounds (W' in kg)." This correction clarifies that impact energy is in ft-lbs.</p>
<p><b>29 CFR 1928.53(d)(2)(ii):</b> Revise the notation to read W = Tractor weight (see 29 CFR 1928.51(a) in lb (W' in kg).</p>	<p>OSHA is revising this notation as recommended.</p>

*Other corrections and technical amendments.* In addition to the revisions described in the table above, OSHA carefully reviewed the direct final rule and found that several additional corrections should be made to the original ROPS standards published in the direct final rule. In this regard, the Agency is making the following two corrections to § 1926.1002(h)(1)(v): Correcting the typographical error in the first sentence from "f" to "of"; and, in the second

sentence, correcting the reference to Figure W-23 to "Figure W-18." A number of figures appear in the original ROPS standards. These figures are: W-14 through W-24 of § 1926.1002; W-25 through W-28 of § 1926.1003; C-1 through C-11 of § 1928.52; and C-12 through C-16 of § 1928.53. After publishing the direct final rule for ROPS in the **Federal Register** (70 FR 76979), the Agency reproduced the figures in these ROPS standards using state-of-the-art computer-design technology to

obtain images that are clearer and more comprehensible than the images used in the direct final rule. Therefore, OSHA is replacing the figures published in the direct final rule with these newly generated figures.

In the process of generating the new figures, the Agency made stylistic, editorial, and technical corrections to them. The following table describes the technical corrections made to the figures.

Figures	Correction
W-15 .....	Added the same legend as the legend to Figure C-10; added the caption "CENTER OF TRACTOR" as in Figure C-10.
C-4 .....	Replaced the legend with the legend to Figure W-18.
C-5 .....	Substituted Figure W-19 for this figure.
C-6 .....	Added the phrase "PIN MARKING POSITION OF" to the caption "CENTER OF GRAVITY" as in Figure W-21.
C-7 .....	Substituted Figure W-24 for this figure.
C-8, C-15, and W-22 .....	Revised the caption addressing the beam under the tractor to read, "BEAM CLAMPED IN FRONT OF BOTH REAR WHEELS AFTER ANCHORING, 6 IN. (15 CM) SQUARE."
C-10 .....	Added the captions "PATH OF TRAVEL" and "RAMP" as in Figure W-15; added the phrase "TEST TRACTOR" to the caption "REAR WHEEL TREAD" as in Figure W-15.

*Exemption from notice and comment procedures.* OSHA has determined that the corrections and technical amendments made by this rulemaking are not subject to the procedures for public notice-and-comment rulemaking specified under Section 4 of the Administrative Procedure Act (5 U.S.C. 553), or Section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)), because these corrections and technical amendments do not affect the substantive requirements or coverage of the ROPS standards for the construction and agriculture industries. This rulemaking does not modify or revoke existing rights and obligations, and new rights and obligations have not been established by this rulemaking. Under this rulemaking, the Agency is merely correcting or clarifying the existing regulatory requirements of the ROPS standards. Therefore, OSHA finds that public notice-and-comment procedures are unnecessary within the meaning of 5 U.S.C. 553(b)(3)(B) and § 1911.5.

**List of Subjects**

29 CFR Part 1926

Construction industry, Motor vehicle safety, Occupational safety and health.

29 CFR Part 1928

Agriculture, Motor vehicle safety, Occupational safety and health.

**Authority and Signature**

This document was prepared under the direction of Edwin G. Foulke, Jr., Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. The Agency is issuing this notice under the following authorities: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*); Secretary of Labor's Order 5-2002 (67 FR 65008); and 29 CFR part 1911.

Signed at Washington, DC on July 12, 2006.

**Edwin G. Foulke, Jr.,**  
Assistant Secretary of Labor.

**Amended Standards**

■ Based on the explanations provided by the preamble to this document, OSHA is amending 29 CFR parts 1926 and 1928 as follows:

**PART 1926—[AMENDED]**

**Subpart W—[Amended]**

■ 1. The authority citation for subpart W of part 1926 continues to read as follows:

**Authority:** Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); and Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), 6-96 (62 FR 111), 3-2000 (65 FR 50017), or 5-2002 (67 FR 65008), as applicable.

■ 2. Revise paragraph (h)(1)(v) of § 1926.1002 to read as follows:

**§ 1926.1002 Protective frames (roll-over protective structures, known as ROPS) for wheel-type agricultural and industrial tractors used in construction.**

\* \* \* \* \*

(h) \* \* \*

(1) \* \* \*

(v) Means shall be provided for indicating the maximum instantaneous deflection along the line of impact. A

simple friction device is illustrated in Figure W-18.

\* \* \* \* \*

■ 3. In Appendix A to subpart W, remove existing Figures W-14 through W-28 and add in their place new Figures W-14 through W-28. [insert figures W-14 through W-28]

\* \* \* \* \*

**PART 1928—[AMENDED]**

**Subpart C—[Amended]**

■ 4. The authority citation to part 1928 continues to read as follows:

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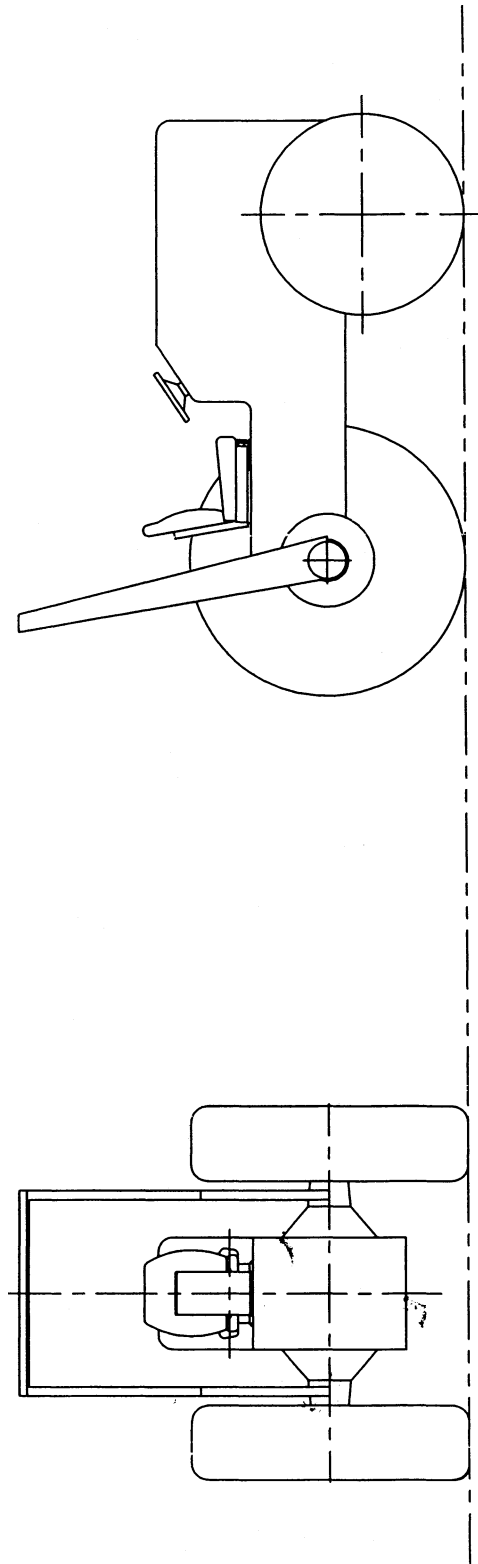


FIGURE W-14 - TYPICAL FRAME CONFIGURATION.

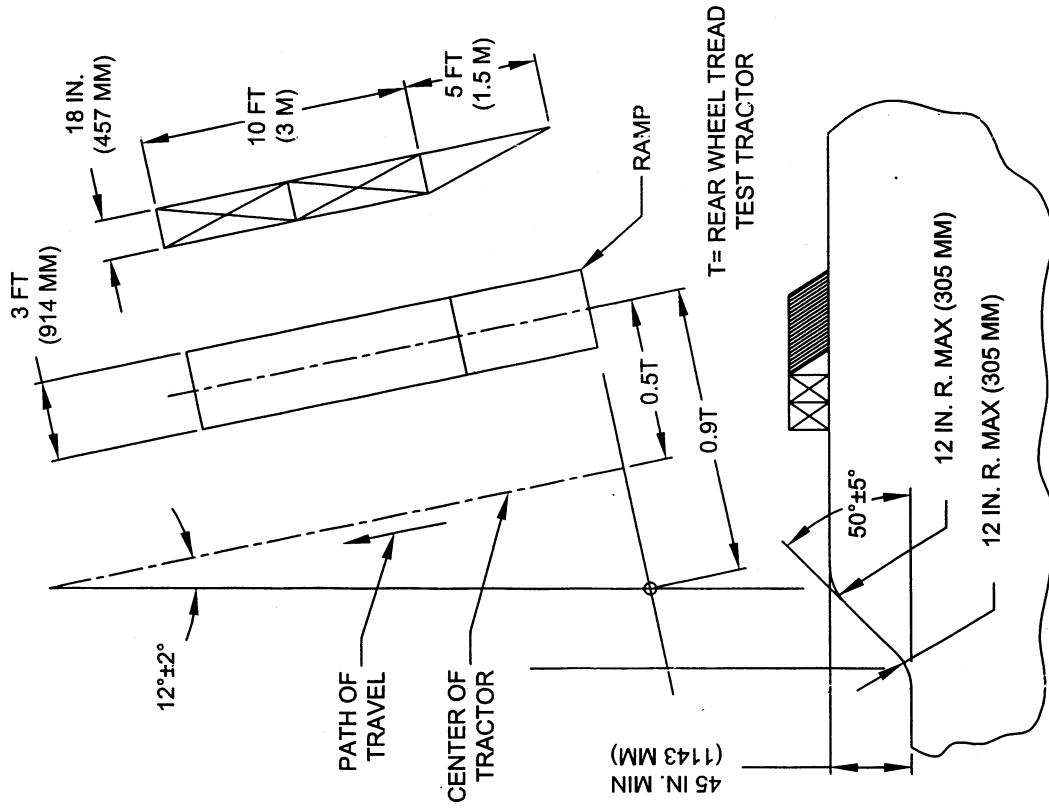


FIGURE W-15 - SIDE OVERTURN BANK AND RAMP.

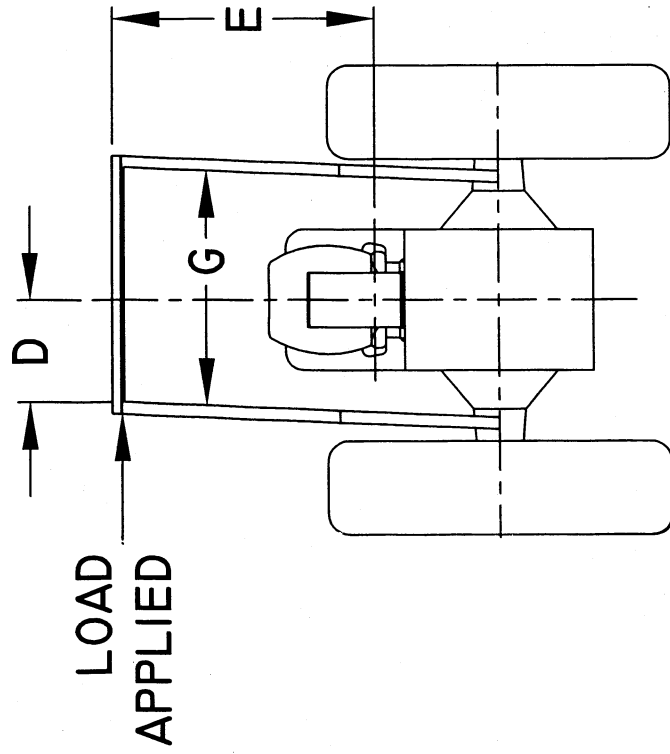


FIGURE W-16 - SIDE LOAD APPLICATION.

