# Digestate Compliance & PAS 110 Quality Manual

### **Document Control**

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## 1.0 Introduction

### 1.1 Purpose

The primary purpose of this Quality Manual is to define the management system, procedures, and controls implemented by [ORG\_LEGAL\_NAME] to ensure the consistent production of safe, high-quality digestate. Adherence to this manual ensures that the final product meets the specification required by BSI PAS 110:2014, thereby achieving “end-of-waste” status under the Biofertiliser Certification Scheme.

### 1.2 Scope

This manual applies to all stages of the anaerobic digestion (AD) process at the [SITE\_ADDRESS] facility, including: - Sourcing, reception, and control of input materials. - Management and validation of the AD process, including pasteurisation. - Sampling, testing, and quality verification of the final digestate. - Storage, labelling, and dispatch of the certified biofertiliser product. - Management of non-conformances and implementation of corrective actions.

### 1.3 Regulatory Basis

This Quality Management System (QMS) is designed to comply with the following key standards and regulations: - **BSI PAS 110:2014:** Specification for whole digestate, separated liquor and separated fibre. - **The Biofertiliser Certification Scheme (BCS):** The certification body’s scheme rules. - **Animal By-Products (Enforcement) (England) Regulations 2013** (and equivalents): Where ABP materials are used as feedstock. - **Environmental Permitting (England and Wales) Regulations 2016:** As per the site’s environmental permit conditions.

## 2.0 Quality Management System (QMS)

### 2.1 Quality Policy

[ORG\_LEGAL\_NAME] is committed to producing a high-quality, safe, and reliable biofertiliser product through the responsible management of biodegradable materials. We will operate a robust Quality Management System that meets or exceeds the requirements of PAS 110:2014, ensuring full regulatory compliance, environmental protection, and customer satisfaction. We are dedicated to continuous improvement in our processes and product quality.

### 2.2 Roles and Responsibilities

Overall responsibility for the implementation of this QMS rests with senior management. Key roles are defined as follows:

| Role | Name/Title | Key Responsibilities |
| --- | --- | --- |
| **Accountable Director** | [DIRECTOR\_NAME] | Ultimate responsibility for QMS effectiveness and resource allocation. |
| **Competent Person** | [COMPETENT\_PERSON\_NAME/TITLE] | Manages the QMS, oversees HACCP plan, liaises with certification body, approves batch releases, and ensures staff are trained. |
| **Operations Staff** | All Site Operatives | Adherence to procedures, monitoring of CCPs, accurate record-keeping, and reporting of non-conformances. |

### 2.3 Document and Record Control

All documents and records related to this QMS shall be controlled to ensure they are accurate, current, and accessible. - **Document Control:** All procedures, forms, and this manual are subject to version control. The Competent Person must approve any changes. - **Record Keeping:** All operational records, including input logs, process monitoring data, test results, and dispatch notes, shall be retained for a minimum of **5 years** and made available for audit.

## 3.0 Feedstock and Input Material Control (CCP 1)

This constitutes **Critical Control Point 1 (CCP 1)** of the site’s Hazard Analysis and Critical Control Points (HACCP) plan. The objective is to prevent unsuitable or contaminated materials from entering the AD process.

### 3.1 Permitted Input Materials

Only source-segregated, biodegradable materials from approved sources are permitted. A master list of approved input materials, specifying their source, EWC code, and any specific handling requirements (e.g., ABP category), is maintained in the document [INPUT\_MATERIAL\_REGISTER\_ID].

### 3.2 Input Material Acceptance Procedure

1. **Pre-Arrival:** All deliveries must be pre-booked and accompanied by a valid Waste Transfer Note or, for Animal By-Products (ABPs), a Commercial Document.
2. **Arrival & Inspection:** Upon arrival, each load is visually inspected by a trained operative for evidence of physical contamination (e.g., plastic, metal, glass) or non-permitted materials.
3. **Documentation Check:** The accompanying paperwork is checked against the delivery and verified for accuracy.
4. **Weighing & Logging:** The load is weighed, and all details (Source, Driver, Vehicle Reg, Material Type, EWC Code, Weight, Date/Time) are recorded in the site’s input log.

