NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION
MINIMUM MANUFACTURING AND PERFORMANCE REQUIREMENTS
FOR
CLOSED CIRCUIT MIXED GAS REBREATHERS

1.0 INTRODUCTION

The purpose of this document is to establish minimum qualification criteria by which closed circuit mixed gas rebreathers (CCRs) will be evaluated for potential use by NOAA, NOAA sponsored, or otherwise NOAA authorized, personnel.

These criteria apply to commercially available off-the-shelf-equipment and are not a design standard. This document only includes a few key items and it is expected that the manufacturer's quality control program will ensure that best commercial practices are followed in the design, manufacture, and testing of the CCR and replacement parts. These criteria are not driven by a particular dive profile. It is the responsibility of the purchaser and user to match their needs with the capabilities of the rebreather.

The system must meet or exceed the tests outlined below, or their equivalent, which are to be conducted and certified by an independent, third party. The unmanned tests described in this document were taken directly from the U.S. Navy unmanned test methods and performance goals[1]. Alternative procedures will be considered on a case-by-case basis.

Requests for approval must be submitted to the Director, NOAA Diving Program, 7600 Sand Point Way, NE, Seattle, WA 98115-0070.

2.0 MANUFACTURED AND TESTED TO A NOAA-APPROVED QUALITY ASSURANCE & MANAGEMENT PROGRAM

The industry standard for quality assurance and management is ISO 9001:2000[2], which includes standards and procedures for monitoring, measuring, and controlling the production process. Manufacturers must provide documentation on the specific QA/QC systems used in the production of their CCRs. QA/QC systems other than ISO 9001:2000 will be considered on a case-by-case basis, but they must demonstrate to NOAA's satisfaction, as documented by a NOAA-approved third party, that it contains the essential elements of an ISO 9001 registered program.

The manufacturer shall support the apparatus design by providing documentation of a failure mode effect and criticality analysis (FMECA) and qualification/acceptance testing for all components, including software, supplied with the unit. The achievement of ISO 9001 certification would also imply a strong quality management system.

3.0 CAPABILITIES AND COMPONENTS

These requirements are designed to qualify candidate CCRs and to provide users and operational units the information they need to select an appropriate CCR and safely conduct training and operations. The CCR must include the specified capabilities / components and meet the listed performance requirements. The documentation for each CCR submitted for approval must include a description of how and when each requirement in this standard was satisfied, and the certification reports from NOAA approved independent third party witnesses.

Only NOAA approved test facilities and procedures will be acceptable for qualifying to this standard.

3.1 Gas Systems

Both automatic and manual addition valves are required for all diluent and oxygen supplies.

3.2 Gas Cylinders

All gas cylinders shall be approved by the DOT, another government agency, or a NOAA approved certifying authority.

Each cylinder shall be fitted with a pressure indicator. If this is an analog gauge it does not require a back up. If the primary display is electronic, then a back up is required.

3.3 Oxygen Control System

The CCR shall contain an electronic oxygen control system that uses a minimum of three oxygen sensors providing the control system with independent voting logic.

The CCR shall under all conditions of use specified by the manufacturer automatically maintain an inspired partial pressure of oxygen greater than 0.20 ATM. The inspired partial pressure of oxygen shall also be maintained at a partial pressure of less than or equal to 1.6 ATM; except during the descent phase(s) of a dive.

The CCR shall include an audible and/or visible warning system for High and Low PO_2 conditions.

3.4 Oxygen Compatibility

All components that come into contact with high-pressure gas with an oxygen content greater than 40% (by volume) shall be designed and manufactured for use with high-pressure oxygen.

The manufacturer shall supply the components cleaned for oxygen service using the instructions in the NOAA Diving manual or an equivalent industry or military standard.

3.5 System Power On/Off Switch

A power on/off switch, protected from being accidentally turned off shall be provided.

3.6 Visual Display

The CCR shall have two separate and independent means of displaying oxygen partial pressure for each sensor.

