



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
P.O. Box 18070
Pittsburgh, PA 15236

Procedure No. CET-APRS-STP-CBRN-0312

Revision: 1.1

Date: 22 December 2005

DETERMINATION OF FIELD OF VIEW FOR FULL FACEPIECE CHEMICAL,
BIOLOGICAL, RADIOLOGICAL AND NUCLEAR (CBRN) RESPIRATORY PROTECTIVE
DEVICES (RPD) STANDARD TEST PROCEDURE (STP)

1. PURPOSE

- 1.1 This test establishes the procedures for ensuring that the level of protection provided by the peripheral field of view (FOV) for full facepiece chemical, biological, radiological and nuclear (CBRN) respiratory protective devices (RPD) submitted for approval, extension of approval, or examined during certified product audits, meets the minimum certification standards set forth in this standard test procedure (STP) as prescribed by *42 CFR, Part 84, Subpart G, Section 84.63(a)(c)(d)* and *Federal Register*, Volume 60, Number 110, June 8, 1995.

The purpose of this test is to quantify the FOV of a CBRN full facepiece RPD by measuring the functional visual field of full facepiece respirators with either a single visor-type lens or a dual eyepiece lens system. This test method utilizes procedures similar to those defined in EN136: 1998¹ for measuring peripheral FOV, but uses the visual field score (VFS) method described by the American Medical Association (AMA) to measure the functional impact of the full facepiece on the visual field loss. Visual field loss has the most functional impact on visual orientation and an individual's mobility skills.² In order to gauge the functional impact of such losses as a single score, the *AMA Guides to the Evaluation of Permanent Impairment*, 5th edition³ utilizes the VFS to estimate the consequences rather than the causes of visual field loss.

¹ 89/686/EEC. European Directive Design. EN136:1998. Minimal Requirements for Overall Masks.

² The International Council of Ophthalmology. *Visual Standards-Aspects and Ranges of Vision Loss*. Resolution of the 29th International Congress of Ophthalmology; 2002 April 20; Sydney, Australia.

³ *Guides to the Evaluation of Permanent Impairment*, American Medical Association, Chicago. 5th Edition (2002).

Approvals:	<u>1st</u> Level	<u>2nd</u> Level	<u>3rd</u> Level
------------	------------------	------------------	------------------

Multidiscipline emergency responders including firefighters, emergency medical technicians, law enforcement officers, decontamination crews and medical staff will most likely wear the CBRN RPD. It is vital that these emergency responders have an adequate functional field of view while wearing a CBRN full facepiece RPD to fulfill their primary operational duties during a response to a terrorist event. This test method objectively measures the FOV of a CBRN full facepiece RPD to ensure the functional field of view requirement is met as defined in the applicable standard.

2. GENERAL

This STP describes the determination of FOV for full facepiece CBRN RPD test in sufficient detail that a person knowledgeable in the appropriate technical field can conduct the test and determine whether or not the product meets the test requirements.

3. EQUIPMENT AND MATERIALS

3.1 Test Equipment

3.1.1 Apertometer, Manufactured by INSPEC, as Defined in EN 136:1998 or Equivalent. Figure 1 shows a complete apertometer assembly that consists of a head form and a graduated spherical shell or hemisphere. Details for dimensions of the hemisphere and head form and positioning of the head form are available in EN 136:1998.

