DIRECTORATE OF FACTORIES
Government of Telangana

SAFETY ALERT No. DOF-SA/LAB/08/2026	Date: 02 May 2026
Sector: Pharmaceutical, Bulk Drug & Chemical Factories	**Classification:** **HIGH PRIORITY – IMMEDIATE ACTION**

SUBJECT: STRATEGIC CONTAINMENT AND RISK MITIGATION IN CHEMICAL R&D AND QC LABORATORIES — INCLUDING LABORATORY GASES, LEL MONITORING, FLP EQUIPMENT AND NITROGEN SAFETY

1. AUTHORITY & RATIONALE

This Alert is issued under the Occupational Safety, Health and Working Conditions (OSH&WC) Code, 2020. It addresses the critical transition from bench-top experimentation to pilot scale, which represents a hazard-density peak requiring stringent engineering controls and human intervention to prevent micro-scale incidents from escalating into macro-scale industrial losses. This Alert incorporates safety provisions on laboratory gases, flammable-vapour monitoring, Flameproof (FLP) electrical equipment, and nitrogen asphyxiation hazards.

2. CORE RISK DOMAINS & MITIGATION

- **The Storage-Containment Paradox:** Fume cupboards must be used strictly as engineering controls, not permanent storage. Reagents must be housed in approved Flammable Material Safety Cabinets (FMSC) to prevent disruption of laminar airflow and vapour escape.
- **Thermal Runaway in Glassware:** Scale-up from 50 mL to 5 L must account for Area-to-Volume (A/V) ratios. Formal HAZOP assessments and review of DSC or RC1 data are mandatory before increasing reaction volumes.
- **Static Charge Accumulation:** Bonding and earthing must be verified before transferring non-conductive solvents (e.g., Toluene, n-Hexane). Anti-static footwear and gloves are mandatory in all solvent-handling zones.
- **Flammable Gas / Vapour Release:** Undetected gas leaks in enclosed laboratory spaces represent a primary ignition risk. Continuous LEL monitoring, FLP-rated electrical installations, and trained emergency response are non-negotiable controls.
- **Nitrogen Asphyxiation:** Nitrogen is an odourless, colourless asphyxiant. A 1% oxygen-depletion event in a closed lab can be fatal within minutes. Oxygen-depletion sensors and permit-to-work controls are mandatory wherever nitrogen is used.

3. MANDATORY TECHNICAL STANDARDS — PROCESS SAFETY

3.1 Fume Hood Containment

- **Testing:** Annual smoke pattern testing for face velocity; monthly digital anemometer logs (Target: 0.4–0.6 m/s).
- **The 150 mm Rule:** Maintain all apparatus at least 150 mm (6 inches) behind the sash plane at all times.
- **Sash Management:** Sashes must never be fully opened during active reactions; auto-closing mechanisms are strongly recommended.

- **Load Restriction:** Maximum of two mid-size apparatus assemblies per fume cupboard at any one time.

3.2 Reaction Safety & Scale-Up

- **Pressure Relief:** Every closed system must include a calibrated relief device or weak-link (e.g., bubbler) to prevent BLEVE-type glassware explosions.
- **Thermal Redundancy:** All heating elements must use independent over-temperature cut-off controllers. Single-point thermal control is strictly prohibited.

3.3 Pyrophoric & Highly Reactive Materials

- **Inertisation:** Use of Schlenk lines or certified glove boxes is mandatory for Grade-I materials such as n-Butyllithium or $LiAlH_4$.
- **Quenching:** Physical execution and laboratory-notebook documentation of quenching protocols are required to formally complete any experiment.

4. LABORATORY GASES, LEL MONITORING, FLP EQUIPMENT & NITROGEN SAFETY

Laboratories in the pharmaceutical, bulk drug and chemical sectors routinely use compressed and liquefied gases — including flammable, toxic, asphyxiant and oxidising types. The following sub-sections lay down mandatory requirements for safe storage, use, monitoring and emergency response.

4.1 Compressed Gas Cylinder Safety & Storage

- **Segregation:** Flammable gas cylinders (Hydrogen, Acetylene, LPG) must be stored separately from oxidising gases (Oxygen, Chlorine) and asphyxiants (Nitrogen, Argon, CO_2). Minimum separation: 3 metres or a fire-rated wall.
- **Securing:** All cylinders must be chained or bracketed upright to a fixed structure at all times — during storage, use, and transit.
- **Valve Protection:** Protective caps must be fitted whenever cylinders are not connected to a regulator. Cylinders must never be rolled, dropped, or subjected to impact.
- **Labelling & Colour Code:** Cylinders must bear the IS 4379 / BIS colour code and hazard label. Unmarked or illegibly labelled cylinders must be quarantined and returned to the supplier immediately.
- **Cylinder Inventory Register:** A live register of all laboratory gas cylinders — recording cylinder ID, gas type, fill date, last inspection date, and assigned location — must be maintained and audited quarterly.
- **Handling in Confined Lab Spaces:** A gas cylinder must never be transported through a laboratory while the valve is open. Trolleys with restraint chains are mandatory for movement. Cylinders must not be stored inside fume cupboards, under benches, or near heat sources (>40°C).

