

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1203

Safety Standard for Bicycle Helmets

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Pursuant to the Children's Bicycle Helmet Safety Act of 1994, the Commission is issuing a safety standard that will require all bicycle helmets to meet impact-attenuation and other requirements.

The standard establishes requirements derived from one or more of the voluntary standards applicable to bicycle helmets. In addition, the standard includes requirements specifically applicable to children's helmets and requirements to prevent helmets from coming off during an accident. The standard also contains testing and recordkeeping requirements to ensure that bicycle helmets meet the standard's requirements.

DATES: *Effective Date:* This rule is effective March 10, 1999.

Applicability Dates: This rule applies to bicycle helmets manufactured after March 10, 1999. Interim mandatory standards that went into effect on March 17, 1995, will continue to apply to bicycle helmets manufactured from March 17, 1995, until March 10, 1999, inclusive. In addition, as of March 10, 1998, firms will have the option of marketing helmets meeting the standard in this final rule before its effective date.

Incorporation by Reference: The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of March 10, 1999.

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Part 1203—Safety Standard for Bicycle Helmets

A. Introduction and Background

1. Introduction

In this notice, the United States Consumer Product Safety Commission ("Commission" or "CPSC") issues a mandatory safety standard for bicycle helmets.¹

2. Injury and Death Data

Data from the National Center for Health Statistics ("NCHS") indicated that in 1993 there were 907 pedalcyclist (primarily bicycle-related) deaths in the United States. Of these, 17 (about 2%) were of children under the age of 5 years. Research has shown that approximately 60% of all bicycle-related deaths involved head injury. For children under age 5, about 64% involved head injury.² Information on the impact forces involved in these fatal incidents was not available, although about 90% of the pedalcyclist deaths, including those of children under age 5, involved collisions with motor vehicles.

Based on data from CPSC's National Electronic Injury Surveillance System ("NEISS"), there were an estimated 566,400 bicycle-related injuries treated in U.S. hospital emergency rooms in 1996. Of these, approximately 30% involved the head and face. A higher proportion of head injuries and facial injuries occurred to young children than to older victims.

CPSC's NEISS data showed that the types of injuries to young children were somewhat different from those to older children and adults. Younger children had a smaller proportion of concussions and internal injuries to the head than did older victims, as well as a larger proportion of relatively minor head injuries (i.e., lacerations, contusions, and abrasions). The extent to which these differences can be attributed to the use of helmets, other aspects of the hazard scenario, or the physiology of young children, is not known. It is also possible that caregivers are more likely to bring young children to the emergency room for relatively minor injuries.

¹ The standard was approved by the Commission unanimously, by a vote of 3-0. Chairman Anne Brown, Commissioner Mary S. Gall, and Commissioner Thomas Moore each issued a separate statement concerning the vote. Copies of these statements are available from the Office of the Secretary.

² Sacks, Jeffrey J., MPH; Holmgren, Patricia, MS; Smith, Suzanne M., MD; Sosin, Daniel M., MD. "Bicycle-Associated Head Injuries and Deaths in the United States from 1984 through 1988," *Journal of the American Medical Association* 266 (December 1991): 3016-3018. Sosin, Daniel M., MD, MPH; Sacks, Jeffrey J., MD, MPH; and Webb, Kevin W., "Pediatric Head Injuries and Deaths from Bicycling in the United States," *Pediatrics* 98 (November 1996): 868-870.

A 1993 Commission staff study of bicycle hazards indicated that when other factors were held constant statistically, the injury risk for children under age 15 was over five times the risk for older riders.³ This study also indicated that children were at particular risk of head injury. About one-half of the injuries to children under age 10 involved the head, compared to one-fifth of the injuries to older riders. This may have been in part because children were significantly less likely to have been wearing a helmet than were older victims (5% of victims younger than 15 were wearing a helmet, compared to 30% of those 15 and older). However, detailed information relating the type of helmet, age of user, and other aspects of the hazard scenario to head injury severity was not available from that study. A Commission study on bicycle and helmet usage patterns found that in 1993 about 18% of bicyclists wore helmets.⁴

A 1996 study of about 3,400 injured bicyclists in the Seattle, Washington, area included an evaluation of the protective effectiveness of helmets in different age groups.⁵ When bicyclists treated in hospital emergency rooms for head injuries were compared to bicyclists who sought care for other types of injuries at the same emergency rooms, helmet use was associated with a reduction in the risk of any head injury by 69%, brain injury by 65%, and severe brain injury by 74%.

By age group, this study showed that the reduction in the risk of head injury ranged from 73% for children under 6 years to 59% for teens in the 13–19 year-old age group.⁶ Based on the results of their study, the authors concluded that helmets were effective for all bicyclists, regardless of age, and that there was no evidence that children younger than 6 years need a different type of helmet. However, for children younger than 6 years, there was only one helmeted child with a brain injury (a concussion), and no helmeted children with severe brain injuries. Thus, the protective effects of helmets on brain injuries and severe brain

injuries were not calculated for this age group.

A widely-cited 1989 study, published by the same authors, found that riders with helmets had an 85% reduction in their risk of head injury, and an 88% reduction in their risk of brain injury, when compared to cyclists without helmets.⁷ These results were found when patients who sought emergency room care for bicycle-related head injuries were compared to bicyclists in the community who had crashes, regardless of injury or medical care. A recent study indicated that helmets may protect more against head injuries than against some facial injuries.⁸

3. *The Children's Bicycle Helmet Safety Act of 1994*

On June 16, 1994, the Children's Bicycle Helmet Safety Act of 1994 (the "Act" or "the Bicycle Helmet Safety Act") became law. 15 U.S.C. 6001–6006. The Act provides that bicycle helmets manufactured after March 16, 1995, conform to at least one of the following interim safety standards: (1) The American National Standards Institute (ANSI) standard designated as Z90.4–1984, (2) the Snell Memorial Foundation standard designated as B–90, (3) the ASTM (formerly the American Society for Testing and Materials) standard designated as F 1447, or (4) any other standard that the Commission determines is appropriate. 15 U.S.C. 6004(a)–(b). On March 23, 1995, the Commission published its determination that five additional voluntary safety standards for bicycle helmets are appropriate as interim mandatory standards. 60 FR 15,231. These standards are ASTM F 1447–1994; Snell B–90S, N–94, and B–95; and the Canadian voluntary standard CAN/CSA–D113.2–M89. In that notice, the Commission also clarified that the ASTM standard F 1447 referred to in the Act is the 1993 version of that standard. The interim standards are codified at 16 CFR 1203.

The Act directed the Consumer Product Safety Commission to begin a proceeding under the Administrative Procedure Act, 5 U.S.C. 553, to:

a. Review the requirements of the interim standards described above and establish a final standard based on such requirements;

b. Include in the final standard a provision to protect against the risk of helmets coming off the heads of bicycle riders;

c. Include in the final standard provisions that address the risk of injury to children; and

d. Include additional provisions as appropriate. 15 U.S.C. 6004(c).

The Act provides that the final standard shall take effect 1 year from the date it is issued. 15 U.S.C. 6004(c). The Act further provides that the final standard shall be considered to be a consumer product safety standard issued under the CPSA. Section 9(g)(1) of the CPSA provides that a "consumer product safety standard shall be applicable only to consumer products manufactured after the effective date." Thus, the final standard, which the Commission is issuing in this notice, will become effective March 10, 1999, as to products manufactured after that date. The Act also provides that failure to conform to an interim standard shall be considered a violation of a consumer product safety standard issued under the Consumer Product Safety Act ("CPSA"), 15 U.S.C. 2051–2084.

The Act states that the CPSA's provisions regarding rulemaking procedures, statutory findings, and judicial review (15 U.S.C. 2056, 2058, 2060, and 2079(d)) shall not apply to the final standard or its rulemaking proceeding. 15 U.S.C. 6004(c).

The final rule is codified at 16 CFR 1203 and will replace the interim standards as to bicycle helmets manufactured on or after March 11, 1999. 15 U.S.C. 6004(d). In addition, the final standard is also being designated an interim standard, so that firms will have the option of marketing helmets meeting CPSC's final standard before its effective date. Because providing this additional interim standard is a substantive rule that grants an exemption or relieves a restriction, the 30-day delay of an effective date otherwise required by 5 U.S.C. 553(d) is inapplicable, and this designation is effective March 10, 1998.

4. *The Current Rulemaking Proceeding*

The Commission reviewed the bicycle helmet standards identified in the Act (ANSI, ASTM, and Snell), as well as international bicycle helmet standards and draft revisions of the ANSI, ASTM, and Snell standards that were then under consideration. Based on this review, the Commission developed a proposed safety standard for bicycle

³Tinsworth, Deborah K., MS; Polen, Curtis; and Cassidy, Suzanne. "Bicycle-Related Injuries: Injury, Hazard, and Risk Patterns," *International Journal for Consumer Safety I* (December 1994): 207–220.

⁴Rogers, Gregory B. "The Characteristics and Use Patterns of Bicycle Riders in the United States," *Journal of Safety Research* 25 (1994): 83–96.

⁵Thompson, Diane C., MS; Rivara, Frederick P., MD, MPH; and Thompson, Robert S., MD. "Effectiveness of Bicycle Safety Helmets in Preventing Head Injuries," *Journal of the American Medical Association* 276 (December 1996): 1968–1973.

⁶The estimated reduction in risk for children 6–12 years of age was 70%.

⁷Thompson, Robert S., MD; Rivara, Frederick P., MD, MPH; and Thompson, Diane C., MS. "A Case Control Study of the Effectiveness of Bicycle Safety Helmets," *The New England Journal of Medicine* 320 (May 1989): 1361–1367.

⁸Recent research indicated that helmets reduced the risk of serious injury to the upper and middle face by about 65%, but had no significant effect on serious injury to the lower face. Thompson, Diane C., MS; Nunn, Martha E., DDS; Thompson, Robert S., MD; and Rivara, Frederick P., MD, MPH. "Effectiveness of Bicycle Safety Helmets in Preventing Serious Facial Injury," *Journal of the American Medical Association* 276 (December 1996): 1974–1975.

helmets. 59 FR 41,719 (August 15, 1994).

The Commission received 37 comments on that proposed bicycle helmet standard from 30 individuals and organizations. After considering these comments and other available information, the Commission proposed certain revisions to the originally proposed standard. 60 FR 62662 (December 6, 1995).

In response to the second proposal, the Commission received 31 comments. These comments, and additional data that have been received by the Commission since the second proposal, are discussed in Sections C–E of this notice.

B. Overall Description of the Standard

The major features of the standard issued in this notice are described below.

1. Impact Attenuation

The standard establishes a performance test to ensure that helmets will adequately protect the head in a collision. This test involves securing the helmet on a headform and dropping the helmet/headform assembly to achieve specified velocities so that the helmet impacts a fixed steel anvil. The helmet must provide protection at all points above a line on the helmet that has a specified relation to the headform.

Under the standard, the helmet is tested with three types of anvils (flat, hemispherical, and “curbstone,” as shown in Figures 11, 12, and 13 of the standard). These anvils represent shapes of surfaces that may be encountered in actual riding conditions.

Instrumentation within the headform records the headform’s impact in multiples of the acceleration due to gravity (“g”). Impact tests are performed on different helmets, each of which has been subjected to one of four environmental conditions. These environments are: ambient (room temperature), high temperature (117–127°F), low temperature (1–9°F), and immersion in water for 4–24 hours.

Impacts are specified on a flat anvil from a height of 2 meters and on hemispherical and curbstone anvils from a height of 1.2 meters. Consistent with the requirements of the ANSI, Snell, and ASTM standards, the peak headform acceleration of any impact shall not exceed 300 g for an adult helmet, the value originally proposed for both adult and child helmets. In the revised proposed standard, the acceptable g value for children’s helmets was reduced to 250 g and a lower headform drop mass than that for adults was specified (3.90 kg). As

explained in section C of this notice, however, the final rule specifies that the 5-kg headform mass and the 300-g peak acceleration criterion will apply to all helmets subject to the standard, as specified in the original proposal.

The standard provides that a helmet fails the performance test if a failure can be induced under any combination of impact site, anvil type, anvil impact order, or conditioning environment permissible under the standard. Thus, the Commission will test for a “worst case” combination of test parameters. What constitutes a worst case may vary, depending on the particular helmet involved.

2. Children’s Helmets: Head Coverage

The standard specifies that helmets for small children (under age 5) must cover a larger portion of the head than must helmets for older persons. A study by Biokinetics & Associates Ltd. found differences in anthropometric characteristics between young children’s heads and older children’s and adult’s heads.⁹

3. Retention System

The standard requires that helmets be able to meet a test of the dynamic strength of the retention system. This test ensures that the chin strap is strong enough to prevent breakage or excessive elongation of the strap that could allow a helmet to come off during an accident.

The test requires that the chin strap remain intact and not elongate more than 30 mm (1.2 in) when subjected to a “shock load” of a 4-kg (8.8-lb) weight falling a distance of 0.6 m (2 ft) onto a steel stop anvil (see Figure 8). This test is performed on one helmet under ambient conditions and on three other helmets after each is subjected to one of the different hot, cold, and wet environments.

4. Peripheral Vision

Section 1203.14 of the standard requires that a helmet shall allow a field of vision of 105 degrees to both the left and right of straight ahead. This requirement is consistent with the ANSI, ASTM, and Snell standards.

5. Labels and Instructions

Section 1203.6 of the standard requires certain labels on the helmet. These labels provide the model designation and warnings regarding the protective limitations of the helmet. The labels also provide instructions

regarding how to care for the helmet and what to do if the helmet receives an impact. The labels also must carry a warning that for maximum protection the helmet must be fitted and attached properly to the wearer’s head in accordance with the manufacturer’s fitting instructions.

The standard also requires that helmets be accompanied by fitting and positioning instructions, including a graphic representation of proper positioning. As noted above, the standard has performance criteria for the effectiveness of the retention system in keeping a helmet on the wearer’s head. However, these criteria may not be effective if the helmet is not well matched to the wearer’s head and carefully adjusted to obtain the best fit.

To avoid damaging the helmet by contacting it with harmful common substances, the helmet must be labeled with any recommended cleaning agents, a list of any known common substances that will cause damage, and instructions to avoid contact between such substances and the helmet.

6. Positional Stability (Roll Off)

The standard specifies a test procedure and requirement for the retention system’s effectiveness in preventing a helmet from “rolling off” a head. The procedure specifies a dynamic impact load of a 4-kg (8.8-lb) weight dropped from a height of 0.6 m (2 ft) to impact a steel stop anvil. This load is applied to the edge of a helmet that is placed on a headform on a support stand (see Figure 7). The helmet fails if it comes off the headform during the test.

The safety requirements discussed in paragraphs (1)–(6) above are issued pursuant to the Bicycle Helmet Safety Act and are codified as Subpart A of the Safety Standard for Bicycle Helmets.

7. Certification Labels and Testing Program

Under the authority of section 14(a) of the CPSA, the Commission is also issuing certification testing and labeling requirements to ensure that bicycle helmets meet the standard’s safety requirements. These certification requirements are in Subpart B of the Safety Standard for Bicycle Helmets and are discussed in section D of this notice.

8. Recordkeeping

Under the authority of section 16(b) of the CPSA, the Commission is issuing requirements that manufacturers (including importers) maintain records of the required certification testing. These recordkeeping requirements are found in Subpart C of the Safety

⁹ Heh, S., Log of ASTM FO8.53 Headgear Subcommittee meeting held May 21, 1992, date of entry June 17, 1992. Office of the Secretary, U.S. Consumer Product Safety Commission, Washington, DC 20207.

Standard for Bicycle Helmets and are discussed in section E of this notice.

9. Interim Standards

The interim standards, which are currently codified as 16 CFR 1203, will continue to apply to bicycle helmets manufactured from March 16, 1995, to March 11, 1999. Accordingly, the interim standards will continue to be codified, as Subpart D of the standard. Also, Subparts A–C of the standard are being added as an interim standard, so that firms will have the option of marketing helmets meeting CPSC's final standard before its effective date.

C. The Final Standard—Comments, Responses, and Other Changes

This section discusses comments on the second proposal, as well as other issues that were dealt with in deciding the requirements of the final rule. Numbers in brackets refer to the number assigned by the Commission's Office of the Secretary to a comment on the second proposal.

1. Accident Scenarios

Mr. Frank Sabatano [14], President of the London Bridge BMX Association, recommended that bike helmets be constructed so as to accommodate more serious accidents that might result from a child bicycle racing or jumping rather than merely riding on a path or street.

While no helmet can protect against every conceivable impact, the available evidence supports the conclusion that helmets designed to meet the CPSC standard will be very effective in protecting against serious injury within a wide range of common bicycle riding conditions. This would include many of the impact conditions that could occur during racing or jumping. Furthermore, a standard for all bicycle helmets has to balance the benefits of more protective helmets against the additional cost, weight, bulk, and discomfort that more protection may impose. Such undesirable qualities may discourage many users from wearing helmets designed to protect against very severe impacts, which could more than cancel the effects of the additional protective qualities. Thus, the force with which the helmets are impacted in the standard's performance test has not been increased.

2. Future Revisions

Randy Swart, Director of the Bicycle Helmet Safety Institute [16], suggested that the following items be considered as future revisions to the CPSC standard as progress in head protection research continues:

a. A test that requires the retention system to be easily adjusted for good fit.

b. A test for protection against rotational injury.

c. A test to limit localized loads or "point loading."

d. A test for damage to the helmet by hair oil or other common consumer preparations.

e. A test of the retention system after impact to simulate field conditions.

f. A test to ensure that visors and mirrors are shatter-resistant and easily peel off in a crash.

The Commission agrees that it is important to periodically review research related to improvements in head protection to determine if revisions should be considered for the CPSC bicycle helmet standard.

3. Compliance With Third-Party Standards as Compliance With the Rule

Jane McCormack [7] requested that the Commission ensure that bike helmets meet the Snell requirements. Norte Vista Medical Center [15] requested that helmets certified to the Snell B–95 or Snell N–94 standards be considered to be in compliance with the mandatory standard.

The Commission declines to make these changes. One of the objectives of the Bicycle Helmet Safety Act is to establish a unified bicycle helmet standard that is recognized nationally by all manufacturers and consumers. It would defeat Congress' intent to add language to the regulation stating that certified conformance to any existing voluntary standard satisfies compliance with the mandatory rule.

4. Scope of the Standard

a. Definition of "Bicycle Helmet"

The original proposal defined bicycle helmet as "any headgear marketed as suitable for providing protection from head injuries while riding a bicycle." The definition of bicycle helmet in the second proposal included not only products specifically marketed for use as a bicycle helmet but also those products that can be reasonably foreseen to be used for that purpose.

Bell Sports [12] suggested that the definition of bicycle helmet should not include all products with a reasonably foreseeable use as a device intended to provide protection from head injuries while riding a bicycle. Bell maintains there are many helmets that have a foreseeable use by bike riders that should not have to be certified to a bike helmet standard (e.g., baseball and roller hockey helmets).

The respondent suggested that football helmets, baseball batting helmets, and motorcycle helmets will also have "easily foreseeable" uses as bicycle helmets.

The Commission did not intend for the definition of bicycle helmet to include football helmets, baseball batting helmets, and motorcycle helmets that are not marketed for use while bicycling. It seems unlikely that a helmet that is not marketed or promoted for bicycle use will have a reasonably foreseeable use as a bicycle helmet. Thus, the "reasonably foreseeable" language is unnecessary. Therefore, in order for the definition to provide more guidance, the "reasonably foreseeable" language has been deleted, and the definition of bicycle helmet has been changed to read: "Bicycle helmet means any headgear that either is specifically marketed as, or implied through marketing or promotion to be, a device intended to provide protection from head injuries while riding a bicycle."

Helmets specifically marketed for exclusive use in a designated activity such as skateboarding, rollerblading, baseball, roller hockey, etc., would be excluded from this definition because the specific focus of their marketing makes it unlikely that such helmets would be purchased for other than their stated use. However, a multi-purpose helmet—one marketed or represented as providing protection either during general use or in a variety of specific activities other than bicycling—would fall within the definition of bicycle helmet if a reasonable consumer could conclude, based on the helmet's marketing or representations, that bicycling is among the activities in which the helmet is intended to be used.

In making this determination, the Commission will consider the types of specific activities, if any, for which the helmet is marketed, the similarity of the appearance, design, and construction of the helmet to other helmets marketed or recognized as bicycle helmets, and the presence, prominence, and clarity of any warnings, on the helmet or its packaging or promotional materials, against the use of the helmet as a bicycle helmet. The presence of warnings or disclaimers advising against the use of a multi-purpose helmet during bicycling is a relevant, but not necessarily controlling, factor in the determination of whether a multi-purpose helmet is a bicycle helmet. A multi-purpose helmet marketed without specific reference to the activities in which the helmet is to be used will be presumed to be a bicycle helmet.

b. Multiple-Activity Helmets

Some commenters on the original proposal recommended that the CPSC include provisions for children's bicycle helmets to provide protection in

activities in addition to bicycling, such as skateboarding, skating, sledding, and the like. Two commenters recommended that the CPSC bike helmet standard also apply to helmets marketed for roller skating and in-line skating. Other comments stated that the Commission should not delay promulgation of the bike helmet standard while multi-activity issues are explored.

The Commission did not propose that the standard address activities other than bicycling, because the CPSC's authority under the Bicycle Helmet Safety Act is to set mandatory requirements for *bicycle* helmets. Establishing criteria for products other than bicycle helmets would require the Commission to follow the procedures and make the findings prescribed by the CPSA or the Federal Hazardous Substances Act ("FHSA").

The National Safe Kids Campaign ("NSKC") [22] and the Consumer Federation of America ("CFA") [23] recognized that the scope of the CPSC standard must be for bicycle helmets, but requested the Commission to move forward in investigating the issues related to multi-activity helmets. In a comment on the revised proposal, Mr. Frank Sabatano, President of the London Bridge BMX Association [14], recommended that bicycle helmets should serve as multi-purpose protective devices for various sports such as bicycle riding, bicycle racing, skateboarding, and in-line skating.

