



DESIGN AND OPERATION OF ON-SITE NITROGEN GENERATORS FOR FOOD USE

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Amendments to 194/15

Section	Change
3.2.11	New definitions added
3.2.12	New definitions added
5.1	New sub-sections added
6.1	New sub-sections added
6.2	New sub-sections added
6.3	New sub-sections added
6.4	New sub-sections added

NOTE Technical changes from the previous edition are marked with a line in the left margin.

1 Introduction

This publication provides specific guidelines for on-site nitrogen generators for food use.

An on-site nitrogen generator separates nitrogen from air for use directly at the user location delivered by pipeline. In terms of gas flow rates, on-site nitrogen generators range from a few litres per minute up to many tons per hour.

In the course of discussions with customers and authorities, requests are often made for compliance certificates related to nitrogen specifications, hazard analysis and critical control point (HACCP) studies, materials of construction and consumable materials for those on-site gas production units: pressure swing adsorption (PSA), membrane air separation system and cryogenic air separation system that are dedicated for food use.

On-site nitrogen generators for food use, for example for modified atmosphere packaging (MAP) or inerting applications, are installed at customer sites by either gas companies or equipment suppliers and can be operated by either gas companies or food companies.

Nitrogen generators which use PSA and membrane technologies have potential hazards that shall be recognised and addressed in view of the applicable food laws.

The nitrogen produced from an on-site generator is used in many food applications as a processing aid (without purity limit) or additive (E941 as per Regulation 2012/231/EC *laying down specific purity criteria on food additives other than colours and sweeteners*) [1].¹ Typical applications include but are not limited to: atmosphere protection of liquid and solid foodstuffs; tank blanketing; liquids mixing; liquid pressure transfer; modified atmosphere packaging; injection in liquid for container pressurisation; decarbonation; deoxygenation; beverage dispensing; and aerosol propulsion.

NOTE No purity criteria are set under European Union (EU) law for the use of gas as a processing aid. However, national legislation can require a purity alignment with those criteria applied to food additives.

2 Scope and purpose

2.1 Scope

The design and operation of on-site nitrogen generators by industrial gas companies for food use.

2.2 Purpose

This publication is intended as a guide for on-site nitrogen generators for food use regarding:

- identification of potential hazards (biological, chemical and physical types) during the equipment design and its operation according to Hazard Analysis and Critical Control Point (HACCP) procedures;
- description of appropriate design, operation, maintenance and modification;
- recommendations concerning traceability, production lots, registration parameters, product analysis; and
- assurance for operators and authorities of the quality and compliance of the gas produced with an on-site nitrogen generator.

¹ References are shown by bracketed numbers and are listed in order of appearance in the reference section.

On-site generators producing nitrogen as a processing aid are not subject to the same legal requirements as food. In this publication the requirements for food gases are indicated with a “shall”, for processing aids it may be read as “should” as the legal requirements do not apply to processing aids.

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Asphyxiation

Effect on the body of inadequate oxygen, usually resulting in loss of consciousness and/or death.

3.2.2 Batch

A discrete, defined quantity whose characteristics can be proven, for example it could be a number of cylinders filled on the same manifold at the same time, an isolated bulk storage tank or tanker or a period of continuous production.

3.2.3 Critical control point (CCP)

A step where a control shall be applied and which is essential to prevent or eliminate a food safety hazard or to reduce it to an acceptable level.

3.2.4 Cryogenic air separation generator

Equipment for the production of high purity nitrogen by means of a cryogenic process.

3.2.5 Cryogenic liquid

Liquid that is extremely cold at a temperature that is lower than –90 °C.

3.2.6 Fail safe

Causing a component or machine to revert to a safe condition in the event of breakdown or malfunction.

3.2.7 Food additive

Any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may reasonably be expected to result, in it or its by-products becoming directly or indirectly a component of such foods as per Regulation (EC) No 1333/2008 *on food additives* [2].

3.2.8 Food business operator

The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control as per Regulation (EC) No 178/2002 *laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety Directive 1333/2008/EC* [3].

3.2.9 Food defence

The efforts to protect food from acts of intentional adulteration.

3.2.10 Food or foodstuff

Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans as per Regulation (EC) No 178/2002 [3].

3.2.11 Food fraud

The act of purposely altering, misrepresenting, mis-labelling, substituting or tampering with any food product at any point along the supply chain.

3.2.12 Food gas

For the purposes of this publication, food gases are defined as food intended to be used as an additive or ingredient.

3.2.13 Food grade lubricant

Synthetic lubricant conforming to ISO 21469, *Safety of machinery. Lubricants with incidental product contact. Hygiene requirements* [4].

3.2.14 Food traceability

Ability to trace and follow a food through all stages of production, processing and distribution. This requires food business operators to know from whom they have received food and to whom they supply it. The principal purpose of the traceability requirement is to enable efficient and rapid withdrawal from the market of any food that may be injurious to the consumer's health.

3.2.15 Good manufacturing practices (GMP)

Safety conditions for operating the supply chain in order not to introduce contamination.

3.2.16 Hazard analysis and critical control points (HACCP)

Method to identify, evaluate, and control hazards which are significant for food safety.

3.2.17 Labelling

Distinctive mark of the on-site nitrogen generator for food use.

3.2.18 Modified atmosphere packaging (MAP)

Application exchanging the air in contact with food with a gas or a gas mixture to increase the shelf-life of food.

3.2.19 Membrane

Polymer material that acts like a filter to separate components such as nitrogen from oxygen in air.

3.2.20 Non-conforming product

Product which does not meet the relevant company specifications nor has other unspecified impurities which are suspected or known to be at levels that might, when used in contact with foods, be injurious to health (company specifications are assumed to comply with legislative specifications).

3.2.21 On-site nitrogen generator

Equipment for the production of nitrogen from air at the customer site; the equipment usually supplies the nitrogen to a distribution pipework system.

3.2.22 Oxygen-deficient atmosphere / nitrogen-enriched atmosphere

Air in which the oxygen concentration by volume is less than 19.5%, also known as nitrogen-enriched atmosphere.

3.2.23 Oxygen-enriched atmosphere

Air in which the oxygen concentration by volume exceeds 23.5%; also known as an oxygen enriched atmosphere.

