Flow

QMS-PRO-005 · QUALITY MANAGEMENT SYSTEM

DRAFT · PENDING APPROVAL

Change Management / Control Procedure

(Management of Change)

9 sections · 40 requirements · 8 record types · 10 roles · 19 pages

DOCUMENT RECORD

DOCUMENT NO	QMS-PRO-005
TYPE	Procedure
REVISION	—
PROCESS OWNER	The Technical & Process Engineering Manager
APPROVER	The General Manager
OWNING STANDARD	ISO 9001
EFFECTIVE DATE	15/08/2026
NEXT REVIEW	15/08/2028

HOW THIS WAS ASSEMBLED — of 9 control values, 5 read from the source, 3 computed, 1 not stated (revision).

7 UNFILLED PLACEHOLDERS

[LIMS] [QMS platform] [LMS] [ERP] [CMMS] [DCS / Historian] [CRM]

INSIDE

1 Purpose

Nothing at this plant breaks quality faster than a change that nobody assessed. A propane cargo from a new loading port with a different sulphur profile, an antioxidant substituted because Trask was short, a control loop left in manual after a maintenance job, a specification limit edited in [LIMS] by someone with the access to do it — each of those is a two-minute decision that can cost a campaign, a customer approval or a food-contact claim. Every one of them has an obvious owner at the moment it is made and no owner three weeks later when the complaint arrives.

This procedure is the plant's Management of Change process. It states what has to go through it, how the impact of a change is scored, who may approve at each level, what has to be finished before the change is allowed to go live, how a temporary change expires, and how the plant proves afterwards that the change did what it was supposed to do. It applies to permanent and temporary changes alike, to changes made in the office and to changes made on shift at three in the morning.

2 Scope

Applies at the complex and the bonded terminal, to every change that could affect product conformity, the certificate the plant issues, a customer requirement, a regulatory obligation on the product, or the ability of the quality management system to do what it is supposed to do. That includes changes to feedstock, catalyst, additive packages, grade recipes, process conditions, equipment, control systems, test methods, specifications, packaging and labelling, suppliers, procedures, records, business systems and organizational responsibilities.

Two things are explicitly outside. Grade changeovers, campaign sequencing and routine set-point moves inside an approved operating envelope are normal operation and run under **QMS-PRO-015**, not through this procedure — putting them here would bury the changes that matter. Process safety, environmental and occupational health changes are managed under the site's separate systems; where a change appears in both, the rule at **QMS-MAN-001 Sec. 4.2.3** applies and this procedure will not approve it until the HSE Manager has confirmed the position from that side.

3 Definitions

Change record

the entry raised in [QMS platform] and registered in **QMS-LOG-005** that carries a change from proposal to closure. One change, one record; a record is not re-used for a second change.

Temporary change

a change adopted for a stated period with a stated expiry date, after which the previous condition returns automatically. A change with no expiry date is a permanent change and is assessed as one.

Pre-startup review (PSR)

the gate at which named roles confirm, before the change is allowed to operate, that everything the change needed has actually been done. The PSR is a signature against named items, not a meeting.

Change envelope

the range within which a Shift Superintendent may act on shift without a prior change record: substitution of a like-for-like spare from the approved spares list, a control loop placed in manual with the reason logged, or a rate move inside the approved operating envelope. Anything outside the envelope waits for a change record.

Impact level

Low, Medium or High, produced by the scoring at **Sec. 4.2.** The level decides who reviews, who approves, how long the lead time is and when effectiveness is read.

4 Requirements

THIS DOCUMENT · BASELINE 40

4.1 What has to go through this procedure

4.1.1 · BASELINE · Change record

A change record is raised before any of the following takes effect. The list is the operating definition of a change at this site and is not open to interpretation on shift:

4.1.2 · BASELINE · Change record

Anyone may raise a change record. The Change Initiator states in **[QMS platform]**: what is changing and from what to what; why; whether it is permanent or temporary and, if temporary, the proposed expiry date; which units, grades, customers and documents they believe are affected; and whether the change is already in place. A change already in place is raised the same day it is discovered and is assessed retrospectively under **Sec. 4.8.4.**

4.1.3 · BASELINE · → QMS-LOG-005 · Change Owner

The Technical & Process Engineering Manager screens every new record within **3** working days and does three things:

- confirms or corrects the category
- names the Change Owner, who is the manager of the process most affected
- and decides whether the record is a change at all.