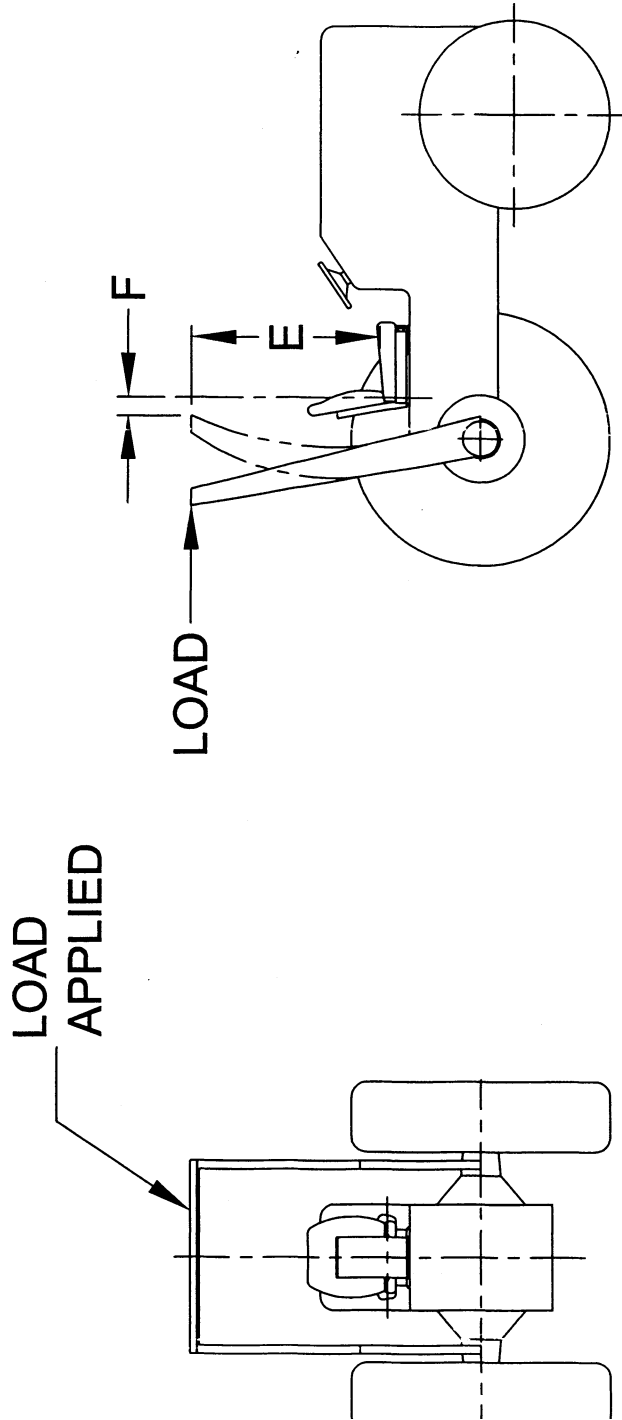


FIGURE W-17 - REAR LOAD APPLICATION.



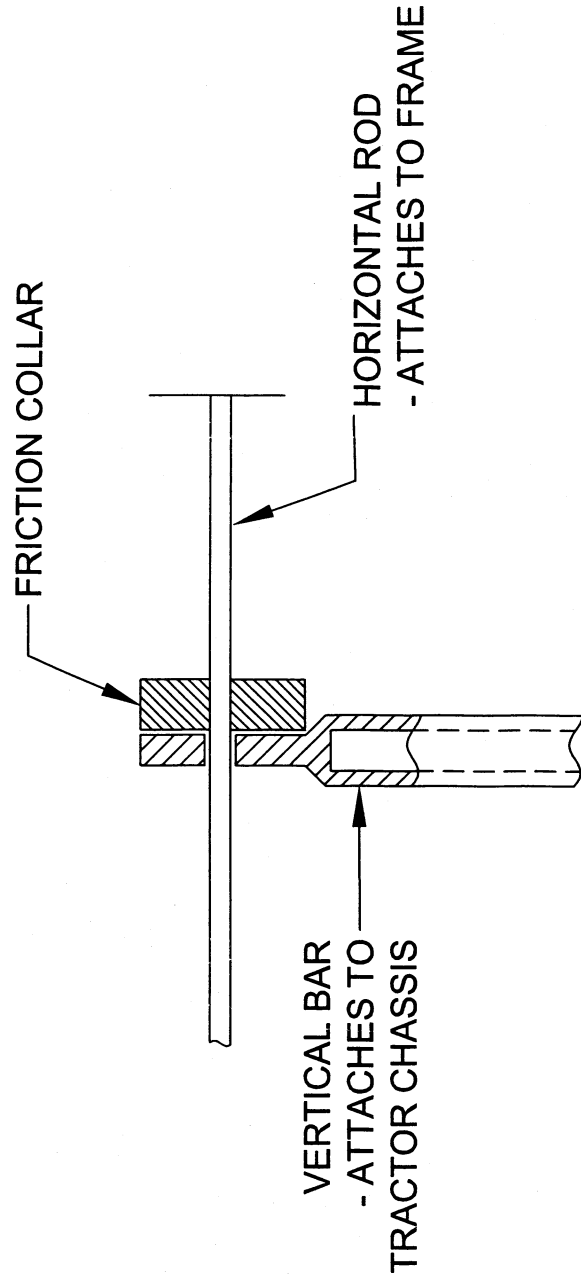


FIGURE W-18 - METHOD OF MEASURING INSTANTANEOUS DEFLECTION.

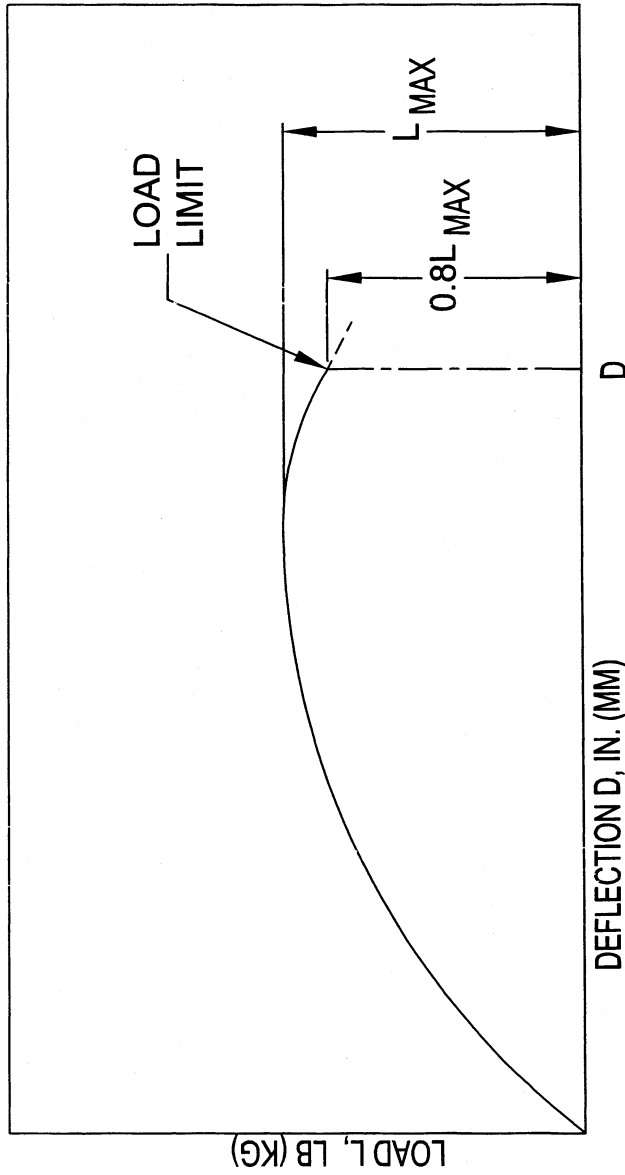


FIGURE W-19 - TYPICAL L-D DIAGRAM.

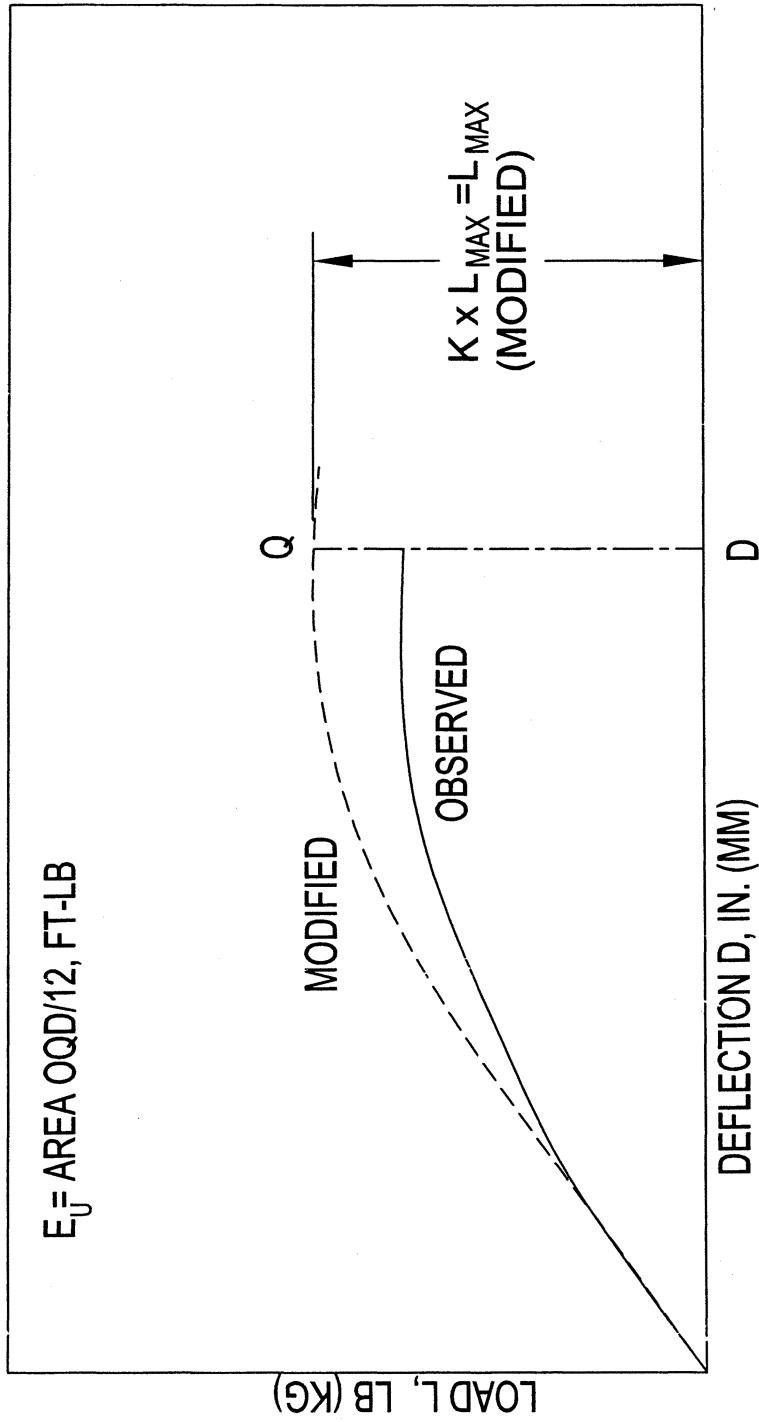


FIGURE W-20 - TYPICAL MODIFIED  $L_M$ - $D_M$  DIAGRAM.

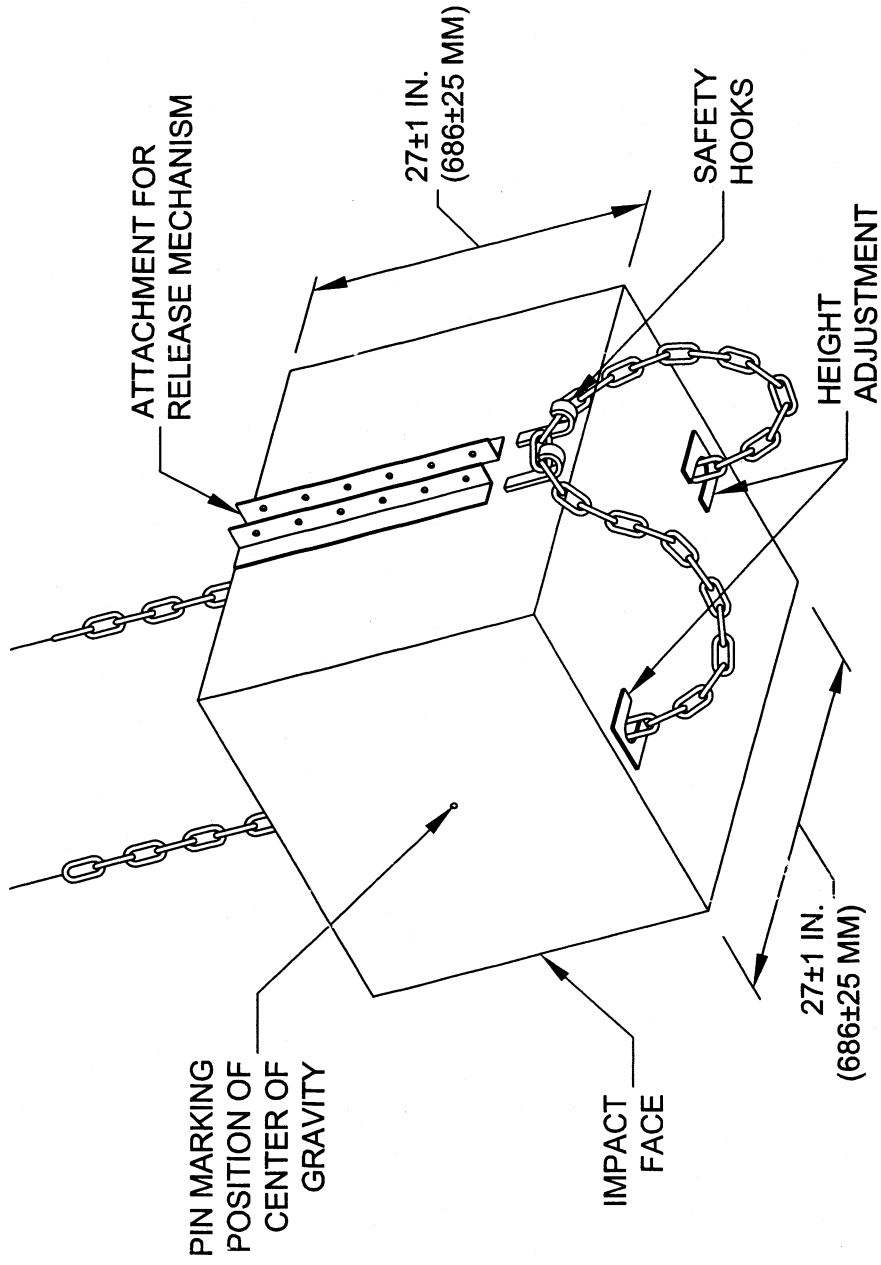


FIGURE W-21 - PENDULUM.

