NIOSH
Conformity Assessment Interpretation Notice

NIOSH CA 2021-1039
November 2021

NIOSH Respirator Approval Program's use of the NIOSH Bivariate Panel during Laboratory Respirator Protection Level Testing of Chemical, Biological, Radiological, and Nuclear (CBRN) Self-Contained Breathing Apparatus, CBRN Air-Purifying Respirators, and CBRN Powered Air-Purifying Respirators beginning November 15, 2021

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

NIOSH Respirator Approval Program's use of the NIOSH Bivariate Panel during Laboratory Respirator Protection Level Testing of Chemical, Biological, Radiological, and Nuclear (CBRN) Self-Contained Breathing Apparatus, CBRN Air-Purifying Respirators, and CBRN Powered Air-Purifying Respirators beginning November 15, 2021

1 SUMMARY

In 2019, NIOSH began phasing out the use of the Los Alamos National Laboratory (LANL) Panels with the publication of NIOSH CA 2019-1011, NIOSH Respirator Approval Program's Use of the NIOSH Bivariate Panel during Isoamyl Acetate Fit Testing, and NIOSH has further updated the following Standard Testing Procedures (STPs) to include use of the NIOSH Bivariate Panel (NIOSH Panel):

- TEB-CBRN-APR-STP-0352: Determination of Laboratory Respirator Protection Level (LRPL) Values for CBRN Self-Contained Breathing Apparatus (SCBA) Facepieces or CBRN Air-Purifying Respirator (APR).
- TEB-CBRN-APR-STP-0552: Determination of Laboratory Respirator Protection Level (LRPL) Values for CBRN Tight-Fitting Powered Air-Purifying Respirator (PAPR).
- TEB-CBRN-APR-STP-0553: Determination of Laboratory Respiratory Protection Level (LRPL) Values for CBRN Loose-Fitting Powered Air-Purifying Respirator (PAPR).

NIOSH informed approval holders regarding implementation of the NIOSH Panel during a Manufacturers Meeting on October 17, 2018. The implementation was delayed due to program workload, the NFPA 1981:2018 update, and the COVID-19 Response.

Implementation of the NIOSH Panel for CBRN air-purifying escape respirators (APERs) will be forthcoming.

The NIOSH Panel's anthropometric limits and individual panel cells (1-10) are shown in Figure 1. The population cell distribution of the NIOSH Panel is given in Table 1, based on a 25-member panel. The updated STPs document how the NIOSH Panel will be implemented for use with 25- , 29- , or 38-member panels based on the number of facepiece sizes. This information is included in Tables 2, 3, and 4, respectively. If an approval holder or applicant submits a respirator design to fit a sub-population of users, the approval holder or applicant shall provide NIOSH with information on the expected size distribution based on the NIOSH Panel (e.g., panel cell numbers, face dimensions). This information will be considered during initial engineering review for assigning and conducting the NIOSH LRPL testing.

Beginning November 15, 2021, NIOSH will implement use of the NIOSH Panel during evaluations of all new approvals of CBRN SCBAs, CBRN APRs, and CBRN PAPRs (tight- and loose-fitting). These types of approval projects, accepted in the NIOSH data management system on or after November 15, 2021, will be evaluated using the NIOSH Panel and the relevant, updated STP. A new approval may include a respirator facepiece configuration previously approved as part of a complete and different respirator approval configuration and will be tested using the NIOSH Panel. Applicants may continue to use the LANL panels to generate pre-submission test data; however, NIOSH recommends using the procedure outlined in the updated STP.

Respirators previously approved following testing with LANL Panels continue to be NIOSH-approved respirators. When these approvals are submitted for an extension of approval and the application requires human subject testing, the respirator will be evaluated using the NIOSH Panel.

Certified product audit testing including the use of the anthropometric panels will allow for the use of the panel used during the original testing for the approval until June 30, 2022. For example, if the full-facepiece LANL panel was used during the original testing, the full-facepiece LANL panel will be used for certified product audit testing until June 30, 2022.