A record rejected as normal operation is closed with the reason visible in **QMS-LOG-005**, so that the boundary between operation and change is a written decision rather than a habit.

4.2 Assessing the impact

4.2.1
BASELINE
Change Owner
The Laboratory Manager

The Change Owner completes the impact assessment within **5** working days of screening, scoring the change on six dimensions from **1** to **5**, scores of **2** and **4** sitting between the anchors described. The assessment is made with the people who will have to live with the change — for a recipe change that means the Laboratory Manager and a Shift Superintendent, not only the process engineer who proposed it.

4.2.2
BASELINE
Impact level
Change Owner

Low 6–10
Medium 11–17
High 18–30

The six scores are added. The total gives the impact level: Low **6** to **10**, Medium **11** to **17**, High **18** to **30**. Four rules override the total upward and are applied by the Change Owner without discretion:

- any single dimension scored **5** makes the change High
- any change touching a food-contact grade is at least Medium
- any change requiring customer notification or approval is at least Medium
- and any change to the dehydrogenation catalyst or to a sole-source critical input is at least Medium.

No rule moves a level downward.

4.2.3
BASELINE
The Quality Manager

The assessment records, against each dimension, the reason for the score in one line. A score without a reason is returned by the Quality Manager, who reviews every completed assessment before it goes to review, in full where it is scored Medium or High, and who may raise a level but not lower one.

4.2.4
BASELINE

The assessment names the risk entries in **QMS-REG-005** and the opportunity entries in **QMS-REG-024** the change bears on, and states whether the change creates a new risk. A change assessed High is itself a trigger for the risk review under **QMS-PRO-004 Sec. 4.2.1** and the Change Owner notifies the Quality Manager on the day the level is set.

→ QMS-REG-005
→ QMS-REG-024
→ QMS-PRO-004
Change Owner

4.3 Review and approval

4.3.1
BASELINE
Change Owner

A Low change is reviewed and approved by the Change Owner together with a Process Engineer nominated by the Technical & Process Engineering Manager. Both signatures are recorded in [QMS platform] with the date. A Low change is not implemented sooner than **5** working days after approval, so that document and training work at **Sec. 4.5** has time to be done.

4.3 CONTINUES → 4.3.2 · p. 5

4.3.2

BASELINE

Change Owner

The Quality Manager

The Laboratory Manager

A Medium change is reviewed by the Change Review Panel: the Technical & Process Engineering Manager in the chair, the Quality Manager, and the Change Owner, joined by the Laboratory Manager where product testing, specification or certification is affected, the Maintenance & Reliability Manager where equipment or calibration is affected, the Supply Chain Manager where a supplier or material is affected, and the Commercial & Customer Service Manager where a customer requirement is affected. The panel meets weekly and out of cycle when a change cannot wait. It is quorate with the chair, the Quality Manager and the Change Owner. Lead time from approval to implementation is **10** working days.

4.3.3

BASELINE

The General Manager

A High change is reviewed by the same panel and approved by the General Manager on the panel's recommendation. Lead time from approval to implementation is **20** working days. The panel's recommendation states what it considered, what it required to be done before startup, and any dissent, with the dissenting member named.

4.3.4

BASELINE

→ QMS-LOG-005

The Quality Manager

The General Manager

The Quality Manager may withhold approval of any change on product-conformity, certification or regulatory grounds at any level. A withheld change goes to the General Manager, who either sustains the objection or approves the change over it and records the General Manager's reason in **QMS-LOG-005**. This is the only route by which a quality objection is overridden, and it leaves a name against it.

4.3.5

BASELINE

Review at every level considers, and the record shows, the same seven things:

- what the change is for and what else it will do
- what it does to the quality management system as a whole — which processes, documents, records and authorities move
- whether the resources and information needed are actually available
- which responsibilities and authorities are re-allocated by it
- who has to be told and when
- how its effectiveness will be measured and when that will be read
- and when the results of the change will be reviewed and by whom.

A review record silent on any of the seven is returned by the chair.

