



THE RADIOPHARMACEUTICAL OPERATIONS GUIDE

Short half-lives. Complete records. Clear decisions.

From supplier qualification to dispatch and recall

A capability and evaluation guide for PET, SPECT and therapeutic radiopharmaceutical producers, radiopharmacies and research sites that want every run to reach its reviewer as one connected, defensible record.



QUALITY

TRACEABILITY

READINESS

Global edition / October 2026

v5ultimate.com

Diagrams show control concepts, not V5 screenshots. Scope and limits are on the final page.

INSIDE THE GUIDE

One run. Many hands. One record.

Radiopharmaceutical work is a relay against the clock. This guide follows the baton: what each handover needs, what evidence it leaves behind, and where software helps or must stay out of the way.

01 / FRAME

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The rules that apply to you

Regimes, release timing, the day against the clock.

02 / FLOW

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Supplier to finished run

Qualification, goods-in, status, master records, execution, aseptic evidence.

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Readiness, labels, genealogy, transport handover, portals, data integrity and AI.

05 / APPLY

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Evidence map and working tools

Evidence map, four worksheets, a phased roadmap and how to run a fair evaluation.

06 / SOURCES

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What this guide rests on

Linked primary sources with status and scope, plus limits of this guide.

Who it is for. Quality units, production leads, radiopharmacists, QC managers and anyone choosing or reviewing a manufacturing and quality system for radiopharmaceutical work.

How to read it. Every operational page ends with a teal Where V5 fits panel. Everything above that panel is practice and regulation, written to be useful whether or not you ever use V5. Regulatory statements cite numbered primary sources; check the current text for your products and markets before you rely on it.

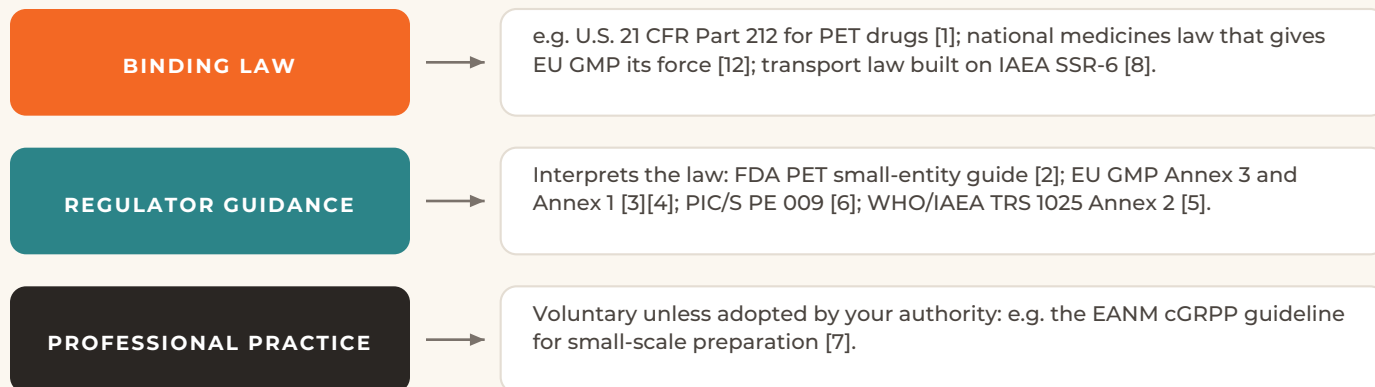
WHERE V5 FITS

V5 records the work your procedures define. It does not calculate activity, decay, dose or transport index, and it never makes a release decision. Those stay with your qualified people and validated methods.

FRAME / 01

Start with what you actually make.

The same tracer can sit under different rules depending on who makes it, where, for whom and under what authorisation. Settle the scope before you design a single record.



Describe the operation

Which radionuclides and products, made by synthesis, generator elution or kit preparation? Commercial manufacture, investigational use or in-house preparation for your own patients? Sterile or not?

Map who regulates what

Medicines quality, radiation protection, pharmacy practice and transport are often separate authorities with separate inspections. The EU Annex 3 itself notes transport and radiation protection sit outside it [3].