The Commission intends to monitor developments relevant to the multi-activity issue. Wheeled recreational activities such as traditional roller skating and in-line skating are typically conducted on the same surfaces as bicycling, and can generate speeds similar to bicycling. Therefore, it is reasonable to assume that helmets that meet the requirements in the CPSC bike helmet standard will also provide head protection for roller/in-line skating and perhaps some other recreational activities. However, as discussed in the December 6, 1995, **Federal Register** notice on the proposed rule, the Commission does not have sufficient data on the benefits and costs of additional features directed at injuries incurred in activities other than bicycling to make the statutory findings that would be needed to issue a requirement for such features under either the CPSA or FHSA. Also, procedures in addition to those required by the Bicycle Helmet Safety Act would have to be followed. The Commission does not want to delay establishment of a mandatory bicycle helmet standard in order to pursue rulemaking for other

types of helmets. Accordingly, the final standard only addresses requirements for bicycle helmets. However, as discussed below, the Commission will examine what actions it could take to encourage the use of bicycle helmets in activities that present head injury risks similar to those in bicycling.

NSKC [22] also urged the CPSC to work with community-based organizations to develop a comprehensive educational campaign regarding the importance of wearing a federally-approved bicycle helmet when participating in non-motorized activities other than bicycling. The Commission will consider what activities are appropriate in this regard when setting its priorities for future activities.

5. Projections

Projections on the inner or outer surface of a helmet can concentrate applied forces and cause injuries. Therefore, the revised proposed standard provided that projections on the outer surface would not exceed 7 mm (0.28 in) unless they break away or collapse on impact and that projections on the helmet's interior not make contact with the headform during testing.

NSKC [22] urged that the Commission prohibit any external projections on helmets intended for children. NSKC believes that external projections, such as visors, are unnecessary components of helmets intended for children.

With regard to a possible hazard from external projections on children's helmets, § 1203.7 of the standard requires that helmets must pass all tests, both with and without any attachments that may be offered by the manufacturer. This provision, and the requirement that any external projections shall break away or collapse, will address the potential hazard of external projections on helmets intended for riders of all ages. The proposed language is consistent with existing voluntary standards, and no changes were made in response to this comment.

SwRI [2] remarked that the proposed standard does not state how to determine if an internal projection makes contact with the headform during testing. NSKC [22] also suggested that instead of requiring inner surface projections to not exceed 2 mm, the inside of the helmet should contain no sharp edges or rigid internal projections.

After considering these comments, the Commission decided to revise the section on internal projections to eliminate the requirement that internal projections not make contact with the headform during testing, while retaining the requirement that such projection not

exceed 2 mm (0.08 in). The purpose of this section is to prohibit potentially hazardous projections but make some allowance for common helmet construction practices. The language above is consistent with Snell helmet standards, and the Commission is not aware of safety problems associated with projections on helmets meeting existing standards.

6. Requirements for Qualities of Fitting Pads

NSKC [22] urged the Commission to include safety requirements for fitting pads in the final standard. The commenter asserted that since fitting pads are often necessary to ensure a secure fit, the standard should address the integrity of the materials used to construct them, as well as their thickness, durability, and adhesiveness.

CPSC staff has no information that long-term integrity of fitting pads is a problem with helmets meeting existing standards. The interim mandatory standards have no provisions of the type suggested by the commenter. Introducing new requirements for fitting pads is not essential at this time, and no change to the proposed standard has been made in response to this comment.

7. Impact Attenuation Criteria

a. Extent of Protection

The originally proposed CPSC standard, and current U.S. voluntary bicycle helmet standards, specified an extent-of-protection boundary and an impact test line. The extent-of-protection boundary defines the area of the head that must be covered by the helmet. The impact test line designates the lowest point on the helmet where the center of an anvil may be aligned for testing. The second proposal specified a single impact test line and no extent-of-protection boundary requirement. Not requiring specific helmet coverage allows manufacturers the flexibility to include desirable features, such as a central rear vent, provided the features do not hinder the helmet's ability to meet the impact requirements if tested anywhere on or above the impact test line. Accordingly, the Commission deleted the extent-of-protection boundary from the revised proposed standard.

In commenting on the latter proposal, Snell [28] discussed the practical problems in certifying helmets when only an impact test line is specified. Snell recommended that the standard be amended to require coverage below the impact test line, particularly at the front and rear of a helmet.

The Commission disagrees with this comment. Coverage does not imply impact protection. The only area on the helmet required to pass impact protection requirements is the area above the impact test line. Therefore, it is unnecessary to specify additional coverage below the test line.

The manufacturers of the Protective Headgear Manufacturing Association ("PHMA") [29] reported that they believed the proposed CPSC standard requires coverage at the rear of the head lower than any other standard. They stated that they are not aware of any studies indicating that lower coverage at the rear is warranted. They also stated their concern that the helmet-wearing public will not purchase helmets that are perceived to be more "clunky" or "bulbous," and that helmets with extended coverage are likely to be so perceived. Mr. Becker of Snell [28] stated that the CPSC-proposed coverages are more extensive than any current U.S. standard, except for Snell's B-95 and N-94 helmet standards. He stated that unless the CPSC coverage is changed, many contemporary helmet models that have protected their wearers from life-threatening injury will disappear from the market. Snell urged that the CPSC adopt the coverage described in the ASTM F1447-94 or Snell B-90 standards. According to this commenter, these coverages reflect the current state of the industry and should be expected of every bicycle helmet.

The proposed CPSC impact test line is not lower at the rear of the helmet than all other standards. The proposed CPSC impact test line is somewhat lower at the rear of the helmet than the impact test lines in the Snell B-90 and ASTM F1447 standards. However, the CPSC line is higher at the rear of the helmet than the impact test lines in the following interim mandatory standards: Snell B-95 and N-94, CAN/CSA-D113.2, and ANSI Z90.4-1984.

CPSC is aware of two studies that show that it is not uncommon for helmets involved in accidents to suffer impacts at the rear portion of the helmet. A Bell Sports study of 1100 helmets involved in accidents found that 26% of the impacts were at the rear of the helmet and that the majority of these rear impacts occurred within 50 mm of the bottom edge of the helmet.¹⁰ Another study, by Technisearch of Australia, examined the effect of lowering the impact test line from the Snell B-90 standard to the impact test lines in the Snell B-95 and N-94

standards.¹¹ The Technisearch study was based on examinations of 104 bicycle helmets whose wearers sustained impacts to the head during accidents. The study concluded that the B-90 standard test line would have provided coverage for 51% of the impacts. The impact test line of the B-95 standard would provide coverage for 65% of the impacts. The increase from 51% to 65% was represented by 20 additional impact sites that would fall within the area of the B-95 coverage, including 8 impact sites at the rear portion of the helmet.

One of the directions of the Children's Bicycle Helmet Safety Act is to include provisions from existing appropriate standards for adoption in the final CPSC standard. The CPSC impact test line is a reasonable requirement that will improve the protective characteristics of helmets overall, while falling within test lines of established North American bicycle helmet standards.

b. Distance Between Impacts

A commenter on the original proposal recommended revising the minimum distance between impact sites from the originally proposed "one fifth the circumference of the helmet" to 120 mm. The Commission believed that 120 mm allows sufficient distance to minimize the effects of impact site proximity and provides a more straightforward measurement than the original one-fifth circumference criteria. Accordingly, the Commission adopted this recommendation in the revised proposal.

Two commenters on the revised proposal [27 and 29] recommended a minimum distance between impacts of 150 mm, or about 6 inches. One of these commenters stated that the CPSC made the minimum distance shorter than those in voluntary standards.

The Commission selected the 120-mm impact spacing based on recently balloted ASTM headgear standards. The Snell B-95 standard also specifies a minimum impact separation of 120 mm. This distance is consistent with the Snell B-90 specification of 1/5th the maximum helmet circumference, if calculated for smaller helmets. A minimum impact spacing of 150 mm would limit flexibility in choosing impact sites, especially on smaller helmets. Therefore, no change to the proposed rule was made in response to this comment.

c. Impact Velocity Tolerance

The University of Southern California's Head Protection Research Lab ("USC-HPRL") [8] suggested that the tolerance for the impact velocity be changed from $\pm 3\%$ to -0% to $+5\%$ to ensure that impact testing is done at no less than the specified velocity.

The difference between tolerances of $\pm 3\%$ and -0% , $+5\%$ has little practical significance for a 300-g criterion. Since the commenter's suggestion would not produce a significant safety benefit, the Commission made no change to the proposed rule in this regard.

d. Other Requirements for Children's Helmets: Peak-G Value and Drop Mass

One of the provisions of The Children's Bicycle Helmet Safety Act of 1994 is that the Commission include in the final CPSC standard provisions that address the risk of injury to children. This does not require that children's helmets be subject to requirements that differ from those for adults' helmets; it requires only that the final standard be appropriate for children's helmets. The issue of whether special standard provisions for young children's helmets are needed has been debated for several years by head protection experts.

A young child's skull has different mechanical properties than the skull of an older child or adult. These differences are especially evident for children under the age of 5 years. Their skulls have a lower degree of calcification, making them more flexible than adult skulls. During an impact to the head, the increased skull flexibility results in a greater transfer of kinetic energy from the impact site to the brain tissue. Besides the different mechanical properties, the mass of a young child's head is also different from that of a more mature person's head. Studies show that the head mass of children under the age of 5 years ranges from approximately 2.8 to 3.9 kg. This mass is lower than the 5-kg test headform mass specified in current U.S. bicycle helmet standards.

The Commission first proposed a safety standard for bicycle helmets on August 15, 1994. In that proposal, the only special provision for helmets for children under 5 years was an increased area of head coverage. On December 6, 1995, however, the Commission proposed special provisions for headform mass, peak-g limit, and head coverage for bicycle helmets for children under 5 years. The special children's provisions were based on the ongoing work of voluntary standards organizations and proposals at that time in the technical literature. The following comparison shows the CPSC-proposed

¹⁰ Dean Fisher and Terry Stern, "Helmets Work!", Bell Sports, Inc., AAAM/IRCOBI Conference, Lyon, France (September 1994).

¹¹ Martin Williams, "Test Line Requirements and Snell B-95 and N-94 Standards," Technisearch Engineering & Scientific Services (August 1994).

test parameters for helmets for children under 5 years and for helmets for older persons.

	Under 5	5 and older
Mass of test headform.	3.9 kg	5.0 kg
Peak-g limit ...	250-g	300-g
Head coverage.	More coverage at rear and sides of head.	

The proposal for increased head coverage of children's helmets is relatively uncontroversial, and the final rule contains this requirement. However, the Commission has reassessed the proposed headform mass and peak-g requirements. The Commission's conclusions are discussed in detail below.

A few respondents to the proposed rule [8, 16] supported the lower mass and lower peak-g provisions, believing that they will lead to an improvement in head protection for small children. One of these respondents, however, urged the Commission to consider the most recent research on this subject before including the special provisions in a final standard. One respondent [12] favored a reduced headform mass provision, but did not recommend a reduced peak-g provision, stating that it could result in a helmet with a lower margin of safety.

Several respondents [3, 4, 6, 9, 10, 13, 15, 18, 19, 27, 28, 29, 30] questioned whether it is advisable to move forward with the provisions of a reduced-mass headform and a lower limit for peak acceleration. Some respondents suggested that special children's provisions should not be adopted since studies show that children's helmets as they exist today provide excellent protection.

Studies by researchers at the Harborview Injury Prevention and Research Center have shown that bicycle helmets that meet existing standards are effective in protecting against serious head and brain injuries.¹² One of the items analyzed in the most recent Harborview study was whether the protective effects of bicycle helmets vary by the age of the user. For four age groups of riders, they estimated the protective effect of helmets against

three levels of injury listed in order of increasing severity: (1) head injury, (2) brain injury, and (3) severe brain injury.

Due to the small number of helmeted case subjects that suffered brain injury and severe brain injury, Harborview researchers could not estimate the protective effect of helmets against these injuries for the under 6-year-old age group. Accordingly, the Commission has not relied on this study in its consideration of whether special requirements are needed for children's helmets. However, one of Harborview's overall conclusions was that helmets are effective for all bicyclists, regardless of age, and that there is no evidence that children younger than 6 years need a different type of helmet.

The Commission requested technical views on this issue from Barry Myers, M.D., Ph.D. Associate Professor, Department of Biomedical Engineering, Duke University. In his report,¹³ Dr. Myers explains that such modifications of the standard should be considered only if it can be shown to improve the protective qualities of helmets. Improvements may be shown by epidemiological or biomechanical evidence. However, considering the degree of head injury protection provided by current helmets, incremental improvement would be difficult to detect, even with a large epidemiological study.

From a biomechanical perspective, it is important to assess how changes in test headform mass and peak-g criteria would affect helmet design and protective capability. This can be done by examining how a helmet functions to protect the head in an impact.

The helmet has a crushable liner typically made of expanded polystyrene foam. If the liner is crushed as the head presses against the inside of the helmet during impact, the liner allows the head to stop over a longer distance and time than would otherwise be the case. This reduces the transfer of energy to the head, thereby reducing the risk of injury.

The degree to which the liner resists being crushed also affects the helmet's protective qualities. For a given impact, a helmet liner that is too soft will "bottom out," thereby losing its protective ability to allow relative movement between the head and the object being impacted. Conversely, a liner that is too hard will not allow sufficient crushing to adequately protect the head.

Proponents of special provisions for young children's helmets believe that these helmets should be tested under different test parameters than helmets intended for older persons. The current test parameters are based primarily on adult head injury tolerance and on a headform mass that is approximately that of an adult head. Supporters of special provisions contend that these adult test parameters result in a helmet with a liner that is too stiff to optimally protect a young child's head. By using a headform weight that better represents a young child's head (e.g., 3.9 kg), and reducing the allowable peak-g, helmets would need to be designed with a lower density ("less stiff") liner to further lessen the impact transmitted to the head.

A simple way to examine the effect of changing headform mass and the peak-g criterion is to model the helmet as a spring and apply the one-dimensional spring-mass impact formulas shown below. This approach is discussed by both Dr. Myers and by Mr. Jim Sundahl, Senior Engineer with Bell Sports, in his response to the proposed rule [12].

$$a_{\text{peak}} = V_o \sqrt{\frac{k}{m}} \quad (1)$$

$$x_{\text{peak}} = V_o \sqrt{\frac{m}{k}} \quad (2)$$

Where:

a_{peak} = peak acceleration (peak-g)

V_o = impact velocity

k = liner stiffness

m = headform mass

x_{peak} = required stopping distance (liner thickness)

If the value for headform mass m is reduced in Equation (1), the value for liner stiffness k must be reduced to achieve the same peak-g at the same impact velocity. This means that if a helmet that meets the standard's criteria with a 5-kg headform did not meet the peak-g requirement using a lighter headform, the helmet liner would need to be made softer so more crushing of the liner could occur.

If the value for peak acceleration a_{peak} is reduced in Equation (1), and the other variables are held constant, the value for liner stiffness k again must be reduced. Thus, a helmet that could not comply with a reduced peak-g criterion also would need a softer liner to allow more crushing. Equation (2) shows that, with a decreased liner stiffness, a greater percentage of the available crush distance will be used during impact.

The biomechanical analysis shows that, for impact conditions that do not result in complete compression of the

¹²Thompson, Robert S., MD; Rivara, Frederick P., MD, MPH; and Thompson, Diane C., MS "A Case Control Study of the Effectiveness of Bicycle Safety Helmets," *The New England Journal of Medicine* 320 [May 1989]: 1361-1367. Thompson, Diane C., MS; Rivara, Frederick P., MD, MPH; and Thompson, Robert S., MD. "Effectiveness of Bicycle Safety Helmets in Preventing Head Injuries," *Journal of the American Medical Association* 276 (December 1996): 1968-1973.

¹³Myers, Barry, M.D., Ph.D. "An Evaluation of A Helmet Standard for Children," Report to the U.S. Consumer Product Safety Commission (July 1997).

helmet's liner, it is possible to lessen the impact energy transmitted to the head (and reduce the risk of injury) by reducing the stiffness of the liner. However as the impact energy increases, a helmet with a softer liner will bottom out (crush beyond its protective capacity) under less severe conditions than a helmet with a more rigid liner of the same thickness. To compensate, the softer helmet would have to be made thicker to prevent bottoming out. However, there is a limit to how thick a helmet can be before it is no longer practical or appealing to the user. Therefore, the goal of helmet design is to optimize liner density and thickness to protect against the widest range of impact conditions and still have a product people will use.

The biomechanical analysis suggests that reducing the liner stiffness could have both a positive and a negative influence on the protection provided by helmets under existing criteria. Therefore, it is necessary to also examine available epidemiological data that relate to this issue. Decreasing the liner stiffness would benefit those who experience injuries with minimal or no liner deformation of current helmets. However, a decrease in liner stiffness could increase the number of head injuries that occur during more severe impacts that cause the helmet liner to bottom out.

To learn the effect on the level of protection offered by softer helmet liners for children under 5, two questions would need to be answered:

1. Are children suffering head injuries with minimal or no deformation of current helmet liners?
2. Are children suffering head injuries with a bottomed-out liner?

Unfortunately, currently available information does not answer either of these questions. Therefore, it is uncertain whether young children would benefit from special provisions for headform mass and peak-g.

The only known study to examine the relationship between helmet damage and head injury was completed in 1996 by the Snell Memorial Foundation and the Harborview Injury Prevention and Research Center.¹⁴ Of those bicycle helmets collected from individuals (of various ages) who went to a hospital, 40% of the helmets had no deformation, 14% had significant damage in which the helmet was approaching a bottomed-out condition, and 7% of the helmets had catastrophic damage. The data were

not presented specifically for the under-5 age group or any other specific age group. The study showed that there was a risk of head and brain injury even with no or minimal helmet damage. The risk of injury increased moderately as the severity of helmet damage increased, until catastrophic damage was reached. As expected, the risk of head and brain injury jumped dramatically when a helmet was damaged catastrophically. This study suggests that if helmets for all ages were designed with softer liners, there is a potential to both improve the protection for lower-severity impacts and increase the risk of injury at the higher-severity impacts.

Since the risk of injury rises dramatically with catastrophic helmet damage, and current helmets are effective in reducing the risk of head and brain injuries, it would be imprudent to require softer helmet liners for bicyclists of all ages. The available data are insufficient to determine that such a change would increase overall protection. When focusing on the age range of under 5 years, currently available information is even more sparse. Therefore, if helmets for children under age 5 were made with softer liners, there are insufficient data to estimate either (1) the level of protection that might be gained at the lower-severity impacts or (2) the protection that might be lost at the severe impact conditions that completely crush the liner.

For the reasons discussed above, the Commission did not include special provisions in the final standard for headform mass and peak-g criteria for young children's helmets. There are insufficient data to justify the changes, and these changes could provide less protection in the most serious impacts. However, should future studies provide evidence that young children, or bicyclists of any age, could benefit from decreased liner stiffness, the Commission could consider revisions to the bicycle helmet standard at that time.

8. Impact Attenuation Test Rig

a. Type of Test Rig

The originally proposed CPSC standard and the current interim mandatory standards allowed the use of either a wire- or rail-guided impact test rig. In the revised proposal, the Commission specified only the monorail test rig, to avoid the possibility that different results would be obtained with the two types of test rigs.

Some helmet manufacturers [5, 29, 30], and the Snell Memorial Foundation [28], disagreed with the specification of the monorail type of impact test rig.

Commenters stated that guidewire rigs were more widely used in the industry. Some commenters claimed that since there is no evidence that directly correlates monorail with guidewire rig results, many firms would be forced to buy monorail rigs to address liability concerns. Trek [5] stated that the burden of this expense may require additional analysis of the financial impact to small business, as required by the Regulatory Flexibility Act. Snell wrote that guidewire rigs have proven reliable, efficient, and highly repeatable. They are less expensive to install than monorail devices, and they are easier to maintain. Snell stated that there is no demonstrated improvement associated with the monorail rig in testing reliability and capability. Most commenters suggested that the Commission allow both monorail and guidewire rigs.

To respond to this issue, the CPSC's staff initiated a seven-laboratory comparison test program. The main purpose of the study was to determine if there are statistically significant mean differences in test results when using monorail and guidewire test rigs under standardized testing conditions.

Seven laboratories participated in the test program, including the CPSC lab. Five of the laboratories tested on both monorail and guidewire rigs. Two laboratories only tested on monorail rigs. Three different helmet models were used. Each helmet was impacted twice, once at the rear of the helmet and once near the crown. Tests were conducted using flat and curbstone anvils, and all testing was performed with ambient-conditioned helmets. This experiment allowed the analysis of the effect of the following variables: rig type, anvil type, helmet model, laboratory, anvil impact sequence, and impact location.

The statistical analysis of the interlaboratory results showed that for the majority of variable combinations, the choice of test rig did not have an appreciable effect on test results. However, on the Model I helmets, and only when the second impact was on the curbstone anvil, the monorail showed a significantly higher mean logarithm for peak-g readings summed across laboratories having both types of test rigs. For reasons completely unrelated to these test results, a curbstone impact in combination with another impact on any single test helmet is no longer permitted in the final standard. Since the interlaboratory data (summed across the laboratories that used both types of test rigs) show no significant differences between guidewire and monorail rigs under test conditions within those allowed in the

¹⁴ Rivara, Frederick P., MD, MPH, Thompson, Diane C., MS, Thompson, Robert S., MD "Circumstances and Severity of Bicycle Injuries," Snell Memorial Foundation/Harborview Injury Prevention and Research Center (1996).

final standard, the standard allows either type of rig to be used for impact attenuation testing.

Over the last 15–20 years, voluntary standards in the U.S. have allowed both monorail and guidewire types of test rigs. Both types of test rigs have been used extensively in independent test laboratories and in manufacturers' in-house test facilities. The Snell Memorial Foundation, one of the established helmet test organizations in the U.S., uses guidewire rigs to test conformance to their standards. The Commission has no evidence that the allowance of both types of test rigs in voluntary standards has resulted in a compromise of safety for bicycle helmet users.