3.7 Battery Condition

The CCR shall include an audible or visual low battery alarm.

4.0 TESTING REQUIREMENTS AND ACCEPTANCE CRITERIA: UNMANNED

4.1 Breathing Loop Gas Analysis

4.1.1 Acceptance criteria

The breathing loop shall be free of any materials or components that could provide a source of ignition or that may off-gas noxious or hazardous gases or otherwise are potentially harmful for human life support, e.g. batteries or PVC coatings.

All trace gases shall be below the allowable limits for life support breathing gas outlined in Section 4.1.2.

If hydrocarbons are detected within the gas sample above the allowable limits, the gas must be analyzed for any other potential contaminant in addition to those specifically targeted.

4.1.2 Testing procedures

Gas sample analysis will be performed on the CCR following the completion of a breathing resistance test at 130 fsw (39.6 msw) and during the decompression from that test. When the chamber reaches 60 fsw (18.3 msw) the ascent is stopped. The surface end of the inspired gas sample line is shifted to a cleaned and evacuated gas analysis cylinder and a sample of the CCR breathing gas is obtained for laboratory analysis.

The sample shall be analyzed for the following constituents:

Constituent	CAS No.	Limit (ppm)
Carbon Monoxide	630-08-0	10
Total hydrocarbons	NA	25
Total halogenated hydrocarbons	NA	10
Benzene	71-43-2	0.1
Methanol	67-56-1	7

1,1,1–Trichloroethane	71-55-6	2.5
Vinylidene chloride	75-35-4	0.15
Trichloroethylene	79-01-6	0.1
1,2-dichloroethylene	540-59-0	0.1
Xylene	1350-20-7	10
Formaldehyde	50-00-0	0.1
Ammonia	7664-41-7	10

4.2 Hydrostatic Imbalance

Hydrostatic imbalance is the difference at end exhalation 'no-flow' between the pressure within the facepiece (see Appendix A) and that at the reference point which could either be the suprasternal notch or the lung centroid of the diver (see Appendix B)[3].

4.2.1 Acceptance criteria

The hydrostatic load shall not exceed the values specified below under the following conditions:

- With 0° diver roll and diver pitch from +180° to -90° (see Appendix C)
- With 0° diver pitch and diver roll from +90° to -90° (see Appendix D)

PITCH DEGREES (Roll at 0 degrees)	Suprasternal Notch + mbar	Suprasternal Notch - mbar
+180	+20	-20
+90	+20	-20
+45	+20	-20
0	+20	-25
-45	+20	-20
-90	+20	-20
ROLL DEGREES (Pitch at 0 degrees)		
+90	+20	-20
+45	+23	-23
0	+20	-25
-45	+23	-23
-90	+20	-20

4.2.2 Testing procedures

The CCR shall be fully rigged on a rotating mannequin according to information supplied by the manufacturer. The CCR and mannequin shall be completely immersed in water at a depth sufficiently deep to preclude surface effects, but no deeper than 6 feet (2 m). The test shall be undertaken at a RMV of 62.5 lpm and the mouth pressure recorded at the end of the exhalation. The hydrostatic load will be mouth pressure referenced to the mannequin's supersternal notch. Because these are static measurements, they will

only be performed once. The data will be reported in a table of position and hydrostatic load reported as + or - mbar.

The gas supply shall be switched on and any adjustable relief valve set to a mechanical midpoint or the manufacturers setting.

For CCRs that do not add gas during tests the breathable volume shall be optimized before starting each measurement. After breathable volume is optimized no further adjustment is allowed for roll and pitch variation measurements.

During this test the mannequin shall be rotated about the lung centroid.

The water temperature in the test chamber shall be stabilized at 39 ± 1 °F (4 ± 1 °C), or lower if specified by the manufacturer.

4.3 Breathing Resistance

4.3.1 Acceptance criteria

The breathing resistance shall not exceed the maximum work of breathing (WOB) outlined below.