### 3.3 Handling Non-Conforming Inputs

Any load that fails inspection (e.g., excessive contamination, incorrect paperwork, unapproved material) will be **rejected**. - The load is quarantined in a designated rejection bay. - The supplier is immediately notified. - A Non-Conformance Report (NCR) is raised. - The load is re-loaded and returned to the supplier, or arrangements are made for disposal via an approved waste management contractor.

## 4.0 Process Control & Validation (CCP 2)

This section details the critical control points within the AD process designed to eliminate pathogens and ensure digestate stability.

### 4.1 Process Overview

The AD process at this facility follows a validated flow: Feedstock Reception -> Maceration/Mixing -> Pasteurisation -> Main Digestion -> Digestate Storage -> Separation (if applicable) -> Dispatch A full process flow diagram is maintained in the site’s HACCP plan documentation ([HACCP\_PLAN\_ID]).

### 4.2 Critical Control Point 2: Pasteurisation & Digestion

To ensure effective pathogen kill, the process must adhere to strictly monitored time and temperature profiles. This constitutes **Critical Control Point 2 (CCP 2)**.

| Parameter | Critical Limit | Monitoring Procedure | Corrective Action |
| --- | --- | --- | --- |
| **Pasteurisation Temperature** | Minimum 70°C | Continuous automated monitoring with calibrated probes. Manual verification once per shift. | If temperature drops below 70°C, the timer resets. The batch must be held for the full duration once the temperature is restored. If the issue persists, the batch is quarantined for investigation. |
| **Pasteurisation Time** | Minimum 60 minutes (uninterrupted) | Automated timer linked to the temperature probe. Recorded for each batch. | If the holding time is interrupted, the timer must be reset. The full 60-minute duration must be completed. |
| **Digestion Retention Time** | Minimum [XX] days (e.g., 25 days) | Calculated based on feed rates and digester volume. Verified weekly. | If calculations show retention time is below the minimum, feed rates must be reduced immediately. |

*Note: The specific time/temperature regime must align with ABP regulations if applicable (e.g., 12mm maximum particle size pre-pasteurisation).*

## 5.0 Digestate Sampling, Testing & Conformance (CCP 3)

Verification of the final product quality against PAS 110 specifications constitutes **Critical Control Point 3 (CCP 3)**.

### 5.1 Sampling Plan

* **Frequency:** A representative sample shall be taken from each defined digestate batch. A “batch” is defined as a quantity of digestate not exceeding [BATCH\_SIZE\_TONNES] tonnes.
* **Methodology:** Sampling will be conducted according to the procedure defined in [SAMPLING\_PROCEDURE\_ID], ensuring a composite sample is taken from multiple points.
* **Laboratory:** All samples will be sent to a laboratory accredited by the certification body for all required tests under PAS 110.

### 5.2 Minimum Quality Requirements

Each batch of digestate must be tested and proven to meet the following limits before it can be released as a PAS 110 certified product.

| Parameter Category | Test Parameter | Maximum Limit (mg/kg dry solids unless stated) |
| --- | --- | --- |
| **Potentially Toxic Elements (PTEs)** | Cadmium (Cd) | 1.5 |
|  | Chromium (Cr) | 100 (Total) |
|  | Copper (Cu) | 200 |
|  | Lead (Pb) | 200 |
|  | Mercury (Hg) | 1 |
|  | Nickel (Ni) | 50 |
|  | Zinc (Zn) | 400 |
| **Physical Contaminants** | Glass, metal, plastic > 2mm | 0.12% by dry weight |
|  | Plastic film or fragments >5mm & <50mm (any dimension) | 80 fragments per litre of separated fibre |
| **Pathogens** | *Escherichia coli* | < 1000 cfu/g (fresh weight) |
|  | *Salmonella spp.* | Not detected in 50g (fresh weight) |
| **Stability** | Residual Biogas Potential (RBP) | < 0.45 litres of biogas per g of volatile solids |