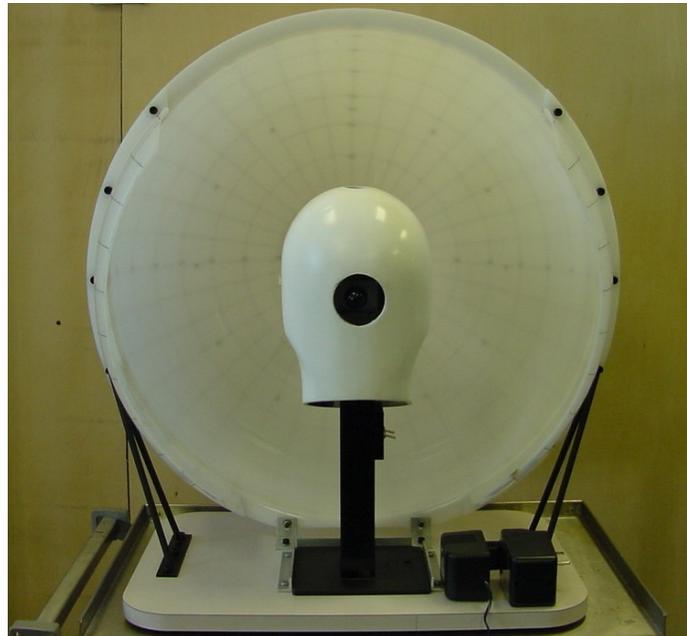


Figure 1. Stoll apertometer test fixture

- 3.1.2 Head Form With Light Bulbs Positioned in Each Eye Socket or Equivalent. Figure 2 shows the head form equipped with electrical light bulbs in the eye sockets with a 67 mm distance between the bulb centers.



Figure 2. Head form front and side views

- 3.1.3 Graduated Spherical Shell or Hemisphere. Figure 3 illustrates the graduated spherical shell or hemisphere with numbered radiuses and meridians on the convex side of the shell.

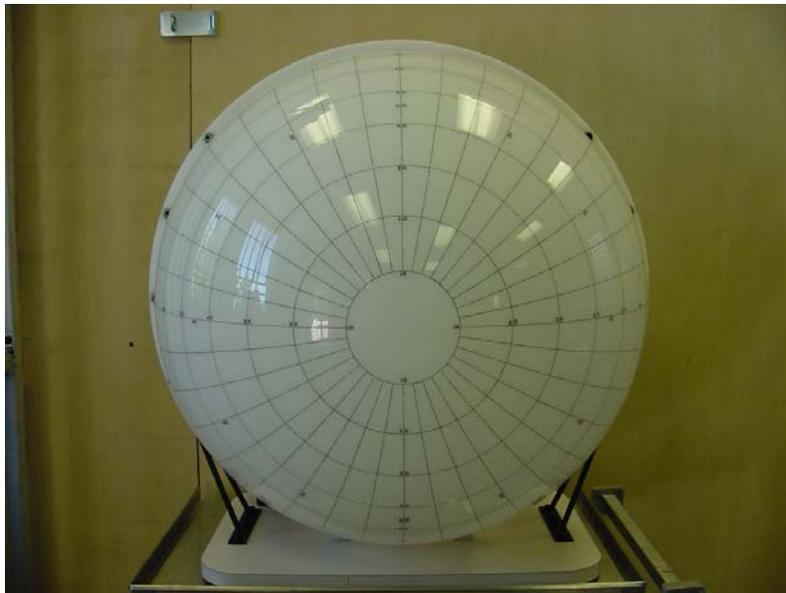


Figure 3. Graduated spherical shell or hemisphere

3.1.4. Field of Vision Plotting Chart. A field of vision chart is needed for plotting the peripheral field of view that is projected into the test assembly. Figure 4 illustrates a plotting chart.