For the reasons discussed above, the Commission concludes that both types of rigs are suitable for impact attenuation testing. Therefore, the final CPSC standard specifies that either a monorail or a guidewire test rig may be used.

b. Accuracy Check

After evaluating the results of the multi-lab testing, the Commission concluded that the instrument system check procedure should include a procedure for calibrating the accuracy of a test rig. Therefore, the final rule includes a precision and accuracy procedure, so that laboratories can verify that their test equipment is recording accurately. The procedure requires that an aluminum sphere (spherical impactor) of a specified dimension be dropped with a certain impact velocity onto a Modular Elastomer Programmer (MEP). A MEP is a cylindrical pad of polyurethane rubber that is used as a consistent impact medium for the systems check procedure. Pre-test and post-test impacts on an MEP to verify system recording is a standard practice of bicycle helmet test labs. All recorded impacts must fall within the range of 380 g to 425 g. In addition, the difference between the high and low values of the three recorded impacts must not be greater than 20 g.

The range of 380 g to 425 g represents an allowable tolerance of about 10%. The interlaboratory testing showed this tolerance to be attainable between laboratories. However, test experience shows that even greater precision can be obtained for the systems check procedure within a given laboratory. The test data from the interlaboratory study show that a target range of 380 g to 425 g and a precision range of 20 g can be achieved.

c. Test Headform Characteristics

SwRI [2] suggested that a more appropriate value for the lower limit on the resonant frequency of the headform material should be 2000 hz instead of 3000 hz.

The important conditions for the test headforms are the material specification and the dimensions defined by the draft ISO/DIS 6220–1983 standard.¹⁵ This goal is accomplished by stating that the headforms shall be rigid and be constructed of K–1A magnesium alloy. Test experience shows that headforms meeting this description will not exhibit resonant frequencies that will interfere with proper data collection. Therefore, § 1203.9 has been changed to delete reference to any lower limit on resonance frequencies. The proposal also stated that another “functionally equivalent” metal could be used as the headform material. This alternative has been eliminated in the final rule to specify the headform apparatus as precisely as possible and ensure against the use of materials that may influence the test results.

Dr. Richard Snyder, President of the George Snively Research Foundation [19], referenced two studies that related helmet fit to head size and shape. The first study was conducted by Dr. Bruce Bradtmiller of the Anthropometry Research Project, Inc. Dr. Bradtmiller also responded to the proposed rule [20]. He concluded that, for proper child-helmet sizing, head breadth and length variables were more accurate guides than using age or head circumference. Dr. Bradtmiller urges caution in basing the CPSC's rules for children's helmets on the draft ISO DIS 6220–1983 standard for test headforms. The study shows variation in the ratio of head length to head breadth. This ratio was found to be the prime determinant for helmet fit. The ISO standard, however, maintains a constant head breadth/length ratio. A second study also concluded that head circumference was not always a good indicator for helmet fit.

ISO headforms are the established norm for headgear testing in the U.S., Canada, Europe, and Australia. No other system of headforms is currently available that can be shown to prevent more injuries. Therefore, the Commission is retaining the ISO headform specification in the final CPSC standard. However, the

¹⁵ Although the draft ISO/DIS 6220–1983 standard was never adopted as an international standard, it has become a consensus national standard because all recent major voluntary standards used in the United States for testing bicycle helmets establish their headform dimensions by referring to the draft ISO standard.

Commission's staff will stay current on developments of test procedures and equipment that could lead to improvements in general helmet fit and in improvements that make it easier to fit and adjust helmets, especially for children.

d. Alignment of Anvils

The Commission amended § 1203.17(a) to specify that the center of the anvil must be aligned with the center vertical axis of the accelerometer. This describes the already standard operating procedure for bicycle helmet testing and is meant to prevent impacting helmets on the “corners” of anvils.

e. Definition of “Spherical Impactor”

SwRI [2] suggested that it is more important to specify a 5-kg combined drop mass for the spherical impactor and the drop assembly than to specify a 4-kg mass for the impactor itself.

The Commission has adopted this suggestion. The more precise specifications for a spherical impactor for use as a system check device are now in § 1203.17(b)(1), under the systems check procedure.

9. Impact Attenuation Test Procedure

a. Anvil Test Schedule and Use of Curbstone Anvil

Six respondents [5, 12, 27, 29, 30, and 31] submitted comments requesting changes to the test schedule in § 1203.13 regarding the use of the curbstone anvil. All of the respondents expressed concern over using two curbstone impacts on a single helmet. As proposed, § 1203.3(d) and Table 1203.13 did not define the conditions of the fourth impact on a helmet. The fourth impact in the proposed standard was left to the discretion of test personnel, and thus could have been a second curbstone impact. One of the commenters was also concerned about impacting the helmet with the curbstone anvil after the helmet was conditioned in a wet environment [12].

There also was concern about the curbstone footprint overlapping other impact sites and violating the “single impact” principle of testing [27 and 31]. The length of the curbstone anvil restricts the location of impact sites that can be used without overlap. The use of a second curbstone anvil, and the damage caused by curbstone impacts, can restrict the selection of test sites further, to the point where only three impacts without overlap may be possible on a small helmet.

The Commission agrees that the previously proposed test schedule

should be revised to prevent the possibility of striking a test helmet with more than one curbstone impact. The potential for overlapping "footprints" of curbstone impacts combined with other impacts on a single test helmet goes beyond the intended principle of a single impact for a given area. The Commission disagrees, however, with those commenters who recommended that only ambient-conditioned helmets be subjected to a curbstone impact. To ensure adequate protection against impact against curbstone-type shapes, tests for that anvil, as well as the other test anvils, should be carried out in all of the environmental conditions prescribed by the standard. Accordingly, revised § 1203.13 and Table 1203.13 contain a revised test schedule to incorporate a single curbstone impact on each of four "clean" helmet samples, one from each of the conditioning environments.

The Commission's staff discovered during testing with the curbstone anvil that severe physical damage—namely splitting of the helmet from the impact point to the edge of the helmet—could occur even though the impact did not exceed the 300 g criterion. This led to consideration of whether in such cases the curbstone anvil test should be repeated on another sample to help ensure that other helmets will not fail this test.

The Commission acknowledges that, when marginal or unusual results occur in any of the standard's tests, retesting may be appropriate, even though the 300-g criterion is not exceeded. Other conditions that may prompt the Commission to undertake verification testing include (but are not limited to) peak-g readings that are very close to the 300-g failure criterion. However, since the option of additional testing inherently exists, it is not necessary to include a provision requiring such retesting in the standard.

b. Definition of "Comfort Padding"

The proposed definition of comfort padding included the statement: "This padding has no significant effect on impact attenuation." SwRI [2] commented that fit padding may have some influence on impact characteristics.

The Commission agrees with this commenter and deleted this statement from the definition.

c. Testing on More Than One Headform

In the revised proposal, the standard would have tested a helmet on all sizes of headform on which it fit. "Fit" was obtained if it was not difficult to put the helmet on the headform and the

helmet's comfort or fit padding was partially compressed.

PHMA [29] recommended that the situation where more than one headform will "fit" a helmet should be addressed by specifying the use of the largest headform that will accommodate the helmet, with comfort padding adjusted to optimize the fit.

The Commission concludes that it is appropriate to simplify the test procedure by testing on only one size headform. This is consistent with the current interim mandatory standards. However, in contrast to the commenter, the Commission believes that it is more appropriate to test on the smallest headform that is appropriate for the test sample. The Commission believes that the smaller headform will represent the more stringent test condition for the positional stability test. Testing on only one size headform will lessen the number of test samples needed to test compliance to the standard.

Therefore, a helmet shall be tested on the smallest of the headforms appropriate for the helmet sample. This size headform is the smallest headform on which all of the helmet's sizing pads are partially compressed when the helmet is equipped with its thickest sizing pads and positioned correctly on the reference headform.

Bell Sports [12] remarked that, where a helmet will "fit" more than one headform size, choosing the conditioning environment for testing on the larger headform(s) that produced the highest g-value in the test on the smallest headform that the helmet fits does not necessarily provide the worst case. The commenter recommended that there be four impacts in any conditioning environment chosen by the test technician. As explained above, the Commission is not going to test a given size helmet on more than one headform size. Accordingly, this comment is no longer applicable.

d. Number of Helmets Required for Testing

Four respondents commented on the number of helmets required for testing when the helmet includes attachments, (e.g., removable visor, face shield) and possible combinations of attachments [5, 12, 29, and 30]. They expressed concern that the proposed standard requires too many production helmet samples to be tested. One respondent [12] offered suggested amending § 1203.7(b) to include the statement that "Helmets can be tested with any combination of accessories."

Section 1203.7(a) of the proposed standard requires helmets to be "tested in the condition in which they are

offered for sale." Additionally, they are required to pass all tests both with and without any attachments that may be offered. To adopt the suggested wording would not maintain the requirement that helmets would meet the standard with all combinations of accessories. However, the Commission agrees with these commenters that it may be impractical and unnecessary to specify an additional set of eight test helmets for each added attachment and each combination of attachments in order to test for compliance with the standard.

To address this issue, the Commission decided to specify that attachments need be tested only when they can affect the test results, and that even then only a "worst case" combination of attachments need be tested. See the changes to § 1203.7(b) and § 1203.12(d)(1). For example, in the case of a removable visor that has no influence on the retention system strength test, it would be unnecessary to test four helmets (one for each conditioning environment) to that test with the visor attached and an additional four helmets without the visor. However, it may be possible for attachments such as visors or faceshields to influence tests such as impact attenuation or peripheral vision.

10. Helmet Conditioning

a. Low-Temperature Environment: Temperature Range

SwRI [#2] commented that the allowable temperature range in the low-temperature environment should parallel the allowable temperature ranges in the other environments.

The Commission believes it is more important for the low-temperature environment range to be consistent with the current interim standards than for the range to parallel the tolerance allowed in the other environments. Thus, this comment was not adopted. However, the proposed temperature range contained a typographical error. The range should have been (– 17 to – 13 °C). This range is consistent with ANSI, ASTM, Snell 95 and CSA standards. This typographical error has been corrected.

b. Water-Immersion Environment

Paula Romeo [26] suggested that the water-immersion environment was unrealistic and recommended a spray conditioning environment.

Commission testing of both immersed and water-sprayed helmets under various time durations showed no consistent trend in resulting peak acceleration levels. The immersion environment has the advantages of

being easier to define and of subjecting the helmet to a uniform conditioning exposure. Since testing showed that these commenters' concerns were unfounded, the immersion method of wet-conditioning is retained.

c. Reconditioning Time

The revised proposed standard provided that a helmet that was removed from its conditioning environment for more than 3 minutes before testing would be reconditioned for 5 minutes for each minute beyond the allotted 3 minutes before testing could be resumed. SwRI [2] noted that there would be potentially no upper limit to the exposure time to recondition a helmet once it is removed from the conditioning environment for more than 3 minutes.

The Commission agrees with this comment and has added a 4-hour limit to the reconditioning time in § 1203.13(c).

11. Labels

a. Label Format and Content

Two respondents [22, 23] urged the Commission to require "an appropriate symbol to appear adjacent to the statement of compliance on the label" and to add wording to warn that "failure to follow the warnings may result in serious injury or death."

The Commission agrees that more emphasis should be placed on the warning labels. Accordingly, the signal word "WARNING" is used with the warnings required by § 1203.6(a)(2)–(5). See § 1203.6(a)(6). The Commission concludes that the signal word will be more effective than a symbol, and the limited size of the inside of a helmet, and the amount of information already required on the labels, prevents the use of both a signal word and a symbol.

The limited space also prevents using the additional suggested language "failure to follow the warnings may result in serious injury or death." In addition, this language could possibly mislead some to conclude that proper use of a helmet will always prevent serious injury or death. Accordingly, the Commission is not requiring a warning symbol or the suggested language that "failure to follow the warnings may result in serious injury or death."

b. Use Label

The proposed standard required a label stating "Not for Motor Vehicle Use." Some comments addressed this choice of language. [Comments 11, 13, 22, 26.]

Two commenters stated that "Not for Motor Vehicle Use" wrongly suggested

the helmet was appropriate for any use other than motor vehicles. Another commenter felt that "Not for Motor Vehicle Use" allows the helmet to be used for other activities similar to bicycle riding, where no alternative helmet exists. A fourth commenter argued that "For Bicycle Use Only" was a positive statement to which users are more likely to respond.

On reconsideration, the Commission concludes that neither the "Not for Motor Vehicle Use" label nor the "For Bicycle Use Only" label adequately conveys the circumstances under which helmets that meet the CPSC standard are appropriate. It is reasonable to assume that helmets that are certified to the CPSC standard will also provide head protection for roller skaters, in-line skaters, and, perhaps, some other recreational activities. In-line skaters should not be discouraged from wearing a helmet by a label stating "For Bicycle Use Only."

The Commission also believes that consumers understand both the differences between bicycle helmets and motorcycle/motorsport helmets and that bicycle helmets would not provide adequate protection for motorsport activities. Therefore, the "Not for Motor Vehicle Use" label is not a critical safety message that should be mandated in the CPSC standard. Therefore, the final CPSC standard does not require a "use" label, but maintains the requirement for a certification label that informs the consumer that the helmet is certified to the U.S. CPSC standard for bicycle helmets.

c. Labeling for Cleaning Products

The second proposal required a label warning the user that the helmet can be damaged by contact with common substances (such as certain solvents, cleaners, etc.) and that this damage may not be visible to the user. This label is also required to state any recommended cleaning agents and procedures, list any known common substances that damage the helmet, and warn against contacting the helmet with these substances.

Several respondents [2, 11, 12, 29] expressed concern that too much information about cleaning products would be needed on the label and argued that consumers should be directed to the instruction manual for the list of cleaning materials.

This label is not intended to list every possible cleaning agent that can or should not be used on the helmet. Since the consumer may not always have the owner's manual, a label on the helmet should provide some general cleaning instructions and warnings. The language

of § 1203.6(a)(5) has been changed to make this intent clear.

d. Warning To Replace After Impact

[Commenters 22, 23, 26.] Some respondents agreed with the proposed standard's provision that the label on the helmet should advise consumers to destroy the helmet or return it to the manufacturer if it is involved in an impact. Others disagreed and requested more guidance on whether the helmet is impaired before a consumer has to return the helmet.

The variety of factors (impact surface, impact location on helmet, impact speed, etc.) that are involved in an impact to a helmet, and the level of interaction of each factor, are so complex that it is inappropriate to address them in a label. It is to the consumer's overall safety benefit to return the helmet to the manufacturer or destroy and replace it. Accordingly, the proposed replacement warning is not changed.

e. Durability of Labels

SwRI [2] remarked that a requirement for labels to be likely to remain legible throughout the life of the helmet cannot be tested and could lead to differences between laboratories. The PHMA [29] also expressed concern about this requirement, stating that it was unaware of any technology that will ensure that a sticker will stand up under 5 years of the type of exposure that a helmet receives.

The Commission shares these commenters' concerns. Current voluntary bicycle helmet standards require "durable" labeling or labeling that is "likely to remain legible for the life of the helmet." These conditions are not quantified in current standards. The Commission is not aware of any existing performance test method that can be applied in this circumstance. Since a requirement for legibility for the life of the helmet is vague and possibly unattainable, the Commission has changed the requirement to require "durable" labels.

f. Labels on Both Helmets and Boxes

The American Society of Safety Engineers ("ASSE") [11] and the NSKC [22] suggested that "proper fit" information should be on both the helmet and the outside of the box.

The Commission does not believe it is necessary to have the actual fitting instructions on the box, because there is no information indicating that such a label would be effective in assuring proper fit. However, it is important that consumers be aware that helmets do come in different sizes and that proper

fit is important. A label on the box promoting the need for proper fit could inform parents, before they buy the helmet, that they need to properly fit the helmet to the child. Therefore, the final standard applies § 1203.6(a)(3) to the helmet's packaging, as well as to the helmet.

12. Instructions for Fitting Children's Helmets

The NSKC [22] recommended that the proposed fitting instructions to accompany children's helmets be in age-specific language.

The Commission believes that age-specific instructions are unnecessary. The proposed standard requires both a graphic representation of proper positioning and written positioning and fitting directions. The graphics will reach more children than would age-specific instructions, because they allow children of all ages to compare the way their helmet looks with the pictures. In addition, graphics convey the critical information to non-English-reading individuals and illiterates. Children and adults are likely to be better able to understand and appreciate pictures than age-specific instructions. This is more likely to effectively deliver the message, allowing both parents and children to become aware of the proper fit.

13. Retention System Strength Test

SwRI [2] asked whether both the peak and residual displacements in the test of the dynamic strength of the retention system should be measured in order to better describe the dynamics of the system.

Only the peak deflection reading is needed to determine failure of the retention system. This is consistent with existing U.S. bicycle helmet standards. Therefore, no change to the proposed rule was made in response to this comment.

USC-HPRL [8] suggested that the retention system test (§ 1203.13(d)) be done after impact testing. The commenter reasons that an accident can damage a helmet and severely compromise the retention system. The retention system must ensure that the helmet remain on the head during an accident sequence.

After considering this comment, the Commission decided to make no changes to the sequence for retention system testing. Testing the retention system prior to impact testing is consistent with the ASTM and Snell standards. The Commission has no evidence that the test sequence in the ASTM and Snell standards allows helmets that do not have adequate retention systems.

The commenter also recommends that the "zero" position for measuring elongation be established without the proposed step of pre-tensioning the straps with a 4-kg mass.

There is no evidence that establishing the "zero" position after pretensioning the retention system, as proposed, would allow helmets that do not have adequate retention systems to pass the test. Therefore, the Commission made no changes to the procedure for establishing the pre-test "zero" position.

14. Positional Stability Test

SwRI [2] remarked that the ASTM Headgear Subcommittee is considering a 7-kg preload to set the helmet during testing. SwRI also asked whether a thin rubber pad should be specified to soften high frequency impact noise.

Testing to support the development of the positional stability test was with equipment specified as proposed in the CPSC standard. Subsequent to initial ASTM discussions about possible revisions to the proposed test procedure, the ASTM F8 Headgear Subcommittee decided not to modify the pre-load and not to specify a rubber impact pad. Therefore, the Commission made no change to this section.

NSKC [22] also recommends that the Commission examine the potential influence that fitting pads may have on the helmet's ability to comply with the retention system requirements.

When testing for positional stability, the standard instructs testers to position and fit the helmet on the test headform according to the manufacturer's instructions. This procedure may involve changing the size and position of the fit pads in order to achieve a secure fit. A similar procedure is followed to fit a bicycle helmet to the user. Although fitting a helmet to a metal headform will not account for all of the human elements involved when consumers fit helmets to their heads, the proposed procedure is the most practical approach at this time and should help keep the helmet secure during an accident. Therefore, no change to the proposed standard was made in response to this comment.

15. Vertical Vision

One commenter on the original proposal suggested that the Commission adopt requirements for a vertical field of vision. The Commission declined to do this because it had no information to indicate that bicycle helmets are posing a risk of injury due to inadequate upward or downward visual clearance.

In response to the second proposal, SwRI [2] suggested that requirements for visual clearance at the brow be

considered and that this would be especially important for racers who ride in the crouch position. However, a brow clearance requirement might, in some cases, reduce the amount of head coverage in the brow area. Further, CPSC has no information to indicate that bicycle helmets meeting existing standards are posing a risk of injury due to inadequate "upward" visual clearance. Therefore, the Commission did not add a "brow" visual clearance requirement to the final standard.

16. Reflectivity

Some comments on the original proposal related to possible requirements for helmets to improve a bicyclist's conspicuity in nighttime conditions. Data do show an increased risk of injury while bicycling during non-daylight hours. The Commission indicated that it would study this issue further in conjunction with planned work on evaluating the bicycle reflector requirements of CPSC's mandatory requirements for bicycles. 16 CFR part 1512. The Commission stated that it would decide whether to propose reflectivity requirements for bicycle helmets under the authority of the Bicycle Helmet Safety Act after that work is completed.

Several commenters on the revised proposal [1, 7, 11, 13, 16, 17, 22, 23, 24, 26] urged that the Commission not postpone implementing bicycle helmet reflectivity requirements.

Since the revised proposal, the Commission conducted field testing on bicycle reflectors and examined the issue of reflectivity on bicycle helmets. In the field testing, half (24/48) of the subjects were tested using bicycle riders with reflective helmets and the other half were tested using riders wearing non-reflective helmets. The reflective tape used on the helmets met a proposed Standard on use of Retroreflective Materials on Bicycle Helmets that was balloted by the ASTM Headgear Subcommittee. The study failed to show that the particular helmet reflective strip used in the study would increase the distance at which a bicycle can be detected or recognized (Schroeder, 1997). Accordingly, the Commission lacks data to support a requirement for bicycle helmet reflective performance.

17. Hard-shell Requirements

In recommendations to the Commission, Duke University researcher Barry Myers M.D., Ph.D., suggested that a test for penetration resistance be considered for the final standard. He reasons that such a test would require helmets to have hard

outer shells. Dr. Myers contends that a hard shell will reduce the risk of penetration-type traumas. He further contends that a hard shell will lessen friction between the helmet and the impact surface and that this has two benefits. First, it would reduce the total change in velocity (ΔV) of the head during impact. Second, by reducing the forces on the head caused by friction between the helmet and the impact surface, it would reduce the risk of neck injury.

In support of hard-shell helmets, Dr. Myers references the latest Harborview¹⁶ study, which reported a "consistent suggestion that hard-shell helmets are more protective against head and brain injuries than non-hard-shell helmets." Dr. Myers acknowledges that the differences measured were not statistically significant. However, he believes that a larger study, containing a sufficient number of severe brain injuries, might show this correlation with statistical significance.

In discussing protection against neck injury, Dr. Myers notes that automotive accidents cause serious neck injuries in about 15 to 25% of the persons who have serious head injuries, suggesting that neck injury is common among the most severely brain injured. However, since there were so few cases with severe brain injuries in Harborview's analysis of bicycling incidents, the significance of neck injury, and its mitigation by hard-shell helmets, among the severe brain injured cannot be determined from the Harborview study.

Although Dr. Myers suggests a penetration test in order to require that bike helmets have a hard shell, he states that a detailed study of the most severe injuries is warranted. He also recommends that, before a requirement that all helmets have a hard shell is adopted, there should be an evaluation of whether this would reduce the number of riders who would wear bicycle helmets.

Currently available information does not show a need to address the hazard of penetration-type head impacts to bicyclists. One study¹⁷ suggests that the majority of helmets involved in bicycle accidents suffer impacts on flat, hard surfaces (asphalt, cement, etc.) and that penetration-type impacts are rare.