Tidal Volume (L)	Breathing Frequency (B/min)	Ventilation Rate (L/min)	Maximum WOB (J/L)
1.5	15	22.5	<1.18
2	20	40	<1.70
2.5	25	62.5	<2.38

4.3.2 Testing procedures

The volume-averaged pressure measured as resistive effort and peak-to-peak mouth pressure will be evaluated at the Respiratory Minute Volumes (RMV) of 22.5, 40, and 62.5 liters per minute (L/min) from the surface (0 fsw/msw) to 165 fsw (50.3 msw) in 33 fsw (10 msw) increments with air as the diluent gas.

The CCR will be set up in a horizontal attitude in ambient water. Ten pressure-volume (P-V) loops will be performed for each RMV at each depth. Peak inhalation and exhalation pressures (kPa) will be measured at each depth and RMV. The area under the curve will be reported as kPa or J/L for each P-V loop generated at each depth and RMV. A graphical representation of all 10 loops for each depth and RMV will also be produced. Breathing resistance (J/L) measured for each depth and RMV will be graphed. Using the acquired P-V loops, peak inhalation and exhalation pressures will be determined at each depth and RMV.

4.4 Oxygen Control System

4.4.1 Acceptance criteria

Once stabilized at a test depth, the oxygen control system must maintain +/- 0.05 ATM throughout the test period.

4.4.2 Testing procedures

The CCR oxygen control is evaluated with air as the diluent at 60 fsw (18.3 msw) and 300 fsw (91.4 msw). The number of set points tested will vary with the capability of each system. If high and low set points are provided, both will be tested. For a CCR with multiple set points the low set point, a mid range set point, and the high set point will be evaluated. The oxygen consumption of an exercising diver will be simulated using oxygen consumption rates of 1.0, 1.5 and 2.5 standard liters per minute (slpm) for the respective ventilation rates of 22.5, 40, and 62.5 L/min.

The CCR is pressurized to a depth of 60 fsw (18.3 msw) at a rate of 60 feet per minute (18.3 mpm). After the oxygen control is stabilized at 60 fsw (18.3 msw), the CCR is tested for 30 minutes. The CCR is then pressurized to 300 fsw (91.4 msw) at a rate of 60 fpm (18.3 mpm). After oxygen control is stabilized the CCR is tested for 30 minutes then depressurized at 30 fpm (9.1 mpm) to a simulated decompression stop at 30 fsw (9.1 msw). After the oxygen control is stabilized at 30 fsw (9.1 msw), the CCR is tested for 30 minutes, then depressurized to the surface. A minimum of five runs per test condition will be performed. Data of PO_2 vs. time will be graphically represented. After the CCR is stabilized at each test depth the mean PO_2 ($\pm$ 1 standard deviation) will be reported. The maximum PO_2 observed during descent and the minimum PO_2 observed during ascent will be noted on the graph. Observations of alarm conditions for low PO_2, high PO_2, and battery during the pre-dive and dive are to be recorded.

4.5 Carbon Dioxide Removal

4.5.1 Acceptance criteria: None. For informational purposes only.

4.5.2 Testing procedures

The CO_2 canister will be filled with the manufacturer's recommended CO_2 removal material per manufacture's filling procedures. With the breathing machine set to simulate a ventilation rate of 40 slpm, CO_2 will be injected into the unit at 1.35 slpm. The diluent gas will be air or nitrox, depending upon the CCR design. The data will be reported in tabular form as time to 0.5, 1.0, 2.0, and 5.0% Surface Equivalent Value (SEV) carbon dioxide (PCO_2), including mean +/- 1 SD. In addition, this data, % SEV PCO2 vs. time will be graphed representing the mean +/- 95 % confidence interval. Two canister runs for each candidate CCR will be performed at each test depth. If the results at a given depth vary by more than 20% of the lowest value a third test will be performed at that depth.