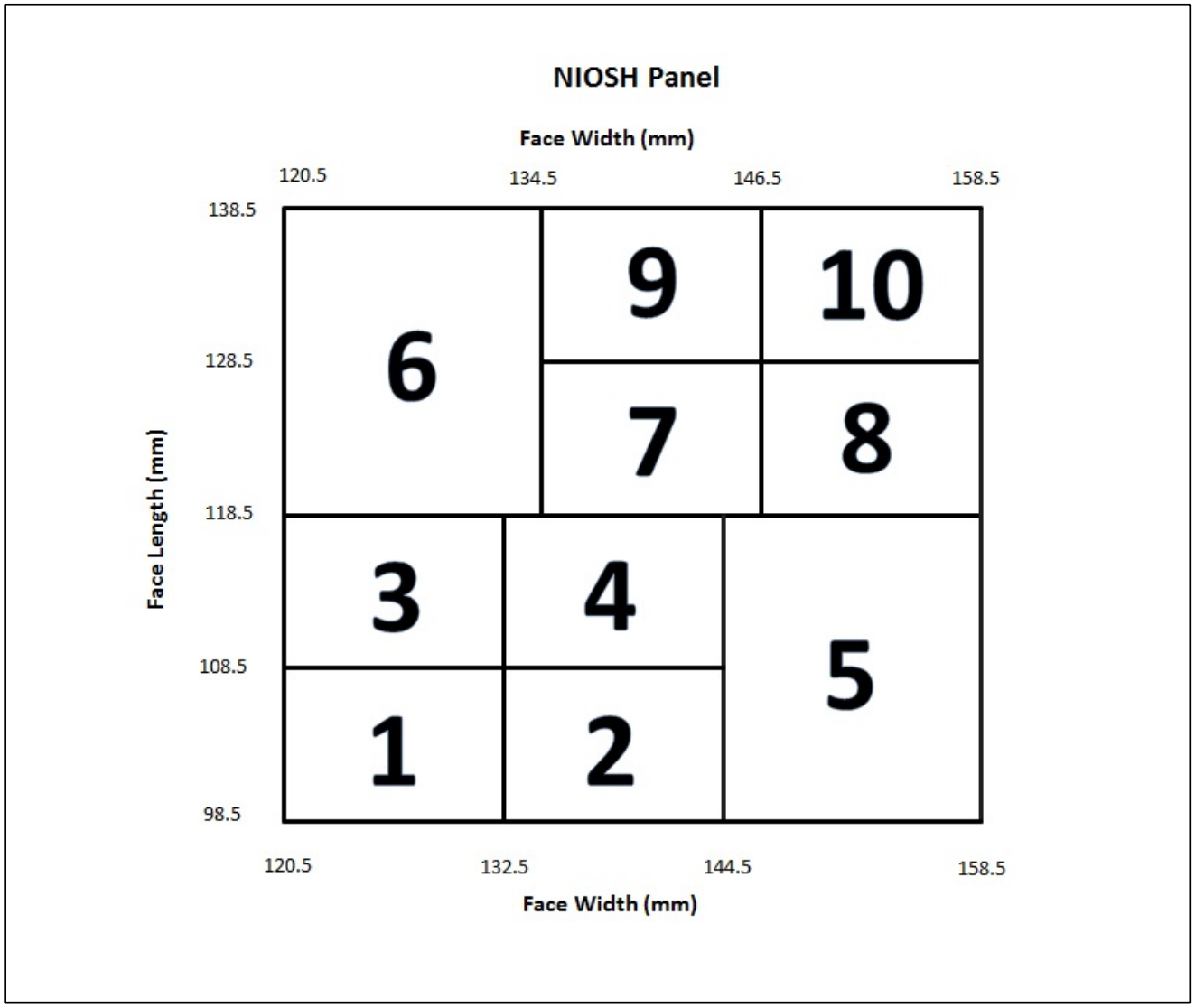

Figure 1. The NIOSH Bivariate Panel (NIOSH Panel) includes ten individual member cells defined by face width and face length (mm).

Table 1: NIOSH Panel cell designations, population distribution, and number of test subjects per cell, based on a 25-member panel [Zhuang 2007].