Regarding the contention that requiring a hard shell may reduce neck injuries, bicycle-related injury data show a low incidence of serious neck injuries. In 1996, there were 566,400 bicycle-related injuries treated in U.S. hospital emergency rooms, based on CPSC data from NEISS. Of these, about 6,630 (1%) involved the neck. Of the neck injuries, about 4,520 (68%) involved strains or sprains, 1,155 (17%) involved contusions or abrasions, 275 (4%) involved lacerations, 240 (4%) involved fractures, and 440 (7%) involved other diagnoses. These numbers show that neck fractures accounted for about 0.04% of the total number of emergency-room-treated bicycle-related injuries in 1996. Detailed information was not available to analyze whether the use of a helmet or type of helmet had an effect on the risk of neck injury.

The Harborview study also reported a low incidence of neck injury. Their report showed that 2.7% of the cases (including both helmeted and non-helmeted cases) suffered neck injury, ranging from sprain to nerve-cord injuries. There was no correlation between neck injury and helmet use or helmet type.

Dr. Myers cites that automotive accidents cause serious neck injuries in about 15 to 25% of the persons who have serious head injuries. However, this statistic may not be relevant to the issue of friction between the shell and the impact surface, since the neck injuries in automotive accidents are not necessarily caused by friction between the head and an impacting surface.

Dr. Myers' advocacy of hard-shell helmets to reduce friction would seem to argue for a test to evaluate friction resistance of a helmet against typical impact surfaces, rather than for a penetration-resistance test.

One study on this issue was done by Voigt Hodgson, Ph.D., at Wayne State University.¹⁸ In this study, test helmets were secured to a modified Hybrid III dummy, and skid-type impacts were done on concrete at various angles from 30 to 60 degrees. Hodgson found that both hard-shell and micro-shell (or thin-shell) helmets tended to slide rather than "hang-up" on impact with concrete. (Thin-shell helmets are the type most commonly sold in the current market). No-shell helmets showed a larger tendency to hang-up on impacts with concrete. One of the conclusions of the study was that any helmet similar to

those tested in the study (hard-, thin-, or no-shell) will protect the brain and neck much better than wearing no helmet.

Harborview reports that there was a consistent trend indicating that hard-shell helmets provided better protection against head and brain injury than non-hard-shell helmets. However, in order for the results to be statistically significant, the number of people in the study would have had to be 11 times greater.

The Commission concludes that the following considerations are relevant to any possible requirement for hard-shell bicycle helmets:

1. Studies of bicycle helmets damaged in accidents suggest that penetration-type helmet impacts are rare occurrences. In addition, bicycle-related injury data suggest a low incidence of serious neck injuries. For the small portion of incidents that involve serious neck injury or penetration-type hazards, available information is insufficient to estimate the degree of improved protective performance that hard-shell helmets may offer over non-hard-shell helmets.

2. Non-hard-shell bicycle helmets are effective in preventing serious head and brain injuries. There are no known studies that report a statistically significant finding that hard-shell helmets offer better protection than non-hard-shell helmets.

3. A standard applying to all bicycle helmets has to balance the protective benefit that might be provided by a hard shell against the additional cost, weight, bulk, and discomfort caused by such a requirement. Such undesirable qualities may discourage some users from wearing helmets, which could more than cancel the effects of any additional protective qualities. This is an especially important consideration, given the popularity of non-hard-shell bicycle helmets.

After considering these factors, the Commission concludes that the available information does not support including a penetration test, or any other test that would require all bike helmets to have a hard shell, in the final rule.

D. Certification Testing and Labeling

1. General

Section 14(a) of the CPSA, 15 U.S.C. 2063(a), requires that every manufacturer (including importers) and private labeler of a product that is subject to a consumer product safety standard issue a certificate that the product conforms to the applicable standard, and to base that certificate either on a test of each product or on a

¹⁶Thompson, Diane C., MS; Rivara, Frederick P, MD, MPH; and Thompson, Robert S., MD. "Effectiveness of Bicycle Safety Helmets in Preventing Head Injuries," *Journal of the American Medical Association* 276 (December 1996): 1968-1973.

¹⁷Dean Fisher and Terry Stern, "Helmets Work!," *Bell Sports, Inc., AAAM/IRCOBI Conference*, Lyon, France (September 1994).

¹⁸Voigt R. Hodgson, Ph.D., "Skid Tests on a Select Group of Bicycle Helmets to Determine Their Head-Neck Protective Characteristics," *Department of Neurosurgery*, Wayne State University, Detroit, MI (March 8, 1991).

“reasonable testing program.” Regulations implementing these certification requirements are codified in Subpart B of the Safety Standard for Bicycle Helmets.

2. The Certification Rule

The proposed certification rule would require manufacturers of bicycle helmets that are manufactured after the final standard becomes effective to affix permanent labels to the helmets stating that the helmet complies with the applicable U.S. CPSC standard. These labels would be the “certificates of compliance,” as that term is used in § 14(a) of the CPSA.

In some instances, the label on the bicycle helmet may not be immediately visible to the ultimate purchaser of the helmet prior to purchase because of packaging or other marketing practices. In those cases, the final rule requires an identical second label on the helmet’s package or, if the package is not visible—as when the item is sold from a catalog, for example—on the promotional material used in connection with the sale of the bicycle helmet.

The certification label also contains the name, address, and telephone number of the manufacturer or importer, and identifies the production lot and the month and year the product was manufactured. Some of the required information may be in code.

The certification rule requires each manufacturer or importer to conduct a reasonable testing program to demonstrate that its bicycle helmets comply with the standard. This reasonable testing program may be defined by the manufacturer or importer, but must include either the tests prescribed in the standard or any other reasonable test procedures that assure compliance with the standard.

The certification rule provides that the required testing program will test bicycle helmets sampled from each production lot so that there is a reasonable assurance that, if the bicycle helmets selected for testing meet the standard, all bicycle helmets in the lot will meet the standard.

The rule provides that bicycle helmet importers may rely in good faith on the foreign manufacturer’s certificate of compliance, provided that a reasonable testing program has been performed by or for the foreign manufacturer and the importer is a U.S. resident or has a resident agent in the U.S.

3. Reasonable Testing Program

Proposed § 1203.33(b)(4) stated that if the reasonable testing program “shows that a bicycle helmet may not comply

with one or more requirements of the standard, no bicycle helmet in the production lot can be certified as complying until all noncomplying helmets in the lot have been identified and destroyed or altered * * * to make them conform to the standard.” Trek USA [5] commented that the proposed language describing a reasonable testing program was restrictive because it implies that if a single helmet fails any aspect of the test procedure, all of the product in the lot cannot be certified until corrective action is taken. The commenter suggested a change in the wording of § 1203.33(b)(4) from “a bicycle helmet” to “any bicycle helmet” that fails to conform to the testing criteria. The commenter asserts that this change would provide more flexibility, as it would remove the possibility of an anomaly in the testing causing a lack of certification of an entire lot.

The Commission did not make the requested change in the wording of § 1203.33(b)(4). First, it does not appear that the requested language would change the meaning of this requirement. Second, the purpose of the testing program is to detect possible failures of bicycle helmets in a production lot and to reasonably ensure that the helmets that are certified comply with the standard. The Commission intends that failure of one helmet would trigger an investigation to determine whether the failure extends to other helmets in the production lot. That investigation should continue until it is reasonably likely that no noncomplying helmets remain in the production lot. The wording of § 1203.33(b)(4) has been changed to make this intent clear.

a. Changes in Materials or Vendors

The proposed standard provides that when there are changes in parts, suppliers, or production methods, a new production lot should be established for the purposes of certification testing. The PHMA [29] wants clarification of when there are material or vendor changes. PHMA requests that the Commission use the Safety Equipment Institute (“SEI”) guidance to help firms understand the terms material changes, design changes, and vendor changes.

The Commission does not think that establishing definitions as stated in the SEI “Definition of Term” would add any significant clarification for the industry as a whole. Each firm can institute its own testing program, as long as the testing program is reasonable. The intent of the regulation is to ensure that all firms establish a reasonable testing program and to provide flexibility for both large and small firms. Each firm has the flexibility to define its own

terms in its quality control program, including material changes, design changes, and vendor changes, as long as the testing program is effective and reasonably able to determine whether all bicycle helmets comply with the standard. The Commission made no revision to the proposed rule in response to this comment. However, manufacturers and importers should keep records describing the testing program and explaining why the program is sufficient to reasonably determine that all of the firm’s bicycle helmets comply with the standard. Similarly, when the testing program detects noncomplying helmets, the firm should record the actions taken and why those actions are sufficient to reasonably ensure that no noncomplying helmets remain in the production lot. See Subpart C of Part 1203.

b. Pre-market Clearance and Market Surveillance

The Snell Memorial Foundation [28] and Paul H. Appel [25] propose the adoption of the pre-market clearance and market surveillance provisions of the Snell standard to ensure that quality bicycle helmets are produced. According to the commenters, without these two Snell provisions, Government efforts will be insufficient to keep inadequate helmets off the market.

All firms must ensure that bicycle helmets sold in the United States are certified to the mandatory bicycle helmet standard, and that the certifications are based on reasonable testing programs. Firms that distribute noncomplying products are subject to various Commission enforcement actions. These actions include recall, injunctions, seizure of the product, and civil or criminal penalties. The penalties for such violations could subject a firm to penalties of up to \$1.5 million and, after notice of noncompliance, fines of up to \$50,000 or imprisonment of individuals for not more than 1 year, or both.

The Commission has statutory authority to inspect manufacturers, importers, distributors, and retailers of bicycle helmets. This authority includes the right to review and copy records relevant to compliance with the bicycle helmet standard. The Commission may also collect samples of bicycle helmets for testing to the standard.

The Commission has a vigorous enforcement program that includes joint import surveillance with U.S. Customs and compliance surveillance of domestic producers, distributors, and retailers. In addition, the staff responds

to all reports of noncompliance with all mandatory standards.

From previous history with other regulations that the Commission enforces, compliance with the various CPSC standards is high. In addition, all firms have a responsibility to report noncompliance with the standard under Section 15(b) of the Consumer Product Safety Act, 15 U.S.C. 2064(b). Failure to report could subject a firm to severe penalties.

Based on these considerations, the agency's enforcement programs and enforcement authority will provide substantial assurance that bicycle helmets will meet the requirements for the mandatory standard. Experience in enforcing other CPSC regulations has shown that a high degree of compliance can be achieved without manufacturers using a pre-market clearance program or a third-party certifying organization. Therefore, the Commission made no revision to the proposed rule in response to this comment.

4. Certificate of Compliance

a. Coding of Date of Manufacture

The proposed standard required the certification label to contain the month and year of manufacture, but allowed this information to be in code. Mr. L.E. Oldendorf, P.E., from ASSE[11], the Bicycle Helmet Safety Institute ("BHISI") [16], the Bicycle Federation of Wisconsin [24], and Paula Romeo [26] opposed allowing manufacturers to code the month and year of manufacture. These commenters felt that uncoded dates would help consumers determine whether their helmet was subject to a recall. One commenter stated that an uncoded production date is necessary to assist consumers when they wish to replace their helmet after 5 years.

As the commenters noted, an uncoded manufacture date would make it easier for consumers to tell when their helmets are subject to a recall. This information also would help users determine when the helmet's useful life is over and the helmet should be replaced. Snell helmet standards require that the manufacture date be uncoded, and it is already a common practice in the industry. Accordingly, the Commission has revised the standard to require an uncoded date of manufacture.

b. Telephone Number on Label

Two commenters [23 and 26] urged that the Commission require labels showing the manufacturer's telephone number. They stated that this requirement would make it easier for the consumer to contact the manufacturer about recall information

and about instructions for returning the helmet to the manufacturer after it has been damaged.

The telephone number would be helpful for consumers during a recall or to inquire about a damaged bicycle helmet because they could determine the status of their helmets quicker than by a written inquiry. Obtaining a quicker response would enable the consumer to replace a defective helmet sooner and thus reduce the possibility of injuries caused by having an accident while wearing a defective helmet. Therefore, the Commission is requiring the telephone number of the U.S. manufacturer or importer on the helmet's labeling.

c. Certification Label on Children's Helmets

PHMA [29] suggested that a label showing certification for children under 5 is needed on the packaging, but is not needed inside the helmet.

The Commission does not agree. Since helmets for small children are likely to be shared with or passed on to multiple users, the sticker on the helmet is likely to be the only source of information available to the second or third user. Further, it is common to display helmets at retail without the box. Thus, the purchaser may not see the box until after selecting the model, if at all. Therefore, this labeling will be required on both the box and the helmet.

d. Minimum Age on Labels for Children's Helmets

Section 14(a) of the CPSA requires that certifying firms issue a certificate certifying that the product conforms to all applicable consumer product safety standards, 15 U.S.C. 2063(a). Accordingly, the original proposal would have required the label statement "Complies with CPSC Safety Standard for Bicycle Helmets (16 CFR part 1203)". This was changed in the revised proposal because the Commission wanted to guard against the possibility that small adult helmets will be purchased for children. Therefore, the revised proposed standard required that helmets that do not comply with the requirements for young children's helmets would be labeled "Complies with CPSC Safety Standard for Bicycle Helmets for Adults and Children Age 5 and Older (16 CFR 1203)". Under that proposal, helmets intended for children 4 years of age and younger would bear a label stating "Complies with CPSC Safety Standard for Bicycle Helmets for Children Under 5 Years (16 CFR 1203)". That proposal further provided that helmets that comply with both

standards could be labeled "Complies with the CPSC Safety Standard for Bicycle Helmets for Persons of All Ages", or equivalent language.

Maurice Keenan, MD, from the American Academy of Pediatrics [21], requested that a minimum age of 1 year be reflected on the label for helmets intended for children under age 5. This would better convey the message that infants (children under age 1) should not be passengers on a bicycle under any circumstance.

The Commission agrees with the commenter that children under 1 year of age should not be on bicycles. Children are just learning to sit unsupported at about 9 months of age. Until this age, infants have not developed sufficient bone mass and muscle tone to enable them to sit unsupported with their backs straight. Pediatricians advise against having infants sitting in a slumped or curled position for prolonged periods. This position may even be exacerbated by the added weight of a bicycle helmet on the infant's head. Because pediatricians recommend against having children under age 1 as passengers on bicycles, the Commission does not want the certification label to imply that children under age 1 can ride safely. Thus, the proposed language that a helmet complies with CPSC's standard "for Children Under 5 Years" or "for persons of all ages" is not suitable, since these phrases include children less than 1 year old.

Further, the only difference between the final requirements for helmets for children of ages 1–4 and for helmets for older persons is that the young children's helmets cover more of the head. Therefore, children's helmets will inherently comply with the requirements for helmets for older persons, and the label need not indicate an upper cutoff of age 5 for meeting CPSC's requirements.

For the reasons given above, the proposed label indicating that helmets comply with the standard for helmets for children under 5 years has been amended to state that the helmets comply with the CPSC standard for "persons age 1 and older."

e. Identifying the Commission

The NSKC [22] encouraged the Commission to modify the certification labeling to require the language "United States Consumer Product Safety Commission" rather than "CPSC." The commenter believes that the acronym is likely to lead to consumer confusion, but that the use of the full name of the Commission will clearly identify the

helmet as meeting a federal safety standard.

The rationale presented by the commenter for using the full name of the Commission instead of using the acronym is logical. However, the use of the Commission's full name may be impractical for some manufacturers. The amount of space available on the inside of a helmet is limited. The proposed regulation requires a number of labels, and each one is supposed to be legible and easily visible to the user. Allowing the use of the acronym is a necessary compromise so that all the labels can be accommodated on the inside of the helmet. However, the Commission concluded that the acronym should include the designation "U.S." before "CPSC" to indicate that the standard is issued by an agency of the Federal Government. Further, the Commission believes manufacturers should have the choice of whether to use the acronym or spell out the agency's name. Accordingly, the following wording has been added to §§ 1203.34(b)(1) and 1203.34(d): "this label may spell out 'U.S. Consumer Product Safety Commission' instead of 'U.S. CPSC'."

f. Certification Label on Packaging

The proposed standard provided that the certification compliance label shall also be on the helmets' packaging or promotional material if the label is not immediately visible on the product. NSKC [22] requested that the final standard require that such package label be legible and prominent, and placed on the main display panel of the packaging so that it is easily visible to the purchaser.

The Commission agrees with the commenter and has added the following wording to § 1203.34(d): "The label shall be legible, readily visible, and placed on the main display panel of the packaging or, if the packaging is not visible before purchase (e.g., catalog sales), on the promotional material used with the sale of the bicycle helmet."

E. Recordkeeping

1. Introduction

Section 16(b) of the CPSA requires that:

Every person who is a manufacturer, private labeler, or distributor of a consumer product shall establish and maintain such records, make such reports, and provide such information as the Commission may reasonably require for the purposes of implementing this Act, or to determine compliance with rules or orders prescribed under this Act.

15 U.S.C. 2065(b)

The rule requires every entity issuing certificates of compliance for bicycle

helmets to maintain records that show the certificates are based on a reasonable testing program. These records were proposed to be maintained for a period of at least 3 years from the date of certification of the last bicycle helmet in each production lot and to be available to any designated officer or employee of the Commission upon request in accordance with § 16(b) of the CPSA, 15 U.S.C. 2065(b).

2. Location of Test Records

The original proposal required that records be kept by the importer in the U.S. to allow inspection by CPSC staff within 48 hours of a request by an employee of the Commission. In response to a comment on the original proposal, the Commission revised the regulation to state that if the importer can provide the records to the CPSC staff within the 48-hour time period, the records will be considered kept in the U.S.

SwRI [2] commented that the 48-hour allowance to provide test records to the Commission should apply to all manufacturers or importers, whether or not the test records are maintained within the U.S.

The Commission agrees with this comment, and the final rule provides that all firms are required to provide records for immediate inspection and copying upon request by a Commission employee. If the records are not physically available during the inspection because they are maintained at another location, the firm must provide them to the staff within 48 hours.

3. Length of Records Retention

Paula Romeo [26] raised the issue of whether certification records should be maintained for longer than 3 years, since helmets can be used for 5 years.

The purpose of records being kept for 3 years is to ensure that the helmets have time to clear the distribution channels and get into the marketplace. If there is a compliance problem or defect in the helmets, 3 years would be sufficient to uncover any problems with the helmets. The Commission's staff would have time to obtain the records to review the firm's testing program and take any necessary enforcement action during this 3-year period. Therefore, no change was made in the rule in response to this comment.

F. Regulatory Flexibility Act Certification

Introduction

When an agency undertakes a rulemaking proceeding, the Regulatory

Flexibility Act, 5 U.S.C. 601 *et seq.*, generally requires the agency to prepare initial and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities.

The purpose of the Regulatory Flexibility Act, as stated in § 2(b) (5 U.S.C. 602 note), is to require agencies, consistent with their objectives, to fit the requirements of regulations to the scale of the businesses, organizations, and governmental jurisdictions subject to the regulations. The Regulatory Flexibility Act provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605.

The Commission's Previous Economic Findings

In the August 1994 notice of proposed rulemaking, the Commission noted that any costs associated with design changes to comply with the original proposal would be spread out over the course of production, and would be small on a per-unit basis. Costs associated with testing and monitoring were not expected to increase, since the vast majority of firms already used third parties to test for conformance to the voluntary standards. The proposal also allowed for self-certification and self-monitoring which, for some companies, may be substantially less costly than third-party certification. The proposed labeling requirements were not expected to have a significant impact on small firms, in that virtually all helmets already bore a similar label. Based on this information, the Commission preliminarily concluded that the proposal would not have a significant impact on a substantial number of small entities. The Commission received no public comment on this conclusion.

As a result of non-economic comments of a technical nature, the Commission proposed a revised standard on December 6, 1995. In that notice, the Commission reiterated its assessment of the economic impact of the standard on small businesses. In the preamble to the 1995 proposal, the Commission again preliminarily certified that the proposed standard, if promulgated, would not have a significant economic effect on a substantial number of small entities.

Current Economic Assessment and Response to Comments

The Commission's Directorate for Economics prepared an economic assessment of the safety standard for

bicycle helmets. The vast majority of helmets now sold conform to one (or more) of three existing voluntary standards. Many of these helmets probably already comply with the impact attenuation requirements of the new rule. On a per-unit basis, costs associated with redesign and testing are expected to be small.

The standard's labeling requirements are unlikely to have a significant impact on firms, since virtually all bicycle helmets now bear a permanent label on their inside surface. Industry sources report that, given sufficient lead time to modify these labels, any increased cost of labeling would be insignificant.

The vast majority of manufacturers now use third-party testing and monitoring for product liability reasons, and are likely to continue to do so in the future. The standard allows for self-certification and self-monitoring, however, which is substantially less costly than third-party testing and monitoring.

The Commission received two comments on the 1995 proposal that related to the economic effects of the revision. These involved the cost associated with the specification of a monorail test device, and the effect of the curbstone testing procedure.

A comment from Trek Bicycle Corporation [5] approved specifying a single test apparatus, but was concerned that the Commission chose a monorail-guided test rig over a guidewire unit. Trek said that the majority of PHMA members test on wire-guided equipment and that some firms may be forced to purchase monorail units to eliminate product liability concerns. The firm stated, "[t]he burden of this unnecessary expense may provide need for additional analysis of the financial impact to small business, as required by the Regulatory Flexibility Act."

Based on contacts with industry and testing facilities, it appears that, of those manufacturers that have in-house test labs, an estimated 5 to 10 have only a wire-guided rig. Most commercial, independent, and academic bicycle helmet test labs have a monorail test rig, and many of those labs also have one or more wire-guided rigs. The estimated cost to purchase a monorail-guided rig is about \$20,000.

An interlaboratory study comparing the results of monorail and guidewire test rigs showed no significant differences between the two types of rigs in test conditions that are within the parameters permitted by the draft standard. Therefore, the final standard has been revised to specify that either a monorail or a guidewire apparatus may be used to test a helmet's impact

attenuation performance. Consequently, the potential cost considerations for laboratories using guidewire rigs no longer apply.

Another commenter, Bell Sports [12], noted that the proposal also included impact testing requirements that allowed two impacts with a device simulating helmet contact with a curb. Bell estimated that "[t]he addition of the curbstone anvil * * * and with the option of using it twice on any helmet might well increase the retail price of bicycle helmets by \$2.00 to \$10.00."