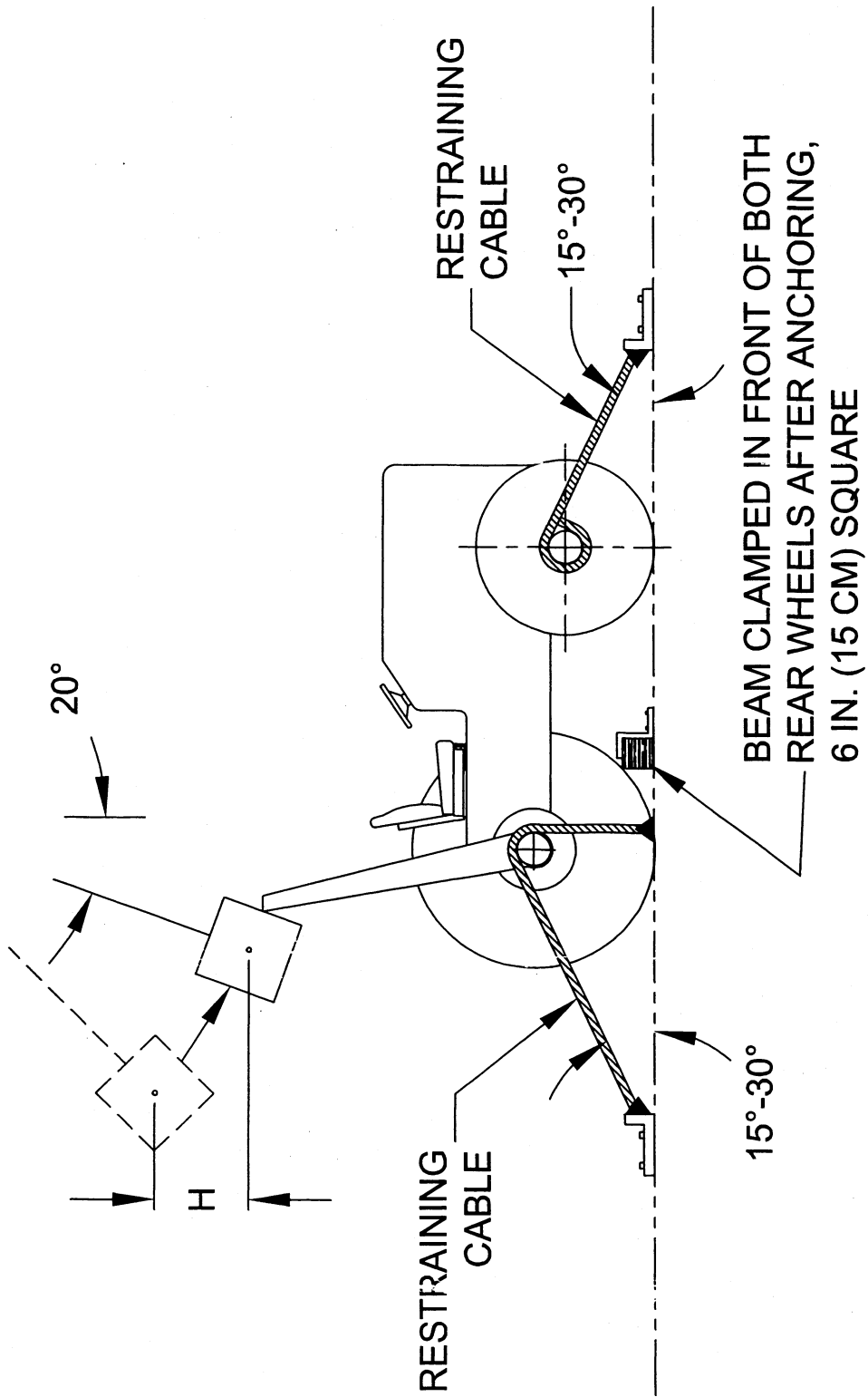


FIGURE W-22 - METHOD OF IMPACT FROM REAR.

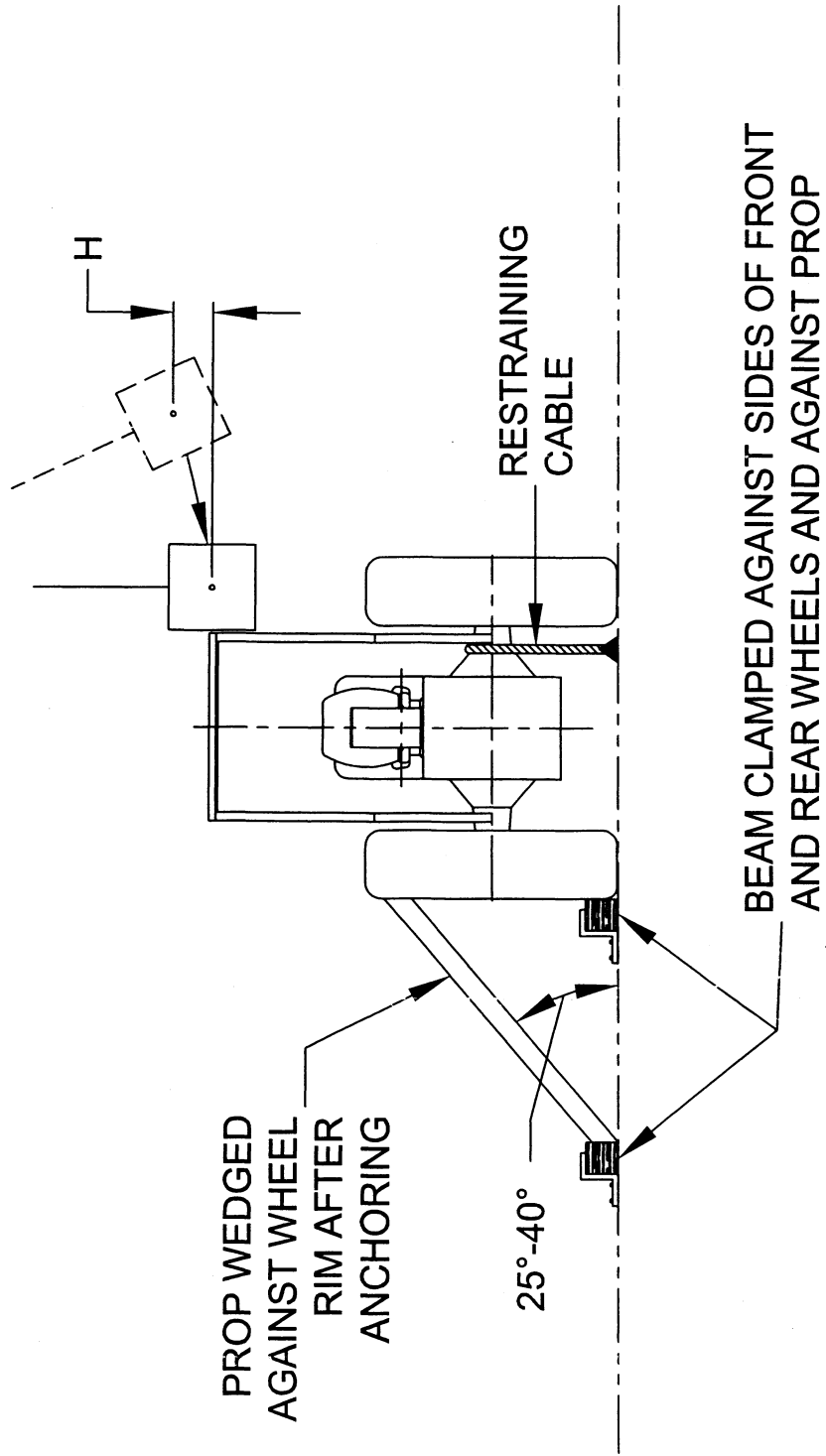
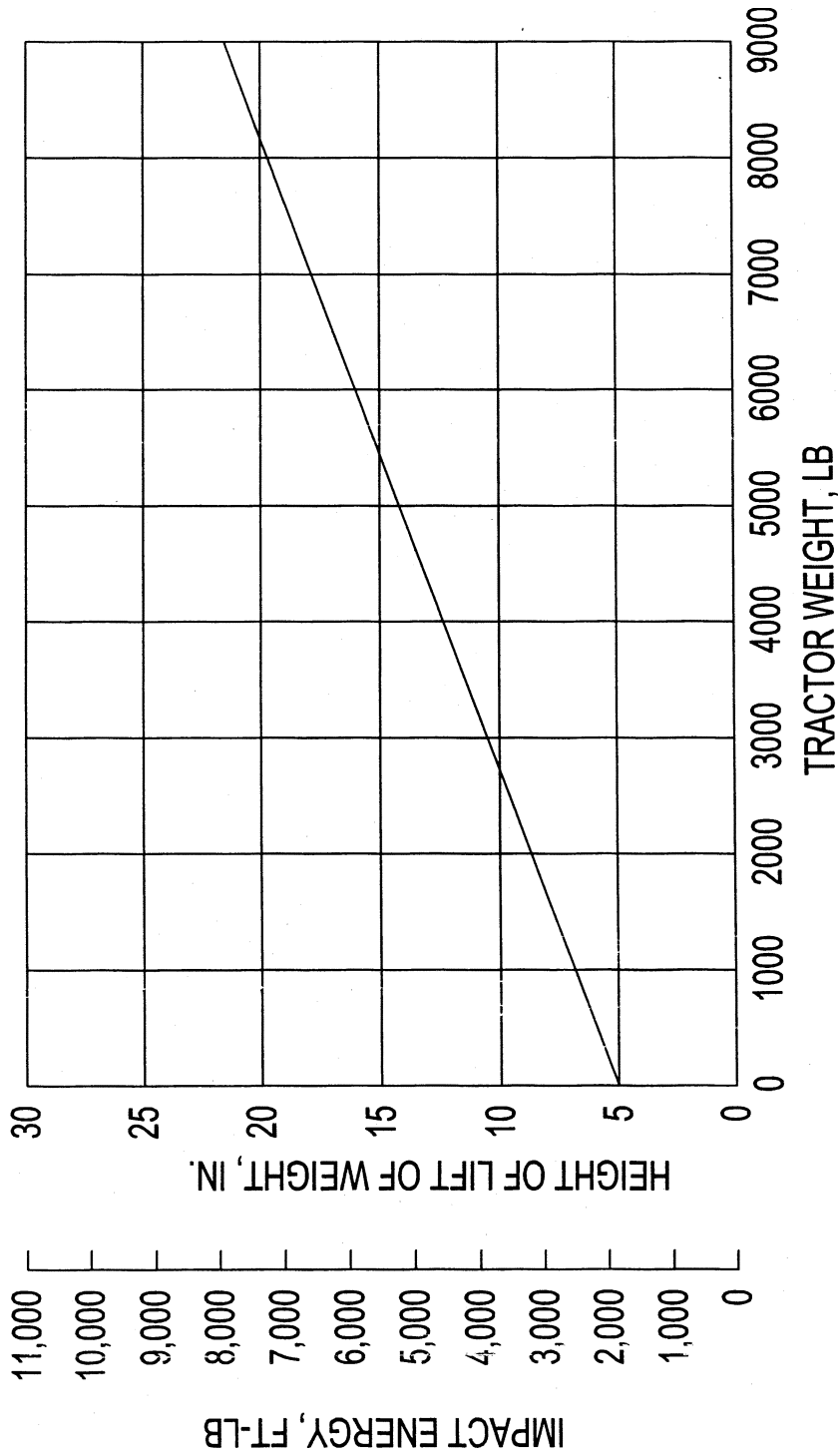


FIGURE W-23 - METHOD OF IMPACT FROM SIDE.