4.3.6

BASELINE

The Quality Manager

The General Manager

A change needed to contain a nonconformity or to protect a customer delivery may be approved on an expedited route by the Quality Manager together with the affected Process Owner, with the General Manager informed the same day. The full assessment, review and record are completed within **5** working days of implementation. Expedited approvals are listed by the Quality Manager at each Business Quality Review; more than four in a quarter is itself reported as a system weakness.

4.4 Temporary changes

4.4.1
BASELINE
Change record
Temporary change

A temporary change carries an expiry date on the day it is approved, and the expiry date is never later than **90** calendar days from implementation. The change record shows the condition that will exist at expiry — normally reversion to the previous state — and who will carry out the reversion.

4.4.2
BASELINE
Temporary change
The Quality Manager

A temporary change is approved at the level its impact score gives it, with two additions: no temporary change is made to a food-contact grade, to a certificate or label content, or to a release criterion without the Quality Manager's signature, whatever its score; and no temporary change to catalyst, feedstock or additive package is approved without the Technical & Process Engineering Manager's signature.

4.4.3
BASELINE
→ QMS-LOG-005
Change record
Temporary change
The Quality Manager

The Quality Manager reviews the temporary change list in **QMS-LOG-005** at the monthly quality performance meeting. Every entry within **20** working days of expiry is named, with its owner and its intended end state. A temporary change may be extended once, by up to **30** calendar days and never past the **90**-day limit at **Sec. 4.4.1**, and only by the General Manager, who records the reason; a change already carrying a **90**-day expiry cannot be extended. A second extension is not available: the change is made permanent through a new change record or it reverts.

4.4.4
BASELINE
→ QMS-PRO-020
Temporary change
Change Owner

On the expiry date the Change Owner reverts the change and records the reversion in [QMS platform], and the Shift Superintendent on tour confirms the plant condition matches the reverted state. Where reversion has not happened by the end of the expiry day, the Shift Superintendent quarantines any product made after that point under **QMS-PRO-020** and calls the on-call Quality Manager. An expired temporary change left running is a nonconformity against the Change Owner's function.

4.4.5
BASELINE
→ QMS-PRO-023
Temporary change

A temporary change raised twice on the same subject within twelve months is not approved a third time as temporary. The Technical & Process Engineering Manager takes it to the Change Review Panel as a permanent change or as a problem to be solved under **QMS-PRO-023**; repeat temporary changes are the plant's most reliable indicator of a control that does not work.

4.5 Preparing the change

4.5.1
BASELINE
→ QMS-PRO-007
Change record
Change Owner

Before implementation the Change Owner completes the preparation list held in the change record, and each item names the person who did it and the date. Documents affected are revised and issued through **QMS-PRO-007** with superseded copies withdrawn from the control rooms, the laboratory, the gantry, the bagging hall and the terminal. Where the change alters a work instruction used on shift, the revised instruction is issued before the training at **Sec. 4.5.2** is delivered, not after.

4.5.2
BASELINE
→ QMS-MTX-004
Change record
Change Owner
The HR & Competence Manager

Training and authorisation are treated as part of the change and not as a follow-up. The Change Owner identifies with the HR & Competence Manager every role affected, and the change record states which of three treatments each role gets:

- a shift briefing at handover
- a training session with a competence check
- or a re-authorisation in [LMS] against **QMS-MTX-004**.

A change that alters how a task is performed is not started until every person who performs that task on all four shifts has been covered — including the crew on days off, who are covered on their first tour back and are barred from the task until then.

4.5.3
BASELINE

System and master data changes are made and verified before startup:

- specification limits, methods and certificate templates in [LIMS]
- release blocks, material masters and despatch rules in [ERP]
- preventive maintenance content and equipment master data in [CMMS].

Verification means a test entry or a dry run against the changed configuration, recorded by the person who made the change and checked by a second person from the affected function.

4.5.4
BASELINE
→ QMS-LOG-013
Change record

Where the assessment showed a customer is affected, the Commercial & Customer Service Manager notifies the customer before implementation, in writing, stating what is changing, when, and what it means for the product they receive. Where the customer's approval is required by contract — as it is for Meridian Films on recipe and additive changes to their film grades — the written approval is attached to the change record and the change is not implemented without it. Notifications and approvals are logged in **QMS-LOG-013**.