The standard is intended to address helmet safety from a single impact on a given area. For this reason, the impact testing requirement has been changed to require only a single curbstone impact simulation test per helmet test sample. Consequently, the potential changes in helmet design that could have been needed to comply with two curbstone impact tests no longer apply.

Small Business Effects

Of the 30 current manufacturers of bicycle helmets, all but two would be considered small businesses under Small Business Administration employment criteria (less than 100 employees). As the Commission found previously, the one-time costs of design are expected to be small on a per-unit basis.

Spokesmen for the PHMA estimate that there are 1,000 to 1,500 bicycle-helmet molds in current use, each of which contains 4 molding cavities. Redesign may be required for one or more cavities in some molds, while other molds may not require any cavity redesign. Using a midpoint estimate of 1,250 molds, there would be some 5,000 cavities in current use in helmet molds.

The PHMA estimates that the top 4 manufacturers of bicycle helmets account for about 700 molds (or some 2,800 cavities) used in helmet production. The other 26 firms account for the remainder or, on average, 21 molds per firm (84 cavities). The PHMA estimates that 10% or less of the existing cavities would require redesign in order for the helmets made by them to comply with the standard. Thus, smaller firms may need to redesign an average of 8.4 cavities. Each cavity costs approximately \$2,500, according to the trade association. On average, the one-time cost of cavity redesign for the smaller 26 firms would be about \$21,000 each.

The top 4 firms account for an estimated 75% of the 9 million helmets sold annually, according to PHMA. The remaining firms thus account for 25%, or 2.25 million helmets annually. If sales are allocated uniformly, each of

the 26 firms would account for about 87,000 units. If spread over a single year's production, the average cavity redesign cost would be about 24 cents per helmet.

Further, the industry routinely replaces molds (and, thus, cavities), either because of style changes in helmet designs or because they wear out. The above estimates, however, assume that no molds would have been replaced absent the standard. Because the standard will not become effective until 1 year after the final rule is published, some of the noncomplying cavities may be replaced in that interim for reasons independent of the final standard. Consequently, the estimated one-time costs associated with the replacement of the smaller firms' mold cavities that would be attributed solely to the standard are likely to be significantly less than \$21,000 each.

Regulatory Flexibility Certification

Because the per-unit costs of modifying production molds will be relatively low, the Commission concludes that the rule will not have a significant impact on a substantial number of small entities.

G. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission assessed the possible environmental effects associated with the safety standard for bicycle helmets.

The Commission's regulations, at 16 CFR 1021.5(c) (1) and (2), state that safety standards and product labeling or certification rules for consumer products normally have little or no potential for affecting the human environment. The analysis of the potential impact of this rule indicates that the rule is not expected to affect preexisting packaging or materials of construction now used by manufacturers. Existing inventories of finished products would not be rendered unusable, since § 9(g)(1) of the CPSA provides that standards apply only to products manufactured after the effective date. Changes in coverage areas for helmets may require modification or replacement of existing injection molds. Industry experts estimate that there are some 1,000 to 1,500 molds currently used by bicycle helmet producers, and that perhaps 10% are likely to be affected by the proposed standard. Molds are constructed of aluminum, commonly weighing 40–50 pounds each. Molds are also routinely replaced

due to wear or to changes in style. Helmet manufacturers send these older molds back to the firm making replacements, and the older units are melted down for use in the replacement molds. Thus, the quantity of discards resulting from the rule is likely to be small.

Especially in view of the statutory 1-year effective date, it is unlikely that significant stocks of current labels will require disposal.

The requirements of the standard are not expected to have a significant effect on the materials used in production or packaging, or on the amount of materials discarded due to the regulation. Therefore, no significant environmental effects are expected from this rule. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

H. Paperwork Reduction Act

As noted above, U.S. manufacturers and importers of bicycle helmets will be required to conduct a reasonable testing program to ensure their products comply with the standard. They will also be required to keep records of such testing so that the Commission's staff can verify that the testing was conducted properly. This will enable the staff to obtain information indicating that a company's helmets comply with the standard, without having itself to test helmets. U.S. manufacturers and importers of bicycle helmets will also have to label their products with specified information.

The rule thus contains "collection of information requirements" subject to the Paperwork Reduction Act of 1995, 15 U.S.C. 3501-3520, Pub. L. No. 104-13, 109 Stat. 163 (1995). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The control number may be displayed by publication in the **Federal Register**. Accordingly, the Commission submitted the proposed collection of information requirements to OMB for review under section 3507(d) of the Paperwork Reduction Act of 1995.

The Commission's staff estimates that there are about 30 manufacturers and importers subject to these collection of information requirements. There are an estimated 200 different models of bicycle helmets currently marketed in the U.S.

Industry sources advised the Commission's staff that the time that will be required to comply with the collection of information requirements will be from 100 to 150 hours per model

per year. Therefore, the total amount of time required for compliance with these requirements will be 20,000 to 30,000 hours per year. However, these estimates are based on the amount of time that is currently expended in complying with the similar requirements that are in the various voluntary standards. Thus, the additional burden of the final collection of information requirements is expected to be only a small fraction of the total hours given above.

The Commission solicited comments on the activities and time required to comply with these requirements and how these differ from usual and customary current industry practices, on the accuracy of the Commission's burden estimate, and on how that burden could be reduced. No comments directly addressed the Commission's burden estimate. Comments addressing the topic of reducing the number of helmets required to be tested under the standard are discussed in section C of this notice.

I. Executive Orders

This rule has been evaluated for federalism implications in accordance with Executive Order No. 12,612, and the rule raises no substantial federalism concerns.

Executive Order No. 12,988 requires agencies to state the preemptive effect, if any, to be given to the regulation. The preemptive effect of this rule is established by 15 U.S.C. 2075(a), which states:

(a) Whenever a consumer product safety standard under [the CPSA] is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribed any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.

Subsection (b) of 15 U.S.C. 2075 provides that subsection (a) does not prevent the Federal Government or the government of any State or political subdivision of a State from establishing or continuing in effect a safety standard applicable to a consumer product for its own (governmental) use, and which is not identical to the consumer product safety standard applicable to the product under the CPSA, if the Federal, State, or political subdivision requirement provides a higher degree of

protection from such risk of injury than the consumer product safety standard.

Subsection (c) of 15 U.S.C. 2075 authorizes a State or a political subdivision of a State to request an exemption from the preemptive effect of a consumer product safety standard. The Commission may grant such a request, by rule, where the State or political subdivision standard or regulation (1) provides a significantly higher degree of protection from such risk of injury than the consumer product safety standard and (2) does not unduly burden interstate commerce.

List of Subjects in 16 CFR Part 1203

Consumer protection, Bicycles, Incorporation by reference, Infants and children, Safety.

For the reasons given above, the Commission revises Part 1203 of Title 16 of the Code of Federal Regulations to read as follows:

PART 1203—SAFETY STANDARD FOR BICYCLE HELMETS

Subpart A—The Standard

Sec.

- 1203.1 Scope, general requirements, and effective date.
- 1203.2 Purpose and basis.
- 1203.3 Referenced documents.
- 1203.4 Definitions.
- 1203.5 Construction requirements—projections.
- 1203.6 Labeling and instructions.
- 1203.7 Samples for testing.
- 1203.8 Conditioning environments.
- 1203.9 Test headforms.
- 1203.10 Selecting the test headform.
- 1203.11 Marking the impact test line.
- 1203.12 Test requirements.
- 1203.13 Test schedule.
- 1203.14 Peripheral vision test.
- 1203.15 Positional stability test (roll-off resistance).
- 1203.16 Dynamic strength of retention system test.
- 1203.17 Impact attenuation test.

Subpart B—Certification

- 1203.30 Purpose, basis, and scope.
- 1203.31 Applicability date.
- 1203.32 Definitions.
- 1203.33 Certification testing.
- 1203.34 Product certification and labeling by manufacturers (including importers).

Subpart C—Recordkeeping

- 1203.40 Effective date.
- 1203.41 Recordkeeping requirements.

Subpart D—Requirements for Bicycle Helmets Manufactured From March 17, 1995, Through March 10, 1999

- 1203.51 Purpose and basis.
- 1203.52 Scope and effective date.
- 1203.53 Interim safety standards.

Figures to Part 1203

Authority: 15 U.S.C. 2056, 2058, and 6001-6006. Subpart B is also issued under 15

U.S.C. 2063. Subpart C is also issued under 15 U.S.C. 2065.

Subpart A—The Standard

§ 1203.1 Scope, general requirements, and effective date.

(a) *Scope.* The standard in this subpart describes test methods and defines minimum performance criteria for all bicycle helmets, as defined in § 1203.4(b).

(b) *General requirements.*

(1) *Projections.* All projections on bicycle helmets must meet the construction requirements of § 1203.5.

(2) *Labeling and instructions.* All bicycle helmets must have the labeling and instructions required by § 1203.6.

(3) *Performance tests.* All bicycle helmets must be capable of meeting the peripheral vision, positional stability, dynamic strength of retention system, and impact-attenuation tests described in §§ 1203.7 through 1203.17.

(4) *Units.* The values stated in International System of Units ("SI") measurements are the standard. The inch-pound values stated in parentheses are for information only.

(c) *Effective date.* The standard shall become effective March 10, 1999 and shall apply to all bicycle helmets manufactured after that date. Bicycle helmets manufactured from March 17, 1995 through March 10, 1999, inclusive, are subject to the requirements of Subpart D, rather than this subpart A.

§ 1203.2 Purpose and basis.

The purpose and basis of this standard is to reduce the likelihood of serious injury and death to bicyclists resulting from impacts to the head, pursuant to 15 U.S.C. 6001–6006.

§ 1203.3 Referenced documents.

(a) The following documents are incorporated by reference in this standard.

(1) Draft ISO/DIS Standard 6220–1983—Headforms for Use in the Testing of Protective Helmets.¹

(2) SAE Recommended Practice SAE J211 OCT88, Instrumentation for Impact Tests.

(b) This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of the standards may be obtained as follows. Copies of the draft ISO/DIS Standard 6220–1983 are available from

American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036. Copies of the SAE Recommended Practice SAE J211 OCT88, Instrumentation for Impact Tests, are available from Society of Automotive Engineers, 400 Commonwealth Dr., Warrendale, PA 15096. Copies may be inspected at the Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, Maryland 20814, or at the Office of the Federal Register, 800 N. Capitol Street NW, Room 700, Washington, DC.

§ 1203.4 Definitions

(a) *Basic plane* means an anatomical plane that includes the auditory meatuses (the external ear openings) and the inferior orbital rims (the bottom edges of the eye sockets). The ISO headforms are marked with a plane corresponding to this basic plane (see Figures 1 and 2 of this part).

(b) *Bicycle helmet* means any headgear that either is marketed as, or implied through marketing or promotion to be, a device intended to provide protection from head injuries while riding a bicycle.²

(c) *Comfort or fit padding* means resilient lining material used to configure the helmet for a range of different head sizes.

(d) *Coronal plane* is an anatomical plane perpendicular to both the basic and midsagittal planes and containing the midpoint of a line connecting the right and left auditory meatuses. The ISO headforms are marked with a transverse plane corresponding to this

¹ Helmets specifically marketed for exclusive use in a designated activity, such as skateboarding, rollerblading, baseball, roller hockey, etc., would be excluded from this definition because the specific focus of their marketing makes it unlikely that such helmets would be purchased for other than their stated use. However, a multi-purpose helmet—one marketed or represented as providing protection either during general use or in a variety of specific activities other than bicycling—would fall within the definition of bicycle helmet if a reasonable consumer could conclude, based on the helmet's marketing or representations, that bicycling is among the activities in which the helmet is intended to be used. In making this determination, the Commission will consider the types of specific activities, if any, for which the helmet is marketed, the similarity of the appearance, design, and construction of the helmet to other helmets marketed or recognized as bicycle helmets, and the presence, prominence, and clarity of any warnings, on the helmet or its packaging or promotional materials, against the use of the helmet as a bicycle helmet. A multi-purpose helmet marketed without specific reference to the activities in which the helmet is to be used will be presumed to be a bicycle helmet. The presence of warnings or disclaimers advising against the use of a multi-purpose helmet during bicycling is a relevant, but not necessarily controlling, factor in the determination of whether a multi-purpose helmet is a bicycle helmet.

coronal plane (see Figures 1 and 2 of this part).

(e) *Field of vision* is the angle of peripheral vision allowed by the helmet when positioned on the reference headform.

(f) *Helmet positioning index ("HPI")* is the vertical distance from the brow of the helmet to the reference plane, when placed on a reference headform. This vertical distance shall be specified by the manufacturer for each size of each model of the manufacturer's helmets, for the appropriate size of headform for each helmet, as described in § 1203.10.

(g) *Midsagittal plane* is an anatomical plane perpendicular to the basic plane and containing the midpoint of the line connecting the notches of the right and left inferior orbital ridges and the midpoint of the line connecting the superior rims of the right and left auditory meatuses. The ISO headforms are marked with a longitudinal plane corresponding to the midsagittal plane (see Figures 1 and 2 of this part).

(h) *Modular elastomer programmer ("MEP")* is a cylindrical pad, typically consisting of a polyurethane rubber, used as a consistent impact medium for the systems check procedure. The MEP shall be 152 mm (6 in) in diameter, and 25 mm (1 in) thick and shall have a durometer of 60 ± 2 Shore A. The MEP shall be affixed to the top surface of a flat 6.35 mm (¼ in) thick aluminum plate. See § 1203.17(b)(1).

(i) *Preload ballast* is a "bean bag" filled with lead shot that is placed on the helmet to secure its position on the headform. The mass of the preload ballast is 5 kg (11 lb).

(j) *Projection* is any part of the helmet, internal or external, that extends beyond the faired surface.

(k) *Reference headform* is a headform used as a measuring device and contoured in the same configuration as one of the test headforms A, E, J, M, and O defined in draft ISO DIS 6220–1983. The reference headform shall include surface markings corresponding to the basic, coronal, midsagittal, and reference planes (see Figures 1 and 2 of this part).

(l) *Reference plane* is a plane marked on the ISO headforms at a specified distance above and parallel to the basic plane (see Figure 3 of this part).

(m) *Retention system* is the complete assembly that secures the helmet in a stable position on the wearer's head.

(n) *Shield* means optional equipment for helmets that is used in place of goggles to protect the eyes.

(o) *Spherical impactor* is an impact fixture used in the instrument system check of § 1203.17(b)(1) to test the impact-attenuation test equipment for

¹ Although the draft ISO/DIS 6220–1983 standard was never adopted as an international standard, it has become a consensus national standard because all recent major voluntary standards used in the United States for testing bicycle helmets establish their headform dimensions by referring to the draft ISO standard.

precision and accuracy. The spherical impactor shall be a 146 mm (5.75 in) diameter aluminum sphere mounted on the ball-arm connector of the drop assembly. The total mass of the spherical-impactor drop assembly shall be 5.0 ± 0.1 kg (11.0 ± 0.22 lb).

(p) *Test headform* is a solid model in the shape of a human head of sizes A, E, J, M, and O as defined in draft ISO/DIS 6220-1983. Headforms used for the impact-attenuation test shall be constructed of low-resonance K-1A magnesium alloy. The test headforms shall include surface markings corresponding to the basic, coronal, midsagittal, and reference planes (see Figure 2 of this part).

(q) *Test region* is the area of the helmet, on and above a specified impact test line, that is subject to impact testing.

§ 1203.5 Construction requirements—projections.

Any unfaired projection extending more than 7 mm (0.28 in.) from the helmet's outer surface shall break away or collapse when impacted with forces equivalent to those produced by the applicable impact-attenuation tests in § 1203.17 of this standard. There shall be no fixture on the helmet's inner surface projecting more than 2 mm into the helmet interior.

§ 1203.6 Labeling and instructions.

(a) *Labeling*. Each helmet shall be marked with durable labeling so that the following information is legible and easily visible to the user:

- (1) Model designation.
- (2) A warning to the user that no helmet can protect against all possible impacts and that serious injury or death could occur.
- (3) A warning on both the helmet and the packaging that for maximum protection the helmet must be fitted and attached properly to the wearer's head in accordance with the manufacturer's fitting instructions.
- (4) A warning to the user that the helmet may, after receiving an impact, be damaged to the point that it is no longer adequate to protect the head against further impacts, and that this damage may not be visible to the user. This label shall also state that a helmet that has sustained an impact should be returned to the manufacturer for inspection, or be destroyed and replaced.
- (5) A warning to the user that the helmet can be damaged by contact with common substances (for example, certain solvents [ammonia], cleaners [bleach], etc.), and that this damage may not be visible to the user. This label

shall state in generic terms some recommended cleaning agents and procedures (for example, wipe with mild soap and water), list the most common substances that damage the helmet, warn against contacting the helmet with these substances, and refer users to the instruction manual for more specific care and cleaning information.

(6) *Signal word*. The labels required by paragraphs (a) (2) through (5) of this section shall include the signal word "WARNING" at the beginning of each statement, unless two or more of the statements appear together on the same label. In that case, the signal word need only appear once, at the beginning of the warnings. The signal word "WARNING" shall be in all capital letters, bold print, and a type size equal to or greater than the other text on the label.

(b) *Instructions*. Each helmet shall have fitting and positioning instructions, including a graphic representation of proper positioning.

§ 1203.7 Samples for testing.

(a) *General*. Helmets shall be tested in the condition in which they are offered for sale. To meet the standard, the helmets must be able to pass all tests, both with and without any attachments that may be offered by the helmet's manufacturer and with all possible combinations of such attachments.

(b) *Number of samples*. To test conformance to this standard, eight samples of each helmet size for each helmet model offered for sale are required.

§ 1203.8 Conditioning environments.

Helmets shall be conditioned to one of the following environments prior to testing in accordance with the test schedule at § 1203.13. The barometric pressure in all conditioning environments shall be 75 to 110 kPa (22.2 to 32.6 in of Hg). All test helmets shall be stabilized within the ambient condition for at least 4 hours prior to further conditioning and testing. Storage or shipment within this ambient range satisfies this requirement.

(a) *Ambient condition*. The ambient condition of the test laboratory shall be within 17°C to 27°C (63°F to 81°F), and 20 to 80% relative humidity. The ambient test helmet does not need further conditioning.

(b) *Low temperature*. The helmet shall be kept at a temperature of -17°C to -13°C (1°F to 9°F) for 4 to 24 hours prior to testing.

(c) *High temperature*. The helmet shall be kept at a temperature of 47°C to 53°C (117°F to 127°F) for 4 to 24 hours prior to testing.

(d) *Water immersion*. The helmet shall be fully immersed "crown" down in potable water at a temperature of 17°C to 27°C (63°F to 81°F) to a crown depth of 305 mm \pm 25 mm (12 in. \pm 1 in.) for 4 to 24 hours prior to testing.

§ 1203.9 Test headforms.

The headforms used for testing shall be selected from sizes A, E, J, M, and O, as defined by DRAFT ISO/DIS 6220-1983, in accordance with § 1203.10. Headforms used for impact testing shall be rigid and be constructed of low-resonance K-1A magnesium alloy.

§ 1203.10 Selecting the test headform.

A helmet shall be tested on the smallest of the headforms appropriate for the helmet sample. A headform size is appropriate for a helmet if all of the helmet's sizing pads are partially compressed when the helmet is equipped with its thickest sizing pads and positioned correctly on the reference headform.

§ 1203.11 Marking the impact test line.

Prior to testing, the impact test line shall be determined for each helmet in the following manner.

(a) Position the helmet on the appropriate headform as specified by the manufacturer's helmet positioning index (HPI), with the brow parallel to the basic plane. Place a 5-kg (11-lb) preload ballast on top of the helmet to set the comfort or fit padding.

(b) Draw the impact test line on the outer surface of the helmet coinciding with the intersection of the surface of the helmet with the impact line planes defined from the reference headform as shown in:

(1) Figure 4 of this part for helmets intended only for persons 5 years of age and older.

(2) Figure 5 of this part for helmets intended for persons age 1 and older.

(c) The center of the impact sites shall be selected at any point on the helmet on or above the impact test line.

§ 1203.12 Test requirements.

(a) *Peripheral vision*. All bicycle helmets shall allow unobstructed vision through a minimum of 105° to the left and right sides of the midsagittal plane when measured in accordance with § 1203.14 of this standard.

(b) *Positional stability*. No bicycle helmet shall come off of the test headform when tested in accordance with § 1203.15 of this standard.

(c) *Dynamic strength of retention system*. All bicycle helmets shall have a retention system that will remain intact without elongating more than 30 mm (1.2 in.) when tested in accordance with § 1203.16 of this standard.

(d) *Impact attenuation criteria.*

(1) *General.* A helmet fails the impact attenuation performance test of this standard if a failure under paragraph (d)(2) of this section can be induced under any combination of impact site, anvil type, anvil impact order, or conditioning environment permissible under the standard, either with or without any attachments, or combinations of attachments, that are provided with the helmet. Thus, the Commission will test for a "worst case" combination of test parameters. What constitutes a worst case may vary, depending on the particular helmet involved.

(2) *Peak acceleration.* The peak acceleration of any impact shall not exceed 300 g when the helmet is tested in accordance with § 1203.17 of this standard.

§ 1203.13 Test schedule.

(a) Helmet sample 1 of the set of eight helmets, as designated in Table 1203.13,

shall be tested for peripheral vision in accordance with § 1203.14 of this standard.

(b) Helmet samples 1 through 8, as designated in Table 1203.13, shall be conditioned in the ambient, high temperature, low temperature, and water immersion environments as follows: helmets 1 and 5—ambient; helmets 2 and 7—high temperature; helmets 3 and 6—low temperature; and helmets 4 and 8—water immersion.

(c) Testing must begin within 2 minutes after the helmet is removed from the conditioning environment. The helmet shall be returned to the conditioning environment within 3 minutes after it was removed, and shall remain in the conditioning environment for a minimum of 2 minutes before testing is resumed. If the helmet is out of the conditioning environment beyond 3 minutes, testing shall not resume until the helmet has been reconditioned for a period equal to at least 5 minutes for

each minute the helmet was out of the conditioning environment beyond the first 3 minutes, or for 4 hours, (whichever reconditioning time is shorter) before testing is resumed.