NOTATION OF FORMULAE

$H = 4.92 + 0.00190W$  or  $H' = 125 + 0.107W'$

W = tractor weight specified by 29 CFR

1926.1002(e)(1) and (e)(3) in lbs ( $W'$  in kg).

**FIGURE W-24 - IMPACT ENERGY AND CORRESPONDING LIFT HEIGHT OF 4,410 lb (2,000 kg) WEIGHT.**

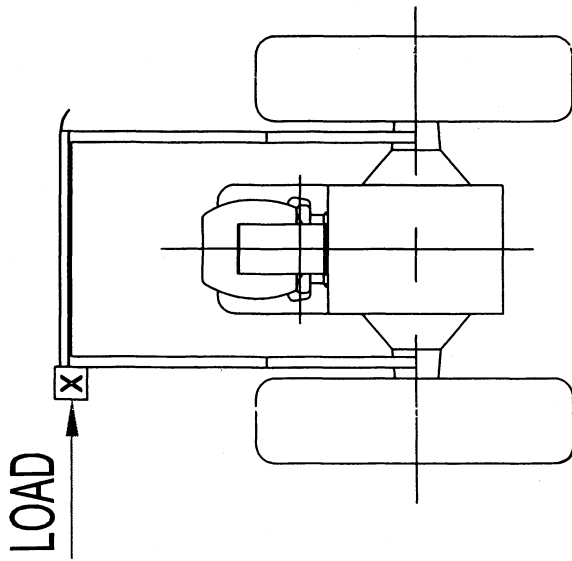
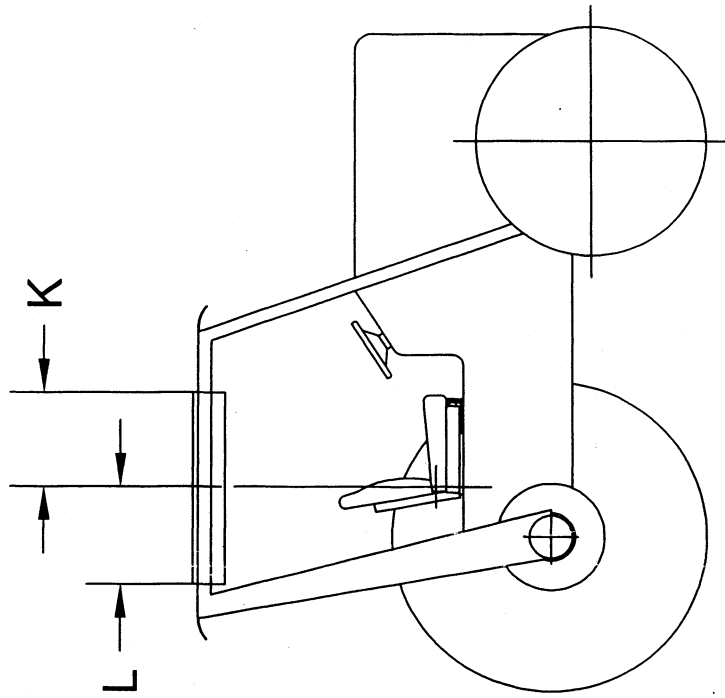


FIGURE W-25 - LOCATION OF SIDE LOAD.



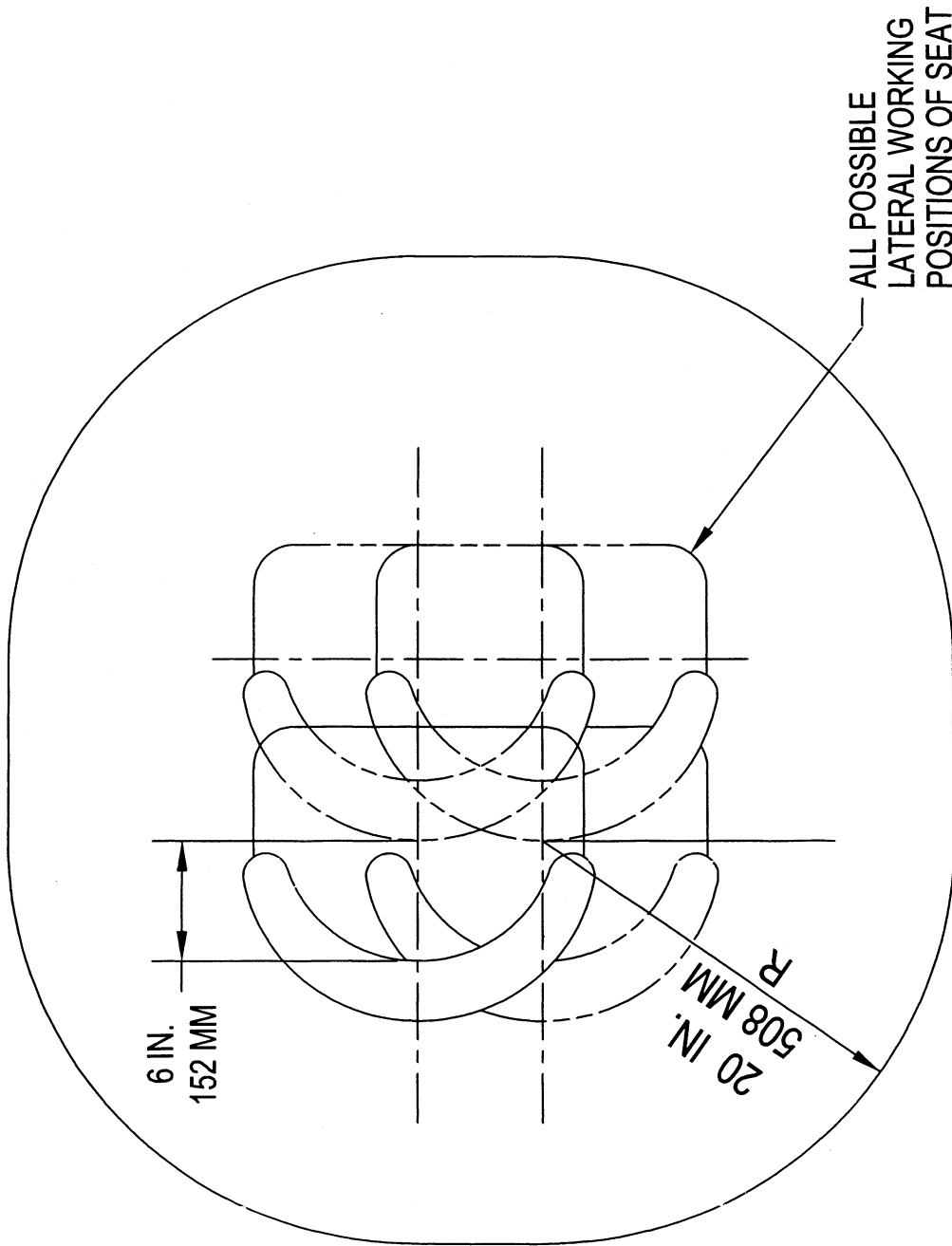


FIGURE W-26 - ZONE OF PROTECTION FOR DROP TEST.

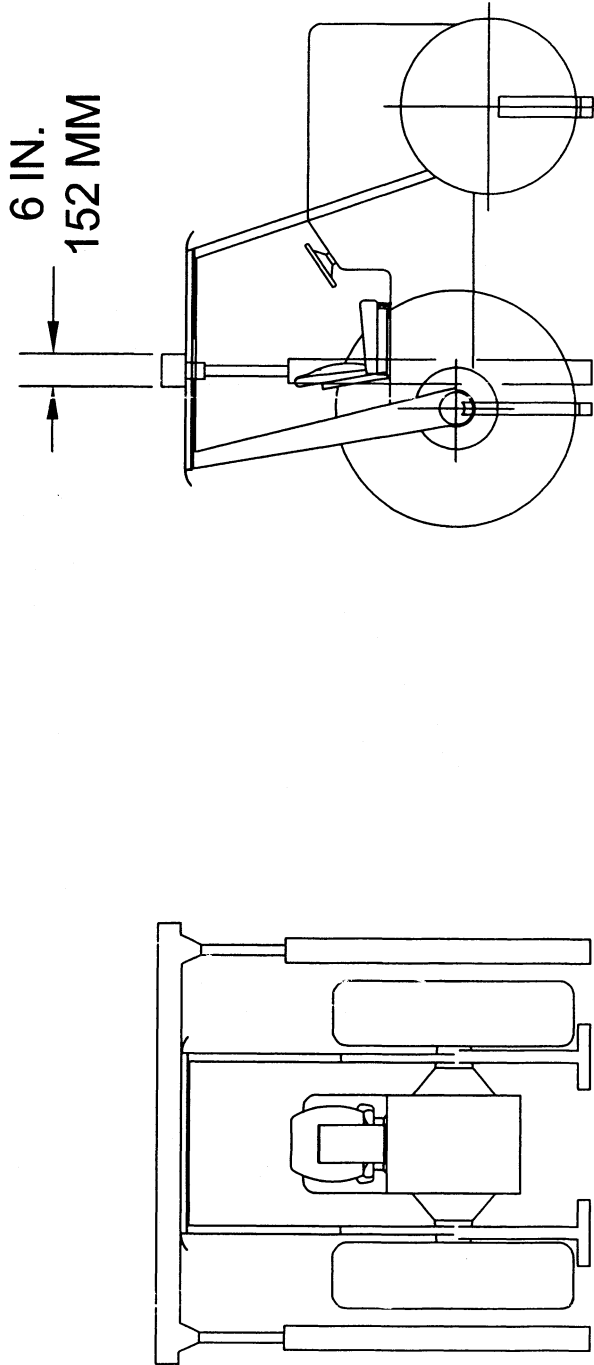


FIGURE W-27 - METHOD OF LOAD APPLICATION FOR CRUSH TEST.

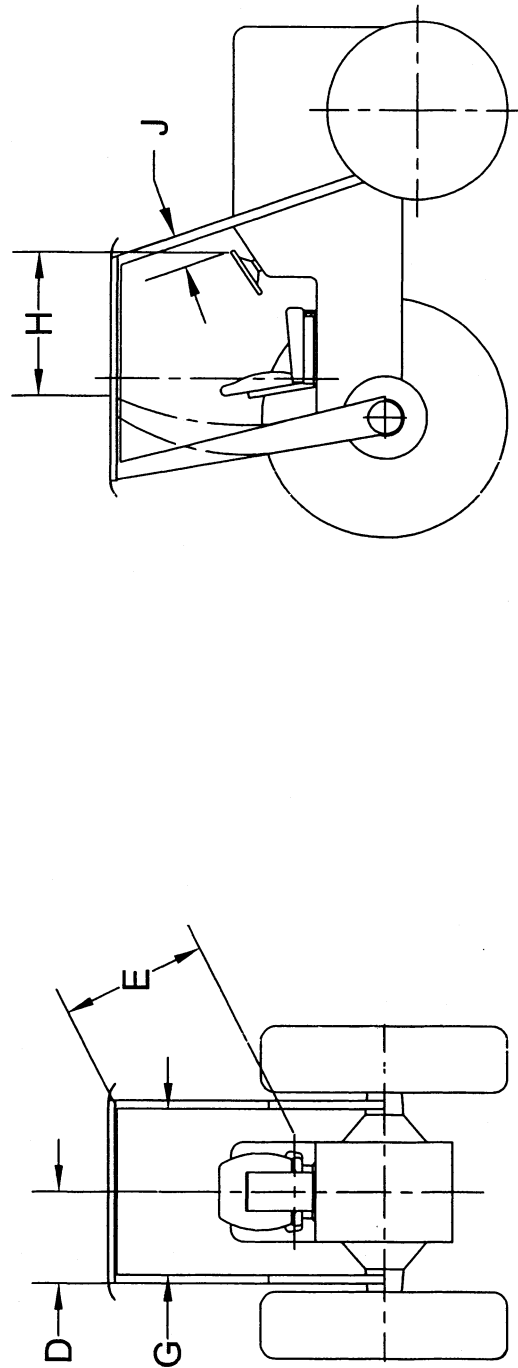


FIGURE W-28 - PROTECTED ZONE DURING CRUSH AND DROP TEST.

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**Authority:** Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); and Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), 6-96 (62 FR 111), 3-2000 (65 FR 50017) or 5-2002 (67 FR 65008) as applicable; and 29 CFR part 1911.

Section 1928.21 also issued under Section 29, Hazardous Materials Transportation Uniform Safety Act of 1990 (Pub. L. 101-615, 104 Stat. 3244 (49 U.S.C. 1801-1819 and 5 U.S.C. 553)).