NIOSH Panel – cell number	Population distribution (%)	Number of test subjects based on the population distribution
1	5.5	2
2	5.3	2
3	10.5	2
4	25.0	5
5	7.1	2
6	5.7	2
7	21.3	4
8	8.7	2
9	5.2	2
10	3.5	2
Total number of subjects		25

Table 2. CBRN APR, SCBA, or PAPR 25-member panel for LRPL testing of a respirator designed and manufactured in one unique size.

25-Member Panel		
NIOSH Panel – cell number	**Number of test subjects**	
1	2 subjects	An additional **six subjects** will be selected from cells **2, 3, 4, 7, 8** with the intent to consider the 25-member population distribution (as given in the Table 1, above). No more than four subjects are permitted from any one panel cell.
2	2 subjects	
3	2 subjects	
4	2 subjects	
5	2 subjects	
6	2 subjects	
7	2 subjects	
8	2 subjects	
9	2 subjects	
10	1 subject	

Table 3. CBRN APR, SCBA, or PAPR 29-member panel for LRPL testing of a respirator designed and manufactured in two unique sizes.

<table>
<tr><th colspan="3">29-Member Panel</th></tr>
<tr><th>NIOSH Panel – cell number</th><th colspan="2">Number of test subjects</th></tr>
<tr><td>1</td><td rowspan="6">14-15 subjects from cells 1-6 (at least one from each cell and no more than four from any one cell for a total of 14-15 subjects)
Smaller size</td><td rowspan="2"></td></tr>
<tr><td>2</td></tr>
<tr><td>3</td></tr>
<tr><td>4</td></tr>
<tr><td>5</td><td rowspan="5">14-15 subjects from cells 5-10 (at least one from each cell and no more than four from any one cell for a total of 14-15 subjects)
Larger size</td></tr>
<tr><td>6</td></tr>
<tr><td>7</td><td rowspan="4"></td></tr>
<tr><td>8</td></tr>
<tr><td>9</td></tr>
<tr><td>10</td></tr>
</table>

Table 4. CBRN APR, SCBA, or PAPR 38-member panel for LRPL testing of a respirator designed and manufactured in three unique sizes. The STPs include information for testing respirator designs that are designed and manufactured in more than three unique sizes.

<table>
<tr><th colspan="4">38-Member Panel</th></tr>
<tr><th>NIOSH Panel – cell number</th><th colspan="3">Number of test subjects</th></tr>
<tr><td>1</td><td rowspan="4">10 subjects from cells 1-4 (at least one from each cell and no more than four from any one cell for a total of 10 subjects)

Smaller Size</td><td></td><td rowspan="4"></td></tr>
<tr><td>2</td><td rowspan="5">17 subjects from cells 3-8 (at least one from each cell and no more than four from any one cell for a total of 17 subjects)

Medium Size</td></tr>
<tr><td>3</td></tr>
<tr><td>4</td></tr>
<tr><td>5</td><td rowspan="6"></td></tr>
<tr><td>6</td><td rowspan="5">11 subjects from cells 7-10 (at least one from each cell and no more than four from any one cell for a total of 11 subjects)

Larger Size</td></tr>
<tr><td>7</td><td rowspan="4"></td></tr>
<tr><td>8</td></tr>
<tr><td>9</td></tr>
<tr><td>10</td></tr>
</table>

2 AUTHORITY

42 C.F.R. Part 84, Approval of Respiratory Protective Devices

Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) Full Facepiece Air Purifying Respirator (APR) (cdc.gov)

Statement of Standard for Self-Contained Breathing Apparatus (SCBA) with Chemical, Biological, Radiological, and Nuclear (CBRN) Protection (cdc.gov)

Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) Powered Air-Purifying Respirators (PAPR) (cdc.gov)

NIOSH Standard Testing Procedures

- Revised TEB-CBRN-APR-STP-0352 (Revision 2.0, Dated 28 September 2021)
- Revised TEB-CBRN-APR-STP-0552 (Revision 2.0, Dated 20 October 2021)
- Revised TEB-CBRN-APR-STP-0553 (Revision 2.0, Dated 20 October 2021)

3 REFERENCES

Approval of Respiratory Protective Devices, 42 C.F.R. Part 84

Hack, A., McConville, J.: Respirator Protection Factors: Part 1-Development of an Anthropometric Test Panel. Am. Ind. Hyg. Assoc. J (39): 970-975 (1978).