The tests will be performed in water at a temperature of 40 +/- 1 F (3.9-5.0 C) and at depths of 60 fsw (18.3 msw), 100 fsw (30.5 msw), and 165 fsw (50.3 msw).

5.0 TESTING REQUIREMENTS AND ACCEPTANCE CRITERIA: MANNED

5.1 General

The manned test program consists of evaluating breathing resistance, while simultaneously measuring oxygen control during six dives of two divers each at depths of 60 fsw (18.3 msw) and 165 fsw (50.3 msw) using air as the diluent gas and one dive of two divers at a depth of 300 fsw (91.4 msw) using helium-oxygen, or nitrogen-helium-oxygen gases.

A minimum of 5 divers with previous experience diving CCRs, and trained on the CCR being tested are to be used for these tests which are to be carried out in water temperature at or above above 65^{o} F (18.5^{o} C).

5.2 Breathing resistance

5.2.1 Acceptance criteria

A mean-weighted average score of 3.0 (moderate or less) for breathing difficulty and a rating on the diver evaluation of adequate is considered acceptable.

5.2.2 Testing procedures

Using a dyspnea (shortness of breath) category rating scale (modified Borg[4] or equivalent, 1 very slight, 2 slight, 3 moderate, 4 somewhat severe, 5 severe, 7 very severe, 10 maximal) each diver will evaluate the CCR's breathing performance for two progressive workloads at each depth using a bicycle ergometer.
Divers warm up during descent exercising at 25 watts. When they reach the test depth the workload is increased to 35 watts for three minutes, then 50 watts for three minutes, then 75 watts until the end of the bottom time, usually 3-5 minutes. During the third minute of each work level each diver uses hand signals to rate his level of breathing difficulty, and that assessment is recorded. During ascent the workload is decreased to 25 watts, and the diver continues to pedal at his own rate. At the end of the dive, including test diver familiarization and training dives, each diver completes an evaluation sheet for the preceding dive that includes: ease of donning, ease of strap adjustment for proper fit, ease of operating valves, ease of movement in the CCR, ease of doffing, and overall comfort.

5.3 Oxygen Control (Measured during breathing resistance testing outlined in 5.2.2)

5.3.1 Acceptance criteria

Once stabilized at a test depth, the oxygen control system must maintain +/- 0.05 ATM throughout the test period.

5.3.2 Testing procedures

A gas sampling port of sufficient size to provide a sampling rate of 500-800 mL/min shall be located in the inhalation hose. Inhalation levels for partial oxygen pressure (PO_2) and partial carbon dioxide levels (PCO_2) shall be measured at 1Hz and real time current value logged once every 30 seconds. Electronic data logging shall record the inspired 0_2 levels from which overshoot, time to stability, and control bandwidth can be determined and graphically presented. The oxygen control of the CCR shall be determined by the mean PO_2 as ATM at steady-state conditions. The beginning and final PCO_2 levels shall be observed and recorded as percent surface equivalent value (%SEV).

6.0 REPORT REQUIREMENTS

The testing laboratory will issue a report that includes: the testing procedures, the data from all of the tests, and a statement certifying which requirements of this standard the CCR met. A compliance verification checklist is attached as Appendix E.

REFERENCES

[1] US Navy Experimental Diving Unit Technical manual No. 01-94, June 1994.

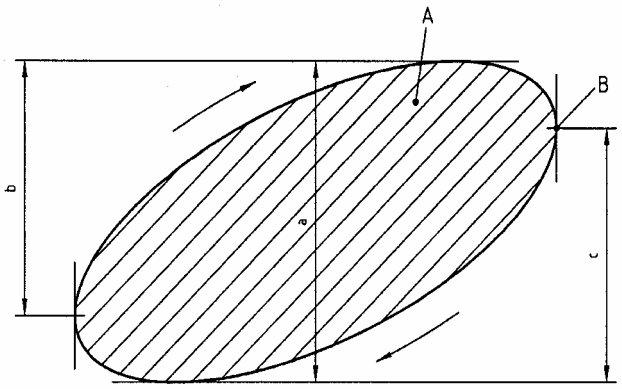
[2] ISO 9001:2000 Quality management systems -- Requirements

[3] EN 14143. European Standard: Respiratory equipment – Self-contained re-breathing diving apparatus. September 2004.