■ 5. Revise paragraph (d)(2)(ii) of § 1928.53 to read as follows:

**§ 1928.53 Protective enclosures for wheel-type agricultural tractors—test procedures and performance requirements.**

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(ii) The following definitions shall apply:

$W$  = Tractor weight (see 29 CFR 1928.51(a)) in lb ( $W'$  in kg);  
 $E_{is}$  = Energy input to be absorbed during side loading in ft-lb ( $E'_{is}$  in J [joules]);  
 $E_{is} = 723 + 0.4 W$  ( $E'_{is} = 100 + 0.12 W'$ );  
 $E_{ir}$  = Energy input to be absorbed during rear loading in ft-lb ( $E'_{ir}$  in J);  
 $E_{ir} = 0.47 W$  ( $E'_{ir} = 0.14 W'$ );  
 $L$  = Static load, lbf [pounds force], (N [newtons]);

$D$  = Deflection under  $L$ , in. (mm);  
 $L-D$  = Static load-deflection diagram;  
 $L_{max}$  = Maximum observed static load;  
**Load Limit** = Point on a continuous  $L-D$  curve where the observed static load is  $0.8 L_{max}$  on the down slope of the curve (see Figure C-5);  
 $E_u$  = Strain energy absorbed by the protective enclosure in ft-lbs (J); area under the  $L-D$  curve;

$FER$  = Factor of energy ratio;  
 $FER_{is} = E_u/E_{is}$ ; and  
 $FER_{ir} = E_u/E_{ir}$ .

\* \* \* \* \*

■ 6. In Appendix B to subpart C, remove existing Figures C-1 through C-16 and add in their place new Figures C-1 through C-16.

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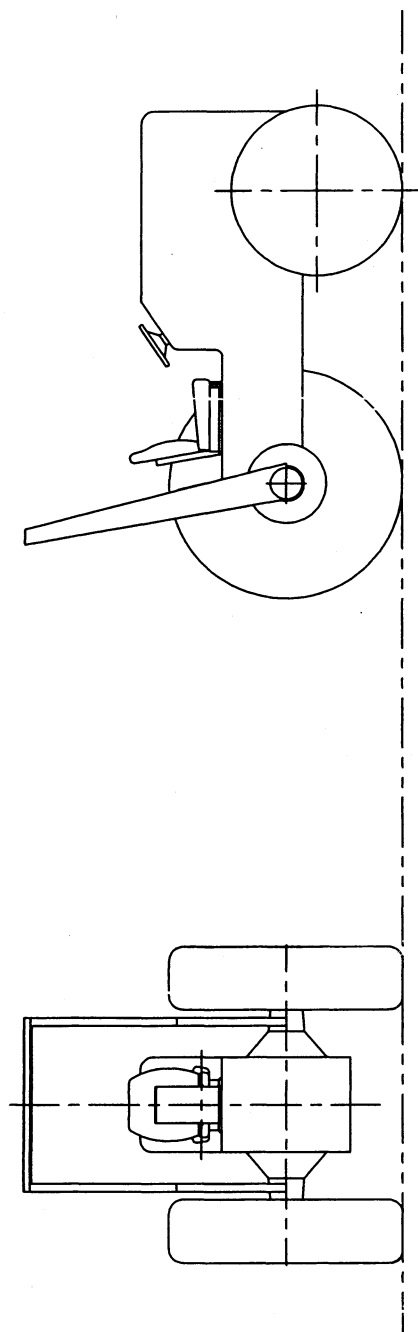


FIGURE C-1 - TRACTOR WITH TYPICAL PROTECTIVE FRAME.

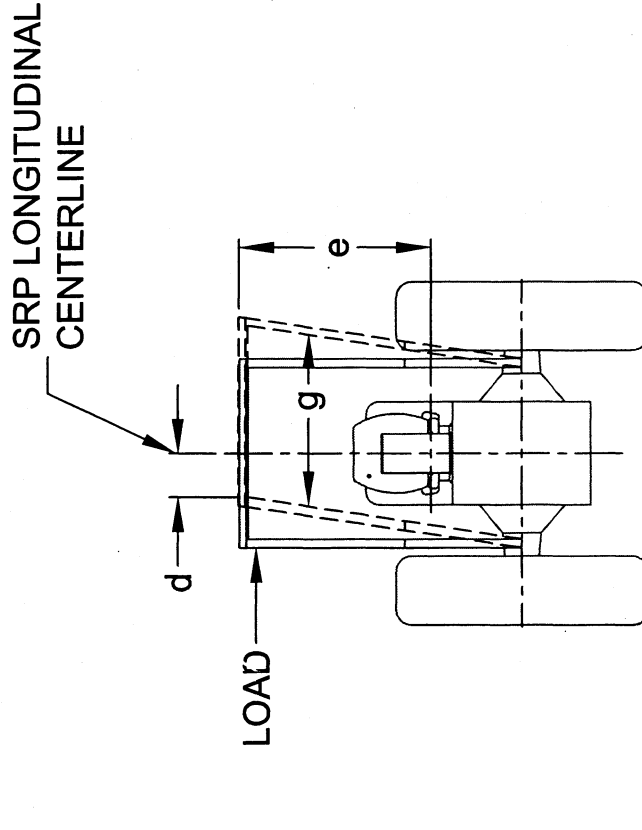


FIGURE C-2 - SIDE LOAD APPLICATION.

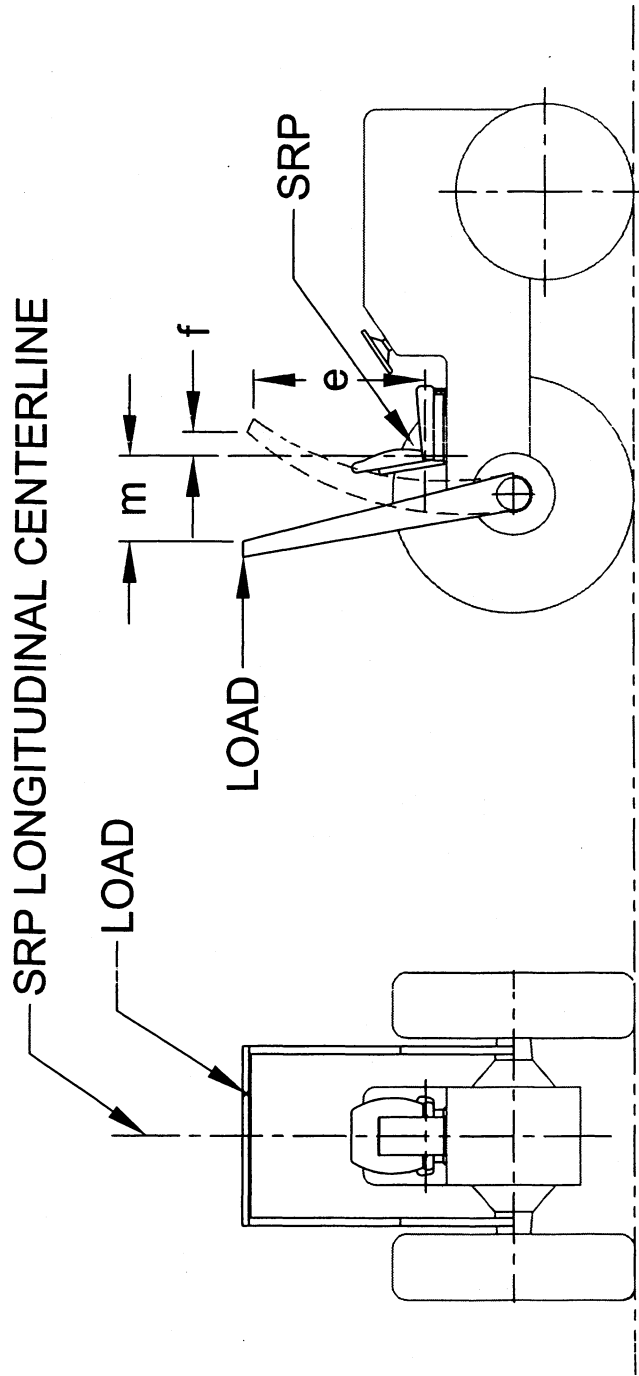


FIGURE C-3 - REAR LOAD APPLICATION.

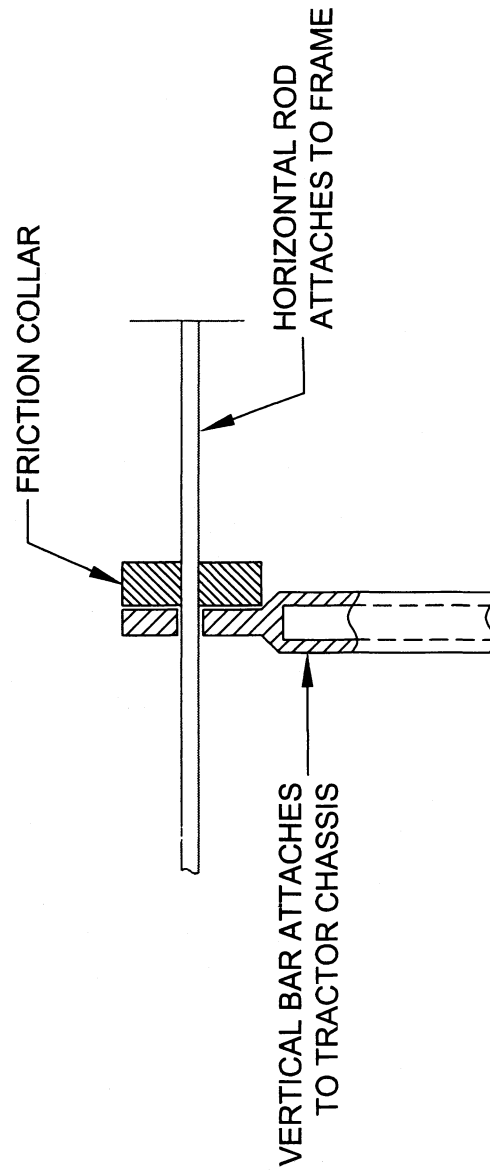


FIGURE C-4 - METHOD OF MEASURING INSTANTANEOUS DEFLECTION.

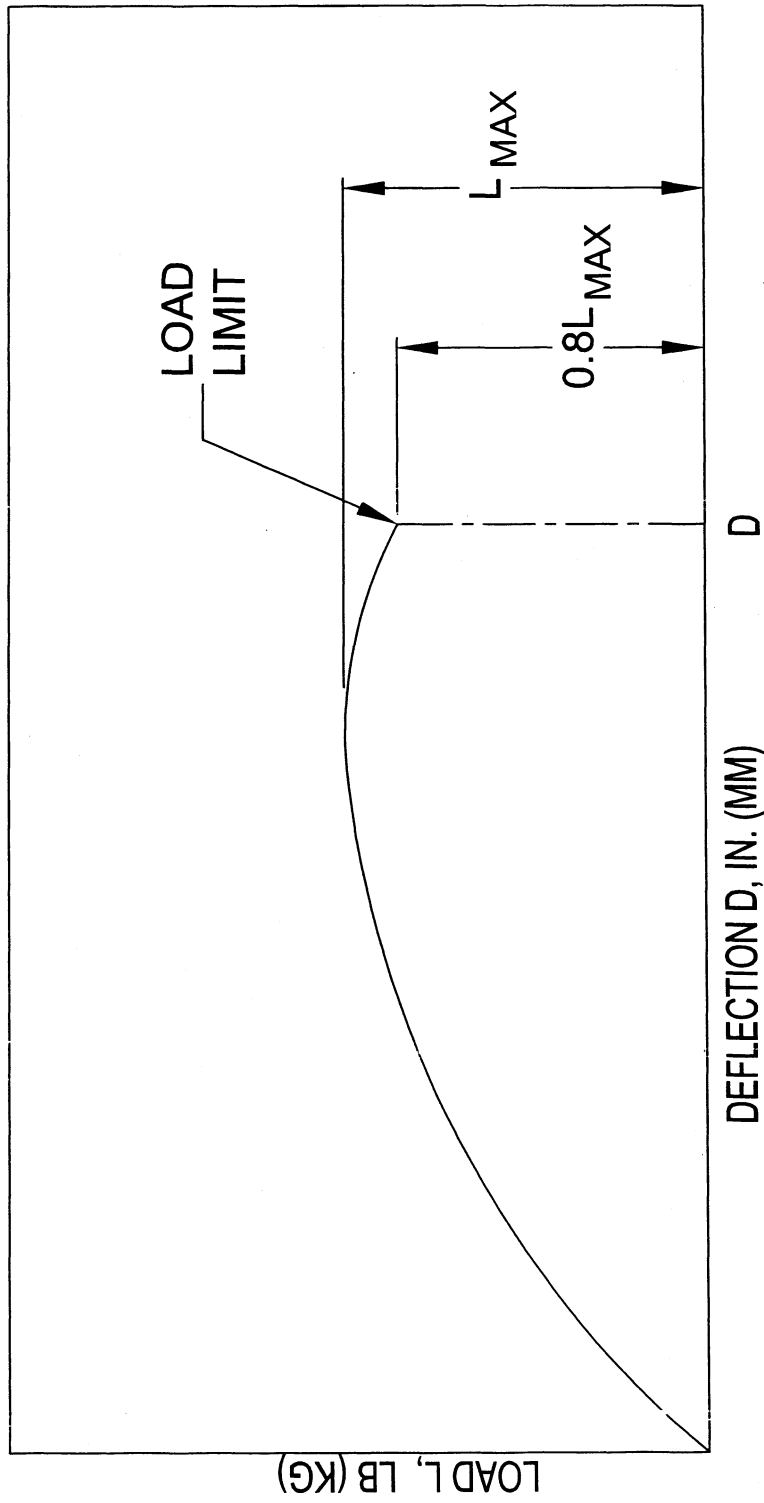


FIGURE C-5 - TYPICAL L-D DIAGRAM.