Write it down once

Record the scope, the rules you apply and why, in a controlled document that your quality unit owns. Revisit it when products, sites, customers or markets change.

WHERE V5 FITS

Keep the scope statement, product list and applicable procedures as controlled documents with revisions, owners and review dates. V5 industry packs adjust wording and screens; they do not decide which rules apply to you.

Sources: [1], [2], [3], [4], [5], [6], [7], [8], [12] (linked on pages 30–31)

FRAME / 02

Release timing is the heart of the matter.

Short half-lives mean some results can arrive after product leaves. Each framework handles that differently, and the words matter.

FRAMEWORK	ROUTINE PATHWAY	WATCH THE WORDING
U.S. PET drugs 21 CFR 212.70 [1][2]	Final release needs the lab determination, review of data showing specs are met except sterility, and authorisation by a designated qualified individual's dated signature. Sterility need not be complete before final release but must start within 30 hours of production.	Conditional final release, 212.70(f), is a narrow exception for a test that cannot be completed because analytical equipment malfunctioned, with conditions attached. It does not cover failure to establish radiochemical identity, purity or specific activity, and is not the routine sterility pathway.
EU GMP Annex 3 [3]	Some products may be released before all QC tests are complete, under an exact written release procedure. Release may be staged: a designated person assesses batch records before transport, then final analytical data is assessed before QP certification.	Where results are not available before use, the QP should conditionally certify before use and finally certify after all results are obtained.
WHO / IAEA TRS 1025 Annex 2 [5]	Release by a responsible person independent of production and QC. Products with extremely short half-life or shelf life may need release and delivery before all characterisation testing, under an SOP that clearly describes the process.	Notes that tests such as sterility, endotoxin and radionuclidic purity may need to be performed post-release.

A common error to avoid. Routine PET release ahead of sterility results is sometimes described as 'conditional release'. Under Part 212 it is final release with the sterility exception in 212.70(c)–(e); conditional final release is the separate equipment-malfunction provision in 212.70(f) [1][2]. Use your own framework's vocabulary in procedures and records.

WHERE V5 FITS

Whatever your pathway, V5 keeps results required before review separate from results that may finish later, keeps every open result visible on the run until it is entered, and records each review stage with the person, meaning and time. Your procedure defines the stages; V5 does not choose them.

FRAME / 03

The day against the clock.

A worked example: a short-lived PET run. Times are an example, not a recommendation. What matters is that every handover is visible to everyone at once.

04:30

Room, module and line clearance checks

05:10

Synthesis to approved instruction

05:55

QC sampling, results start arriving

06:20

Review stage before transport

06:45

Courier collection, dispatch record

Later

Sterility and other post-release results entered and reviewed

Plan to the dispatch time

Work back from the collection time and the shelf life, not forward from when people arrive. Make the plan visible on the floor and in QC.

See slippage early

A late synthesis start compresses QC and review. A shared plan lets the reviewer and the courier know before the window is lost.

Never hide what is open

Results that legitimately finish later should be a visible, owned task on the run, with a due time and a named person, until closed.

WHERE V5 FITS

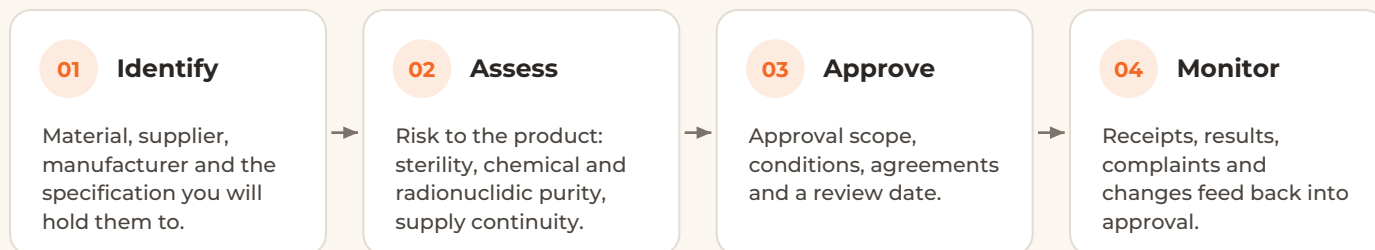
Runs sit on the scheduling board against their planned times, shifts and equipment. Planning results depend on the capacity and timing data you keep. V5 does not calculate decay or activity at calibration time; use your validated methods and record the results.