3.2.24 Prerequisite programmes procedure (PRP)

Basic food safety conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption.

3.2.25 Operational prerequisite programme (OPRP)

PRP identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards and / or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment.

3.2.26 Pressure relief device

Device designed to protect a vessel or piping from reaching pressures higher or lower (vacuum) than its design limits in order to avoid the failure of the pipe or vessel.

NOTE As these devices can have significant flow when activated, the discharge should be directed towards a safe area.

3.2.27 Pressure swing adsorption (PSA)

Family of generators that separates one gas from another by passing a feed gas over a bed of adsorbent material at one pressure and cleaning the waste product off the adsorbent material at another pressure, hence the term pressure swing.

3.2.28 Processing aid

Any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients to fulfil a certain technological purpose during treatment or processing, and

which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product as per Directive 1333/2008/EC [2].

3.2.29 Safe area

Location where exhaust gases can be discharged safely causing no harm to personnel or property. A safe area is also a place where surrounding materials are compatible with the exhaust gas.

3.2.30 Safety permits (permit to work)

Procedural documents highlighting specific safety considerations that are issued to allow work to commence in a specific location.

3.2.31 Standard operating procedure (SOP)

Formal method of management to control the supply chain system operation and maintenance, in order to supply safe product.

4 Production process

4.1 Nitrogen quality

For any food use, on-site generated nitrogen shall comply with the general principles described in the EIGA Doc 125, *Guide to the Use of Gases in Foods* [5].

In the case where on-site generated nitrogen is used as a food additive, such as in the modified atmosphere packaging (MAP) application, nitrogen should comply with minimum purity criteria for E941 additive described in EIGA Doc 126, *Minimum Specifications for Food Gases Applications* [1, 6]:

- nitrogen $\geq 99\%$ vol

NOTE 99% including other inert gases such as noble gases (argon mainly).

- oxygen $\leq 1\%$ vol
- water $\leq 0.05\%$ vol

Impurities:

- carbon monoxide ≤ 10 ppmv
- methane and other hydrocarbons (as methane) ≤ 100 ppmv
- nitrogen monoxide and nitrogen dioxide ≤ 10 ppmv

In the case where on-site generated nitrogen is used as a processing aid / propellant, in accordance with the user's specifications, the on-site generator can be designed to produce different nitrogen assay values (typically between 90% and 99% nitrogen, with the balance predominantly noble gases and oxygen).

NOTE Propellant in this case refers to the use of nitrogen as a carrier gas for beverage dispensing.

At least one continuously online residual oxygen analyser shall be installed in the generated nitrogen gas stream to ensure the end-user's product quality and traceability requirements. Consideration should be given to the installation of an online residual moisture analyser. In any event the process and its environment shall be subject to a food safety risk assessment.

For small scale membrane generator producing less than 10 litres/min nitrogen, the compliance with purity requirements may be assured by effective process design, monitoring of key parameters and periodic analysis where it is not viable to fit an online analyser.

In the event that the online instrumentation detects the produced nitrogen stream to be out of specification range for oxygen, this nitrogen stream shall be vented to a safe location, with an automatic switch to another nitrogen source. In case no alternative source is available, an alarm for off specification should be routed to the operator so that corrective action can be initiated.

An indication of the oxygen concentration from the analyser shall be present on the front panel of the gas generator and ideally be transmitted to the user.

When commissioned, the on-site generator shall be tested under standard operating conditions to demonstrate that the residual impurities are below the specification limits. A cylinder may be used to take a sample for remote analysis. It should therefore not be necessary to install a dedicated analyser for residual impurities. The risk of potential contamination with impurities shall be periodically reviewed and e. g. verified by repeated analysis.

4.2 Infeed air compression

A typical on-site nitrogen generator will employ one of three different technologies:

- pressure swing adsorption (PSA);
- membrane separation; or
- cryogenic separation.

In all cases the first step in the process is the compression and initial filtration and drying of air. The fundamental requirements for the infeed air compression systems are common to all of the downstream separation technologies.

Feed air compression systems for PSA, membrane or cryogenic generators producing nitrogen for use in food applications will typically, though not exclusively, use oil-free screw compressors and, less frequently, oil-free reciprocating or centrifugal compressors. If oil-lubricated compressors are used, an oil separation system shall be installed, controlled and maintained in order to prevent oil carry-over and downstream contamination. A food grade lubricant may be used following a review to ensure it is suitable for the application.

Pre-treatment of the infeed air varies depending on the compressor type and separation technology used, typical treatment steps include:

- dust and particulate filtration;
- coalescing-type filters to remove entrained oil and water droplets, entrained mist, and aerosols;
- air dryers (refrigeration or desiccant) to reduce water vapour content and prevent condensation;
- carbon adsorption filters to remove hydrocarbons and other chemicals;
- molecular sieve beds to remove undesirable chemical vapours; and
- air heaters to control the temperature of the feed air supply.

For specific details, reference shall be made to the equipment manufacturer's manuals.

4.3 Pressure swing adsorption

Pressure swing adsorption (PSA) nitrogen generators are used to produce gaseous nitrogen at a specified purity (food gas), flow, and pressure from a compressed air source.

The technology involves the separation of nitrogen from oxygen by passing air through a bed of adsorbent material, typically a carbon molecular sieve (CMS). Under pressure, the CMS material preferentially adsorbs oxygen and system operation moisture while it allows nitrogen to pass through the vessel. During generator operation, the CMS becomes saturated with oxygen. The CMS is systematically regenerated by desorbing the oxygen and moisture at a lower pressure.

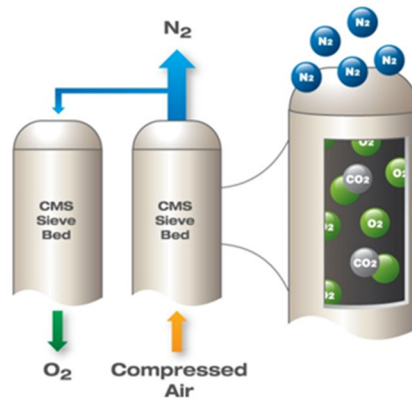


Figure 1 – Schematic of a pressure swing adsorber

Major equipment components include a feed air compression system; feed air pre-treatment equipment; vessels containing adsorbent; process piping and valves; a nitrogen compressor (when the customer requires pressures greater than the PSA pressure); process control systems; and other auxiliary components such as coolers, separators, storage receivers, and instrument air systems.