### 5.3 Test Failure and Non-Conformance

If any test result for a batch exceeds the PAS 110 limits, the entire batch is deemed **non-compliant**. - The batch must be clearly labelled as “NON-CONFORMING DIGESTATE - NOT FOR SALE” and held in quarantine. - It cannot be sold or supplied as a PAS 110 product. - A full CAPA procedure (see Section 6.0) must be initiated. - The material must be either re-processed through the AD system or disposed of as a waste material in accordance with environmental regulations.

## 6.0 Non-Conformance, Corrective and Preventive Action (CAPA) Procedure

### 6.1 Identification of Non-Conformance

A non-conformance is any deviation from the requirements of the QMS or PAS 110, including: - Failure of a CCP (e.g., incorrect temperature, failed lab test). - Rejected input material. - Customer complaint related to product quality. - Breach of a documented procedure.

All non-conformances must be recorded on a Non-Conformance Report (NCR) form ([NCR\_FORM\_ID]).

### 6.2 Investigation and Root Cause Analysis

The Competent Person is responsible for investigating every NCR to determine the root cause of the issue. The investigation will consider all contributing factors, including equipment, materials, personnel, and procedures.

### 6.3 Corrective and Preventive Actions

* **Corrective Action:** Immediate steps taken to address the non-conforming product or situation (e.g., quarantining a batch, repairing equipment).
* **Preventive Action:** Long-term changes made to systems or procedures to prevent the non-conformance from recurring (e.g., updating a procedure, providing additional training, installing new monitoring equipment).

All actions taken must be documented on the NCR form and signed off by the Competent Person upon verification of their effectiveness.

## 7.0 Storage, Dispatch, and Labelling

### 7.1 Digestate Storage

* Certified, compliant digestate must be stored in designated, clean tanks or bays, physically separate from any non-conforming batches or raw input materials.
* Storage areas must be designed and managed to prevent contamination from external sources (e.g., pests, wind-blown litter, run-off).

### 7.2 Labelling Requirements

All storage containers (e.g., tanks, bays) and documents relating to a batch of certified digestate must be clearly labelled.

**Example Storage Bay Label:**

------------------------------------------------------------  
\*\*PAS 110 CERTIFIED BIOFERTILISER\*\*  
  
\*\*Product:\*\* Whole Digestate  
\*\*Batch ID:\*\* 20250828-001  
\*\*Status:\*\* PASSED - AWAITING DISPATCH  
\*\*Producer:\*\* [ORG\_LEGAL\_NAME], [SITE\_ADDRESS]  
\*\*Certification:\*\* [Certification Body Name] - [CERT-XXXXX]  
  
\*Store in a designated area away from contaminants.  
Refer to Buyer Information Sheet for application rates.\*  
------------------------------------------------------------

### 7.3 Dispatch Procedure

1. **Batch Release:** No digestate may be dispatched until a **Digestate Batch Release Form** (see Template 8.1) has been completed and signed by the Competent Person, confirming all PAS 110 criteria have been met.
2. **Documentation:** Every consignment leaving the site must be accompanied by:
   * A dispatch note/delivery ticket.
   * A **Digestate Buyer Information Sheet** (see Template 8.2).
3. **Record Keeping:** A record of all dispatches, including customer details, quantity, and batch ID, must be maintained.