Sources: [3], [5] (linked on pages 30–31)

FLOW / 01

Qualify the supplier before the delivery.

Precursors, reagent kits, sterile cassettes, target material, generators and critical consumables shape the quality of a product that may be used before it is fully tested.



Specify what matters

For each critical material, define identity, grade, purity and microbiological expectations, and which certificate values you will verify. WHO/IAEA guidance treats starting materials as a defined control area [5]; Annex 3 points to GMP Part II for active substances used as starting materials [3].

Treat certificates as evidence

A certificate of analysis is a claim. Decide which values are checked on receipt, which are accepted on supplier approval, and how you periodically confirm that trust is still deserved.

Control change

Ask suppliers to notify changes to manufacturing site, process or specification. A changed cassette or precursor can change a validated synthesis.

WHERE V5 FITS

Supplier qualification and ongoing monitoring sit with purchasing and receiving, so an unapproved supplier or material can be seen at the point of use. Supplier audit findings can route to corrective action. Supplier document submission is available through the supplier portal where configured.

Sources: [3], [5], [11] (linked on pages 30–31)

FLOW / 02

Goods-in decides what the floor can trust.

Receiving is where a supplier lot becomes your lot. Get identity, status and certificate evidence right here and every later trace gets easier.



Match the delivery

Purchase order, supplier, material, supplier lot, quantity, expiry and transport condition, recorded once at the bench.

Quarantine by default

New lots stay unusable until the checks your procedure requires are complete and a person changes the status.

Capture the certificate

Keep the certificate with the lot and record who checked which values against your specification.

Radioactive receipts

Incoming radioactive material, such as generators, has radiation-protection receipt duties that are outside GMP and often outside a quality system. Keep the two procedures linked but distinct.

Short-dated materials

Record expiry with time where it matters. A material that is valid at receipt can be invalid by the run.

Rejections and returns

Record the reason, segregate physically and in the record, and feed the result into supplier monitoring.

WHERE V5 FITS

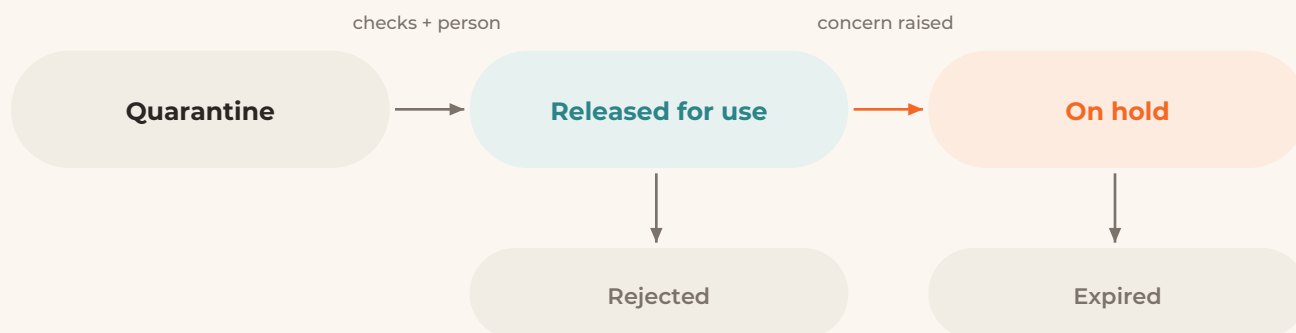
Receiving records lot, expiry and status against the purchase order, and lots can start in quarantine. Certificate values can be read from a photo or PDF and presented for a person to confirm before anything changes; AI extraction never releases a lot.

Sources: [3], [5] (linked on pages 30–31)

FLOW / 03

Know what you can use, right now.