[4] Borg (1982). Category Rating Scale of Perceived Exertion (CR-10) Psychophysical Basis of Perceived Exertion. Medicine and Science in Sports and Exercise, 14:377-381.

APPENDIX A

ANALYSIS OF PRESSURE VOLUME LOOP



Key

a) peak to peak respiratory pressure

b) peak expired respiratory pressure (end inhalation to peak exhalation)

c) peak inspired respiratory pressure (end exhalation to peak inhalation)

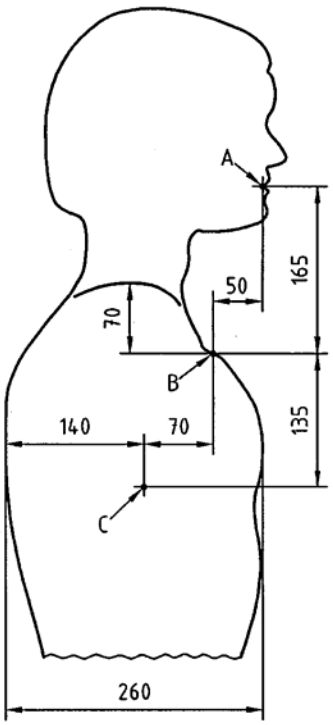
A WOB

B Reference point of hydrostatic imbalance; end of exhalation ("no flow")

Figure taken from EN 14143 - European Standard: Respiratory equipment – Self-contained re-breathing diving apparatus. September 2004. Figure 1 – Analysis of pressure volume loop, page 34.