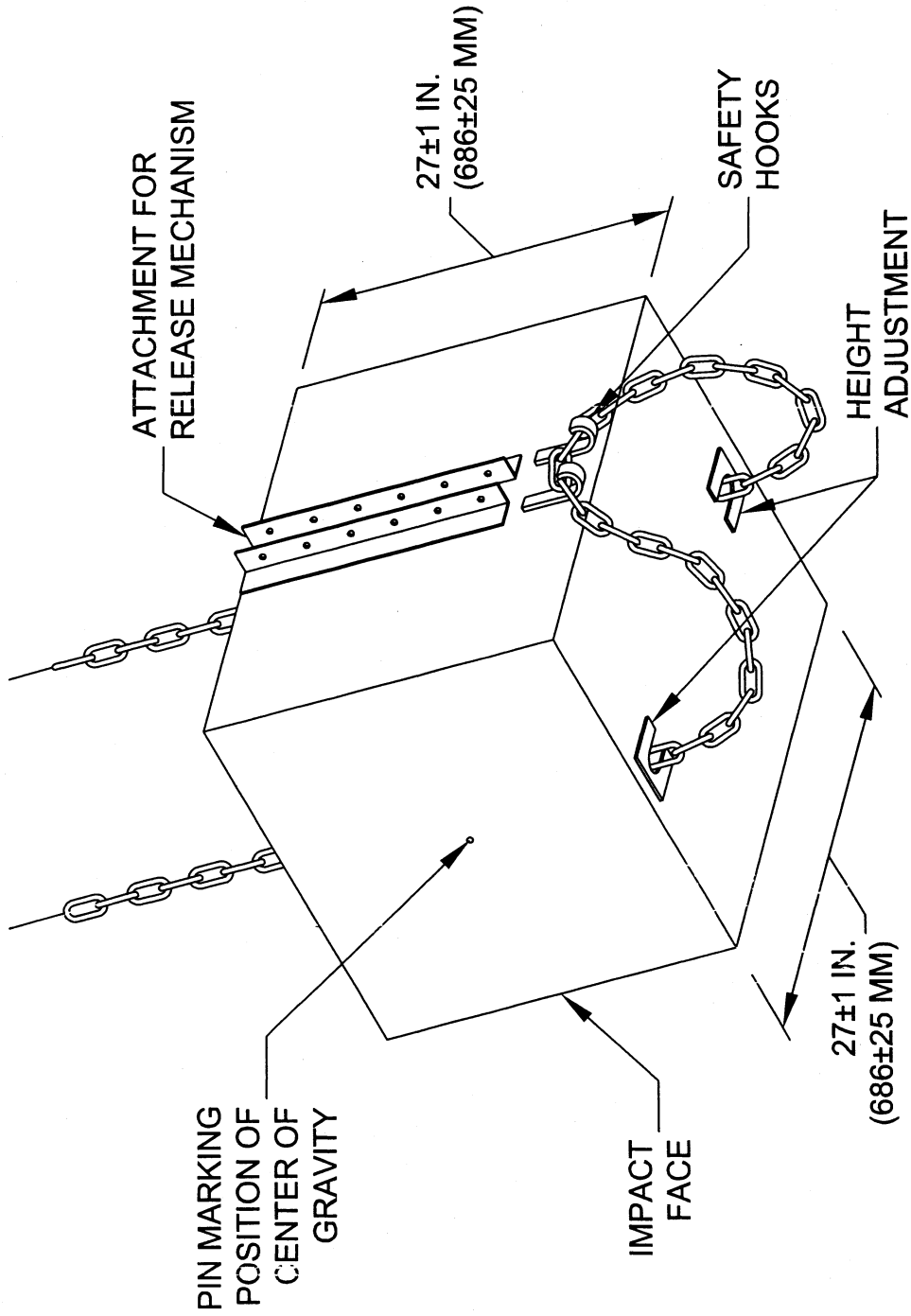
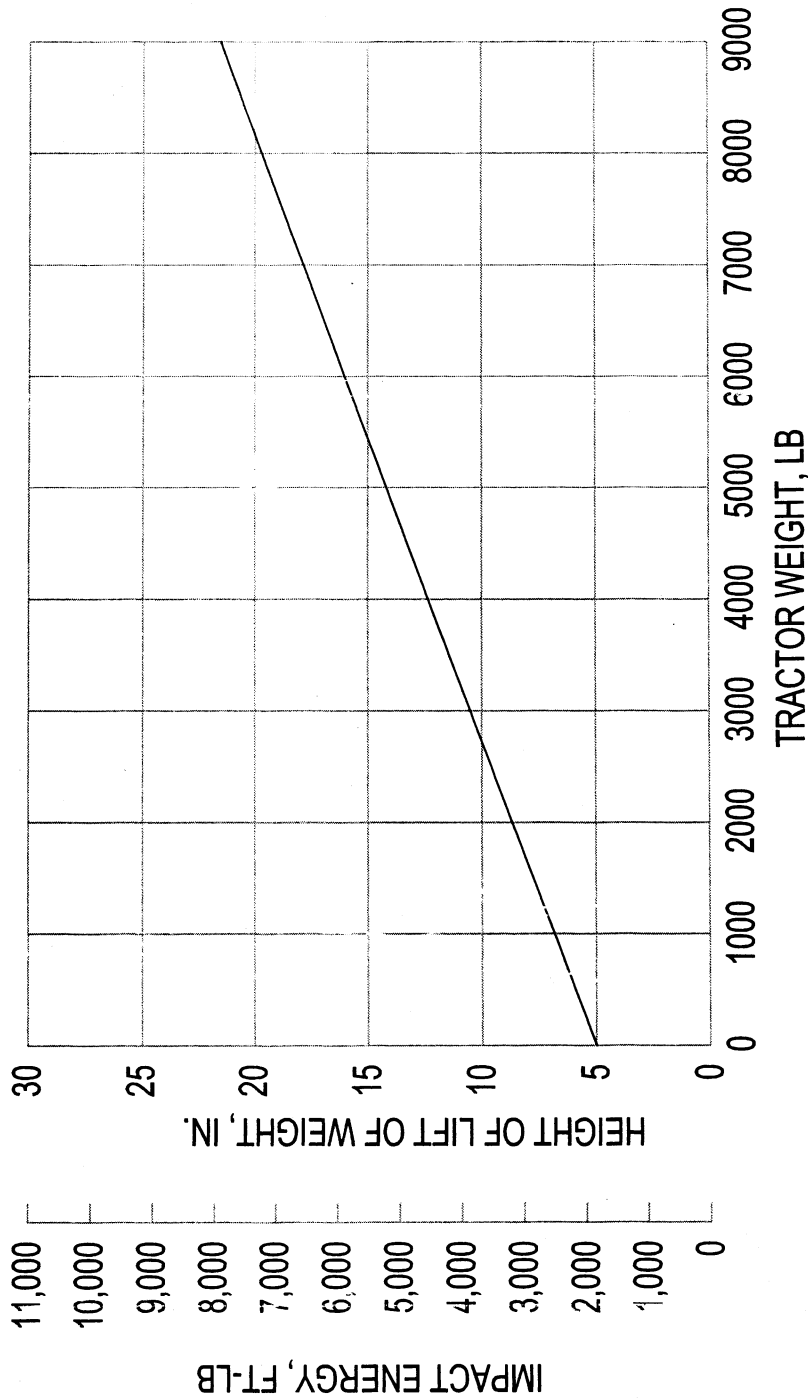


FIGURE C-6 - PENDULUM.



NOTATION OF FORMULAE

$H=4.92+0.00190W$  or  $H'=125+0.107W'$

W=tractor weight specified by 29 CFR 1928.51(a) in lbs (W' in kg).

**FIGURE C-7 - IMPACT ENERGY AND CORRESPONDING LIFT HEIGHT OF 4,410 LB (2,000 kg) WEIGHT.**

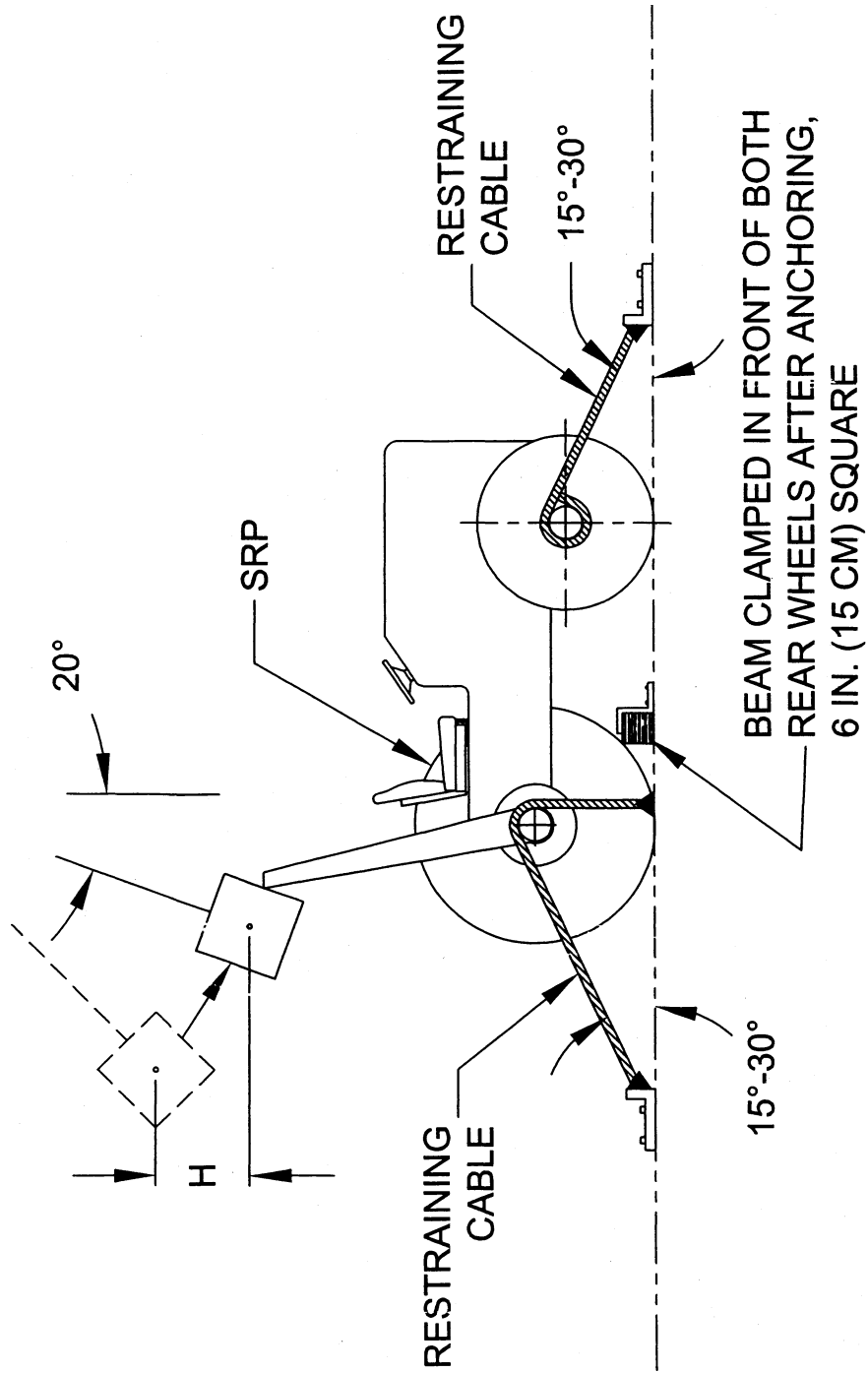


FIGURE C-8 - REAR IMPACT APPLICATION.