Status, location and expiry decide whether a material can enter a run. Short shelf lives and segregated storage make that decision time-critical.



Status is a decision

Only named roles change status, and the record says who, when and why. A status that changes silently is a status nobody can defend.

Store by risk

Separate radioactive, sterile, temperature-sensitive and quarantined stock as your procedures require, and keep the system location matching the shelf.

Expiry first

Issue earliest-expiry-first where it fits, and block expired material at the scan rather than relying on a visual check at 04:30.

WHERE V5 FITS

Lots carry status, location and expiry, with FEFO/FIFO issue and storage zones. Scanning a held, rejected or expired lot at the kiosk stops the step according to your workspace rules. Room and storage readings can stream in with alerts through a supported, configured sensor connection.

Sources: [3], [5] (linked on pages 30–31)

FLOW / 04

One approved way to make each product.

The master record and its instructions are the reference every run is compared against. Change them deliberately, never by habit.

MASTER RECORD · REV 4

- Materials and quantities
- Equipment and cassette type
- Steps, limits and hold points
- Sampling and tests
- Label and dispatch data

**PROPOSED REV 5 · IMPACT**

New cassette lot format from the supplier. Assess: synthesis validation, cleaning, QC methods, training, labels, open runs. Approve with signatures before the effective date; runs in progress stay on rev 4.

Control the master

Identity, components, equipment, steps, limits, tests, yields where meaningful and label content in one approved revision. Part 212 requires master production and control records and batch records that reference them [1].

Validate what you change

Annex 3 and WHO/IAEA guidance expect qualification and validation sized by risk, often including process simulation for aseptic steps [3][5]. A software change that alters a step is a change too.

Fix the revision at release

A run should carry the revision it was released with, so the record compares actual work to the instruction that was in force at the time.

WHERE V5 FITS

Formulas, master records and step instructions are kept under revision, with two-signature approval and change control with impact assessment where your plan includes them. Existing SOPs or batch books can be uploaded and drafted into instructions for your team to check and approve.

Sources: [1], [3], [5], [11] (linked on pages 30–31)

FLOW / 05

Record the run while it happens.

Inside the hot cell much is automated; around it, people still verify, connect, sign and decide. The record should capture both without slowing either.

Line clearance and readiness

Room, module, cassette, reagents and previous-run remnants checked and signed before the run starts.

Materials verified at use

Scan each critical material so the run links to the exact lots, and a held or expired lot stops the step.

Module data with the run

Keep the synthesis report or module output with the run record, with the reviewer able to see it.

Exceptions at the step

A failed or aborted synthesis is a recorded event with its reason, not a deleted run.



Radiation protection and GMP pull in different directions. Shielding and remote handling reduce operator dose but can reduce visibility. Annex 3 asks for premises and equipment that serve both aims [3]. Design records so that a step you cannot see directly is still evidenced, for example by module logs, photos or a second-person check.

WHERE V5 FITS

Operators follow approved steps on the kiosk with scanning, photos and signatures. Device and module data can be attached or captured through supported, configured connections; each needs its own set-up. Where steps are not recorded in V5, they cannot appear in its record.

Sources: [3], [5] (linked on pages 30–31)

FLOW / 06

Aseptic evidence is part of the release.

For sterile products the environment, the people and the filtration are evidence about the batch, and some of it is only available after the fact.

Environmental and personnel monitoring

Annex 3 says monitoring data for premises and processes should be recorded and evaluated as part of the release process [3]. Annex 1 (2022) sets the wider contamination-control expectations for sterile manufacture [4].

Filter integrity

Where a final sterilising filter is used, the integrity result belongs with the run and the reviewer should see it.

Process simulation

Aseptic process simulations and their results show that the people and process can do the work aseptically, and they expire.

Gowning and access

Who entered which grade of area, trained and qualified for it, matters when a monitoring result is out of limit.

Check scope carefully. Annex 1 applies to sterile medicinal products in the EU and PIC/S regions [4][6]; small-scale hospital preparation from licensed kits may fall under national pharmacy rules instead [3][7].