A typical PSA nitrogen generator flow diagram is shown in Figure 2.

Product purity is affected by adjusting the operating pressure, temperature, bed switch frequency and flow through the adsorber vessels.

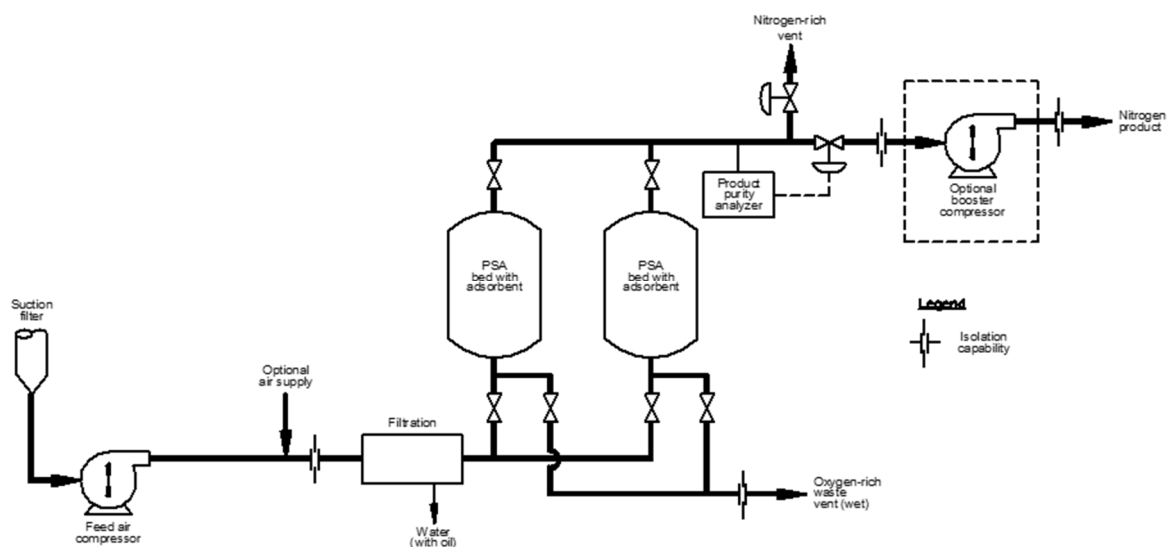


Figure 2 – Typical PSA nitrogen generator flow diagram

4.4 34 Membrane nitrogen generators

Membrane nitrogen generators are used to produce gaseous nitrogen at a specified purity, flow, and pressure from a compressed air source.

At the core of these systems is the membrane module. This module typically consists of thousands of small diameter hollow fibres that are bound together on each end by tube sheaths, formed into bundles, and contained within a protective outer shell. The compressed air feed stream can be introduced either on the shell or bore side of the membrane fibres as shown in Figure 5. Since oxygen permeates more rapidly than nitrogen through the membrane wall, the feed air is separated into two gas streams. The first stream (nitrogen), is produced at a pressure approximately 2 bar lower than the compressed air pressure. The second stream (waste), is enriched in oxygen and is at a much lower pressure, generally close to atmospheric pressure.

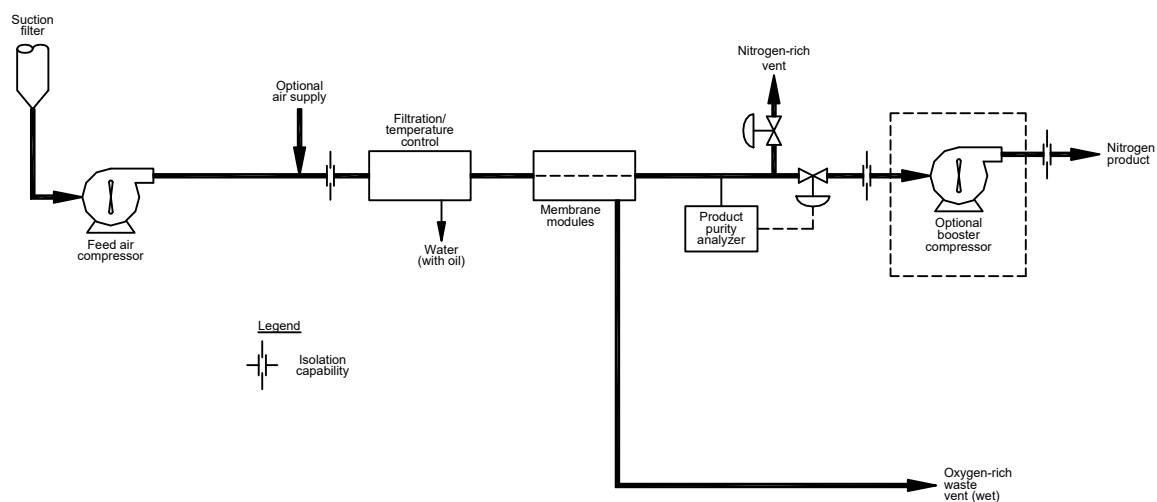


Figure 3 – Typical membrane nitrogen generator flow diagram

Major equipment components include the feed air compression system; feed air pre-treatment equipment; membrane modules; process piping and valves; a nitrogen compressor (when the user's process requires higher pressures than the nitrogen membrane output pressure); process control systems and other auxiliary components such as separators, storage receivers, and instrument air systems.

The compressed air is generally treated to remove any condensed liquids, entrained mists, solid particulates, and sometimes vapour-phase contaminants before introduction into the membrane separator. The degree of clean up required depends on the particular contaminants present, the effects those contaminants will have on the performance and lifetime of the membrane, and the final product purity requirements. Pre-treatment steps typically include filtration, and temperature and/or pressure control. After pre-treatment, the clean compressed air is fed to the membrane separator(s), which can be arranged alone or in multiple parallel or series banks.