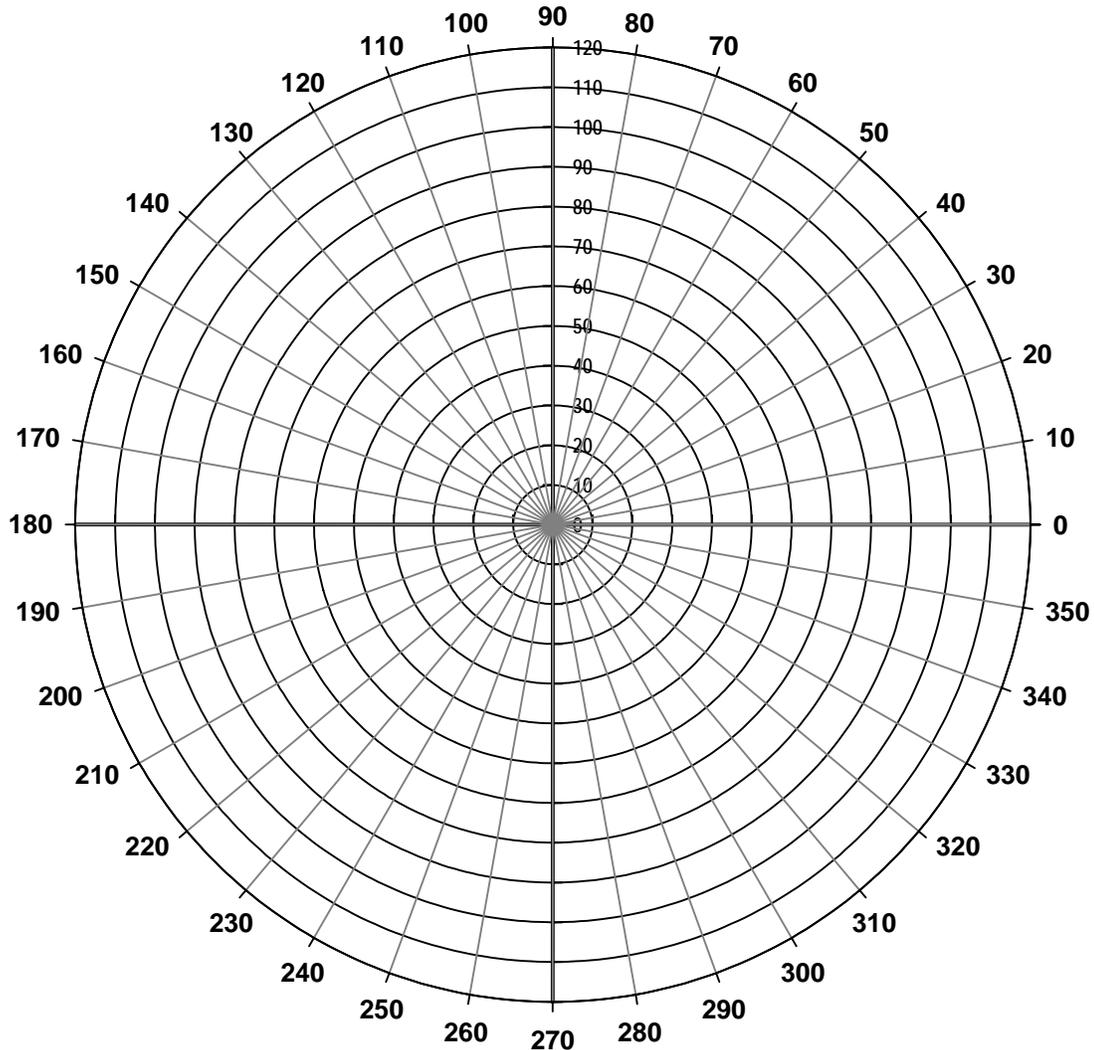


Figure 4. Field of vision plotting chart

3.1.5. Visual Field Score Scoring Grid Overlay. Figure 5 is an illustration of the visual field score scoring grid overlay that is used as an overlay for the field of vision chart illustrated in Figure 4. The grid assigns 110 points to a field within a radius of 70°. Fifty points are assigned to the central area, up to 10° of fixation. The remaining 60 points are assigned to the area beyond 10°. The grid points are located along ten meridians (two in each of the

upper quadrants, three in each of the lower quadrants) at 25°, 65°, 115°, 155°, 195°, 225°, 255°, 285°, 315°, and 345° (Fig.5). On each meridian dots are placed at 1°, 3°, 5°, 7°, 9°, 15°, 25°, 35°, 45°, 55°, and 65°. In order to be used as an overlay, the scoring grid and the field of vision plotting chart of Figure 4 must be made to the same scale.