(d) Prior to being tested for impact attenuation, helmets 1–4 (conditioned in ambient, high temperature, low temperature, and water immersion environments, respectively) shall be tested in accordance with the dynamic retention system strength test at § 1203.16. Helmets 1–4 shall then be tested in accordance with the impact attenuation tests on the flat and hemispherical anvils in accordance with the procedure at § 1203.17. Helmet 5 (ambient-conditioned) shall be tested in accordance with the positional stability tests at § 1203.15 prior to impact testing. Helmets 5–8 shall then be tested in accordance with the impact attenuation tests on the curbstone anvil in accordance with § 1203.17. Table 1203.13 summarizes the test schedule.

TABLE 1203.13.—TEST SCHEDULE

	§ 1203.14 Peripheral vision	§ 1203.15 Positional stability	§ 1203.16 Retention system strength	§ 1203.17 Impact tests	
				Anvil	Number of Impacts
Helmet 1, Ambient	X	X	X Flat	2
Helmet 2, High Temperature	X	X Hemi	2
Helmet 3, Low Temperature	X	X Flat	2
Helmet 4, Water Immersion	X	X Hemi	2
Helmet 5, Ambient	X	X Flat	2
Helmet 6, Low Temperature	X Hemi	2
Helmet 7, High Temperature	X Flat	2
Helmet 8, Water Immersion	X Hemi	2
				X Curb	1
				X Curb	1
				X Curb	1
				X Curb	1

§ 1203.14 Peripheral vision test.

Position the helmet on a reference headform in accordance with the HPI and place a 5-kg (11-lb) preload ballast on top of the helmet to set the comfort or fit padding. (**Note:** Peripheral vision clearance may be determined when the helmet is positioned for marking the test lines.) Peripheral vision is measured horizontally from each side of the midsagittal plane around the point K (see Figure 6 of this part). Point K is located on the front surface of the reference headform at the intersection of the basic and midsagittal planes. The vision shall not be obstructed within 105 degrees from point K on each side of the midsagittal plane.

§ 1203.15 Positional stability test (roll-off resistance).(a) *Test equipment.*

(1) *Headforms.* The test headforms shall comply with the dimensions of the full chin ISO reference headforms sizes A, E, J, M, and O.

(2) *Test fixture.* The headform shall be secured in a test fixture with the headform's vertical axis pointing downward and 45 degrees to the direction of gravity (see Figure 7 of this part). The test fixture shall permit rotation of the headform about its vertical axis and include means to lock the headform in the face up and face down positions.

(3) *Dynamic impact apparatus.* A dynamic impact apparatus shall be used to apply a shock load to a helmet secured to the test headform. The dynamic impact apparatus shall allow a 4-kg (8.8-lb) drop weight to slide in a guided free fall to impact a rigid stop anvil (see Figure 7 of this part). The entire mass of the dynamic impact

assembly, including the drop weight, shall be no more than 5 kg (11 lb).

(4) *Strap or cable.* A hook and flexible strap or cable shall be used to connect the dynamic impact apparatus to the helmet. The strap or cable shall be of a material having an elongation of no more than 5 mm (0.20 in.) per 300 mm (11.8 in.) when loaded with a 22-kg (48.5 lb) weight in a free hanging position.

(b) *Test procedure.*

(1) Orient the headform so that its face is down, and lock it in that orientation.

(2) Place the helmet on the appropriate size full chin headform in accordance with the HPI and fasten the retention system in accordance with the manufacturer's instructions. Adjust the straps to remove any slack.

(3) Suspend the dynamic impact system from the helmet by positioning the flexible strap over the helmet along

the midsagittal plane and attaching the hook over the edge of the helmet as shown in Figure 7 of this part.

(4) Raise the drop weight to a height of 0.6 m (2 ft) from the stop anvil and release it, so that it impacts the stop anvil.

(5) The test shall be repeated with the headform's face pointing upwards, so that the helmet is pulled from front to rear.

§ 1203.16 Dynamic strength of retention system test.

(a) Test equipment.

(1) ISO headforms without the lower chin portion shall be used.

(2) The retention system strength test equipment shall consist of a dynamic impact apparatus that allows a 4-kg (8.8-lb) drop weight to slide in a guided free fall to impact a rigid stop anvil (see Figure 8 of this part). Two cylindrical rollers that spin freely, with a diameter of 12.5 ± 0.5 mm (0.49 in. \pm 0.02 in.) and a center-to-center distance of 76.0 ± 1 mm (3.0 \pm 0.04 in.), shall make up a stirrup that represents the bone structure of the lower jaw. The entire dynamic test apparatus hangs freely on the retention system. The entire mass of the support assembly, including the 4-kg (8.8-lb) drop weight, shall be 11 kg \pm 0.5 kg (24.2 lb \pm 1.1 lb).

(b) Test procedure.

(1) Place the helmet on the appropriate size headform on the test device according to the HPI. Fasten the strap of the retention system under the stirrup.

(2) Mark the pre-test position of the retention system, with the entire dynamic test apparatus hanging freely on the retention system.

(3) Raise the 4-kg (8.8-lb) drop weight to a height of 0.6 m (2 ft) from the stop anvil and release it, so that it impacts the stop anvil.

(4) Record the maximum elongation of the retention system during the impact. A marker system or a displacement transducer, as shown in Figure 8 of this part, are two methods of measuring the elongation.

§ 1203.17 Impact attenuation test.

(a) Impact test instruments and equipment.

(1) *Measurement of impact attenuation.* Impact attenuation is determined by measuring the acceleration of the test headform during impact. Acceleration is measured with a uniaxial accelerometer that is capable of withstanding a shock of at least 1000 g. The helmet is secured onto the headform and dropped in a guided free fall, using a monorail or guidewire test apparatus (see Figure 9 of this part),

onto an anvil fixed to a rigid base. The center of the anvil shall be aligned with the center vertical axis of the accelerometer. The base shall consist of a solid mass of at least 135 kg (298 lb), the upper surface of which shall consist of a steel plate at least 12 mm (0.47 in.) thick and having a surface area of at least 0.10 m² (1.08 ft²).

(2) *Accelerometer.* A uniaxial accelerometer shall be mounted at the center of gravity of the test headform, with the sensitive axis aligned within 5 degrees of vertical when the test headform is in the impact position. The acceleration data channel and filtering shall comply with SAE Recommended Practice J211 OCT88, Instrumentation for Impact Tests, Requirements for Channel Class 1000.

(3) *Headform and drop assembly—centers of gravity.* The center of gravity of the test headform shall be at the center of the mounting ball on the support assembly and within an inverted cone having its axis vertical and a 10-degree included angle with the vertex at the point of impact. The location of the center of gravity of the drop assembly (combined test headform and support assembly) must meet the specifications of Federal Motor Vehicle Safety Standard No. 218, Motorcycle Helmets, 49 CFR 571.218 (S7.1.8). The center of gravity of the drop assembly shall lie within the rectangular volume bounded by $x = -6.4$ mm (-0.25 in.), $x = 21.6$ mm (0.85 in.), $y = 6.4$ mm (0.25 in.), and $y = -6.4$ mm (-0.25 in.), with the origin located at the center of gravity of the test headform. The origin of the coordinate axes is at the center of the mounting ball on the support assembly. The rectangular volume has no boundary along the z-axis. The positive z-axis is downward. The x-y-z axes are mutually perpendicular and have positive or negative designations as shown in Figure 10 of this part. Figure 10 shows an overhead view of the x-y boundary of the drop assembly center of gravity.

(4) *Drop assembly.* The combined mass of the drop assembly, which consists of instrumented test headform and support assembly (excluding the test helmet), shall be 5.0 ± 0.1 kg (11.00 \pm 0.22 lb).

(5) *Impact anvils.* Impact tests shall be performed against the three different solid (*i.e.*, without internal cavities) steel anvils described in this paragraph (a)(5).

(i) *Flat anvil.* The flat anvil shall have a flat surface with an impact face having a minimum diameter of 125 mm (4.92 in.). It shall be at least 24 mm (0.94 in.) thick (see Figure 11 of this part).

(ii) *Hemispherical anvil.* The hemispherical anvil shall have a hemispherical impact surface with a radius of 48 ± 1 mm (1.89 ± 0.04 in.) (see Figure 12 of this part).

(iii) *Curbstone anvil.* The curbstone anvil shall have two flat faces making an angle of 105 degrees and meeting along a striking edge having a radius of 15 mm \pm 0.5 mm (0.59 ± 0.02 in.). The height of the curbstone anvil shall not be less than 50 mm (1.97 in.), and the length shall not be less than 200 mm (7.87 in.) (see Figure 13 of this part).

(b) Test Procedure.

(1) *Instrument system check (precision and accuracy).* The impact-attenuation test instrumentation shall be checked before and after each series of tests (at least at the beginning and end of each test day) by dropping a spherical impactor onto an elastomeric test medium (MEP). The spherical impactor shall be a 146 mm (5.75 in.) diameter aluminum sphere that is mounted on the ball-arm connector of the drop assembly. The total mass of the spherical-impactor drop assembly shall be 5.0 ± 0.1 kg (11.0 ± 0.22 lb). The MEP shall be 152 mm (6 in.) in diameter and 25 mm (1 in.) thick, and shall have a durometer of 60 ± 2 Shore A. The MEP shall be affixed to the top surface of a flat 6.35 mm ($\frac{1}{4}$ in.) thick aluminum plate. The geometric center of the MEP pad shall be aligned with the center vertical axis of the accelerometer (see paragraph (a)(2) of this section). The impactor shall be dropped onto the MEP at an impact velocity of 5.44 m/s \pm 2%. (Typically, this requires a minimum drop height of 1.50 meters (4.9 ft) plus a height adjustment to account for friction losses.) Six impacts, at intervals of 75 ± 15 seconds, shall be performed at the beginning and end of the test series (at a minimum at the beginning and end of each test day). The first three of six impacts shall be considered warm-up drops, and their impact values shall be discarded from the series. The second three impacts shall be recorded. All recorded impacts shall fall within the range of 380 g to 425 g. In addition, the difference between the high and low values of the three recorded impacts shall not be greater than 20 g.

(2) *Impact sites.* Each of helmets 1 through 4 (one helmet for each conditioning environment) shall impact at four different sites, with two impacts on the flat anvil and two impacts on the hemispherical anvil. The center of any impact may be anywhere on or above the test line, provided it is at least 120 mm (4.72 in.), measured on the surface of the helmet, from any prior impact center. Each of helmets 5 through 8 (one helmet for each conditioning

environment) shall impact at one site on the curbstone anvil. The center of the curbstone impacts may be on or anywhere above the test line. The curbstone anvil may be placed in any orientation as long as the center of the anvil is aligned with the axis of the accelerometer. As noted in § 1203.12(d)(1), impact sites, the order of anvil use (flat and hemispherical), and curbstone anvil sites and orientation shall be chosen by the test personnel to provide the most severe test for the helmet. Rivets and other mechanical fasteners, vents, and any other helmet feature within the test region are valid test sites.

(3) *Impact velocity.* The helmet shall be dropped onto the flat anvil with an impact velocity of $6.2 \text{ m/s} \pm 3\%$ ($20.34 \text{ ft/s} \pm 3\%$). (Typically, this requires a minimum drop height of 2 meters (6.56 ft), plus a height adjustment to account for friction losses.) The helmet shall be dropped onto the hemispherical and curbstone anvils with an impact velocity of $4.8 \text{ m/s} \pm 3\%$ ($15.75 \text{ ft/s} \pm 3\%$). (Typically, this requires a minimum drop height of 1.2 meters (3.94 ft), plus a height adjustment to account for friction losses.) The impact velocity shall be measured during the last 40 mm (1.57 in) of free-fall for each test.

(4) *Helmet position.* Prior to each test, the helmet shall be positioned on the test headform in accordance with the HPI. The helmet shall be secured so that it does not shift position prior to impact. The helmet retention system shall be secured in a manner that does not interfere with free-fall or impact.

(5) *Data.* Record the maximum acceleration in g's during impact. See Subpart C, § 1203.41(b).

Subpart B—Certification

§ 1203.30 Purpose, basis, and scope.

(a) *Purpose.* The purpose of this subpart is to establish requirements that manufacturers and importers of bicycle helmets subject to the Safety Standard for Bicycle Helmets (subpart A of this part 1203) shall issue certificates of compliance in the form specified.

(b) *Basis.* Section 14(a)(1) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2063(a)(1), requires every manufacturer (including importers) and private labeler of a product which is subject to a consumer product safety standard to issue a certificate that the product conforms to the applicable standard. Section 14(a)(1) further requires that the certificate be based either on a test of each product or on a "reasonable testing program." The Commission may, by rule, designate one

or more of the manufacturers and private labelers as the persons who shall issue the required certificate. 15 U.S.C. 2063(a)(2).

(c) *Scope.* The provisions of this subpart apply to all bicycle helmets that are subject to the requirements of the Safety Standard for Bicycle Helmets, subpart A of this part 1203.

§ 1203.31 Applicability date.

All bicycle helmets manufactured on or after March 11, 1999, must meet the standard and must be certified as complying with the standard in accordance with this subpart B.

§ 1203.32 Definitions.

The following definitions shall apply to this subpart:

(a) *Foreign manufacturer* means an entity that manufactured a bicycle helmet outside the United States, as defined in 15 2052(a)(10) and (14).

(b) *Manufacturer* means the entity that either manufactured a helmet in the United States or imported a helmet manufactured outside the United States.

(c) *Private labeler* means an owner of a brand or trademark that is used on a bicycle helmet subject to the standard and that is not the brand or trademark of the manufacturer of the bicycle helmet, provided the owner of the brand or trademark caused, authorized, or approved its use.

(d) *Production lot* means a quantity of bicycle helmets from which certain bicycle helmets are selected for testing prior to certifying the lot. All bicycle helmets in a lot must be essentially identical in those design, construction, and material features that relate to the ability of a bicycle helmet to comply with the standard.

(e) *Reasonable testing program* means any tests which are identical or equivalent to, or more stringent than, the tests defined in the standard and which are performed on one or more bicycle helmets selected from the production lot to determine whether there is reasonable assurance that all of the bicycle helmets in that lot comply with the requirements of the standard.

§ 1203.33 Certification testing.

(a) *General.* Manufacturers, as defined in § 1203.32(b) to include importers, shall conduct a reasonable testing program to demonstrate that their bicycle helmets comply with the requirements of the standard.

(b) *Reasonable testing program.* This paragraph provides guidance for establishing a reasonable testing program.

(1) Within the requirements set forth in this paragraph (b), manufacturers and

importers may define their own reasonable testing programs. Reasonable testing programs may, at the option of manufacturers and importers, be conducted by an independent third party qualified to perform such testing programs. However, manufacturers and importers are responsible for ensuring compliance with all requirements of the standard in subpart A of this part.

(2) As part of the reasonable testing program, the bicycle helmets shall be divided into production lots, and sample bicycle helmets from each production lot shall be tested. Whenever there is a change in parts, suppliers of parts, or production methods, and the change could affect the ability of the bicycle helmet to comply with the requirements of the standard, the manufacturer shall establish a new production lot for testing.

(3) The Commission will test for compliance with the standard by using the standard's test procedures. However, a reasonable testing program need not be identical to the tests prescribed in the standard.

(4) If the reasonable testing program shows that a bicycle helmet may not comply with one or more requirements of the standard, no bicycle helmet in the production lot can be certified as complying until sufficient actions are taken that it is reasonably likely that no noncomplying bicycle helmets remain in the production lot. All identified noncomplying helmets in the lot must be destroyed or altered by repair, redesign, or use of a different material or component, to the extent necessary to make them conform to the standard.

(5) The sale or offering for sale of a bicycle helmet that does not comply with the standard is a prohibited act and a violation of section 19(a) of the CPSA (15 U.S.C. 2068(a)), regardless of whether the bicycle helmet has been validly certified.

§ 1203.34 Product certification and labeling by manufacturers (including importers).

(a) *Form of permanent label of certification.* Manufacturers, as defined in § 1203.32(a), shall issue certificates of compliance for bicycle helmets manufactured after March 11, 1999, in the form of a durable, legible, and readily visible label meeting the requirements of this section. This label is the helmet's certificate of compliance, as that term is used in section 14 of the CPSA, 15 U.S.C. 2063.

(b) *Contents of certification label.* The certification labels required by this section shall contain the following:

(1) The statement "Complies with U.S. CPSC Safety Standard for Bicycle

Helmets for Persons Age 5 and Older" or "Complies with U.S. CPSC Safety Standard for Bicycle Helmets for Persons Age 1 and Older (Extended Head Coverage)", as appropriate; this label may spell out "U.S. Consumer Product Safety Commission" instead of "U.S. CPSC";

(2) The name of the U.S. manufacturer or importer responsible for issuing the certificate or the name of a private labeler;

(3) The address of the U.S. manufacturer or importer responsible for issuing the certificate or, if the name of a private labeler is on the label, the address of the private labeler;

(4) The name and address of the foreign manufacturer, if the helmet was manufactured outside the United States;

(5) The telephone number of the U.S. manufacturer or importer responsible for issuing the certificate or, if the name of a private labeler is on the label, the telephone number of the private labeler;

(6) An identification of the production lot; and

(7) The uncoded month and year the product was manufactured.

(c) *Coding.* (1) The information required by paragraphs (b)(4) and (b)(6) of this section, and the information referred to in paragraph (c)(2) of this section, may be in code, provided:

(i) The person or firm issuing the certificate maintains a written record of the meaning of each symbol used in the code, and

(ii) The record shall be made available to the distributor, retailer, consumer, and Commission upon request.

(2) A serial number may be used in place of a production lot identification on the helmet if it can serve as a code to identify the production lot. If a bicycle helmet is manufactured for sale by a private labeler, and if the name of the private labeler is on the certification label, the name of the manufacturer or importer issuing the certificate, and the name and address of any foreign manufacturer, may also be in code.

(d) *Placement of the label(s).* The information required by paragraphs (b)(2), (b)(3), and (b)(5) of this section must be on one label. The other required information may be on separate labels. The label(s) required by this section must be affixed to the bicycle helmet. If the label(s) are not immediately visible to the ultimate purchaser of the bicycle helmet prior to purchase because of packaging or other marketing practices, a second label is required. That label shall state, as appropriate, "Complies with U.S. CPSC Safety Standard for Bicycle Helmets for Persons Age 5 and Older", or "Complies with U.S. CPSC Safety Standard for Bicycle Helmets for

Persons Age 1 and Older (Extended Head Coverage)". The label shall be legible, readily visible, and placed on the main display panel of the packaging or, if the packaging is not visible before purchase (e.g., catalog sales), on the promotional material used with the sale of the bicycle helmet. This label may spell out "U.S. Consumer Product Safety Commission" instead of "U.S. CPSC."

(e) *Additional provisions for importers.*

(1) *General.* The importer of any bicycle helmet subject to the standard in subpart A of this part 1203 must issue the certificate of compliance required by section 14(a) of the CPSA and this section. If a reasonable testing program meeting the requirements of this subpart has been performed by or for the foreign manufacturer of the product, the importer may rely in good faith on such tests to support the certificate of compliance, provided:

(i) The importer is a resident of the United States or has a resident agent in the United States,

(ii) There are records of such tests required by § 1203.41 of subpart C of this part, and

(iii) Such records are available to the Commission within 48 hours of a request to the importer.

(2) *Responsibility of importers.* Importers that rely on tests by the foreign manufacturer to support the certificate of compliance shall—in addition to complying with paragraph (e)(1) of this section—examine the records supplied by the manufacturer to determine that they comply with § 1203.41 of subpart C of this part.

Subpart C—Recordkeeping

§ 1203.40 Effective date.

This subpart is effective March 10, 1999, and applies to bicycle helmets manufactured after that date.

§ 1203.41 Recordkeeping requirements.

(a) *General.* Every person issuing certificates of compliance for bicycle helmets subject to the standard in subpart A of this part shall maintain records which show that the certificates are based on a reasonable testing program. The records shall be maintained for a period of at least 3 years from the date of certification of the last bicycle helmet in each production lot. These records shall be available, upon request, to any designated officer or employee of the Commission, in accordance with section 16(b) of the CPSA, 15 U.S.C. 2065(b). If the records are not physically available during the inspection because they are maintained

at another location, the firm must provide them to the staff within 48 hours.

(b) *Records of helmet tests.* Complete test records shall be maintained. These records shall contain the following information.

(1) An identification of the bicycle helmets tested;

(2) An identification of the production lot;

(3) The results of the tests, including the precise nature of any failures;

(4) A description of the specific actions taken to address any failures;

(5) A detailed description of the tests, including the helmet positioning index (HPI) used to define the proper position of the helmet on the headform;

(6) The manufacturer's name and address;

(7) The model and size of each helmet tested;

(8) Identifying information for each helmet tested, including the production lot for each helmet;

(9) The environmental condition under which each helmet was tested, the duration of the helmet's conditioning, the temperatures in each conditioning environment, and the relative humidity and temperature of the laboratory;

(10) The peripheral vision clearance;

(11) A description of any failures to conform to any of the labeling and instruction requirements;

(12) Performance impact results, stating the precise location of impact, type of anvil used, velocity prior to impact, and maximum acceleration measured in g's;

(13) The results of the positional stability test;

(14) The results of the dynamic strength of retention system test;

(15) The name and location of the test laboratory;

(16) The name of the person(s) who performed the test;

(17) The date of the test; and

(18) The system check results.

(c) *Format for records.* The records required to be maintained by this section may be in any appropriate form or format that clearly provides the required information. Certification test results may be kept on paper, microfiche, computer disk, or other retrievable media. Where records are kept on computer disk or other retrievable media, the records shall be made available to the Commission on paper copies, or via electronic mail in the same format as paper copies, upon request.

Subpart D—Requirements For Bicycle Helmets Manufactured From March 17, 1995, Through March 10, 1999**§ 1203.51 Purpose and basis.**

The purpose and basis of this subpart is to protect bicyclists from head injuries by ensuring that bicycle helmets comply with the requirements of appropriate existing voluntary standards, as provided in 15 U.S.C. 6004(a).

§ 1203.52 Scope and effective date.

(a) This subpart D is effective March 17, 1995, except for § 1203.53(a)(8), which is effective March 10, 1998. This subpart D shall apply to bicycle helmets manufactured from March 17, 1995, through March 10, 1999, inclusive. Such bicycle helmets shall comply with the requirements of one of the standards specified in § 1203.53. This subpart shall be considered a consumer product safety standard issued under the Consumer Product Safety Act.