The nitrogen purity is affected by controlling the operating pressure, temperature, and flow through the membrane module.

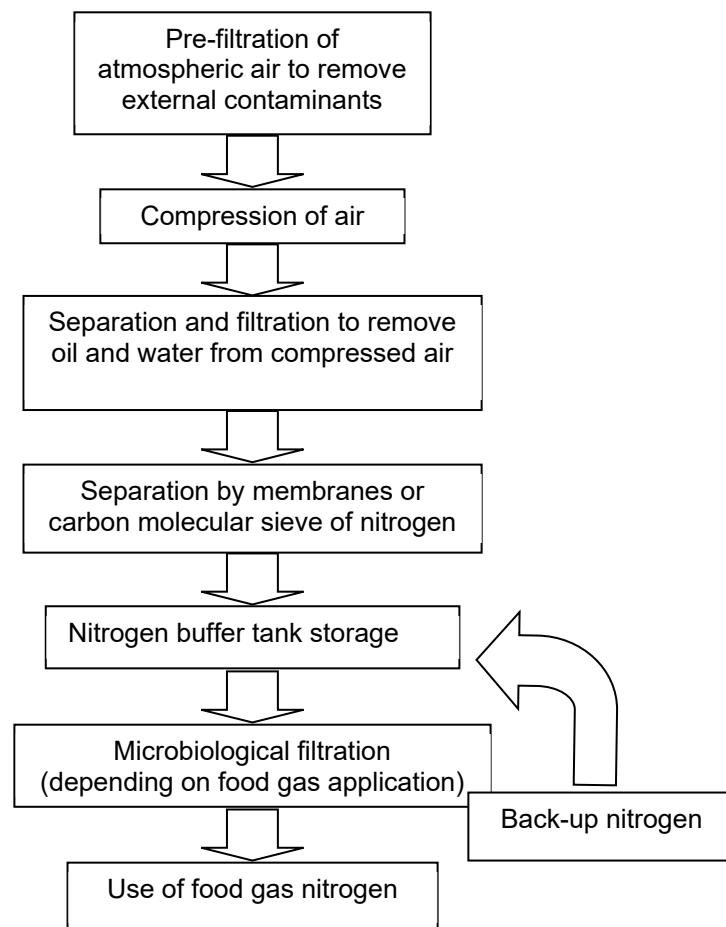


Figure 4 – Typical flow chart of an on-site nitrogen generator

4.5 Cryogenic separation

The cryogenic process separates air by means of distillation. This process uses the different boiling temperatures of the air components. There are inlet filters in the plants which remove external contaminants from the air before it enters the air compressor. Here the air is compressed to the required process pressure. After moving through an oil separator, the air enters one of two carbon molecular sieves (usually composed of CMS and alumina), where impurities such as water and carbon dioxide are removed. Here, one carbon molecular sieve is always effective while the other is being regenerated by residual gas from the separation process.

The processed air is then cooled at a liquefaction temperature in the main heat exchanger and then fed into the bottom of the distillation column. The pure nitrogen fraction is removed from the top of the column and fed into the product line. Cold is supplied in the form of liquid nitrogen (LIN) from the back-up system, which is regenerated with an expansion turbine. The pure nitrogen is stored in cylinders or storage tanks and then distributed.