4.5.5
BASELINE
→ QMS-MAN-001
Change Owner

Before approval, where the assessment scored **3** or more on the process safety and asset integrity dimension, the Change Owner obtains the HSE Manager's written confirmation in [QMS platform] that the PSM review is complete or not required, per **QMS-MAN-001 Sec. 4.2.3.** The change is not approved without it.

4.5 CONTINUES → 4.5.6 · p. 8

4.5.6
BASELINE
→ QMS-LOG-002
Change Owner

The Change Owner states in the record how the change will be communicated and to whom: the four shift teams, the laboratory, maintenance, supply chain, the terminal, contracted personnel on site, and named external providers and customers. Communication is by shift handover for people on tour, by [QMS platform] notification for office-based functions, and in writing for external parties. Delivery is recorded in **QMS-LOG-002**.

4.6 The pre-startup review

4.6.1
BASELINE

No change operates until its pre-startup review is signed. The PSR confirms, item by item:

- documents issued and superseded copies withdrawn
- training and authorisations complete for all four shifts
- system and master data changed and verified
- equipment mechanically complete, calibrated and returned to service in [CMMS]
- the sampling and testing plan for the first production after the change agreed with the laboratory
- customer notification sent or approval received
- HSE confirmation obtained where **Sec. 4.5.5** applies
- and the effectiveness measure and its reading date recorded.

4.6.2
BASELINE
Change Owner
The Quality Manager
The Laboratory Manager
The Operations Manager

The PSR is signed by the Change Owner, the Quality Manager and the Technical & Process Engineering Manager for every Medium and High change, and additionally by the Laboratory Manager where a specification, method or release criterion moved, by the Maintenance & Reliability Manager where equipment moved, and by the Operations Manager where the change is implemented on an operating unit. For a Low change the Change Owner and the nominated Process Engineer sign.

4.6.3
BASELINE
→ QMS-PRO-020
The Quality Manager

An incomplete item on the PSR stops the change. It is not signed subject to conditions and it is not signed retrospectively; where a change has been started without a signed PSR, the Shift Superintendent or the Quality Manager reverts the plant to its pre-change state, quarantines the product made under it, and the event is raised as a nonconformity under **QMS-PRO-020**.

4.6.4
BASELINE
The Laboratory Manager

The Technical & Process Engineering Manager sets the startup conditions in the record for changes affecting production: the first quantity to be made under the change, the sampling frequency during it, who authorises continuation, and what happens if the first result is off specification. For a resin grade change that means the first lot is sampled to a tightened plan, held in a segregated silo and released only by the Laboratory Manager.

4.7 Changes made at the point of production

4.7.1
BASELINE

On shift, a Shift Superintendent may act inside the change envelope defined at **Sec. 3** without a prior change record. Everything outside it — a substitute additive lot, a non-identical spare on quality-critical equipment, an analyser taken out of service, a sampling point moved, a release test omitted — requires a change record before it takes effect, and the on-call Quality Manager is called out where it cannot wait.

Change record
Change envelope

4.7.2
BASELINE
Change record
The Operations Manager

Where a change inside the envelope has been made on shift, the Shift Superintendent records it in the shift log and in [DCS / Historian] at the time, and raises a change record within **24 hours** if the condition is still in place at the end of the tour. A condition carried across three consecutive tours is escalated by the Operations Manager to the Change Review Panel whether or not the Shift Superintendent has raised it.

4.7.3
BASELINE
Change record
The Laboratory Manager

Product made while a production change was in effect is identified as such in [LIMS] and in the lot record, so that the affected lots can be found later from the change record and the change record can be found from the lot. The Laboratory Manager decides the release basis for that product; a lot made under an unapproved change is not released until the change has been assessed and the product tested against the full grade specification.

4.7.4
BASELINE

Every production or service change carries in its record the result of the review, the name of the person who authorised it, and the actions the review required. These three are the minimum evidence retained for every change at every level, and the Internal Audit Lead samples them in each audit of an operating function.

4.8 Verifying that the change worked

4.8.1
BASELINE
Change Owner

The effectiveness measure fixed before approval is read on the date set in the record: **30** calendar days after implementation for a Low change, **60** for Medium, **90** for High. The reading is made by the Change Owner from the system named in the record — [LIMS] results, [CMMS] compliance, [ERP] delivery performance, [CRM] complaints or [DCS / Historian] process data — and never from opinion.