(b) The term "bicycle helmet" is defined at § 1203.4(b).

(c) These interim mandatory safety standards will not apply to bicycle helmets manufactured after March 10, 1999. Those helmets are subject to the requirements of Subparts A through C of this part 1203.

§ 1203.53 Interim safety standards.

(a) Bicycle helmets must comply with one or more of the following standards. The standards in paragraphs (a)(1) through (a)(7) of this section are incorporated herein by reference:

(1) American National Standards Institute (ANSI) standard Z90.4–1984, Protective Headgear for Bicyclists,

(2) ASTM standards F 1447–93 or F 1447–94, Standard Specification for Protective Headgear Used in Bicycling, incorporating the relevant provisions of ASTM F 1446–93 or ASTM F 1446–94, Standard Test Methods for Equipment and Procedures Used in Evaluating the Performance Characteristics of Protective Headgear, respectively,

(3) Canadian Standards Association standard, Cycling Helmets—CAN/CSA–D113.2–M89,

(4) Snell Memorial Foundation (Snell) 1990 Standard for Protective Headgear for Use in Bicycling (designation B–90),

(5) Snell 1990 Standard for Protective Headgear for Use in Bicycling, including March 9, 1994 Supplement (designation B–90S),

(6) Snell 1994 Standard for Protective Headgear for Use in Non-Motorized Sports (designation N–94), or

(7) Snell 1995 standard for Protective Headgear for Use with Bicycles B–95.

(8) Subparts A through C of this part 1203.

(b) The incorporation by reference of the standards listed in paragraphs (a)(1) through (a)(7) are approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the standards may be obtained as follows. Copies of the ANSI Z90.4 standard are available from: American National Standards Institute, 11 W. 42nd Street, 13th Floor, New York, NY 10036. Copies of the ASTM standards are available from: ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. Copies of the Canadian Standards Association CAN/CSA–D113.2–M89 standard are available from: CSA, 178 Rexdale Boulevard, Rexdale (Toronto), Ontario, Canada, M9W 1R3. Copies of the Snell standards are available from: Snell Memorial Foundation, Inc., 6731–A 32nd Street, North Highlands, CA 95660. Copies may be inspected at the Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, Maryland 20814, or at the Office of the Federal Register, 800 N. Capitol Street NW, Room 700, Washington, DC.

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Figures to Part 1203

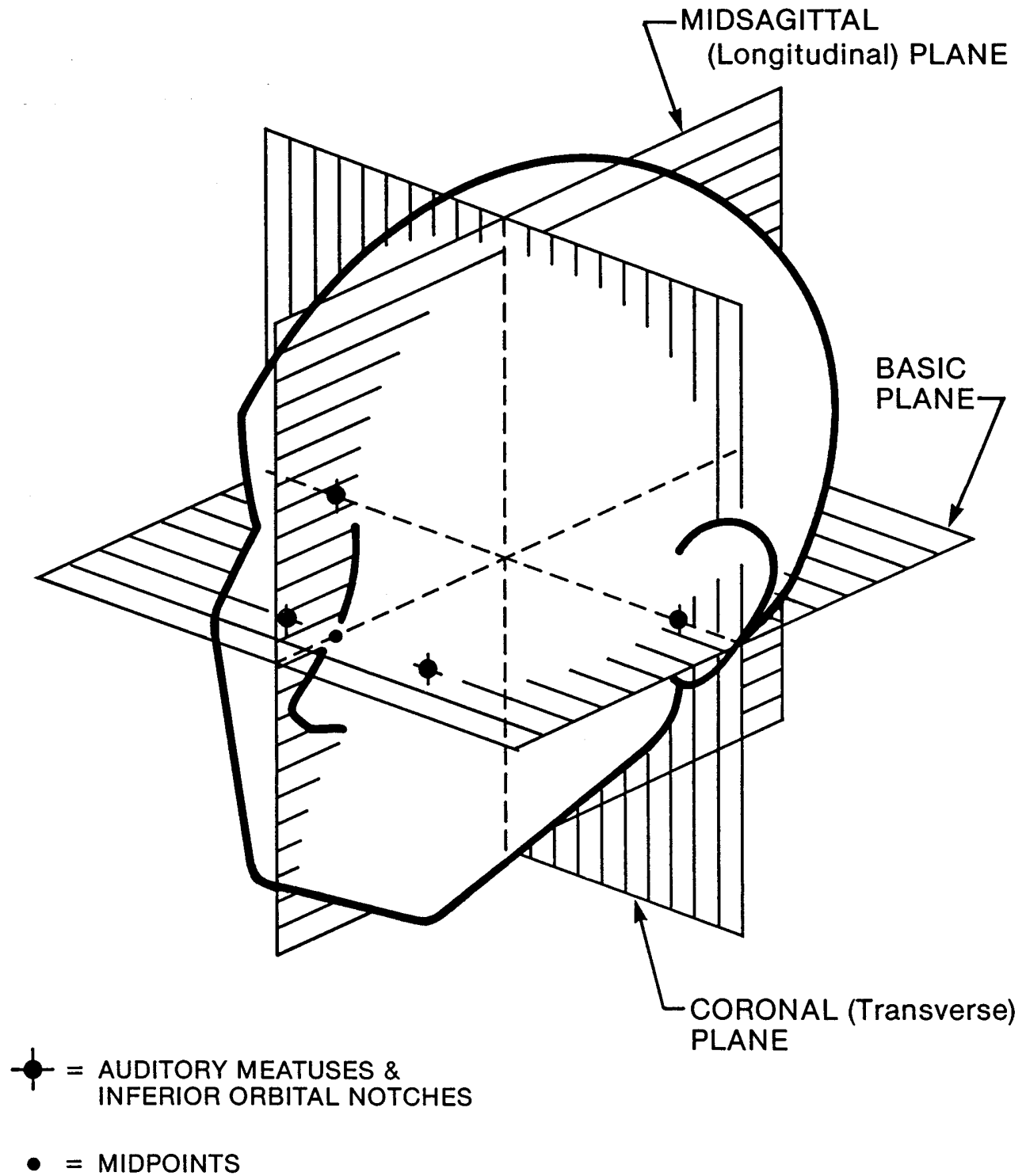


Figure 1. Anatomical Planes

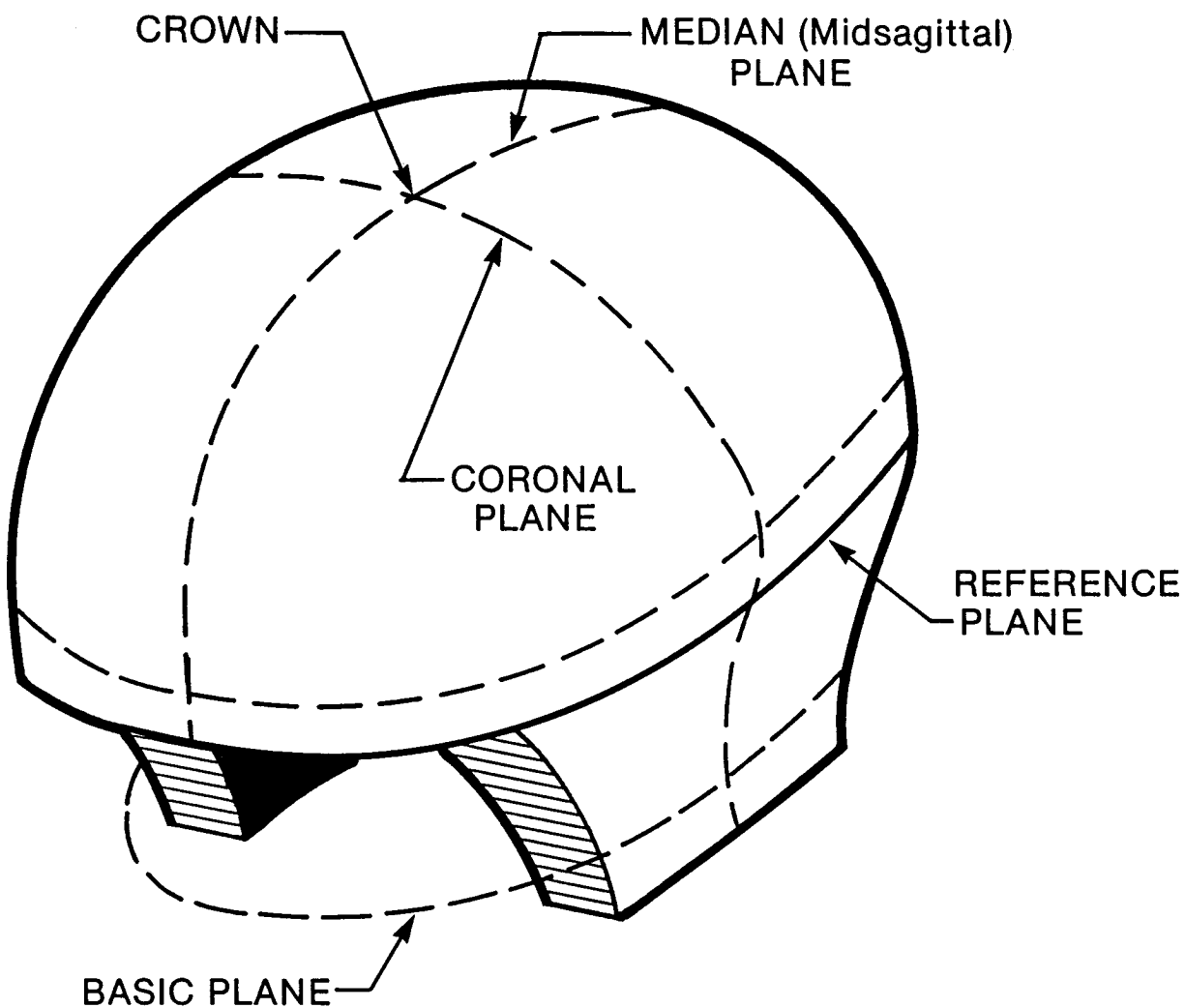
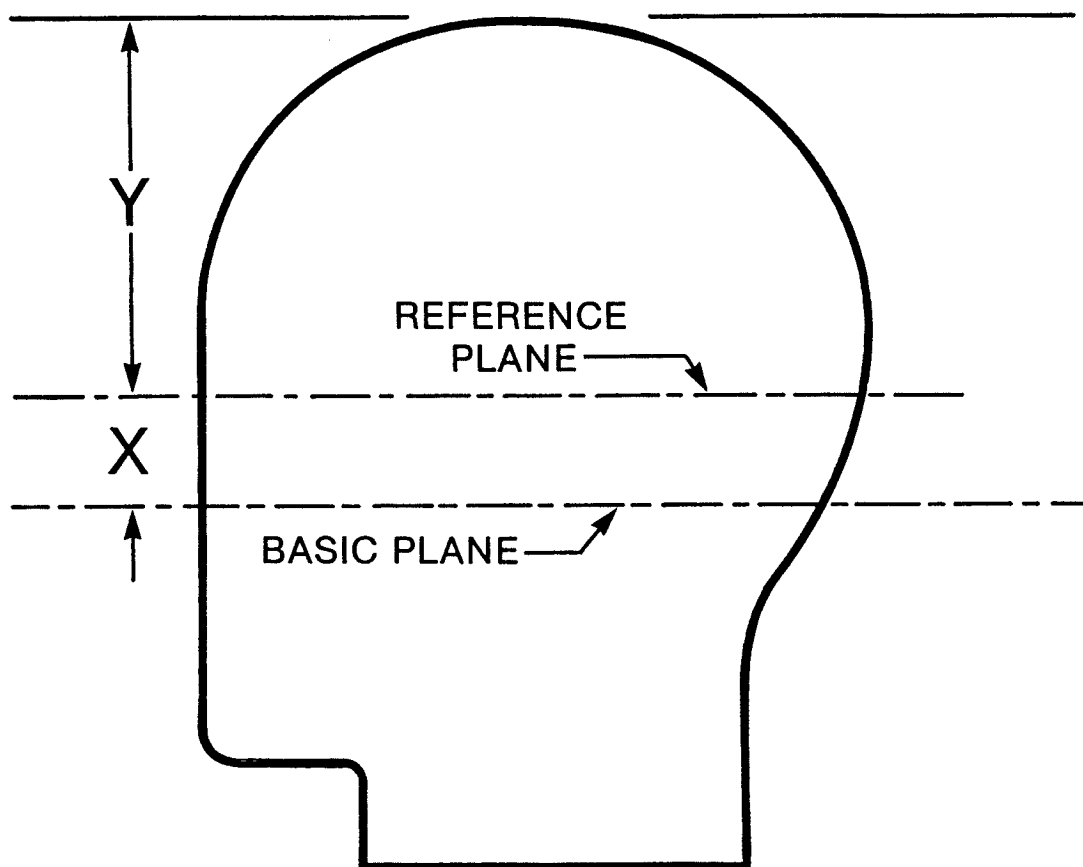


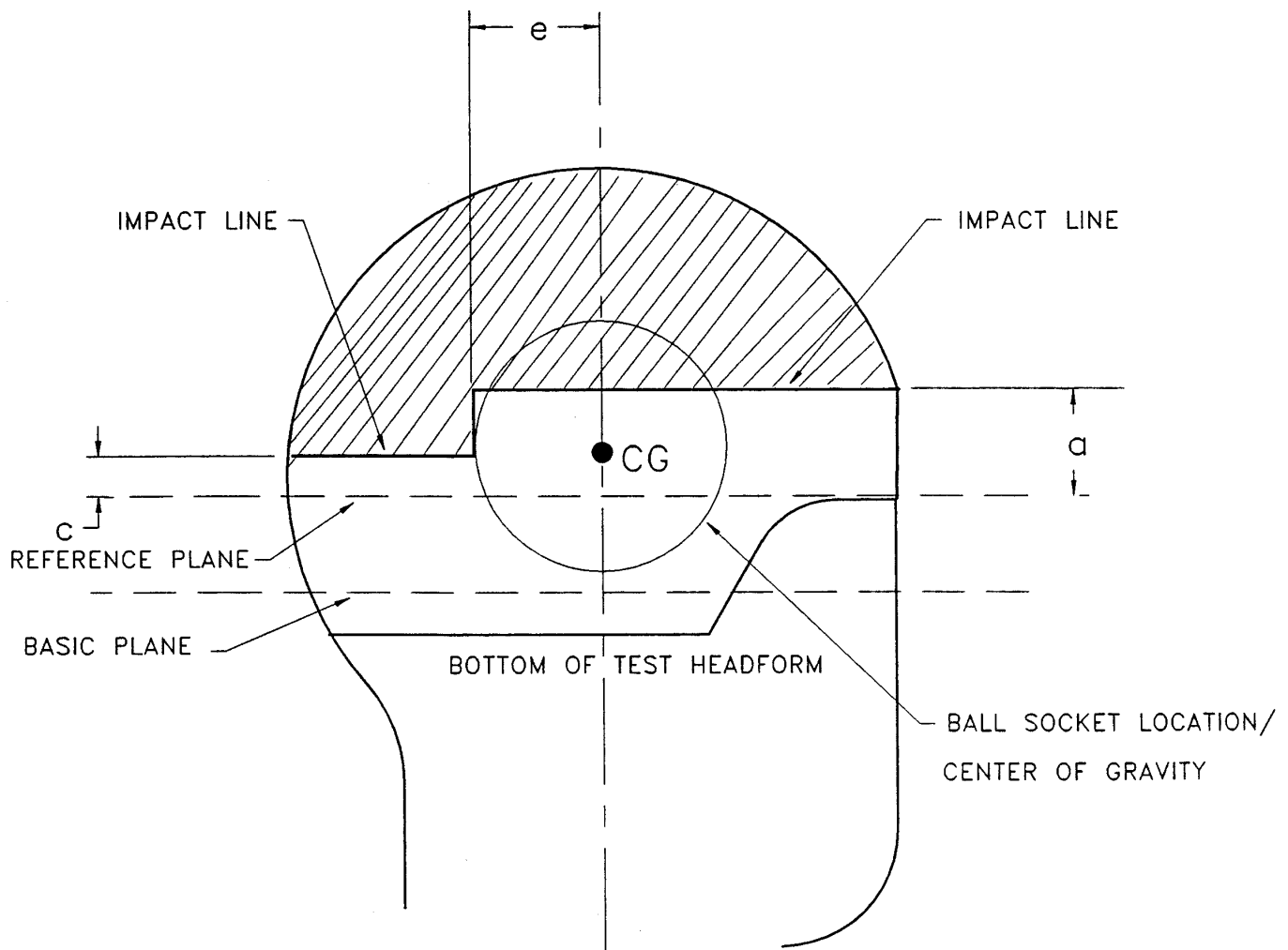
Figure 2. ISO Headform-Basic, Reference, and Median Planes



HEADFORM	SIZE	X	Y
A	500	24	90
E	540	26	96
J	570	27.5	102.5
M	600	29	107
O	620	30	110

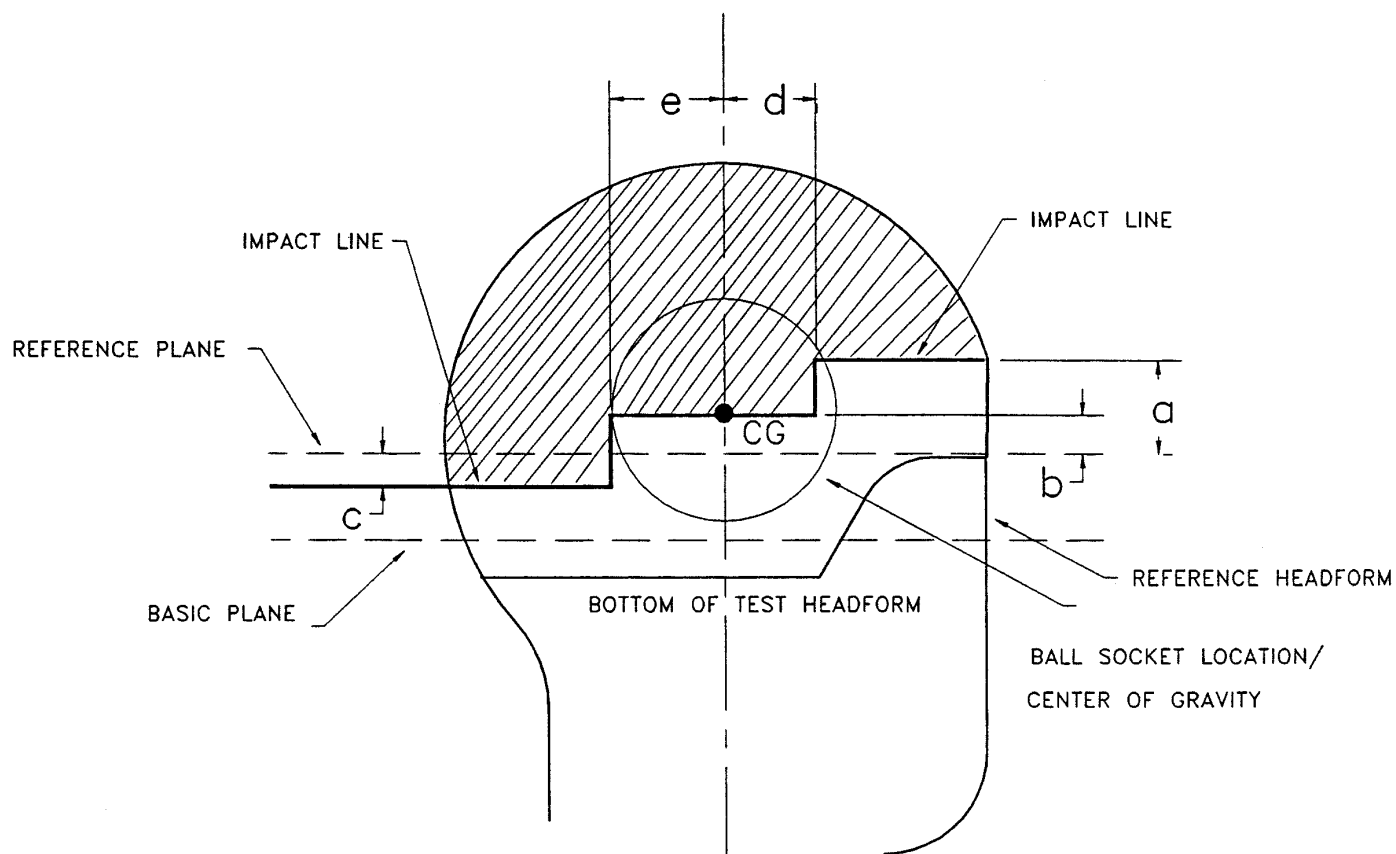
DIMENSIONS IN MILLIMETERS

Figure 3. Location of Reference Plane



HEADFORM	DIMENSIONS mm(in)		
	a	c	e
ISO A	38 (1.49)	27 (1.06)	49 (1.93)
ISO E	39 (1.54)	27 (1.06)	52 (2.05)
ISO J	41 (1.61)	27 (1.06)	54 (2.13)
ISO M	41 (1.61)	27 (1.06)	55 (2.16)
ISO O	42 (1.65)	27 (1.06)	56 (2.20)

Figure 4. Location of Test Lines for Helmets Intended for Persons Five (5) Years of Age and Older.