4.2 LEL (Lower Explosive Limit) Sensor Requirements

Regulatory Basis: Fixed LEL monitoring is mandatory in all laboratory spaces handling flammable solvents or gases. Portable LEL meters must be available as a supplementary control.

- **Sensor Type:** Catalytic bead (pellistor) or infrared (IR) LEL sensors — calibrated per the manufacturer's schedule and certified to IS 17636 / IEC 60079-29-1. IR sensors are preferred for hydrogen-rich or silicone-contaminated environments.
- **Sensor Placement:** For gases heavier than air (LPG, solvent vapours, Diethyl Ether): sensors at floor level, ≤0.5 m from ground. For gases lighter than air (Hydrogen, Methane): sensors at ceiling level, ≥0.3 m from roof. Nitrogen/oxygen depletion: sensors at breathing zone height (1.2–1.5 m).
- **Alarm Thresholds:** First alarm (warning) at 10% LEL — evacuation preparation. Second alarm (action) at 20% LEL — mandatory evacuation and isolation of ignition sources. No re-entry permitted until LEL reading returns to <5%.

- **Interlock Integration:** LEL sensor alarms at 20% LEL must be interlocked to automatically shut off gas supply solenoid valves and activate emergency ventilation. Bypass of interlocks requires written authorisation from the Factory Manager.
- **Calibration & Maintenance:** Bump testing at the start of every working day; full calibration with certified reference gas every 6 months. Calibration records must be retained for a minimum of 3 years. **Portable LEL Meters:** At least one calibrated portable multi-gas detector (LEL + O_2 + H_2 S + CO) must be available per laboratory wing for pre-entry checks, maintenance work, and emergency response. Portable meters must not substitute for fixed sensors.

LEL / UEL Reference Table for Common Laboratory Gases and Vapours:

Gas / Vapour	LEL	UEL	Key Control Measure
Hydrogen (H_2)	4%	75%	Fixed sensor + auto alarm; buddy system mandatory
Acetylene (C_2H_2)	2.5%	100%	No Cu/Ag fittings; flashback arrestors compulsory
LPG / Propane	1.8%	9.5%	Sensor at floor level (≤0.5 m); no flame ignition source
Methanol Vapour	6%	36.5%	Catalytic bead sensor; ATEX Zone 1 classification
Ethanol Vapour	3.1%	27.7%	Ground bonding before dispensing; FLP storage
Diethyl Ether	1.9%	36%	Sensor at bench level; anti-static containers mandatory
Nitrogen (N_2)	Asphyxiant	—	Oxygen depletion sensor; confined space entry PTW required

4.3 Flameproof (FLP) and Explosion-Protected Electrical Equipment

Mandatory Standard: All electrical equipment installed in or adjacent to areas classified as hazardous (Zone 1 or Zone 2 per IEC 60079-10 / IS 5572) must be certified FLP / Ex-rated. This includes: refrigerators, centrifuges, stirrer hotplates, vacuum pumps, extraction fans, and lighting fixtures.

- **Hazardous Area Classification:** Laboratory areas where flammable solvent vapours or gases are handled must be formally classified as Zone 1 (present during normal operation) or Zone 2 (present in abnormal conditions) per IEC 60079-10-1. Classification drawings must be displayed at the laboratory entrance.
- **FLP Refrigerators:** Standard domestic or laboratory refrigerators are strictly prohibited for storing flammable solvents. Only FLP-rated (spark-free interior) refrigerators — compliant with IEC 60068 or equivalent — are permitted..
- **Stirrer Hotplates & Heating Equipment:** In Zone 1 / Zone 2 areas, only a certified stirrer hotplates with enclosed heating elements may be used. Open coil hotplates are strictly prohibited.
- **Vacuum Pumps:** Exhaust discharge from vacuum pumps handling flammable solvent vapours must be directed to the fume extraction system. Pump motors must be Ex-rated (Ex d or Ex e) or equivalent if located in classified zones.
- **Electrical Isolation:** Emergency electrical isolation panels (EIPs) must be located outside each classified laboratory zone, clearly labelled in English and Telugu, and kept unobstructed at all times.
- **Prohibited Equipment:** The following are strictly prohibited in any flammable-vapour handling area: open-coil hotplates, non-FLP domestic refrigerators, unenclosed motor fans, mains extension cables with standard sockets, and incandescent lighting.
- **Inspection & Certification:** FLP equipment must be inspected by a competent electrical engineer at least annually. Inspection records and equipment certificates (Ex certificates) must be filed
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4.4 Nitrogen (N_2) Safety — Asphyxiation Hazard

⚠ **CRITICAL HAZARD — SILENT KILLER:** Nitrogen is colourless, odourless and tasteless. It gives NO warning of release. At 17% O_2 (normal: 20.9%) cognitive impairment begins. At 12% O_2, loss of consciousness can occur within seconds. At 6% Oxygen death follows rapidly. Nitrogen safety failures have caused multiple fatalities in Indian pharmaceutical facilities.