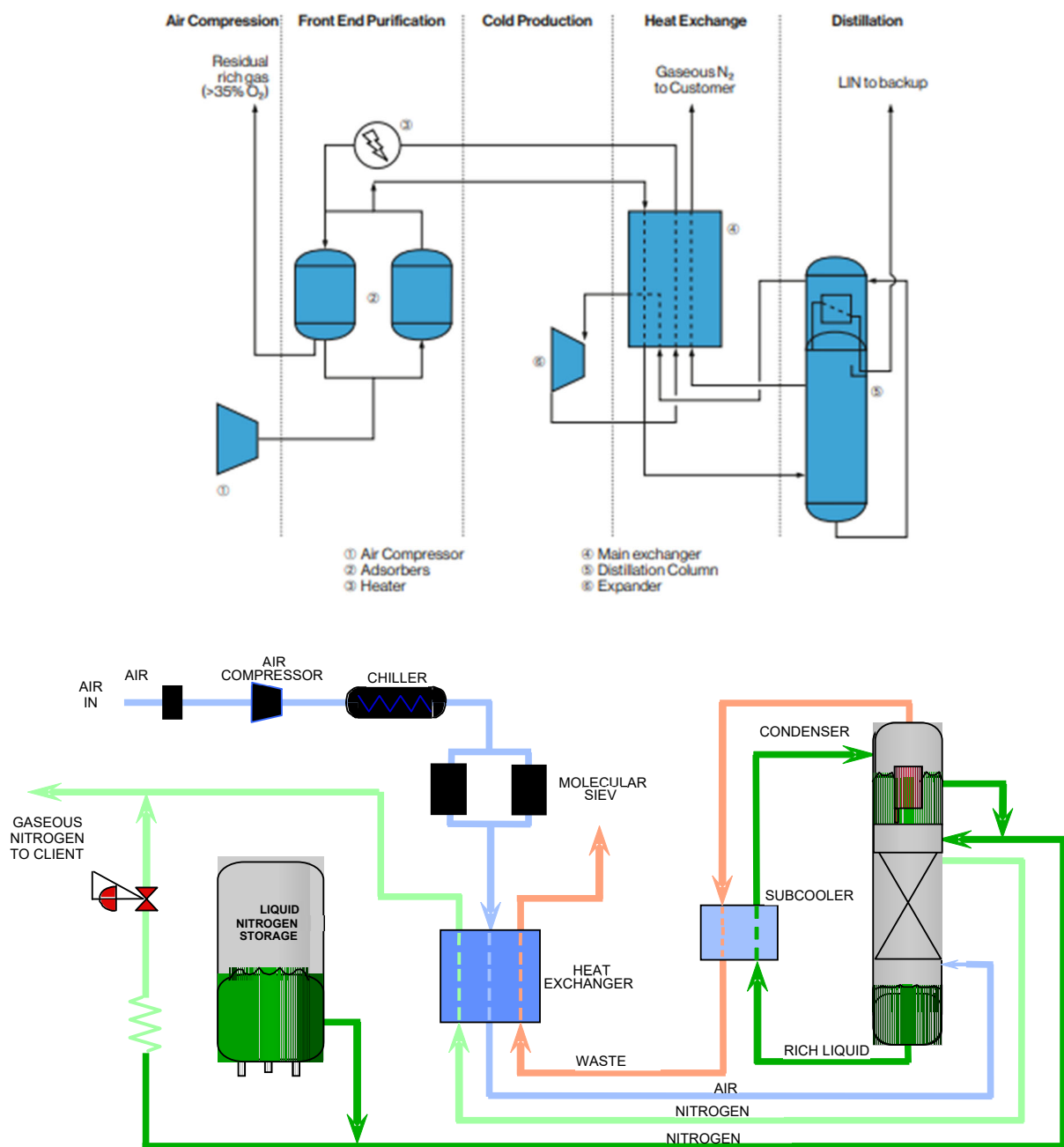


Figure 5 – Typical cryogenic nitrogen generator flow diagram

4.6 Food safety risk assessment

On-site generators producing food gas shall be subject to a food safety risk assessment. For more information see EIGA Doc 125, *Guide to the Supply of Gases for the Use in Foods* [5].

This risk assessment should be structured to systematically examine all relevant parts of the equipment design and operation including both normal and malfunctioning conditions, and interaction of the generator with its surroundings.

When carrying out this risk assessment study, general procedures can be used, which are described in EIGA Doc 149, *Safe Installation and Operation of PSA and Membrane Oxygen and Nitrogen Generators* (Section 5.11) [7].

In order to control the physical, chemical and biological contamination of the nitrogen output, the risk assessment shall cover to the following process elements:

- filtration of atmospheric air;
- mode of air compression (oil lubricated compressor or oil-free compressor);
- removal of oil, water and particles from the compressed air;
- materials for separation of nitrogen from oxygen with membrane modules (plastic polymers) or carbon molecular sieve;
- materials, design and construction of the nitrogen buffer tank;
- microbiological filtration of nitrogen if required by specific HACCP analysis; and
- nitrogen specification control with continuous control of the oxygen concentration.

As air is the raw material for an on-site gas production system, its quality (type and degree of contamination with pollutants such as dust, allergens, pollens, odours, hydrocarbons, acid gases, carbon monoxide, nitrogen oxide, microbes, bacteria, viruses, spores) are the major considerations in selecting a suitable area of installation.

The physical location of the generator shall be subject to a comprehensive risk assessment regarding physical, chemical and microbiological contamination of the nitrogen in order to identify potential food contamination hazards and to generate recommendations to reduce the probability of their occurrence and their consequences.

The generator should not be located adjacent to an obvious potential source of pollution (proximity to boiler combustion exhaust, solvents or chemicals venting, cooling air towers, aerosols, open or vented sewage systems, parking areas, main roads, etc.). Any modification of the adjacent environment of the on-site gas production system will require the food business operator to re-assess possible sources of additional pollution of the intake air and may require the end user to stop the generator.

For the location of the installation, refer to EIGA Doc 149 (Section 5.1) [7].

Refer to HACCP Plan in section 6 (also ISO 22000, *Food Safety Management*, and FSSC 22000 *Food Safety Management Systems*) [8, 9].

The use of best practice methods such as Good Manufacturing Practices (GMP), Standard Operating Procedures (SOP), and Critical Control Point – Control Procedures (CCP-CP) within the on-site gas production process ensure that contamination levels are kept within specification.

Where, as part of the on-site gas production process, water, oil or any consumables (for cleaning, washing or cooling) come in contact with the nitrogen stream their compliance should be controlled as defined in the GMP guide using validated methods for substances approved for contact with foods.

5 Manufacture and installation

Air environment solutions, additional specific filters and also active carbon, zeolite adsorbers or other materials suitable for food use shall be designed to eliminate gas pollutants and all unwanted impurities.

The inlet air compressor should be oil-free as it carries less risk of oil contamination because there is no contact between the oil and the product stream and there is therefore no requirement to maintain an oil/condensate separation and drainage system.

If a lubricated type air compressor is installed, attention shall be paid to the issues mentioned above, and an oil separation system shall be installed, controlled and maintained.

An air humidity filtration or dryer and condensate trap system shall be installed before the membrane or carbon molecular sieve as applicable.

The design of membrane modules for membrane units should consider, the ageing phenomena of modules and their polymer material. The membrane performance will reduce over time and after micro pollutant capture. A membrane specific life-cycle management programme shall be implemented.

A microbiological filter may be installed downstream of the on-site gas production system, after the gas back-up system or at the point of use.

Cleaning procedures requiring the use of only approved materials or equipment (for example washing / cleaning agents, lubricants, oils, ethyl alcohol, potable water) shall be used during manufacturing and installation.

The buffer tank shall be labelled with food gas name ("nitrogen"), E941 [1], and "for food use".

5.1 Food contact materials

Consideration shall be given to Regulation (EC) No 1935/2004 *on materials and articles intended to come into contact with food* [10]. Materials and equipment that come in contact with the nitrogen stream shall not be harmful or release constituents into the food that would change the organoleptic properties (odour, colour, taste).

The nitrogen gas becomes a food after the analyser to confirm that the minimum purity criteria for according to the Regulation 2012/231/EC (see also EIGA Doc 126) [1, 6]. This means that the materials before the analyser do not need to conform to the materials in contact with food regulation such as compressors, membranes, carbon molecular sieves etc.

Where available, certificates of food compatibility for components, consumable materials or materials of construction will contribute to the overall food safety validation of the system. Manufacture shall follow good manufacturing practice (GMP) as per the requirements in Regulation (EC) 2023/2006 *on good manufacturing practice for materials and articles intended to come into contact with food* [11].

In practice this means that the compatibility of the seals, lubricants, metals and plastics with foodstuffs shall be risk assessed.

See also Regulation (EU) No 10/2011 of 14 January 2011 *on plastic materials and articles intended to come into contact with food regarding plastics* [12].

NOTE There is a positive list, controlled by the European Food Safety Agency (EFSA) of authorised plastics for food use.

NOTE There may be local legislation regarding materials in contact with food.