APPENDIX B

REFERENCE POINTS



Key

A) mouth

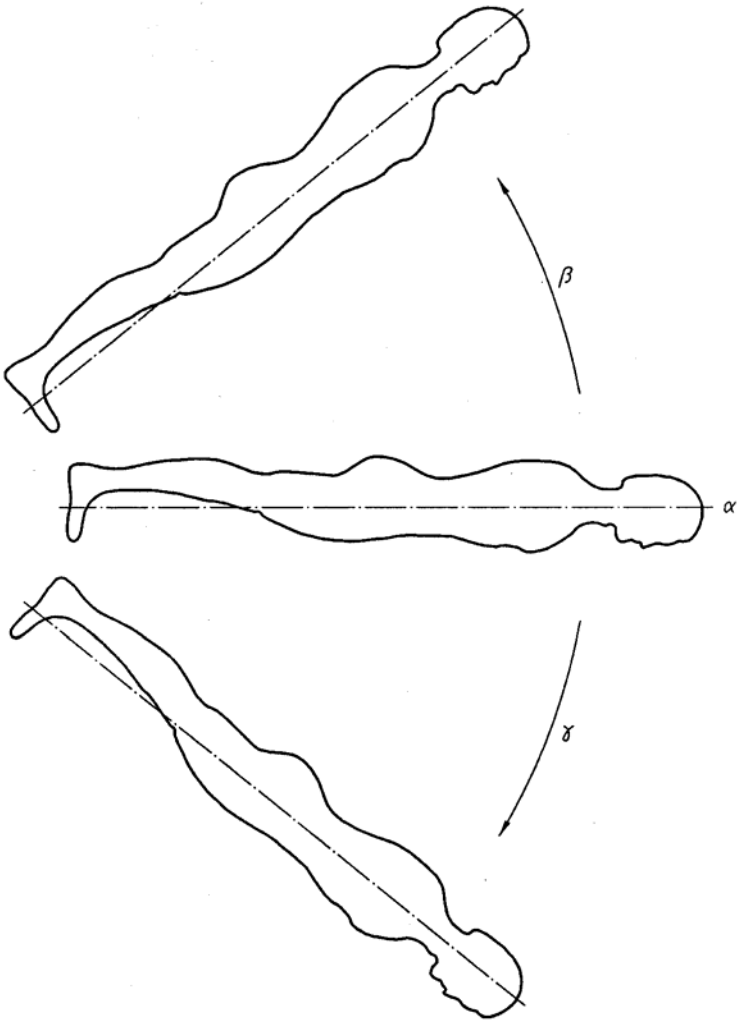
B) suprasternal notch

C) lung centroid

Figure taken from EN 14143 - European Standard: Respiratory equipment – Self-contained re-breathing diving apparatus. September 2004. Figure 2 – Reference points, page 35.

APPENDIX C

DIVER PITCH



Key

α) horizontal face down – roll 0°

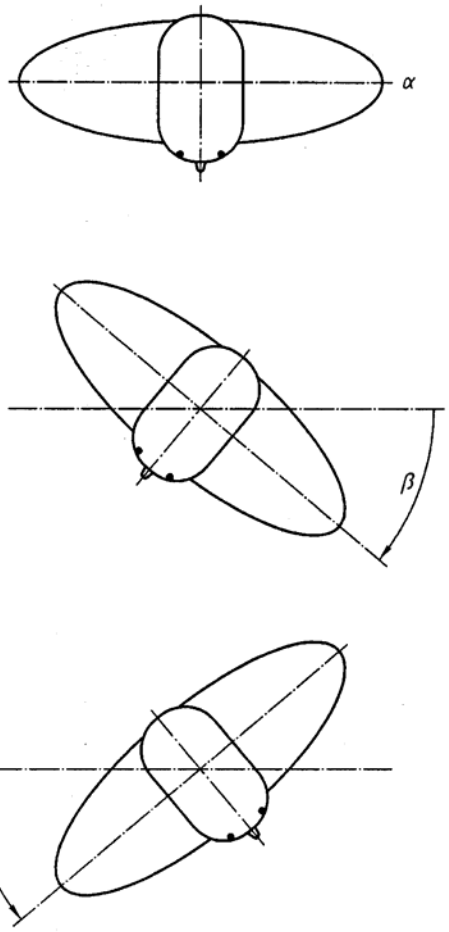
β) positive pitch (+ degrees)

γ) negative pitch (- degrees)

Figure taken from EN 14143 - European Standard: Respiratory equipment – Self-contained re-breathing diving apparatus. September 2004. Figure 4 – Diver pitch, page 37.

APPENDIX D

DIVER ROLL



Key

α) horizontal face down - roll 0°

β) positive roll (+ degrees)

γ) negative roll (- degrees)

Figure taken from EN 14143 - European Standard: Respiratory equipment – Self-contained re-breathing diving apparatus. September 2004. Figure 3 – Diver roll, page 36.

APPENDIX E

NOAA MINIMUM CCR MANUFACTURING AND PERFORMANCE REQUIREMENTS COMPLIANCE VERIFICATION

Name of Manufacturer: _____

Point of contact: _____

Address: _____

_____

_____

Name of CCR Model:_____

Serial number(s): _____ _____

Name of Third Party Inspector: _____

Ref.	Qualification Criteria	Yes	No	Compliance Reference	Initial
1.0	**Is the CCR commercially available?**				
2.0	**Is the unit manufactured and tested to ISO 9001 or equivalent QC program?**				
3.0	**Capabilities / Components** ▪ Was the CCR tested at a NOAA approved test facility? ▪ Was the CCR tested per NOAA procedures specified in the requirements document?				
3.1	Gas Systems ▪ Does the unit have automatic and manual diluent addition valves? ▪ Does the unit have automatic and manual oxygen addition valves?				
3.2	Gas Cylinders ▪ Are all gas cylinders approved by the DOT, another government agency, or a NOAA approved certifying authority? ▪ Are all cylinders fitted with pressure indicators? ▪ If the primary cylinder pressure indicator is digital, does the unit have a back up? If not digital indicate N/A.				

