Agreement Data Requirements List (ADRL)

Portable Oxygen Generator System (POGS) Prototype Project

Status	Active
Author	Project Management Office
Date	June 29, 2026
Version	1.0

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1.0 Background and Purpose

This document outlines the Agreement Data Requirements List (ADRL) for the Portable Oxygen Generator System (POGS) Prototype Project. This prototype effort is executed under the Other Transaction Authority (OTA) pursuant to 10 U.S.C. § 4022. The POGS is a critical medical device used in deployed field hospitals at Role of Care (ROC) 3. The system provides medical-grade oxygen to support patient care, anesthesia equipment, ventilators, and high-pressure cylinder refilling in austere and remote operational environments. The deliverables outlined in this ADRL are critical for ensuring the prototype meets all operational, technical, and regulatory requirements, including FDA clearance, cyber security compliance (MDERA), and MIL-STD-810H environmental survivability.

2.0 Deliverable Instructions

The Performer shall provide the following deliverables in accordance with the specified due dates, frequencies, and formats. Deliverables encompass hardware prototypes, technical manuals, regulatory documentation, and programmatic reports. The Agreements Officer Representative (AOR) and designated Government stakeholders will review all submitted data and documentation to ensure adherence to the Critical Operational Device Specifications (CODS) and Critical Logistical Specifications (CLS).

3.0 ADRL Matrix

ADRL	Deliverable	Due Date / Frequency	Format / Notes
D-001	Prototype POGS Units (2 per vendor)	120–180 days after award	Physical delivery (Per CODS/CLS specifications)
D-002	User/Operator Manual	With unit delivery	1 Physical, 1 Digital per device (English language)
D-003	Maintenance/Service Manual	With unit delivery	1 Physical, 1 Digital per device (English language)
D-004	Repair Parts List	15 days after award	Electronic spreadsheet (Identifying high-failure parts, OEM/commercial availability)
D-005	MDERA Questionnaire	30 days after award	Digital PDF (Completed PM SMD template)
D-006	TAA Compliance Certificate	With proposal / At Award	Signed Document (DFARS 252.225-7020)
D-007	Training - On-Site CONUS Operator Sessions	TBD - coordinated with Government	2 Sessions (Approx. 5–10 personnel per session)

ADRL	Deliverable	Due Date / Frequency	Format / Notes
D-008	Operational Training Video	TBD - per device	Digital delivery or access to training site
D-009	FDA Pre-Submitted Package	TBD – before FDA submission	Digital copy of FDA pre-submitted FDA approval
D-010	FDA Clearance Documentation	Within 12–24 months of award	Official FDA clearance letter (510(k) or Class I)
D-011	Special Tools List	15 days after award	Electronic Document (Identifying tools and procurement sources)
D-012	Copyright/Distribution Release	60 days after award	Written release letter (Supporting Army TM distribution)
D-013	Test Support - Technical Representative	During Government T&E events	Vendor-funded representation
D-014	Bi-Weekly Meetings	Commencing 15 days after award	Virtual / Teleconference & digital documentation
D-015	Risk Reporting	Within 2 business days of identification	Email/Digital notification to the Agreements Officer Representative (AOR)
D-016	Item Unique Identification (IUID) registration	TBD -Before delivery of device	Email/ IUID registration confirmation

4.0 Notes and Additional Requirements

- **Language Requirements:** All physical and digital technical manuals (D-002 and D-003) must be provided in the English language.
- **FDA Clearance (D-009):** This is a Key Performance Parameter (KPP) for this effort. The Performer must maintain regular communication regarding their regulatory pathway and milestone schedule to achieve this within the proposed 12 to 24-month timeframe.
- **Bi-weekly Meetings (D-014):** Meeting agenda, meeting minutes, and all relevant briefing materials will be provided for each bi-weekly meeting. These documents should be shared in advance whenever possible to allow adequate time for review and to help facilitate productive discussions. Timely submission of these materials will support effective coordination and ensure that all stakeholders remain informed and aligned**.**
- **Risk Reporting (D-015):** Added based on Section 4.1 of the Statement of Work (SOW), which requires the performer to proactively notify the AOR of any risks or issues that impact the delivery schedule or technical performance within two (2) business days of identification.

- **IUID Marking(D-016):** The contractor shall apply one Item Unique Identification (IUID) mark to each POGS unit in accordance with DFARS 252.211-7003. The IUID shall be a compliant 2D Data Matrix placed in a visible, durable, and permanent location on the exterior of the unit. The contractor is responsible for ensuring accuracy, permanence, and readability of the mark, and shall register all required data elements in the DoD IUID Registry prior to shipment. No internal components require IUID marking unless otherwise specified by the Government. All IUID data must accompany shipment documentation to support Government acceptance, accountability, and lifecycle management.