HEADFORM	DIMENSIONS mm (in)				
	a	b	c	d	e
ISO A	30 (1.18)	12.7 (0.50)	15 (0.59)	25 (0.98)	30 (1.18)
ISO E	32 (1.26)	12.7 (0.50)	16 (0.63)	27 (1.06)	32 (1.26)

Figure 5. Location of Test Lines for Helmets Intended for Persons Ages 1 and Older

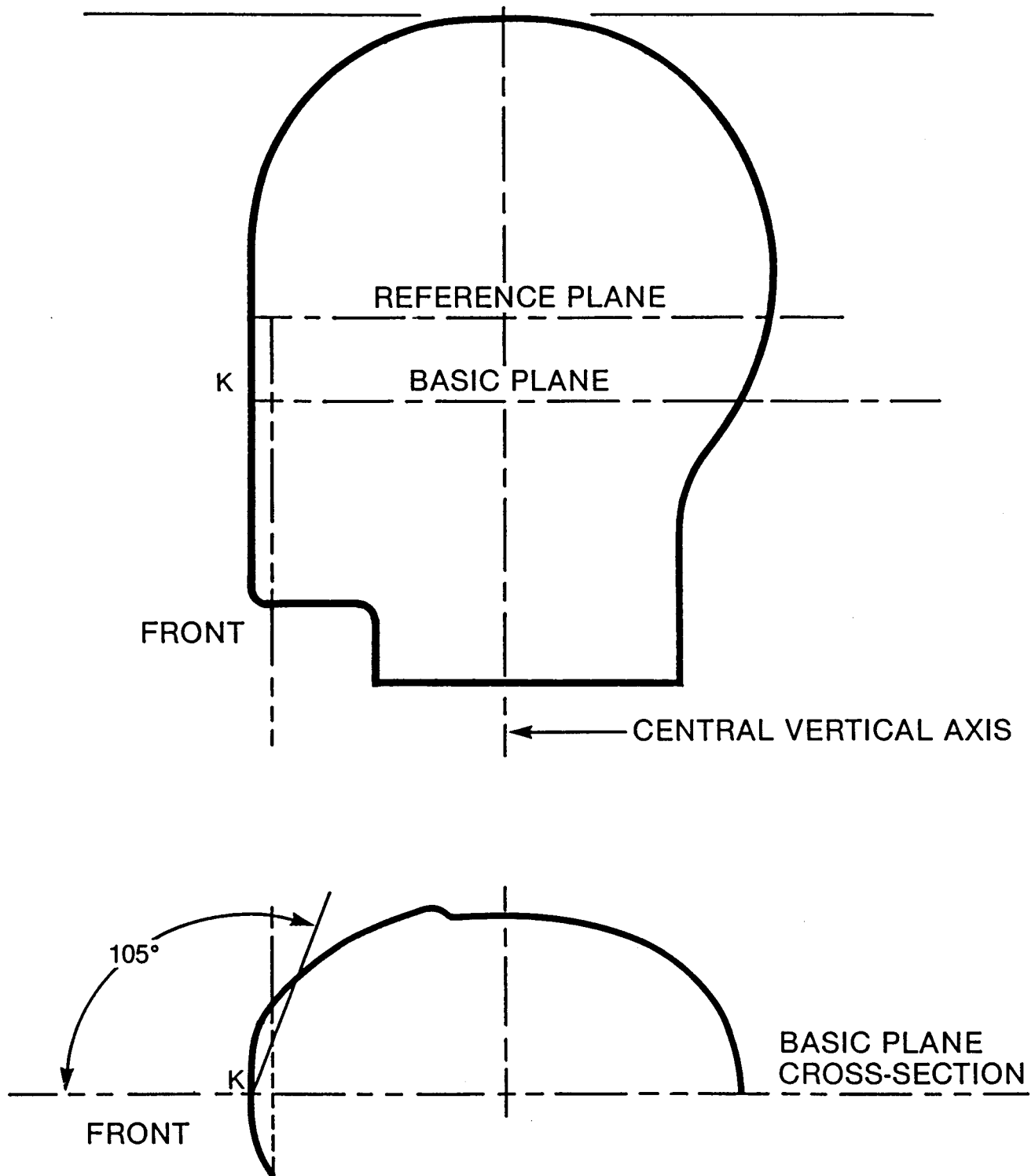


Figure 6. Field of Vision

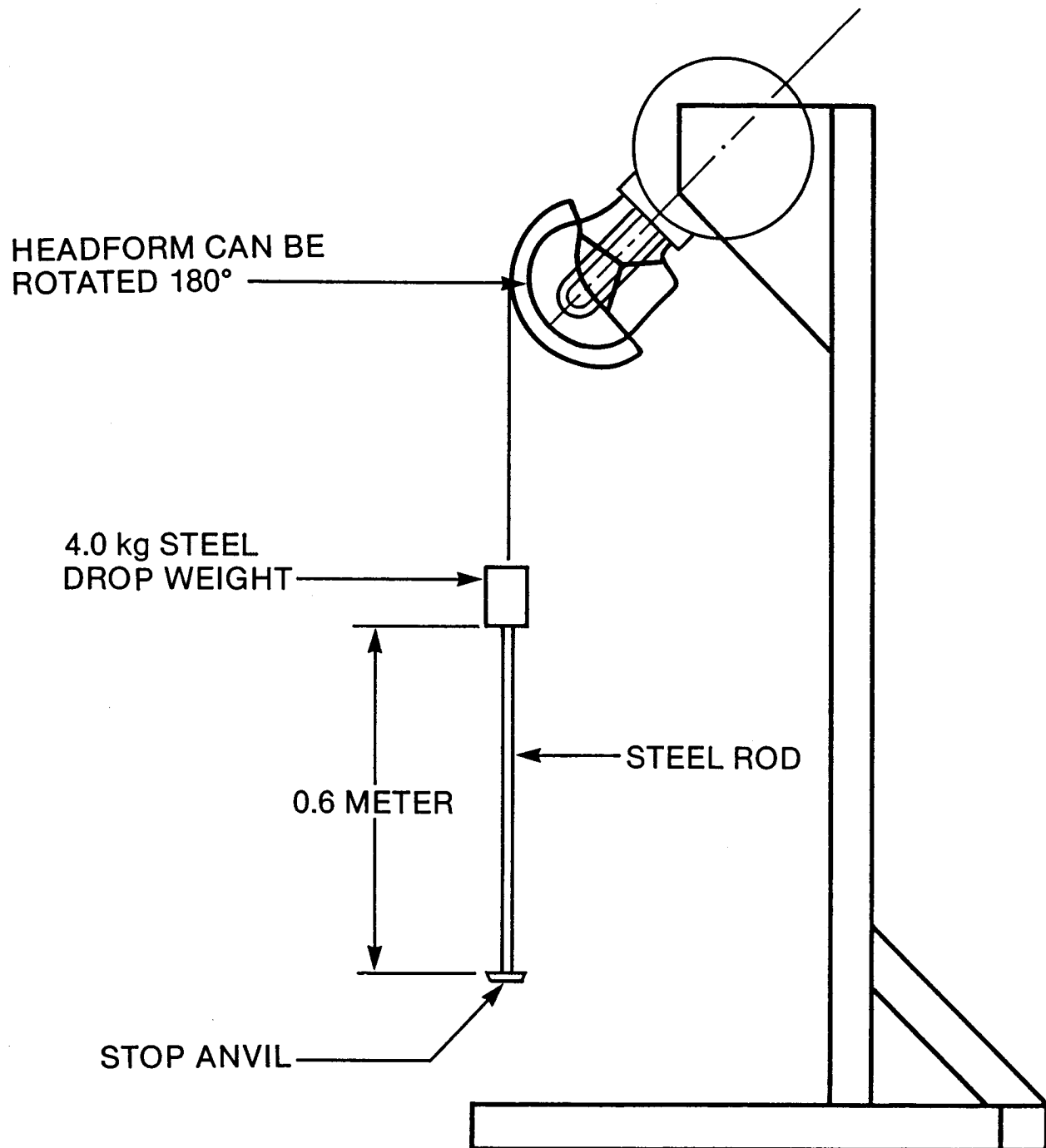


Figure 7. Typical Test Apparatus for Positional Stability Test

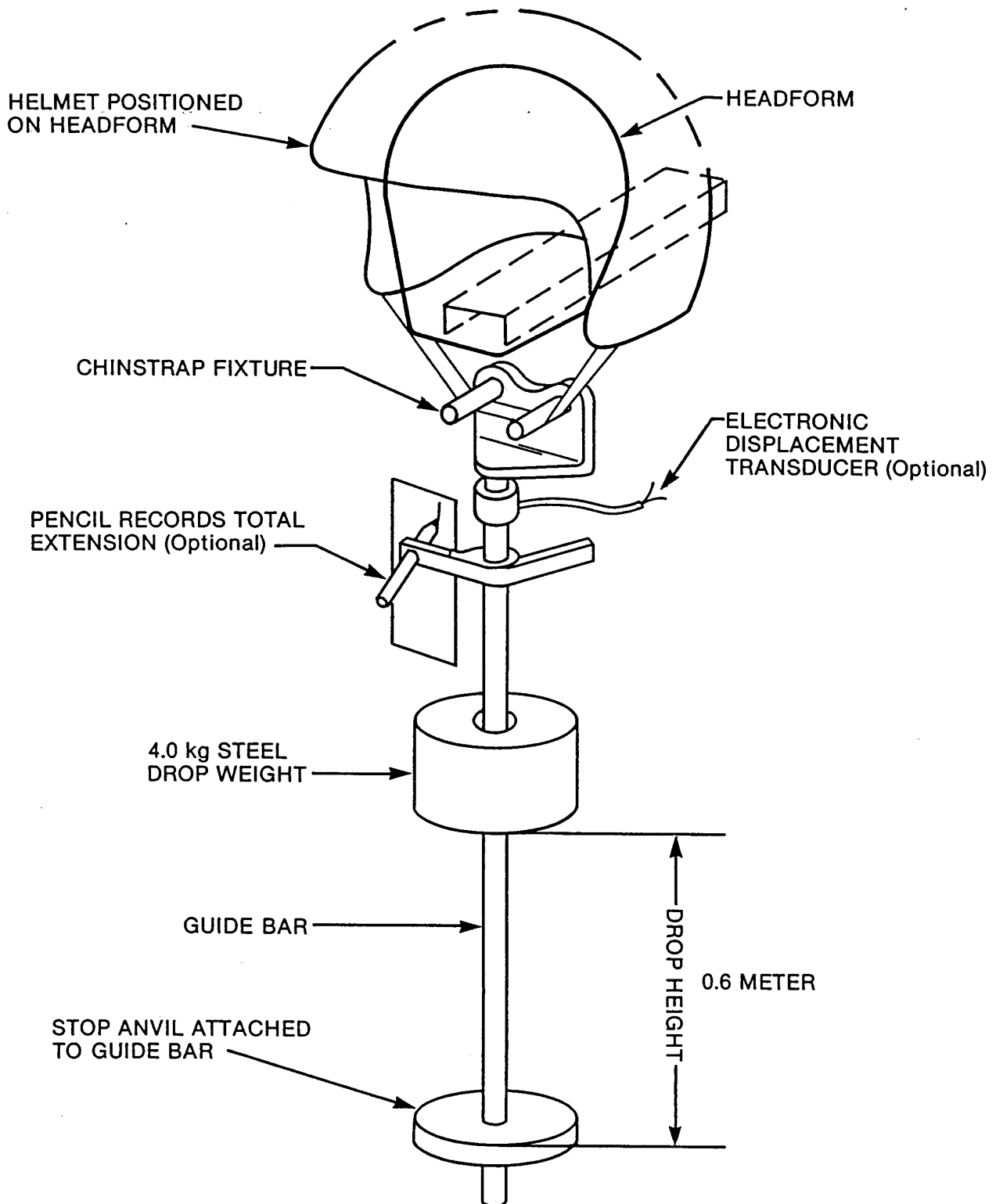


Figure 8. Apparatus for Test of Retention System Strength

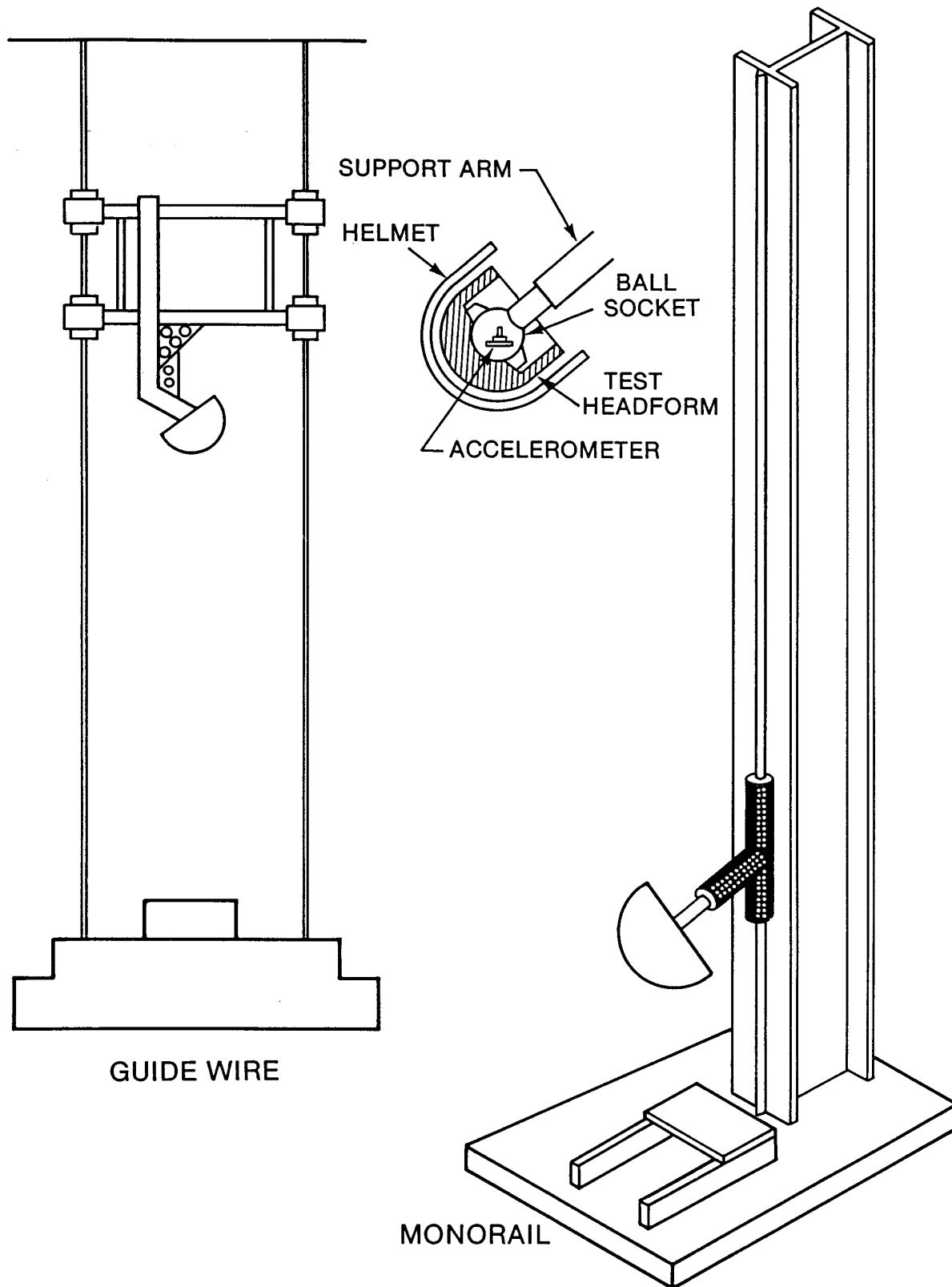


Figure 9. Impact Test Apparatus

Overhead View of Ball-Arm as Installed on Impact Test Apparatus

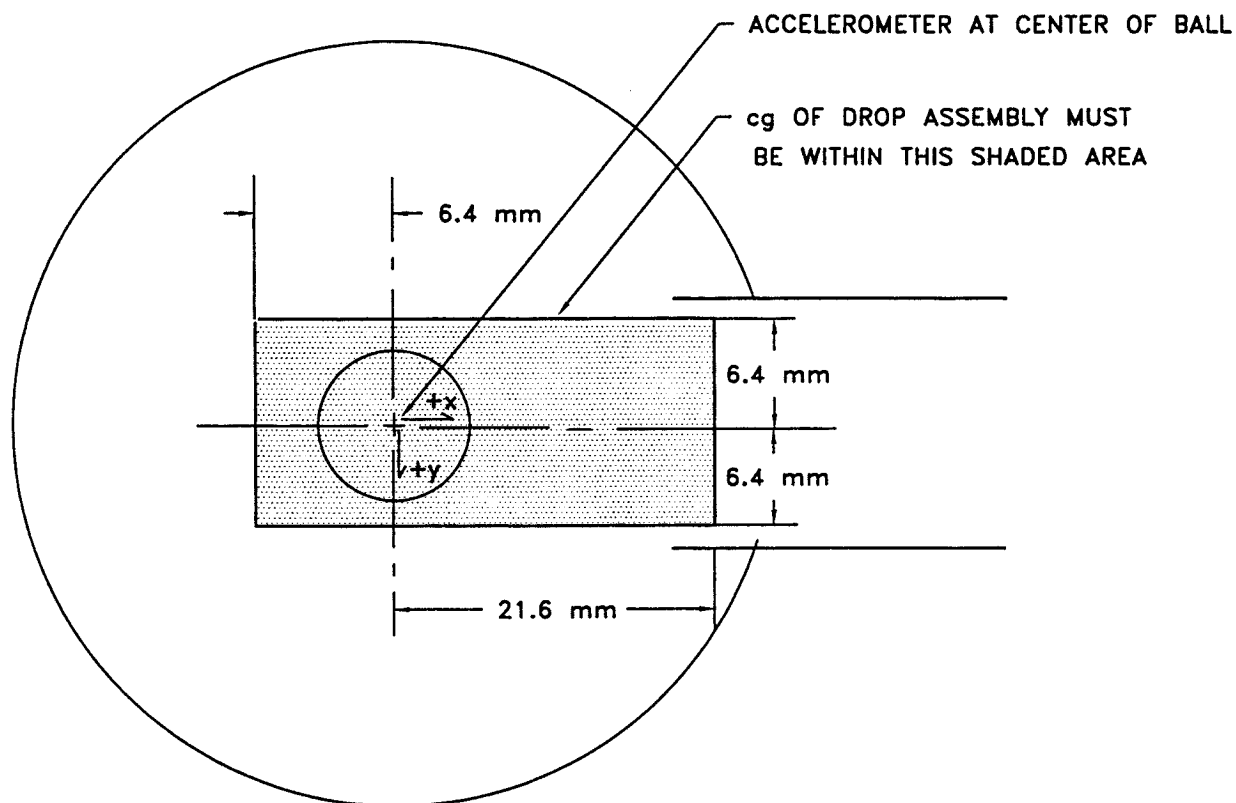


Figure 10. Center of Gravity for Drop Assembly

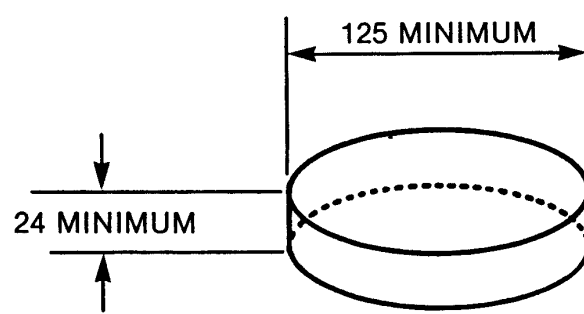


Figure 11. Flat Anvil

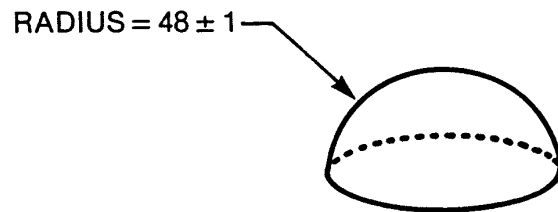


Figure 12. Hemispherical Anvil

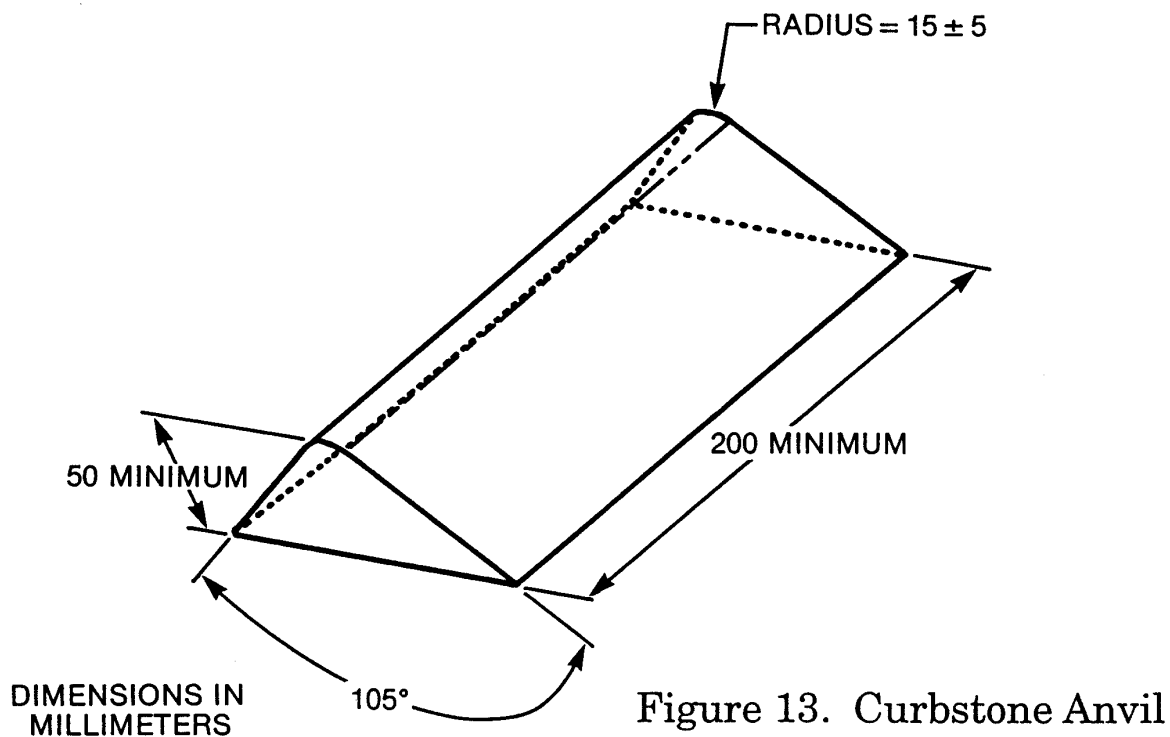


Figure 13. Curbstone Anvil

Dated: February 13, 1998.

Todd A. Stevenson,
*Acting Secretary, Consumer Product Safety
Commission.*

[FR Doc. 98-4214 Filed 3-9-98; 8:45 am]

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