- **Oxygen Depletion Sensors:** Fixed oxygen depletion sensors must be installed at breathing zone height (1.2–1.5 m) in all areas where nitrogen is used for blanketing, purging, pressure transfer, or inerting. Alarm at <19.5% Oxygen (warning); mandatory evacuation at <18% Oxygen.
- **Permit to Work (PTW):** A signed PTW is mandatory before any entry into any space that has been nitrogen-purged or nitrogen-blanketed, including reactor vessels, storage tanks, drying ovens, and enclosed pipelines. PTW must include atmospheric testing results at the point of entry.
- **Purging Operations:** Nitrogen purging of equipment must only be performed by trained personnel. Purge start and end points must be clearly identified on P&ID diagrams. Vent lines from purging operations must be directed to a safe outdoor location — never into the laboratory working area.
- **Inert Atmosphere Work (Schlenk / Glove Box):** When using nitrogen as an inert blanket in Schlenk lines or glove boxes, the exhaust must be vented to the fume extraction system. Laboratory windows and doors must remain open or mechanical ventilation must be confirmed active before commencing operations.
- **Cryogenic Nitrogen (LNitrogen):** Liquid nitrogen handling requires cryogenic gloves, face shield, and lab coat. Filling operations must never take place in enclosed spaces without confirmed mechanical ventilation. Storage dewars must be pressure-relief vented and never stored in sealed rooms or overnight in unventilated laboratories.
- **Emergency Response for Nitrogen Asphyxiation:** Never enter an oxygen-deficient atmosphere to rescue a victim without SCBA (self-contained breathing apparatus). Activate emergency services immediately. Administer first aid in fresh air. Display Nitrogen emergency response posters at all nitrogen use points in English and Telugu.
- **Lone Working Prohibition:** Lone working is absolutely prohibited in any area where nitrogen is in use or has recently been used for purging. Buddy system and periodic check-ins (every 30 minutes minimum) are mandatory.

5. LAB-TO-PLANT TRANSITION PROTOCOL (PSSR)

Before any process is transferred to the manufacturing floor, a Pre-Startup Safety Review (PSSR) must be documented, specifically addressing:

- **Exothermicity:** Approval of DSC/RC1 calorimetry data by the Process Safety Officer.
- **Compatibility:** Verification of seal and gasket compatibility with all process solvents.
- **Emergency Venting:** Vent sizing calculations based on DIERS methodology for worst-case decomposition scenarios.
- **Hazardous Area Re-classification:** If scale-up introduces new gas or vapour sources, the hazardous area classification (Zone 0/1/2) must be reviewed and updated before commissioning.
- **LEL Sensor Adequacy Review:** Confirm that sensor types, placement and alarm setpoints are appropriate for the scaled-up process chemistry.
- **Operational Readiness:** Completion of HAZOP/HIRA studies and establishment of LOTO procedures before commissioning.

6. ADMINISTRATIVE MEASURES

Requirement	Specification / Standard

Inventory Control	Do not exceed Maximum Allowable Quantity (MAQ) for flammables per laboratory.
Signage	HAZARD RATING must be posted on every laboratory entrance door.
Buddy System	Strict prohibition on lone working for high-pressure systems, toxic gases, or pyrophoric materials.
Spill Control	Acid / Base / Solvent kits must be within 10 seconds walking distance of any active workstation.
Gas Cylinder Register	All laboratory gas cylinders must be logged in a live inventory register with cylinder ID, fill date, and expiry.
Gap Analysis	Formal analysis against this Alert must be conducted within 30 days of receipt.

Action Required — Occupiers and Laboratory Heads must:

1. Update the **Chemical Compatibility Matrix** for all storage and operational areas.
2. Complete **hazardous area classification drawings** and install FLP/Ex-rated equipment where required
3. Install and calibrate **fixed LEL and O_2 depletion sensors** in all applicable laboratory areas
4. Establish **Nitrogen PTW and confined-space entry procedures** and train all laboratory staff
5. Include **Laboratory Gas Safety, LEL Monitoring and FLP Equipment** as dedicated modules in the annual mandatory Safety Audit.
6. Submit a signed compliance report to the jurisdictional **Inspector of Factories**
7.

Issued in the interest of Industrial Safety and Prevention of Accidents. **The above advisory is to create awareness on safety systems. This will not absolve the responsibility of managements to comply with statutory norms under relevant statutory provisions**

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Director of Factories