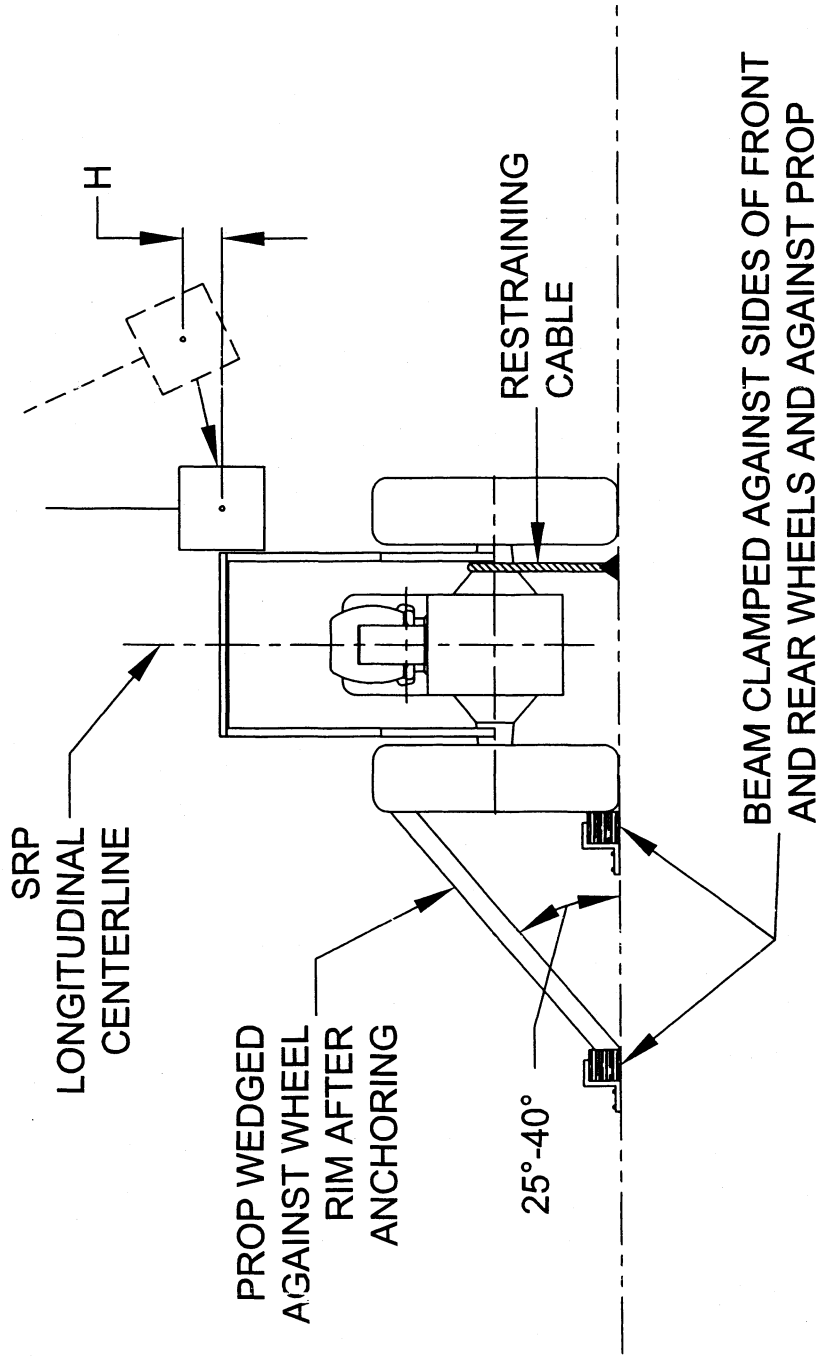


FIGURE C-9 - SIDE IMPACT APPLICATION.

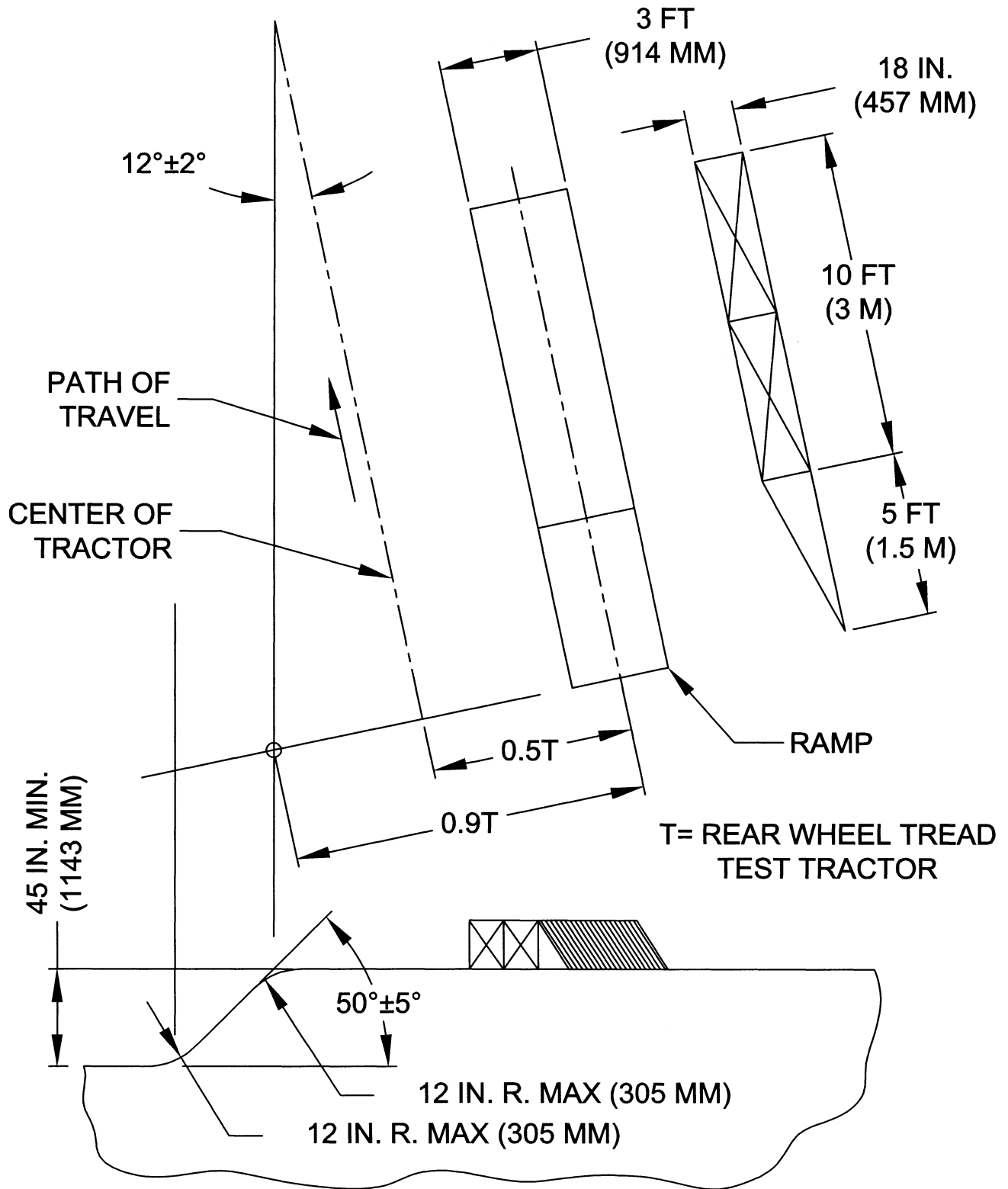


FIGURE C-10 - SIDE OVERTURN BANK AND RAMP.

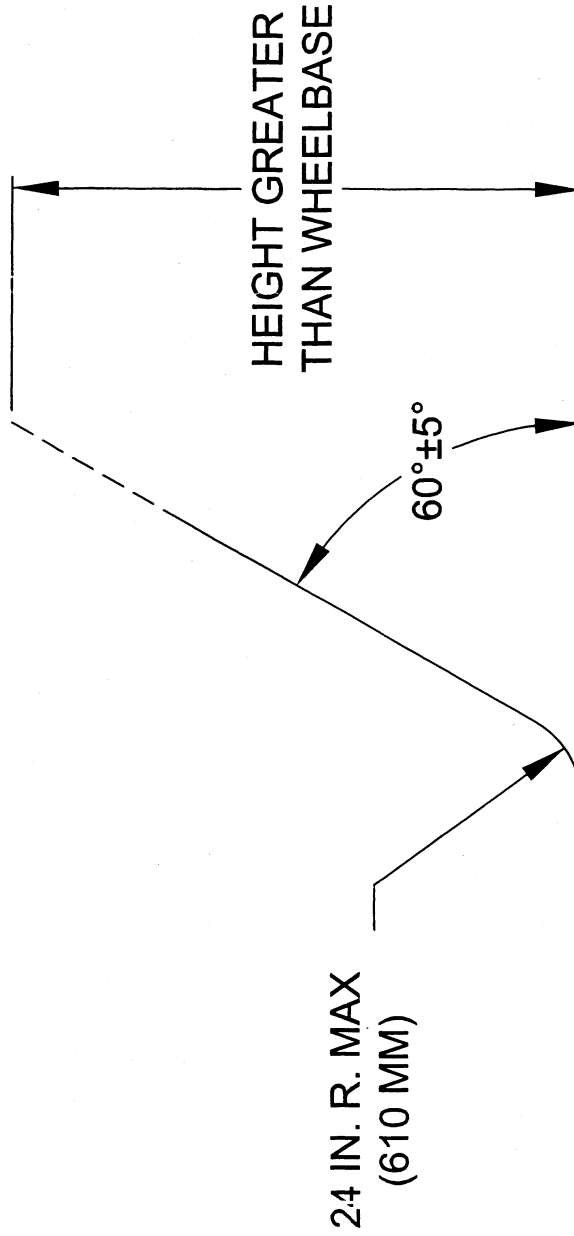


FIGURE C-11 - TYPICAL REAR OVERTURN BANK.

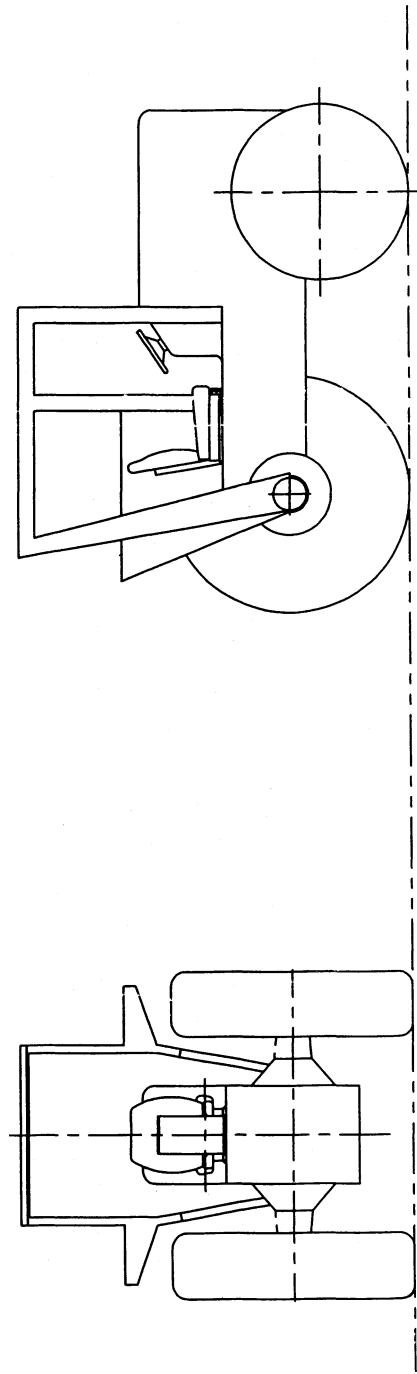


FIGURE C-12 - TRACTOR WITH TYPICAL PROTECTIVE ENCLOSURE.