4.8 CONTINUES → 4.8.2 · p. 10

4.8.2

BASELINE

→ QMS-PRO-023

Change record

Change Owner

The post-implementation review records one of three conclusions and the evidence for it:

- the change achieved what it was for and is confirmed
- it partly achieved it, with further action named, owned and dated
- or it did not, in which case the Change Owner either reverts the change through a new change record or raises a corrective action under **QMS-PRO-023**, and the Change Review Panel is told at its next meeting.

4.8.3

BASELINE

→ QMS-REG-007

Change record

The review also asks what the change did that was not intended, using three specific checks:

- nonconformities and complaints attributable to the affected process since implementation
- the objective readings in **QMS-REG-007** the change was expected to move and any it was not
- and whether any document, training record or system field turned out to have been missed at **Sec. 4.5.**

Anything found is closed before the change record is closed.

4.8.4

BASELINE

→ QMS-PRO-020

The Laboratory Manager

A change discovered to have been made without a record — found in audit, in an investigation or at a review — is entered retrospectively by the Technical & Process Engineering Manager on the day it is discovered, assessed as though it were being proposed, and either confirmed or reversed. The event is raised as a nonconformity under **QMS-PRO-020** against the function that made it, and the product made under it is assessed for release status by the Laboratory Manager.

4.8.5

BASELINE

→ QMS-REG-005

→ QMS-REG-024

→ QMS-LOG-005

Change record

A change record is closed by the Quality Manager, not by its owner, or by the General Manager where the Quality Manager is the Change Owner, and only when the preparation list, the PSR, the effectiveness reading and the checks at **Sec. 4.8.3** are all complete and any risk or opportunity entry it touched has been updated in **QMS-REG-005** or **QMS-REG-024**. Closure and its date are recorded in **QMS-LOG-005**.

4.9 Keeping the change process honest

4.9.1 · BASELINE · The Quality Manager

The Quality Manager reports change performance to each Business Quality Review:

- records raised by category and level
- records open past their planned implementation date
- temporary changes approaching expiry
- expired temporary changes still running
- expedited approvals
- retrospective records
- and effectiveness readings overdue by more than **10** working days.

4.9.2 · BASELINE

The Internal Audit Lead audits this procedure at least once per audit year and includes in every functional audit a check that the changes visible on the plant — the documents in use, the set points running, the suppliers delivering — match the change records. A difference between what the plant is doing and what its records say it is doing is raised as a major finding.

4.9.3 · BASELINE · → QMS-PRO-022

Changes are an input to the February planning session and to management review under **QMS-PRO-022**, presented as: what was changed, what it achieved, what had to be reverted, and where the plant is repeatedly changing the same thing. Where the same subject has carried three or more change records in a calendar year, the Technical & Process Engineering Manager brings a root cause statement rather than a fourth change.

CHANGE CATEGORY	EXAMPLES THAT HAVE TO BE RAISED
Feedstock	A new propane supplier or loading port; a cargo outside the accepted quality envelope on purity, sulphur or moisture; a change of term supply arrangement; use of an alternative feed stream
Catalyst	A change of catalyst type or grade from Halvern Catalysts; a change of manufacturing site or batch source; a change to the loading, activation or regeneration method; qualification of an alternative supplier
Additive package	A change of antioxidant, stabiliser, nucleator or process aid; a change of supplier or of Trask Additives' own formulation; a change of dose rate or dosing point; substitution during a shortage
Grade recipe and specification	A change to a grade recipe, to process conditions defining a grade, to a specification limit in [LIMS], to a test method, or to the release criteria in **QMS-WI-009**

CHANGE CATEGORY	EXAMPLES THAT HAVE TO BE RAISED
Equipment and control	Replacement or modification of quality-critical equipment; a change to an on-line analyser, its sample system or its calibration basis; a control loop retuned or re-ranged; a change to silo blending or homogenisation arrangements; a change to bagging or bulk-bag sealing
Packaging and labelling	A change of bag, bulk bag or IBC specification or supplier; a change to labelling, GHS classification text, food-contact declarations or lot marking
Supplier and external provider	A new supplier of a critical input; a change of an existing supplier's manufacturing site or subcontractor; a change of calibration or referee laboratory; a change of haulier for bulk product
Procedure and record	A revision to any controlled procedure, work instruction, inspection plan, form or record that changes what a person does or what is recorded
Business system	A change to **[LIMS]** specification limits, methods or certificate templates; to **[ERP]** release blocks or despatch rules; to **[CMMS]** preventive maintenance content on quality-critical equipment; to **[QMS platform]** workflows
Organization	A change to a role holding a quality authority in **QMS-MAN-003**, to an approval limit in **QMS-MTX-003**, to the shift structure, or to the resourcing of the laboratory or the quality function
Customer requirement	A change to an agreed specification, certificate content, packing or delivery requirement notified by a customer