3.3	Oxygen Control System • Does the unit have an electronic oxygen control system that uses a minimum of three oxygen sensors providing the control system with independent voting logic? • Does the unit have an audible and/or visible warning system for High and Low PO_2 conditions?				
3.4	Oxygen Compatibility • Are all components contacting high-pressure gas with an oxygen content greater than 40% (by volume) designed and manufactured for use with high-pressure oxygen? • Are all components cleaned for oxygen service per the NOAA Diving manual or an equivalent industry or military standard? (State standard used)				
3.5	System Power On/Off Switch ▪ Does the unit have a power on/off switch that is protected from being accidentally turned off?				
3.6	Visual Display ▪ Does the unit have two separate and independent means of displaying oxygen partial pressure for each sensor?				
3.7	Battery Condition ▪ Does the unit have an audible or visual low battery alarm?				

Ref.	Qualification Criteria	Yes	No	Compliance Reference	Initial
4.0	**Performance Requirements: Unmanned**				
4.1	Breathing Loop Gas Analysis ▪ Is the breathing loop free of any materials or components that could provide a source of ignition or that may off-gas noxious or hazardous gases or otherwise are potentially harmful for human life-support? ▪ Was the gas sample analyzed for all the constituents gases outlined in section 4.1.1 of the requirements document? ▪ Were all gases sampled below the allowable limits outlined in section 4.1.1 of the requirements document? ▪ Was the gas sample analysis performed per procedures outlined in section 4.1.2 of the requirements document?				
4.2	Hydrostatic Load ▪ Were all hydrostatic loads within the specifications outlined in 4.2.1 of the requirements document? ▪ Was the hydrostatic load test performed per procedures outlined in section 4.2.2 of the requirements document?				
4.3	Breathing Resistance ▪ Was the breathing resistance within specifications outlined in 4.3.1 of the requirements document? ▪ Was the breathing resistance test performed per procedures outlined in section 4.3.2 of the requirements document?				
4.4	Oxygen Control System ▪ Did the oxygen control system maintain set points within specifications outlined in section 4.4.1 of the requirements document? ▪ Was the oxygen control system tested per procedures outlined in section 4.4.2 of the requirements document?				

4.5	Carbon Dioxide Removal • Was the CO2 canister testing per procedures outlined in section 4.5.2 of the requirements document? • Were test results tabulated and graphed per instructions outlined in section 5.4.2 of the requirements document?				

Ref.	Qualification Criteria	Yes	No	Compliance Reference	Initial
5.0	**Manned Testing**				
5.1	General • Were the breathing resistance and oxygen control systems tested per instructions outlined in section 5.1 of the requirements document?				
5.2	Breathing Resistance ▪ Was the breathing resistance within specifications outlined in section 5.2.1 of the requirements document? ▪ Was the breathing resistance test performed per procedures outlined in section 5.2.2 of the requirements document?				
5.3	Oxygen Control ▪ Did the unit maintain the inspired PO2 within specifications outlined in section 5.3.1 of the requirements document? ▪ Was the oxygen control system tested per procedures outlined in section 5.3.2 of the requirements document?				
6.0	Report ▪ Did the testing laboratory issue a report that included the items listed in section 6.0 of the requirements document?				
7.0	Documentation ▪ Are copies of all documents listed as a compliance reference attached?				

Based on inspection of the subject CCR and review of the information provided by the manufacturer for compliance with the NOAA Minimum Manufacturing and Performance Requirements, I find that the unit:

☐ Meets all NOAA requirements.

☐ Does not meet all NOAA requirements.

Printed Name of Inspector: _____ Date: _____

Signature of Inspector: _____

License, certification, or credentials: _____

Company/agency name: _____

Street address or PO Box: _____

State/Province: _____ Zip code: _____ Country: _____

Telephone #: _____ Fax #: _____

E-mail address: _____