Zhuang, Z., Bradmiller, B., Shaffer, R.: New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force. J. Occup. Environ. Hyg. 4: 647-659 (2007).

Federal Register: Development of Inward Leakage Standards for Half-Mask Air-Purifying Particulate Respirators. Request for comment and notice of public meeting.

Transitioning to the NIOSH Panel presented at the October 17, 2018 Manufacturers Meeting: NIOSH Conformity Assessment Notice (CA 2018-1007) | NPPTL | NIOSH | CDC

NIOSH CA 2019 -1011 NIOSH Respirator Approval Program's use of the NIOSH Bivariate Panel during Isoamyl Acetate Fit Testing beginning February 1, 2019.

Appendix A – Background and Supplemental Information

Prior to November 1, 2021, the NIOSH Respirator Approval Program used human test subjects, identified by the LANL panels (Figures A1 and A2), to assess fit in accordance with 42 Code of Federal Regulations Part 84 (42 CFR Part 84).

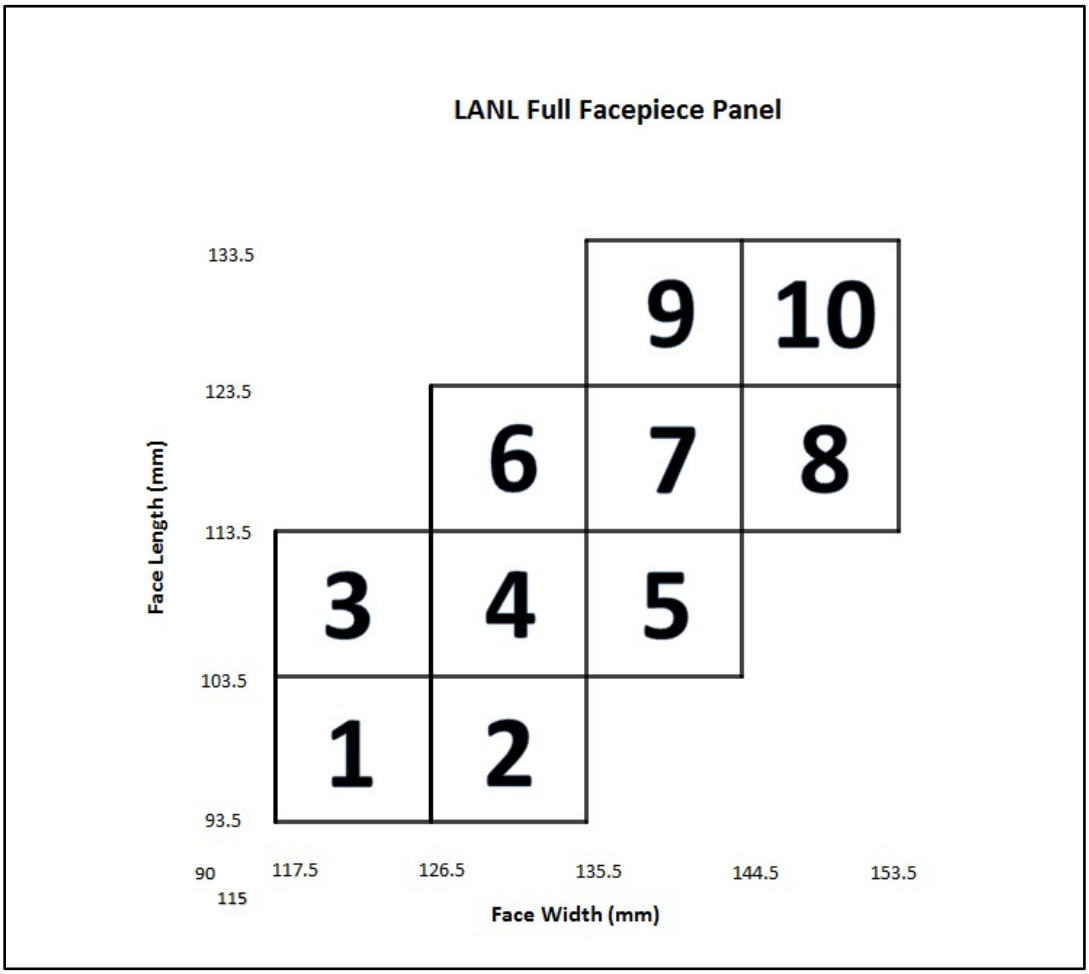

Figure A1. Los Alamos National Laboratory Full Facepiece Panel, with 10 cell boxes identified.