DIMENSION	SCORE 1	SCORE 3	SCORE 5
D1 — Product conformity	No product property can move; change is outside the product path	A measured property could move within specification; first-lot confirmation needed	A specification-defining property or a release criterion changes; grade identity is affected
D2 — Customer	No customer would notice or need to be told	A customer is told after the fact; no approval needed	A customer approval, re-qualification or contract amendment is needed before implementation
D3 — Regulatory and food contact	No registered obligation touched	A declaration, label or safety document needs re-issue	A food-contact grade, a REACH registration position or a GHS classification is affected

DIMENSION	SCORE 1	SCORE 3	SCORE 5
D4 — Process safety and asset integrity interface	No interface; no HSE involvement	HSE informed; no PSM review required	Process conditions, containment, relief or fired equipment affected; PSM review required per **QMS-MAN-001 Sec. 4.2.3**
D5 — Documents, competence and systems	One document, no training, no system change	Up to three documents, a briefing, one system field	Multiple documents, a competence re-authorisation, or a change to [LIMS], [ERP] or [CMMS] master data
D6 — Reversibility	Reversible within one shift at no cost	Reversible within a week at contained cost	Not practically reversible, or reversal would itself need a change record

5 Responsibilities & Competence

TPE

The Technical & Process Engineering Manager

Owns: This procedure, the screening decision, the Change Review Panel and system integrity through change; May approve: Category and Change Owner at screening; rejection of a record as normal operation; the panel recommendation; Escalates: A High change to the General Manager; a repeat temporary change to the panel; a third record on one subject to management review

COM

Change Owner (manager of the affected process)

Owns: The assessment, the preparation list, the PSR items, implementation and the effectiveness reading; May approve: A Low change with the nominated Process Engineer; the reversion of a temporary change; Escalates: A missed preparation item before startup; a change that did not work, at the next panel

QM

The Quality Manager

Owns: Review of every Medium and High assessment, the PSR signature, closure of every record and change reporting; May approve: Raising an impact level; withholding approval on conformity grounds; expedited approval with the Process Owner; closure; Escalates: A withheld approval to the General Manager; expired temporary changes and overdue effectiveness readings

GM

The General Manager

Owns: Approval of High changes and of the single **30**-day extension; May approve: High changes; overriding a withheld approval, with the General Manager's reason recorded; one extension per temporary change; Escalates: A change the panel cannot make safe, to management review

LM **The Laboratory Manager**

Owns: Testing, specification and release consequences of a change; May approve: The first-lot sampling plan; release basis for product made under a change; Escalates: A lot made under an unapproved change, to the Quality Manager the same day

SS **Shift Superintendents**

Owns: Changes made on shift inside the envelope and the plant condition at reversion; May approve: Action inside the change envelope; quarantine of product made under an expired or unapproved change; Escalates: Anything outside the envelope to the on-call Quality Manager before it takes effect

HCM **The HR & Competence Manager**

Owns: Training and authorisation arising from a change; May approve: The training treatment assigned to each affected role; Escalates: A shift crew not covered before startup, to the Change Owner and the Quality Manager

CCS **The Commercial & Customer Service Manager**

Owns: Customer notification and customer approval on affected changes; May approve: The wording of a customer notification; Escalates: A customer approval refused or delayed, to the Change Review Panel

OM **The Operations Manager**

Owns: The plant condition on the units where a change is implemented; May approve: The PSR signature where the change is implemented on an operating unit; Escalates: A condition carried across three consecutive tours, to the Change Review Panel

MRM **The Maintenance & Reliability Manager**

Owns: Equipment, calibration and return to service through a change; May approve: The PSR signature where equipment moved; Escalates: Equipment not mechanically complete at the PSR, to the Change Owner