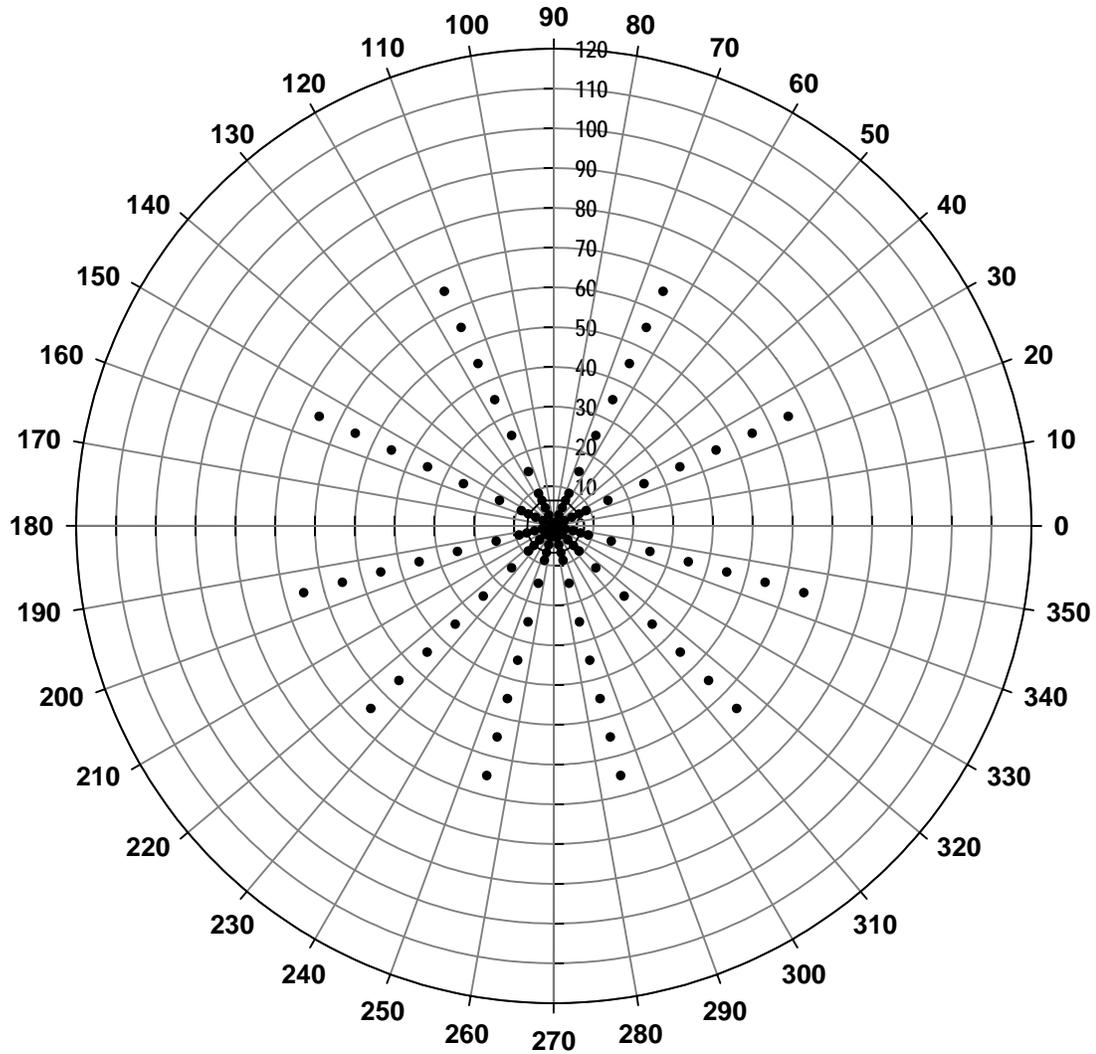


Figure 5. Visual Field Score Scoring Grid Overlay

3.1.6. Talcum Powder.

3.2. Human Subjects

No human subjects will be used in the FOV test described in this STP.

3.3. Required CBRN RPD Test Items

All facepiece sizes of the CBRN RPD application shall be used in the FOV test; however, only the facepiece that anatomically fits the head form the best will be

tested. Only the associated canister or filter model received with the application will be used in the FOV test; in other words, the larger 5" diameter canister used for other interoperability tests will not be used in this test.

