EpiC Oxygen Quality Assurance

This document outlines the quality assurance and risk mitigation activities implemented by the Meeting Targets and Maintaining Epidemic Control (EpiC) project led by FHI 360 to provide assurance for the quality of medical oxygen procured by FHI 360 with funding from the United States Agency for International Development (USAID).

The documents and standards set forth in the table below should be reviewed and documented before proceeding with an oxygen procurement.

Quality Assurance Document	Quality Standard (if Relevant)	Reviewed by EpiC/Notes
Legal Status		
One or more of the following is required:		
Documents showing that supplier/producer is legally registered and in good standing		
Documents showing that the supplier/ producer is authorized to supply or produce and store medical oxygen (as relevant)		
Production Quality		
Required: Certificate of analysis (COA) showing tests on the quality of oxygen and possible impurities (on the lots procured)	**For gas O_2:** • Assay: contains NLT 99.0% by volume of oxygen (O_2) • Carbon Dioxide: NMT 300 ppm • Carbon Monoxide: NMT 10 ppm **OR**	

This brief is made possible by the generous support of the American people through the United States Agency for International Development (USAID) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The contents are the responsibility of FHI 360 and do not necessarily reflect the views of USAID, PEPFAR, or the United States Government.

Quality Assurance Document	Quality Standard (if Relevant)	Reviewed by EpiC/Notes
	• Assay: Minimum of 99.5% by volume of oxygen (O2) • Carbon Dioxide: NMT 300 ppm v/v • Carbon Monoxide: NMT 5 ppm v/v • Water Vapour: NMT 67 ppm v/v **For liquid oxygen (LOX):** • Assay: contains NLT 99.0% by volume of oxygen (O_2) **OR** • Assay: Minimum of 99.5% by volume of oxygen (O_2) Water Vapour: NMT 67 ppm v/v	
One of more of the following is required:		
Proof of compliance with current Good Manufacturing Practices	A documented Quality Management System (ISO 9001 or GMP Certificate)	
Approval of production of medical oxygen by a regulatory authority	Example: Registration with U.S. Food and Drug Administration (FDA) and recent inspection results from the U.S. FDA or another regulatory authority	
Storage and Distribution		
Required: Label clearly indicating that oxygen is being stored	The cylinder should carry a label stating “Oxygen.” In addition, “Oxygen” or the symbol “O_2” should be stenciled in paint on the shoulder of the cylinder. **OR** The label states if oxygen was produced by the air-liquefaction process, as applicable. Where it is piped directly from the cylinder or	

Quality Assurance Document	Quality Standard (if Relevant)	Reviewed by EpiC/Notes
	storage tank to the patient point of use, label each outlet “Oxygen.”	
Required: ISO certificate	Verification of the quality of the oxygen tank to determine that it has been manufactured to appropriate standards, is inspected regularly, and is labeled accordingly.	
Required: Description of how medical oxygen is stored and distributed from production through final delivery		
One or more of the following is required:		
Evidence/certification of compliance with Good Storage and Good Distribution Practices		
Documentation on previous export of medical oxygen and evidence of approval from the regulatory authority of the recipient country		

Process

Please document each step in the process: who was involved, the point of origin and destination for the oxygen, and how every step took place. Below are suggestions for what to include. **[Replace all current suggestions with your country-specific process.]**

Procurement

- What suppliers did you contact?
- Is the supplier different than the producer? If so, please check the appropriate legal items for both as part of your quality assurance process.
- What did you consider in your decision-making to determine where to source the oxygen?

    - Availability
    - Location in relation to where oxygen is needed
    - Appropriate quality assurances
    - Price
- Indicate that the team confirmed the standards listed in the table above and that the relevant documents are attached to this memo for reference.

Transportation

- Which transporters did you contact?
- Can they meet EpiC's transportation needs?
    - Do they have appropriate vehicles to move the amount of oxygen needed?
    - Do they have the safety protocols in place to transport oxygen?
    - Are they available to meet the time constraints needed?
- Is this a one-time delivery or a recurring delivery?

Distribution

- What facilities received the oxygen?
- How much did each facility receive?
- Have all of the necessary quality assurance standards in the table above been met?

Other concerns

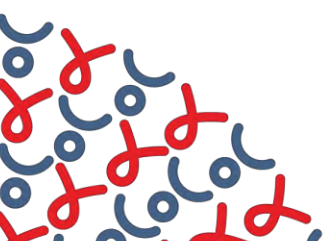
- Describe any security concerns.
- Describe any logistical concerns.

End the process section by confirming that all of the documents from the table above have been reviewed and meet the minimum standards.

Glossary

Medical liquid oxygen: Supplied and stored as a liquid at very low temperatures, in vessels and storage tanks. It is converted to medical oxygen, a gas at normal temperatures, when required. In hospitals, the converted medical oxygen is supplied via a medical gas pipeline system.

Medical oxygen: Oxygen of high purity developed for use in the human body and that is used for medical treatments. Medical oxygen cylinders contain oxygen gas of high purity; to prevent contamination, no other types of gases are allowed in the cylinder. Medical oxygen is used in a variety of settings and is commonly administered in medical facilities like hospitals and clinics during anesthesia, emergency first aid resuscitation, life support for patients unable to breathe on their own, and oxygen therapy.



Oxygen concentrator: Medical devices intended to provide a continuous flow of concentrated oxygen meeting the requirements of the “Oxygen 93 Percent” USP monograph directly to patients or to supply hospital systems. They are not air separation units (ASUs).

Transfiller: Firm that manufactures medical gas by transferring the gas in a liquid or gaseous state from a larger container into smaller containers. The smaller containers — either high-pressure cylinders or cryogenic vessels — are filled from larger containers (in a process known as “cascading”) or from permanently mounted tanks. Transfillers may fill single or multiple types of gases. Most medical gas establishments are transfillers. Manufacturers that mix different gases obtained in bulk are also considered transfillers.

Air separation unit (ASU): Site where atmospheric air is separated into its constituent gases of oxygen, nitrogen, and argon through a process of precleaning, compression, cooling, and fractional distillation of liquefied air. Most bulk liquid oxygen and nitrogen, for both medical and industrial purposes, are produced at ASUs. The Current Good Manufacturing Practice (CGMP) regulations pertaining to in-process controls and testing, as well as validation of automated control systems and equipment, have greater direct applicability at these sites than at transfilling sites. The term “prefill” refers to steps completed at a firm that manufactures by transfilling, prior to the actual fill