6 Guidelines for food safety hazard analysis

6.1 Preliminary steps to enable hazard analysis

A food safety team should be appointed with a combination of knowledge from various disciplines and experience in the development and implementation of the food safety management system.

The activities included in the HACCP shall be clearly defined.

A flow chart shall be prepared with a description of the steps of the process. The flow chart shall be detailed enough to perform the hazard analysis. The flow chart should include the sequence and interaction of all steps of the operation, see Figure 8 for example.

The accuracy of the flow chart shall be confirmed on site.

The process and environment shall be described to the extent necessary to perform the hazard analysis, including:

- the layout of the facility;
- processing equipment;
- contact materials and material flow;
- existing PRPs;
- process parameters;
- control measures; and
- variations resulting from expected seasonal changes.

6.2 Hazard analysis

An identification of all reasonably foreseeable food safety hazards shall be carried out including biological, physical and chemical contamination.

Hazards shall be considered in sufficient detail to allow hazard assessment and selection of appropriate control measures.

The stages in which each hazard can be presented, introduced, increased or maintained shall be indicated. When identifying hazards, consider: the preceding and following stages in the food chain, all stages in the flow chart, process equipment, facilities, process environment, and people.

For each hazard the acceptable level in the finished product shall be determined. Each hazard shall be evaluated to determine whether its prevention or reduction to acceptable levels is essential. Each hazard shall be assessed with respect to the probability of its occurrence in the finished product prior to the application of control measures and the severity of its adverse health effects in relation to the intended use. Each significant hazard must be evaluated. The methodology used shall be described.

A control measure or an appropriate combination of control measures that can prevent or reduce the identified significant hazards to defined acceptable levels shall be selected. The control measures identified and selected shall be categorized to be managed as OPRPs or in the CCPs. This categorisation should be carried out using a systematic approach.

For detailed analysis of the HACCP, refer to the decision tree in ISO 22000 [8].

6.3 Potential hazards

6.3.1 Biological contamination

Biological contamination includes:

- Bacteria
- Moulds
- Yeasts
- Viruses
- Parasites

Biological contamination shall be considered as part of the risk assessment with appropriate mitigation measures taken if necessary, such as a 0.2 micron porosity filter downstream of the generator.

6.3.2 Physical contamination

Physical contamination includes carbon molecular sieve or other solid carried over from manufacturing such as metal / plastic particles.

Physical contamination shall be considered as part of the risk assessment with appropriate mitigation measures taken if necessary, such as a filter downstream of the generator.

6.3.3 Chemical contamination

Examples of chemical contamination are shown in Table 1.

Table 1 – Chemical contamination

Type of contaminant	Possible contaminant	Reason for taking into account or not these contaminants
Residues in distribution system	Cleaning agents (i.e. solvents)	Hydrocarbons shall not be present in food gases above 100 ppm
Impurities from process	Volatile compounds such as VOC, oxygen, water	Applicable for on-site generators depending on the location of the air inlet
Incompatible materials	Degradation by chemical or thermal reactions	Presence of polymer in the process
Metal contaminants and impurities	Arsenic, lead, mercury, cadmium, aluminium, nickel, silver, cobalt	Specific release limits (SRL) according to the <i>Metals and alloys practical guide for manufacturers and regulators</i> EDQM 2013 edition [13]. See Regulation (EC) No 1881/2006 and Directive 2001/22/EC [14, 15]
Others	Dioxins and dioxin-like PCBs	Applicable for on-site generators depending on their location. See Regulation (EC) No 1881/2006 and Directive 2001/22/EC [14, 15]

6.4 Hazard evaluation**6.4.1 Example of a generic HACCP for nitrogen PSA / membrane Unit**

Table 2 – Example of generic HACCP for a nitrogen PSA / membrane unit

Process Step	Description	Hazard	Preventive Measure	Significant Hazard (Y/N)	Monitoring Procedure	Corrective Action	Comments
1	Site air quality	Contaminated (physical, biological or chemical) air enters the compressor	Compressor is located away from sources of potential air contamination Monitoring of the compressor location by operator	N OPRP	Operator periodic checks	N/A	Site air quality is vital to the quality of nitrogen produced. It will also help to prolong the PSA lifetime and keep the compressor and PSA Unit downtime with target levels
2	Compressor air intake (filter mats and air inlet filter)	Failure of filter would lead to physical contamination	None.	N OPRP	Operator periodic filter checks. Regular preventative maintenance checks on the filter.	None Should filter become blocked or PSA shutdown, revert to back up supply if present until situation returns to normal.	No food safety hazard from blocked filter. Filter failure would allow large particles through, see below. Filter is specified to remove at least 98% of particles 2µm or larger. This should remove most microbiological contamination. Any physical contamination from heavy metals will be removed by the filter. Blocked filter would cause a reduced air flow into the compressor. This would result in a lower outlet pressure which is continuously monitored. PSA would then shutdown.
3	Air compressor	Wear from compressor	Oil lubricated screw minimises wear.	N	Excessive wear would be evident in cooling oil.	Re-new Air End as necessary	Any particles from wear of compressor are too small to be hazardous. Downstream coalescing filters will remove any solid particles for both oil-lubricated and oil-free compressors.
		Physical contaminants entering compressor through air intake	Lubricating oil captures contaminants. Oil is then separated and filtered. Air intake is located to ensure maximum inlet air quality	N	Oil temperature and pressure continuously monitored.	Replacement of oil, and oil filter at regular intervals.	Air intake location is particularly critical for oil-free compressors as no lubricating oil is present to capture contaminants.
		Chemical contamination	Oil free compressor or food grade lubricant	N	Regular preventative maintenance checks	Replacement of oil, and oil filter at regular intervals (if applicable)	
		Microbiological contamination	High temperatures within the compressor will destroy most microbiological contaminants	N	Compressed air temperature typically above 80°C.	None	