4. TESTING REQUIREMENTS AND CONDITIONS

- 4.1. Any laboratory using this procedure to supply certification test data to NIOSH will be subject to the provisions of the NIOSH Supplier Qualifications Program (SQP). This program is based on the tenets of ISO/IEC 17025, the NIOSH Manual of Analytical Methods and other NIOSH guidelines. An initial complete quality system audit and follow on audits are requirements of the Program. Additional details of the Program and its requirements can be obtained directly from the Institute.
- 4.2. Precision and accuracy (P&A) must be determined for each instrument in accordance with laboratory procedures and NIOSH/NPPTL guidance. Sound practice requires, under NIOSH Manual of Analytical Methods, demonstrating a tolerance range of expected data performance of a plus or minus 25% of a 95% confidence interval of the stated standard requirement. NIOSH/NPPTL P&A tolerance can be higher but not lower.
- 4.3. Prior to beginning any testing, all measuring equipment to be used must have been calibrated in accordance with the manufacturer's calibration procedure and schedule. At a minimum, all measuring equipment utilized for this testing must have been calibrated within the preceding 12 months using a method traceable to the National Institute of Standards and Technology (NIST).
- 4.4. Normal laboratory safety practices must be observed. This includes safety precautions described in the current *Centers for Disease Control and Prevention (CDC) General Laboratory Health and Safety Manual* or site-specific procedures that are applicable to the health and safety requirements.
 - 4.4.1. Work benches must be maintained free of clutter and non-essential test equipment.

5. PROCEDURE

Note: Reference Section 3. for equipment, model numbers and manufacturers. For calibration purposes, use those described in the manufacturer's operation and maintenance manuals.

- 5.1. This procedure describes the FOV test for ensuring that the level of protection provided by full facepiece CBRN RPD meets or exceeds the requirements outlined in the *Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Full Facepiece Air-Purifying Respirator (APR)*, 7 March 2003.

Other types of CBRN RPD may be tested for FOV using this procedure: Refer to the primary statement of standard for the CBRN RPD being tested for the FOV performance requirements. This procedure describes the required sample size, test equipment, test procedure, data collection methods and the pass or fail criteria for the type of CBRN RPD being tested.

5.2. Test Items

5.2.1. Test Items.

Indicate on the test data sheet the following general pretest information about the CBRN RPD on the test record documentation:

- NIOSH application number (TN):
- Name of manufacturer:
- Model number of CBRN RPD:
- Model number of canister (if applicable):
- Date arrived:
- Date tested:
- General condition of packaging:
- Appearance of CBRN RPD and canisters (if applicable):
- Any specific physical anomalies:
- Type of test being conducted:

5.2.2. Number Test Items.

All test items shall be individually numbered with a tag in a sequence that the number can be correlated to the NIOSH application number, manufacturer, and model number so it can be tracked throughout the series of tests. For example, the number sequence can be S1, M1, and L1. The S1 meaning a small CBRN RPD# 1, M1 meaning a medium CBRN RPD#1 and L1 meaning a large CBRN RPD#1.

5.3. Mount Respirator on Head Form

From all the full facepiece sizes associated with the NIOSH CBRN RPD application, select the full facepiece that anatomically best fits the head form of the Apertometer by mounting the CBRN RPD on the head form in accordance with the manufacture's donning instructions. Apply talcum powder to the facepiece being tested as required to allow easy sliding of the facepiece when adjusting. If the CRBN RPD has a chin-cup on the facepiece, first place the head form chin in the "cup" of the facepiece and seal facepiece against the face of the head form. The headharness straps shall be passed over the head form and adjusted to maximize the field of view. The facepiece shall be symmetrically mounted on the head form. Perform this procedure with all the full facepieces in order to determine which size full facepiece fits best on the test head form.

5.3.1. Once the correct size RPD is determined, mount the full facepiece onto the head form as described in the above paragraph 5.3.1. and in accordance with manufacture's donning instructions.

5.4. Obtain Performance Data

5.4.1. Illuminate both lights located in the eye-sockets of the head form by plugging the cord's plug into a 110 volt electrical outlet.