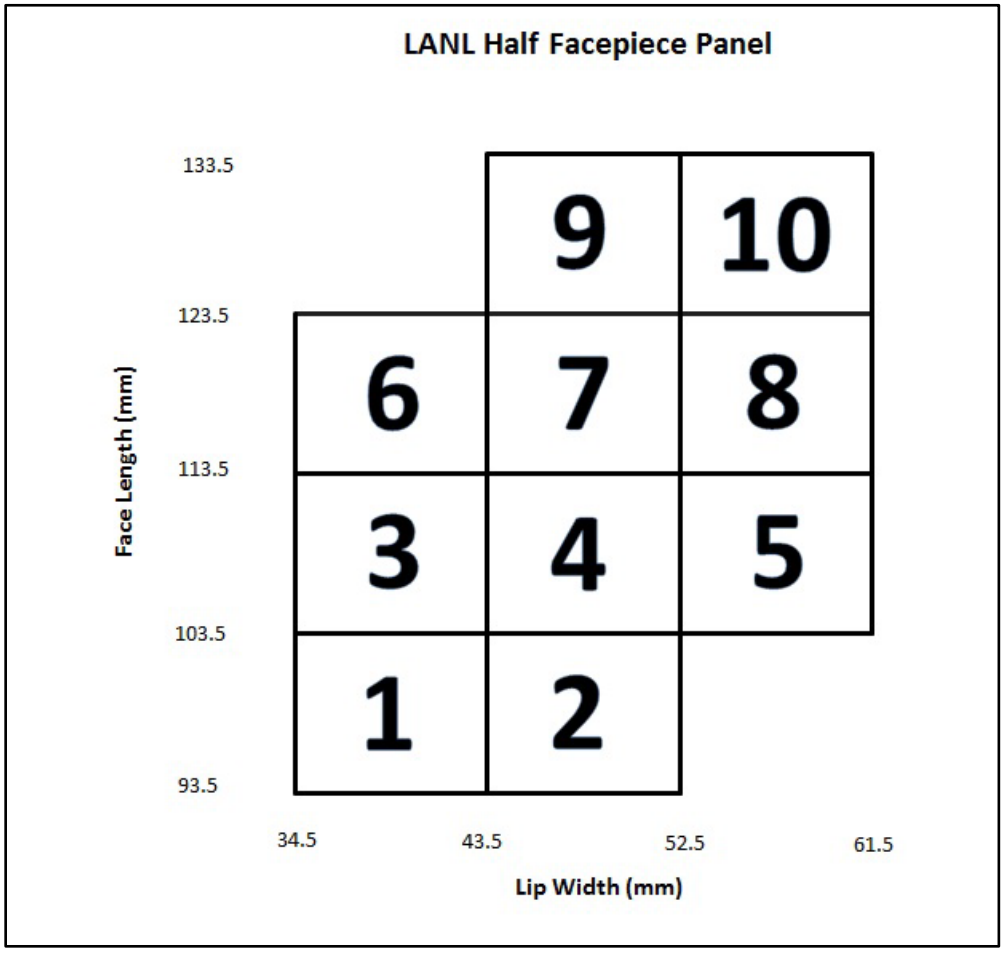

Figure A2. Los Alamos National Laboratory Half Facepiece Panel, with 10 cell boxes identified.

Note: While working to provide this notice and update STP-0352, NIOSH marked the historical reference to Attachment C of the SCBA Statement of Standard (provided to stakeholders on November 17, 2001) as superseded. Attachment C was superseded when STP-0352 was finalized as Revision 1.0 on June 10, 2008.