Process Step	Description	Hazard	Preventative Measure	Significant Hazard (Y/N)	Monitoring Procedure	Corrective Action	Comments
4	Water Separator and Filtration system	Failure to remove oil and water, and other large molecules.	Regular maintenance and replacement of filter elements when necessary (10 year design life).	Y	Monitor the condition of the filter using differential pressure gauges or sight glass.	Revert to liquid supply and change filter element.	Serious blocking of filter will result in low air pressure at the PSA generator. This low air pressure will be detected automatically, and the generator will shut down.
5	Refrigeration Drier (if present)	Failure to remove condensate	Regular maintenance	N	Drier status alarm. Monitor the condition of the drier.	Revert to liquid supply and repair drier.	Failure of drier will result in performance loss due to lower section of carbon molecular sieve within the PSA becoming saturated with condensate. The performance loss will be high and the PSA will be unable to separate oxygen and nitrogen, shutting down the plant. Drier failure is therefore an economic problem rather than a food safety issue.
6	Carbon Filter for removing oil vapour.	Oil vapour entering the adsorber vessels will coat the CMS (Carbon Molecular Sieve) leading to loss of separation efficiency.	Activated carbon operating life is 2 years and carbon fill material is replaced periodically based on analysis/saturation	N	Preventative maintenance system.	Revert to liquid supply and change filter carbon.	Failure of carbon filter will result in performance loss due to lower section of carbon molecular sieve within the PSA becoming coated with oil. The performance loss will be so dramatic as to render the PSA unable to separate oxygen and nitrogen, shutting down the plant, before any oil can be carried past the top section of CMS in the vessels. Carbon filter failure is therefore an economic problem rather than a food safety issue.
7	Condensate traps Mist Eliminator (coalescing filter) and air buffer vessel	Failure could result in liquid oil/water carry over.	Traps are fitted with a high level alarm connected to the control system which will shut down the PSA generator. Regular maintenance of condensate traps to ensure removal of oily water from the system	N	Generator will display visual and audible alarm to warn customer and dial out via telemetry Preventative maintenance system	Liquid level in traps to remain below alarm set point.	Revert to liquid supply and repair or change automatic drain.
8	Air Receiver	Possible biological growth inside the wet air receiver.	None at this stage	N	None		Biological contamination would be limited by step (3) above and additionally by the active carbon

Process Step	Description	Hazard	Preventative Measure	Significant Hazard (Y/N)	Monitoring Procedure	Corrective Action	Comments
9	Adsorber Vessels	Failure to remove oxygen from the air stream	Continuous oxygen analysis	N OPRP	Continuous oxygen analyser	Plant shutdown. Revert to liquid supply if present	The PSA control system will prevent out of specification product entering the customer pipeline. The out of spec gas will be directed to vent until it again reaches the required purity when it will be re-directed to the customer pipeline
		Failure to carbon monoxide from the air stream	Inlet air specification should be guaranteed by the customer	N	Not required providing PSA is operating within nitrogen purity specification	Recommend alternative separation technology if inlet spec cannot be met	Note: The Carbon Monoxide Time Weighted Average exposure as per Directive 2017/164 is 20 ppm – as compressor feed stock is atmospheric air CO into PSA should be below this level, otherwise there would be a serious operator health and safety issue at the site
		High dew point in nitrogen stream	Inlet air specification should be guaranteed by the operator Continuous moisture analysis	N	Continuous moisture analyser Not required providing PSA is operating within nitrogen purity specification	Plant shutdown. Revert to liquid supply if present Recommend alternative separation technology if inlet spec cannot be met	
		Failure to remove hydrocarbons from the air stream	Traps are fitted with a high level alarm connected to the control system which will shut down the PSA generator Regular maintenance of condensate traps to ensure removal of oily water from the system	N	Generator will display visual and audible alarm to warn customer and dial out via telemetry Preventative maintenance system	Install hydrocarbon analyser	

Process Step	Description	Hazard	Preventative Measure	Significant Hazard (Y/N)	Monitoring Procedure	Corrective Action	Comments
10	Adsorber vessels and product after filter	Carbon dust particles (from CMS) in nitrogen stream	Internal filters and screens are designed to hold CMS in place PSA is operated within limits to prevent movement of CMS which might lead to dusting Product after filter will remove particles down to <1 micron For Mini-PSAs, a sintered after filter is built-in to the CMS columns so an external after filter is not included	N OPRP	Monitor filter differential pressure	Plant shutdown. Revert to liquid supply if present	The PSA control system will prevent out of specification product entering the customer pipeline. The out of spec gas will be directed to vent until it again reaches the required purity when it will be re-directed to the customer pipeline

6.4.2 Example CCPs and OPRP determination

If at any step of the process it had been determined that there is a significant hazard to food safety, this phase of the process would determine whether it is necessary to establish surveillance or control procedures to prevent the hazard, eliminate it, or reduce it to an acceptable level. If it is determined that it is necessary, the stage would be a critical control point (CCP) or an operational prerequisite (OPRP) for the specific hazard.

Table 3 – Example CCP and OPRP decision tree

Type of hazard	Q1 Is the mitigation procedure specifically designed to eliminate the hazard or reduce it to an acceptable level?	Q2 Is it necessary to establish a critical limit?	Q3 Is an immediate intervention needed?	Output	Suggested monitoring procedures
Bacteria	Y	N	N	OPRP-SOP	Prerequisite programme
Carbon molecular sieve	Y	N	N	OPRP-SOP	Prerequisite programme
High oxygen-reduced shelf life of food	Y	N	N	OPRP	Online analysis – Shift to back-up nitrogen
High moisture – reduced shelf life of food	Y	N	N	OPRP	Online analysis – Shift to back-up nitrogen
Contamination from maintenance activities	Y	N	N	OPRP-SOP	Prerequisite programmes

6.5 Operational prerequisite programmes

Food safety risks are primarily managed by prerequisite programmes applied before the installation and during the periodic maintenance procedures and schedules, including for example:

- inspection of generator condition and operating parameters such as temperature and differential pressures across key components such as filters, if the differential pressure is too low or too high, the filter element shall be changed;
- visual inspection and exchange of oil filters, carbon beds, dust filters etc.;
- inspection and exchange of microbiological filter, if installed;
- instrument calibration; and
- reassessment with the food operator of any modification in the adjacent environment that could lead to contamination of the atmospheric air supply to the site generator, for example a new exhaust outlet.