5.4.2. The light from the head form will be projected through the RPD lens system onto the apertometer hemisphere. Using the field of vision plotting chart (see Fig. 4), transfer the outline of the light projected onto the hemisphere's surface by marking the point at which the light changes to a shadow along each of the 36 meridians within the hemisphere. An alternate method is to transfer the outline of the light projected onto the hemisphere's surface directly to the visual field score scoring grid overlay (see Fig. 5): For alternate method, use visual field score scoring grid overlay on page 3 of 3 of the data sheet in Appendix A.

5.4.3. Once the points have been plotted along each meridian, connect the points from one meridian to the next in numerical order. The solid line connecting the points represents the peripheral isopter for the CBRN RPD.

5.4.4. Repeat the procedures identified in Sections 5.3.2. through 5.4.3. to obtain the VFS for the other two facepiece fittings. The final VFS will be the average of three fittings of the same respirator on the head form.

5.5. Data Analysis

5.5.1. Properly align the visual field score scoring grid overlay (see Fig. 5) over the plotted field of view grid that was transferred onto the field of vision plotting chart from Section 5.4.2. **NOTE:** In order for the visual field

score scoring grid overlay (see Fig. 5) to be used as an overlay, it and the field of vision plotting chart (see Fig. 4) must be made to the same scale.

NOTE: If the alternate method described in Section 5.4.2. was used, then the solid line drawn that connects the points representing the peripheral isopter already exists encompassing the grid points.

5.5.2. Count the VFS grid points that fall on or inside of the peripheral isopter for the CBRN RPD. For example, the points that are contained internal to the line of Figure 6 are the VFS grid points that shall be counted. All points that are outside of the peripheral isopter shall be ignored.

5.5.3. Record remarks concerning unit operation and adequacy of the RPD fit to the test head form on field of view for full facepiece CBRN RDP Test Data Sheet 1 of 2 in Appendix A.

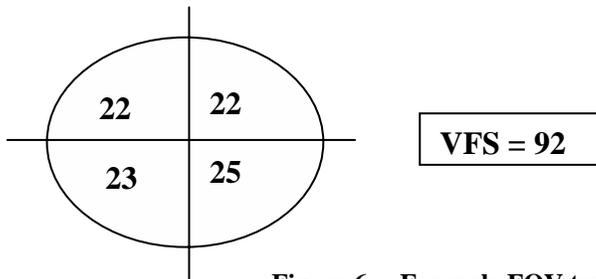
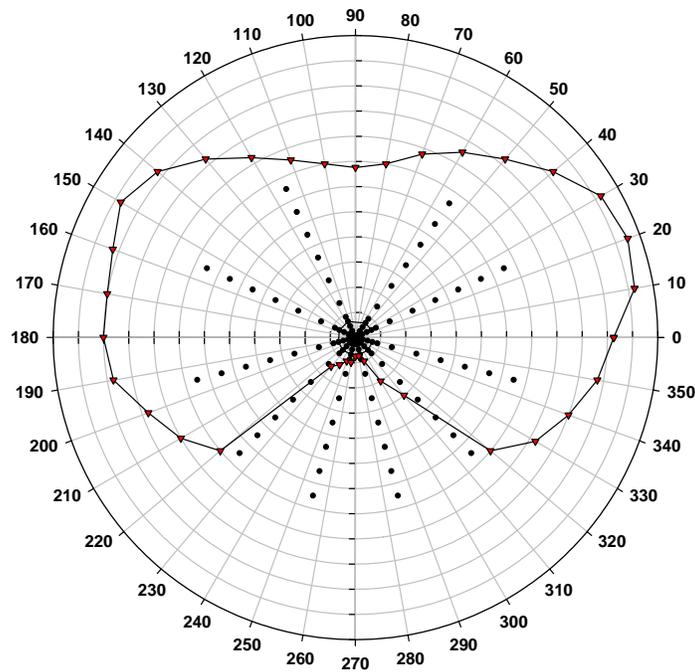


Figure 6. Example FOV test results analysis

6. PASS OR FAIL CRITERIA

6.1 The criterion for passing this test is set forth in *42 CFR, Part 84, Subpart G, Section 84.63(a)(c)(d)*.

6.2 This test establishes the standard procedure for ensuring that:

84.63 Test requirements; general.

(a) Each respirator and respirator component shall when tested by the applicant and by the Institute, meet the applicable requirements set forth in subparts H through L of this part.