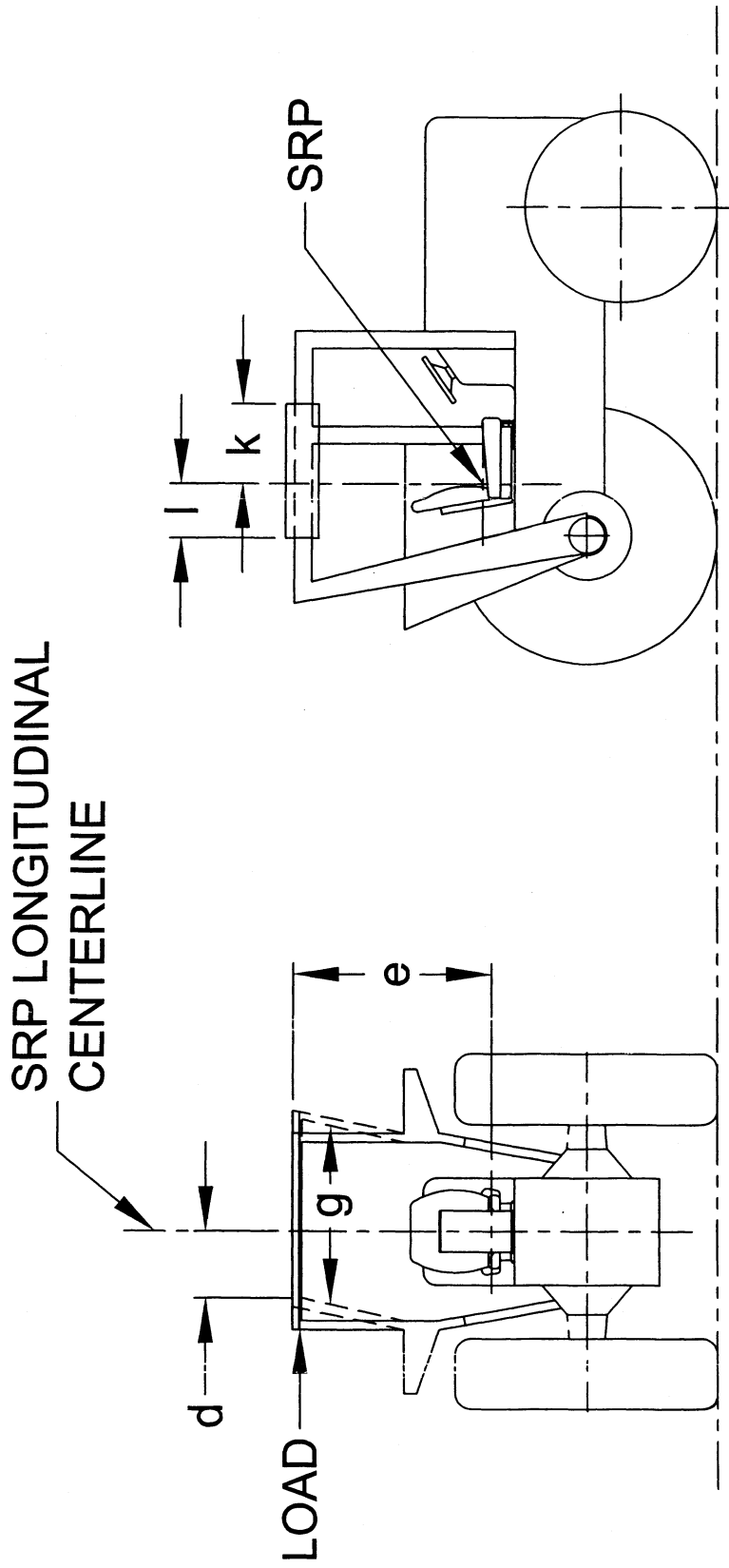


FIGURE C-13 - SIDE LOAD APPLICATION.



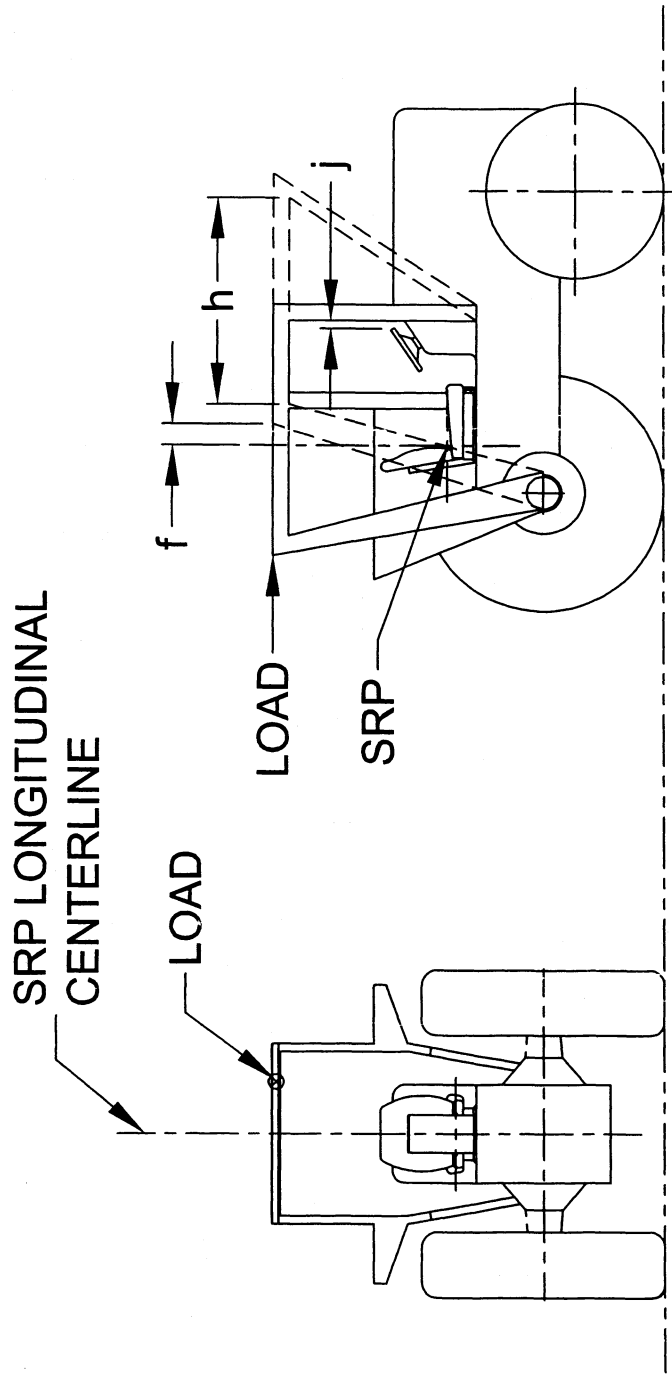


FIGURE C-14 - REAR LOAD APPLICATION.

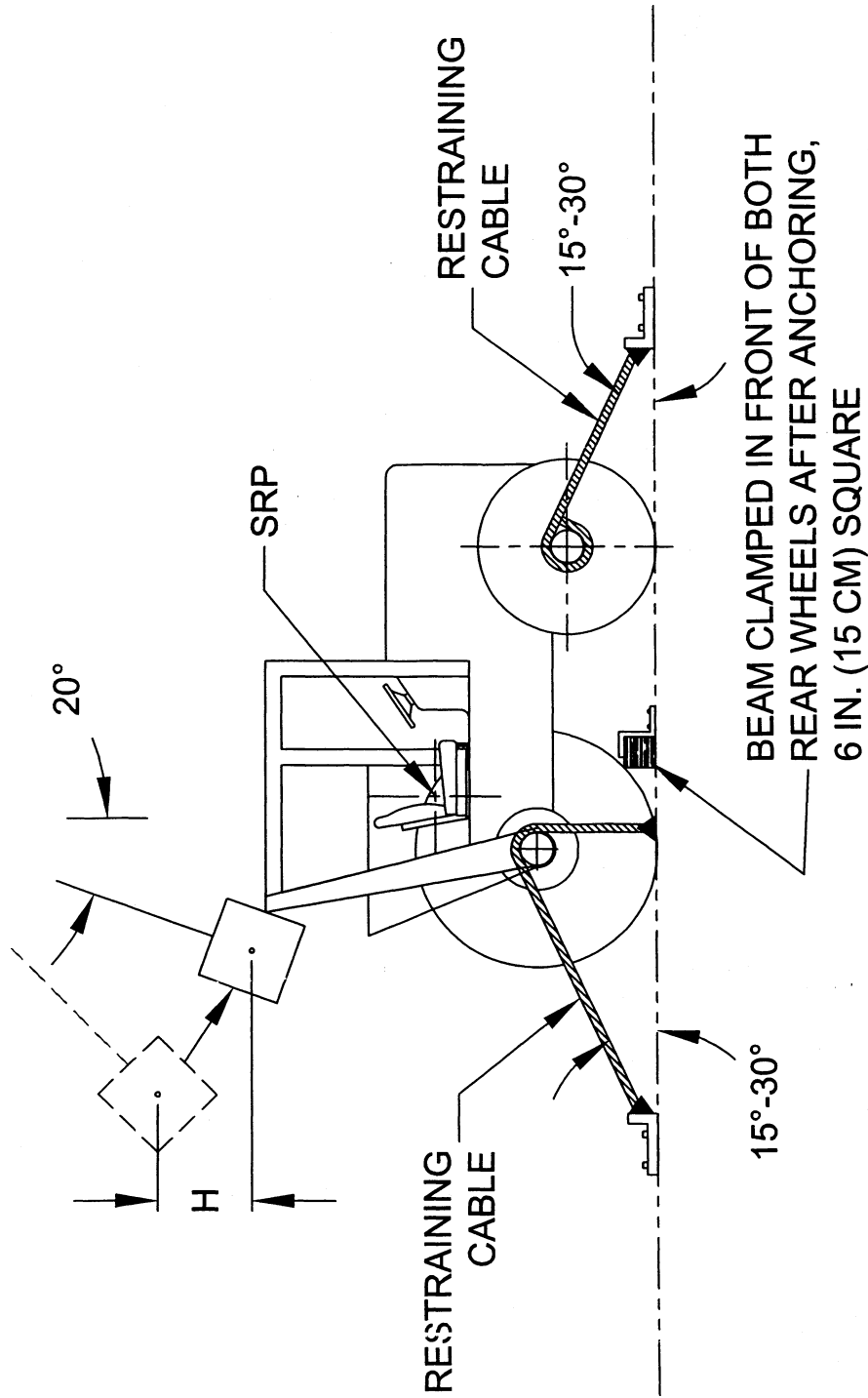


FIGURE C-15 - REAR IMPACT APPLICATION.

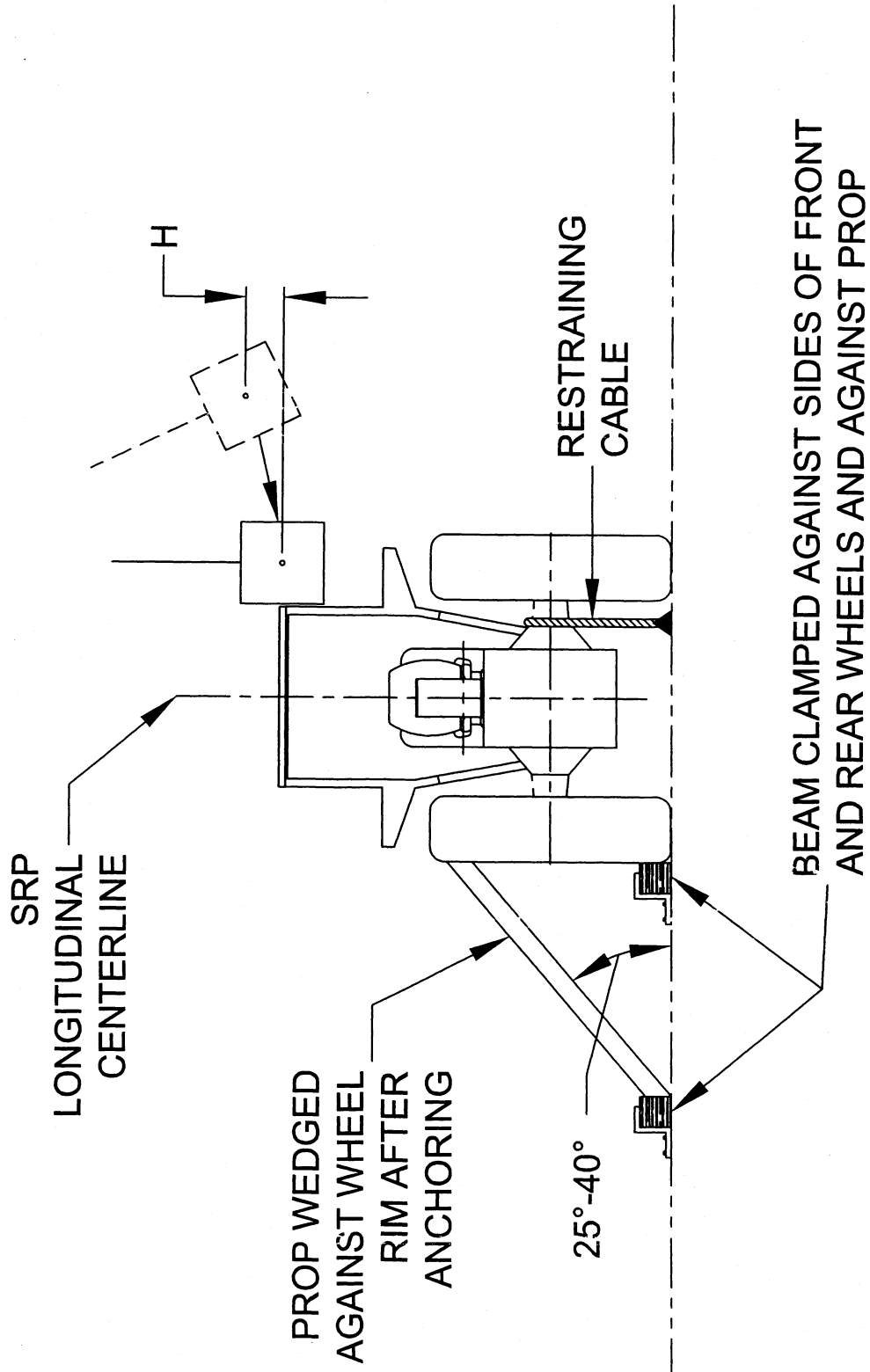


FIGURE C-16 - SIDE IMPACT APPLICATION.

\* \* \* \* \*

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