7 Liquid and gas backup system

On-site nitrogen generators should be installed with a liquid or gaseous back-up system that are intended to maintain a supply of nitrogen to the user's process in the event of:

- generator downtime due to maintenance or failure;
- detection of off-specification generation, typically high oxygen or moisture; and

- high peak demand.

The back-up system shall comply with EIGA Doc 125 and EIGA Doc 126 [5, 6].

Where, as part of the manufacturing process, impurities come in contact with the process gas, the level of the impurities is monitored as defined in the Good Manufacturing Practices (GMP) guide using validated methods. This ensures that the introduction of contamination into the onsite nitrogen production is limited.

For cryogenic onsite equipment, refer to EIGA Doc 125, *Guide to the Use of Gases in Foods* [5].

8 Traceability and batch definition for onsite nitrogen production

Any raw material in the food chain requires traceability in compliance with Regulation (EC) 178/2002 Article 18 [3]. Since onsite generators are usually supplying only one gas to only one end user, a set of control parameters and quality critical criteria shall be agreed with the end user and recorded. Data may be made available online to the end user or vice versa.

The production of nitrogen can be divided into batches, according to a period of production defined by the operator (for example 1 hour). A batch definition may be not necessary, if a continuous recording with defined intervals of analysis is available.

The batch identifier for the nitrogen produced by the onsite generator is the period of time comprising continuous and uninterrupted nitrogen production with a minimum and maximum duration fixed by the operator.

The food business operator shall define the parameters that are to be recorded and traced during each production batch, including but not limited to:

- date;
- time;
- oxygen concentration / other specified parameters (for example moisture); and
- process online / offline status / backup online (if present).

9 Quality_verification

The food business operator shall review the validity of the food safety risk assessment / HACCP for the nitrogen generation system periodically. If ISO 22000 / FSSC 22000 certification is in place, then additional periodic reviews, for example food defence, should be put in place [8, 9].

10 Equipment maintenance

10.1 General considerations

A rigorous preventive maintenance programme is a crucial element of any food safety programme designed to maintain the nitrogen food gas compliance. The generator maintenance programme shall include periodic functional checks of the plant shut-down system to ensure that it performs as required in an emergency. The operation of pressure and temperature gauges, pressure regulators, automatic valves, and controllers shall be checked, and purity analysers shall be calibrated.

During the maintenance of the nitrogen generator, it is possible to use nitrogen from the back-up system where food gas quality is present in the cryogenic tank or in cylinders or bundles [1].

Procedures shall be in place for maintenance on equipment where food gas nitrogen is produced in order to avoid contamination of the system during maintenance operations, including inspection before and after completing maintenance.

Maintenance personnel shall be familiar with all safety regulations and be made aware of all potential hazards.

One of the most significant personal hazards associated with pressure swing adsorption nitrogen generators is exposure to hazardous atmospheres inside the adsorber vessels while loading, removing, or inspecting the sieve material or its supports. Even when the generator is not in service, the sieve material can adsorb or desorb oxygen due to changes in the ambient temperature.

Nitrogen generators are often enclosed in cabinets that can be considered confined spaces. Such spaces can become oxygen deficient, see EIGA Doc 44, *Hazards of inert gases and oxygen depletion* [16].

10.2 Management

With regard to procedures relating to the hazard analysis and critical control points (HACCP), factors affecting food hygiene shall be identified and suitably controlled during the maintenance. These factors are broadly associated with the people working within the workplace and the materials which can be in contact with the food gas quality nitrogen during the maintenance operation.

The following is a non-exhaustive list of pre-requisite factors that shall be considered and controlled in order to manage the food safety risk:

- For maintenance, a check list of control points and procedures shall be used.
- Materials and spare parts in contact with the produced food gas quality nitrogen shall be suitable for use in food applications.
- Washing and cleaning products for the components in contact with the produced food gas quality nitrogen shall be suitable for food (potable water, ethanol, etc.).
- Hygiene of the operator and protection of the equipment in the area where food gas quality nitrogen is produced.
- Specific food safety training for the operator involved in the maintenance;
- Oil change frequencies and oil control parameters shall comply with the operation manual of the on-site nitrogen generator.
- Periodic calibration of the installed analysis instruments.
- Periodic maintenance of the dust filter(s) of carbon molecular sieves.

Upon completion of the maintenance, the purity of the nitrogen flow shall be checked to confirm it meets the product specification.

11 References

Unless otherwise specified, the latest edition shall apply.

- [1] Regulation 2012/231/EC *laying down specific purity criteria on food additives other than colours and sweeteners*, www.europa.eu.
- [2] Regulation (EC) No 1333/2008 *on food additives*, www.europa.eu.
- [3] Regulation (EC) No 178/2002 *laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety Directive 1333/2008/EC*, www.europa.eu.

- [4] ISO 21469, *Safety of machinery. Lubricants with incidental product contact. Hygiene Requirements*, www.iso.org.
- [5] EIGA Doc 125, *Guide to the Use of Gases in Foods*, www.eiga.eu.
- [6] EIGA Doc 126, *Minimum Specifications for Food Gas Applications*, www.eiga.eu.
- [7] EIGA Doc 149, *Safe Installation and Operation of PSA and Membrane Oxygen and Nitrogen Generators*, www.eiga.eu.
- [8] ISO 22000, *Food Safety Management*, www.iso.org.
- [9] FSSC 22000, *Food Safety Management Systems*, www.fssc22000.com.
- [10] Regulation (EC) No 1935/2004 *on materials and articles intended to come into contact with food*, www.europa.eu.
- [11] Regulation (EC) 2023/2006 *on good manufacturing practice for materials and articles intended to come into contact with food*, www.europa.eu.
- [12] Regulation (EU) No 10/2011 *on plastic materials and articles intended to come into contact with food*, www.europa.eu.
- [13] *Metals and alloys practical guide for manufacturers and regulators* 2013 edition www.edqm.eu.
- [14] Regulation (EC) No 1881/2006 *setting maximum levels for certain contaminants in foodstuffs*, www.europa.eu.
- [15] Directive 2001/22/EC *laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs*, www.europa.eu.
- [16] EIGA Doc 44, *Hazards of Inert Gases and Oxygen Depletion*, www.eiga.eu.