(b) In addition to the minimum requirements set forth in subparts H through L of this part, the Institute reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

6.3 Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

6.4 A candidate CBRN APR in accordance with the *Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) Full Facepiece Air Purifying Respirators (APR), March 7, 2003* must obtain an average visual field score of greater than or equal to 90 to meet the field of view requirement. A candidate CBRN (air-purifying or self contained) escape respirator in accordance with the *Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) (Air Purifying/Self Contained) Escape Respirators, August, 2003* must obtain an average visual field score of greater than or equal to 70 to meet the field of view requirement. Other types of CBRN RPD may be tested for FOV using this procedure: Refer to the primary statement of standard for that particular CBRN RPD being tested for the FOV performance requirements.

7. RECORDS AND TEST DATA SHEETS

7.1. All test data shall be recorded on the Field Of View for Full Facepiece Chemical Biological Radiological Nuclear (CBRN) Respiratory Protective Devices (RPD) Data Sheet located in Appendix A.

- 7.2. All videotapes and photographs of the actual test being performed, or of the tested equipment shall be maintained in the task file as part of the permanent record.
- 7.3. All equipment failing any portion of this test shall be handled as follows:
 - 7.3.1. If the failure occurs on a new certification application, or extension of approval application, send a test report to the Certification, Evaluation and Testing (CET) Team Leader and prepare the hardware for return to the manufacture.
 - 7.3.2. If the failure occurs on hardware examined under an off-the shelf audit, the hardware will be examined by the test operator and the CET Section Leader for cause. All equipment failing any portion of this test may be sent to the manufacturer for examination and then returned to NIOSH. However, the hardware tested shall be held at the testing laboratory until authorized for release by the CET Team Leader, or his designee, following the standard operating procedures outlined in the *Procedure for Scheduling, and Processing Post-Certification Product Audits, RB-SOP-0005-00*.

APPENDIX A

**Field of View for Full Facepiece CBRN
Respiratory Protective Devices (RPD) Data Sheets**

(Test Data Sheet 1 of 3)

NIOSH Application Number: _____

Type RPD being Tested: _____

Name of Manufacturer: _____

Model Number of CBRN RPD: _____

Model Number of Canister (If Applicable): _____

Date Arrived: _____

Date Tested: _____

General Condition of Packaging: _____

Appearance of CBRN RPS and Canisters: _____

Any Specific Physical Anomalies: _____

Remarks concerning unit operation and adequacy of the RPD fit to the test head form

APPENDIX A

**Field of View for Full Facepiece CBRN
Respiratory Protective Devices (RPD) Data Sheets**

(Test Data Sheet 2 of 3)

NIOSH Application Number: _____

Date: _____

Manufacturer of the RPD: _____

Respirator Type (APR, Escape Mask PAPR, Etc): _____

Requirement: A full facepiece CBRN gas mask must obtain an average visual field score (VFS) of greater than or equal to 90 to meet the field of view requirement.

A CBRN escape respirator must obtain an average visual field score (VFS) of greater than or equal to 70 to meet the field of view requirement.

Results:

Meridian (°)	Number of Points within Peripheral Isopter		
	Fitting 1	Fitting 2	Fitting 3
25			
65			
115			
155			
195			
225			
255			
285			
315			
345			
Total VFS Grid Score			

Average VFS =
$$\frac{\text{VFS Grid Score}_{\text{Fitting 1}} + \text{VFS Grid Score}_{\text{Fitting 2}} + \text{VFS Grid Score}_{\text{Fittings 3}}}{3}$$