## 8.0 Document Templates

### 8.1 Template: Digestate Batch Release Form

| **BATCH RELEASE FORM** | Document ID: [BRF-FORM-ID] |
| --- | --- |
| **Batch ID:** | [YYYYMMDD-BN] |
| **Product Type:** | Whole Digestate / Separated Liquor / Separated Fibre |

**Compliance Checklist (To be completed by Competent Person)**

| Checkpoint | Criteria | Verification (Initial/Date) |
| --- | --- | --- |
| **CCP 1: Inputs** | All inputs for this batch conformed to the approved materials list. |  |
| **CCP 2: Process** | Pasteurisation records show time/temp met critical limits (>70°C for >60 min). |  |
| **CCP 3: Testing** | Lab report [Report ID] received and all parameters are within PAS 110 limits. |  |
| **Documentation** | All required process and input logs are complete and accurate for this batch. |  |

**Release Authorisation**

I hereby confirm that the batch referenced above has been produced and tested in full compliance with the PAS 110 Quality Manual and meets all requirements for release as a certified biofertiliser.

* **Signed (Competent Person):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* **Name:** [COMPETENT\_PERSON\_NAME]
* **Date:** [Date]

### 8.2 Template: Digestate Buyer Information Sheet

#### **Biofertiliser Product Information**

* **Product Name:** [Product Name, e.g., 'Eco-Gro Whole Digestate']
* **Producer:** [ORG\_LEGAL\_NAME], [SITE\_ADDRESS], Tel: [Phone Number]
* **Certification:** Produced in accordance with BSI PAS 110 and certified under the Biofertiliser Certification Scheme (Cert No: [CERT-XXXXX]).
* **Product Type:** Whole Digestate / Separated Liquor / Separated Fibre
* **Batch ID:** [YYYYMMDD-BN]

#### **1. Typical Nutrient Content (as supplied)**

*Note: This is a typical analysis. For specific batch analysis, please contact the producer.*

| Nutrient | Unit | Typical Value |
| --- | --- | --- |
| Total Nitrogen (N) | kg/t | [Value] |
| Available Nitrogen (NH4-N) | kg/t | [Value] |
| Total Phosphorus (P2O5) | kg/t | [Value] |
| Total Potassium (K2O) | kg/t | [Value] |
| Dry Matter | % | [Value] |
| pH |  | [Value] |

#### **2. Application and Spreading Guidelines**

* This biofertiliser is a valuable source of organic matter and nutrients. Application rates should be based on soil analysis and crop nutrient requirements.
* Do not apply where there is a risk of run-off to watercourses. Adhere to all NVZ rules if applicable.
* For best results, incorporate into the soil shortly after application to minimise nitrogen loss.
* Consult a FACTS qualified advisor for detailed application planning.

#### **3. Storage and Safety Information**

* **Storage:** Store on a firm, impermeable surface away from watercourses, boreholes, and wells. Prevent run-off from the storage area.
* **Health & Safety:** While this product is certified as safe, we recommend standard agricultural hygiene practices. Avoid ingestion and wash hands after handling. When spreading, consider wind direction to minimise spray drift. Keep livestock off treated land for at least 21 days.
* **Waste Status:** This material has been produced to the PAS 110 standard and is no longer considered a waste when used as a biofertiliser. If you intend to dispose of it, it must be handled as a controlled waste.

## 9.0 Sources

This manual was produced with reference to the following foundational research and compliance documents: - biogas operations compliance document outline.md - cross-border waste shipment Annex VII documentation.md - DSEAR regulations biogas facilities risk assessment UK.md - EN 14214 biodiesel fuel standard.md - EU RED II RED III biodiesel UCO.md - EWC LoW codes waste classification.md - Health & Safety at Work Act HSWA requirements UK.md - ISCC certification biodiesel UCO.md - PAS 110 digestate quality standards UK.md - REACH CLP regulations biogas biodiesel chemicals.md - UK biogas Animal By-Products ABP feedstock regulations.md - UK biogas energy offtake compliance CHP G99 GSMR.md - UK biogas environmental permitting Environment Agency NRW SEPA.md - UK Duty of Care waste management.md - UK EU biogas food waste anaerobic digestion regulations.md - UK EU biodiesel Used Cooking Oil UCO regulations.md - UK EU waste management legal frameworks.md - UK RTFO biodiesel UCO.md - ADR transport UCO biodiesel regulations.md