6 Records

RECORD	REGISTER ID	RETENTION	LOCATION	OWNER
Change records: proposal, assessment, review, approval, PSR, effectiveness and closure	QMS-LOG-005	Per **QMS-SCH-001**	[QMS platform]	—
Temporary change list with expiry dates, extensions and reversions	QMS-LOG-005	Per **QMS-SCH-001**	[QMS platform]	—
Customer change notifications and customer approvals	QMS-LOG-013	Per **QMS-SCH-001**	[CRM] / [QMS platform]	—
Change communication and shift-handover delivery	QMS-LOG-002	Per **QMS-SCH-001**	[QMS platform]	—

RECORD	REGISTER ID	RETENTION	LOCATION	OWNER
Training, competence checks and re-authorisations arising from changes	QMS-LOG-008 / QMS-REG-013	Per **QMS-SCH-001**	[LMS]	—
Production changes made on shift and the lots made under them	QMS-LOG-009 / lot record in (LIMS)	Per **QMS-SCH-001**	[DCS / Historian] and [LIMS]	—
Risk and opportunity entries updated by a change	QMS-REG-005 / QMS-REG-024	Per **QMS-SCH-001**	[QMS platform]	—
Nonconformities raised for unapproved, unreverted or unrecorded changes	QMS-LOG-027	Per **QMS-SCH-001**	[QMS platform]	—

7 References

QMS-MAN-001

Sec. 4.2.3 — the process safety, environmental and occupational health interface rule applied at **Sec. 4.5.5**.

QMS-MAN-002

Quality Manual **Sec. 4.4.4** and **QMS-MAN-003 Sec. 4.2.6** — why every definition and authority change comes through here.

QMS-PRO-004

Risk and Opportunity — the High-change trigger and the register entries updated before closure.

QMS-PRO-007

Document Control; **QMS-PRO-015** Production and Service Provision; **QMS-PRO-020** Nonconforming Output; **QMS-PRO-023** Corrective Action; **QMS-PRO-021** Internal Audit; **QMS-PRO-022** Management Review.

QMS-PRO-009

External Provision; **QMS-PRO-013** Design and Development; **QMS-WI-009** Release Criteria; **QMS-PLN-006** Training and Development Plan; **QMS-MTX-003** and **QMS-MTX-004**.

QMS-LOG-002, **QMS-LOG-005**, **QMS-LOG-008**, **QMS-LOG-009**, **QMS-LOG-013**, **QMS-LOG-027**; **QMS-REG-005**, **QMS-REG-007**, **QMS-REG-013**, **QMS-REG-024**; **QMS-SCH-001**.

REFERENCES CONTINUES

ISO 9001:2026 is the standard against which this quality management system is written.

8 Requirement Traceability & Compliance Matrix

#		
Atomic Requirement	ISO 9001	BASELINE
Basis	Sec.	
4.1.1	Eleven change categories fixed as the operating definition of a change	BASELINE
6.3	Org.	4.1
4.1.2	Change raised before effect, with from-to, reason, permanence and expiry	BASELINE
6.3 a)	Baseline	4.1
4.1.3	Screening in 3 working days: category, Change Owner, or rejection with reason	BASELINE
6.3	Org.	4.1
4.2.1	Six-dimension impact assessment completed with those affected by the change	BASELINE
6.3 a)	Baseline	4.2
4.2.2	Scored bands with four non-discretionary upward escalation rules	BASELINE
6.3 a)	Org.	4.2
4.2.3	Reason recorded per dimension; QM reviews Medium and High and may raise a level	BASELINE
6.3 a)	Org.	4.2
4.2.4	Risk and opportunity entries named; High change triggers the risk review	BASELINE
6.3 b)	6.1.1	6.1.3 (see PRO-004)
Ref.	4.2	
4.3.1	Low: two-signature approval and 5-working-day lead time	BASELINE
6.3	Org.	4.3
4.3.2	Medium: Change Review Panel with defined membership, quorum and 10-day lead time	BASELINE
6.3	Org.	4.3
4.3.3	High: panel recommendation, GM approval, 20-day lead time, dissent recorded	BASELINE
6.3	Org.	4.3
4.3.4	Quality veto at any level; override only by the GM with the GM's reason recorded	BASELINE
6.3 d)	Org.	4.3