Average VFS = _____

Comments: _____

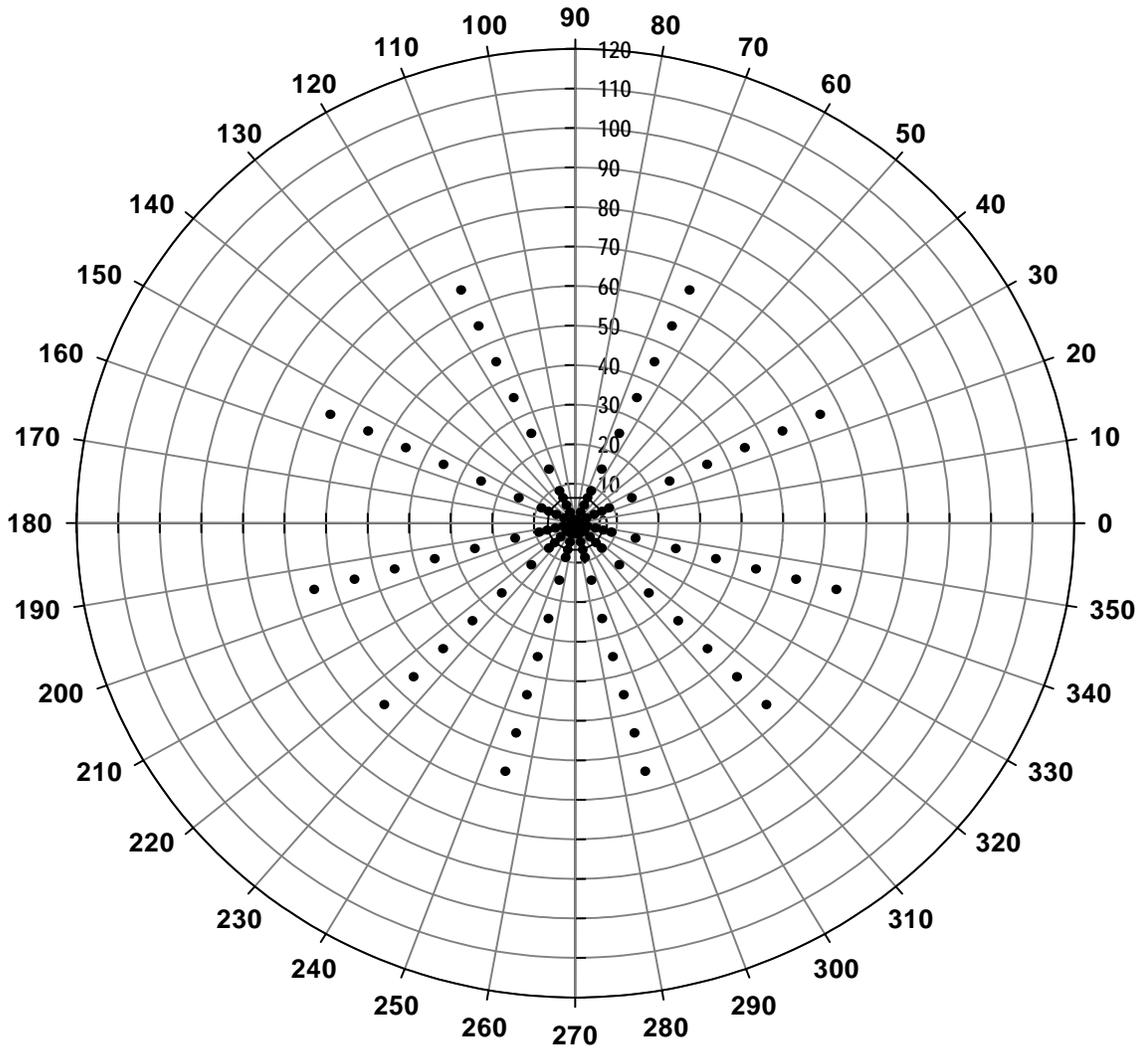
Test administrator signature: _____ Date: _____ Pass ___ Fail ___

Laboratory supervisor signature: _____ Date: _____

APPENDIX A

**Field of View for Full Facepiece CBRN
Respiratory Protective Devices (RPD) Data Sheets
Visual Field Score Scoring Grid Overlay**

(Test Data Sheet 3 of 3)



NIOSH Application Number _____; RPD Being Tested _____

Name of Manufacturer _____; Date of Testing _____

Fitting: _____ of 3; Model Number of CBRN RPD _____

Revision History

Revision	Date	Reason for Revision
00	16 September 2004	Historic document
1.1	22 December 2005	Update header and format No changes to method