4.3.5
BASELINE

Seven things every review considers: purpose and consequences, system integrity, resources and information, responsibilities and authorities, communication, effectiveness measure, results review

6.3 a)–g) | Baseline | 4.3

4.3.6
BASELINE

Expedited route for containment changes, completed in 5 days and reported quarterly

6.3 | Org. | 4.3

4.4.1
BASELINE

Temporary changes carry an expiry date of no more than 90 days and an end state

6.3 a) | Org. | 4.4

4.4.2
BASELINE

Additional signatures for temporary changes to food-contact, certificates, release criteria, catalyst and feed

8.5.6 | Org. | 4.4

4.4.3
BASELINE

Monthly expiry watch; one extension of up to 30 days by the GM only, within the 90-day limit; no second extension

6.3 c) | d) | Org. | 4.4

4.4.4
BASELINE

Reversion on the expiry day, confirmed on shift; product quarantined if it has not happened

8.5.6 | Org. | 4.4

4.4.5
BASELINE

A third temporary change on one subject goes to the panel or to corrective action

6.3 | Org. | 4.4

4.5.1
BASELINE

Documents revised and issued, superseded copies withdrawn, before training

6.3 b) (see PRO-007) | Ref. | 4.5

4.5.2
BASELINE

Training and re-authorisation completed on all four shifts before startup

6.3 c) (see PLN-006) | Ref. | 4.5

4.5.3
BASELINE

System and master data changed and verified by test entry and second check

6.3 c) | Org. | 4.5

4.5.4
BASELINE

Customer notified before implementation; contractual approval attached where required

6.3 e) / 8.5.6 | Baseline | 4.5

4.5.5
BASELINE

HSE confirmation obtained where the PSM interface dimension scores 3 or more

6.3 b) | Org. | 4.5

4.5.6 BASELINE

Communication plan naming audience, channel and timing; delivery recorded

6.3 e) | Baseline | 4.5

4.6.1 BASELINE

Pre-startup review gate with eight named confirmation items

6.3 / 8.5.6 | Org. | 4.6

4.6.2 BASELINE

PSR signatories fixed by what the change touches

8.5.6 | Org. | 4.6

4.6.3 BASELINE

No conditional or retrospective PSR; unauthorised start reverts and quarantines

8.5.6 | Org. | 4.6

4.6.4 BASELINE

Startup conditions set: first quantity, sampling, continuation authority, off-spec route

8.5.6 | Org. | 4.6

4.7.1 BASELINE

Change envelope defines what a Shift Superintendent may do without a record

8.5.6 | Org. | 4.7

4.7.2 BASELINE

Shift changes logged at the time; record within 24 hours; three-tour escalation

8.5.6 | Org. | 4.7

4.7.3 BASELINE

Product made under a change is identifiable both ways; release basis decided

8.5.6 | Baseline | 4.7

4.7.4 BASELINE

Every change retains review result, authorising person and required actions

8.5.6 | Baseline | 4.7

4.8.1 BASELINE

Effectiveness read at 30, 60 or 90 days by level, from the named system

6.3 f) | Baseline | 4.8

4.8.2 BASELINE

Three-way post-implementation conclusion; failure reverts or raises corrective action

6.3 g) | Baseline | 4.8

4.8.3 BASELINE

Unintended consequences checked against NCRs, objectives and missed preparation items

6.3 g) | Org. | 4.8

4.8.4 BASELINE

Unrecorded changes entered retrospectively, assessed, and raised as nonconformities

8.5.6 | Org. | 4.8

4.8.5 BASELINE

Closure by the Quality Manager only, with registers updated

6.3 g) | Org. | 4.8

4.9.1 BASELINE

Change performance reported quarterly on seven named measures

6.3 Org. 4.9

4.9.2 BASELINE

Audit tests plant condition against change records; mismatch is a major finding

8.5.6 (see PRO-021) Ref. 4.9

4.9.3 BASELINE

Changes reported to planning and management review; three records on one subject force a root cause

6.3 g) (see PRO-022) Ref. 4.9

Coverage summary: **41** atomic requirements — 41 baseline, **0** supplemental. Read from the traceability matrix in the source document.

9 Approval

Prepared by

The Technical & Process Engineering Manager

SIGNATURE _____ DATE _____

Approved by

The General Manager

SIGNATURE _____ DATE _____