WHERE V5 FITS

Environmental readings, monitoring results and integrity tests can be recorded against the run or room and kept visible to the reviewer. Sensor streams need supported, configured devices. Training and qualification records can gate who may perform steps at the kiosk where configured.

Sources: [3], [4], [6], [7] (linked on pages 30–31)

DECIDE / 01

Know which results are in, and which are not.

Quality control on a short-lived product is a race and an inventory. The reviewer needs to see both, at a glance, on the run they belong to.



RUN R-0917 · QC RESULTS · WORKED EXAMPLE

Appearance	Pass
pH	Pass
Radiochemical purity	Pass
Filter integrity	Pass
Endotoxin	Required before review
Sterility	Started · result later

Methods and limits are yours

Which tests, which methods and which must be complete before which stage come from your specifications and marketing authorisation, not from software.

Representative samples

Small batches make sampling a design decision. WHO/IAEA guidance asks that samples represent the batch and are kept identified and segregated [5].

WHERE V5 FITS

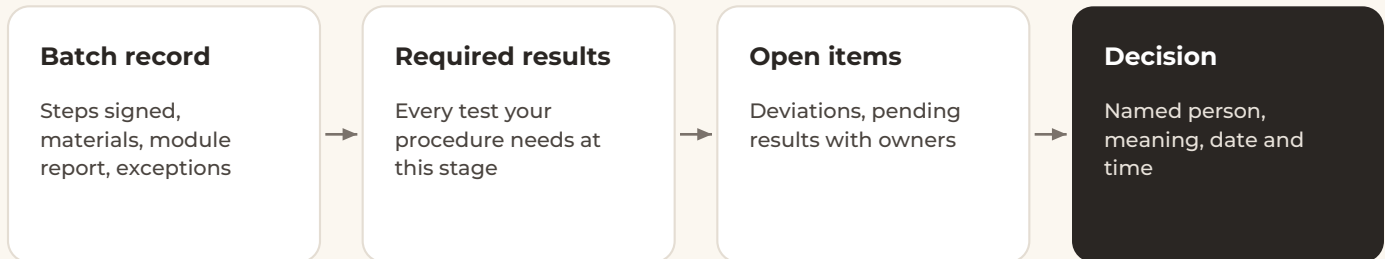
Lab & QC organises sample plans, requests, result queues and out-of-specification handling, with method-specific SPC for trend review. Each result can be marked required before review or allowed later, so open results stay visible on the run until entered.

Sources: [1], [3], [5] (linked on pages 30–31)

DECIDE / 02

A person decides. The record shows why.

Release is an authority, not a calculation. The system's job is to put complete, honest evidence in front of the right person in time.



Who may decide

Part 212 requires a designated qualified individual's dated signature [1]. In the EU the Qualified Person certifies [3]. WHO/IAEA guidance asks for a responsible person independent of production and QC [5].

Staged decisions

If your procedure releases for transport before all results, record each stage separately, with what was known at the time, and keep the later stage open until it is done [3].

After the decision

Late results are reviewed against the same specification. A failure triggers your procedure, not a quiet edit of the earlier decision.



WHERE V5 FITS

The QA review queue shows the run with open items first. Electronic signatures with meaning and time are designed for 21 CFR Part 11 where your plan includes them. V5 never releases product by itself; your procedures and role permissions decide who can approve.

Sources: [1], [3], [5], [9] (linked on pages 30–31)

DECIDE / 03

When a result fails after dispatch.

The scenario everyone plans for and hopes never happens. Rehearse it on paper before you need it at 07:00 on a Saturday.

1

Failure recorded

Late result out of specification, entered and flagged on the run.

2

Scope known

Every dispatch and receiving facility from that run, from the record.

3

Notify

Your procedure and law decide who is told, how fast and how it is documented.

4

Investigate

Root cause, other runs affected, and the findings shared as required.

Know your obligation. For U.S. PET drugs, if a product fails a sterility criterion the producer must immediately notify all facilities that received it, document the notification and, on completing the investigation, notify them of the findings [1]. Other frameworks and national rules set their own expectations; Annex 3 requires failing product to be rejected and returned product not to be reprocessed [3].

WHERE V5 FITS

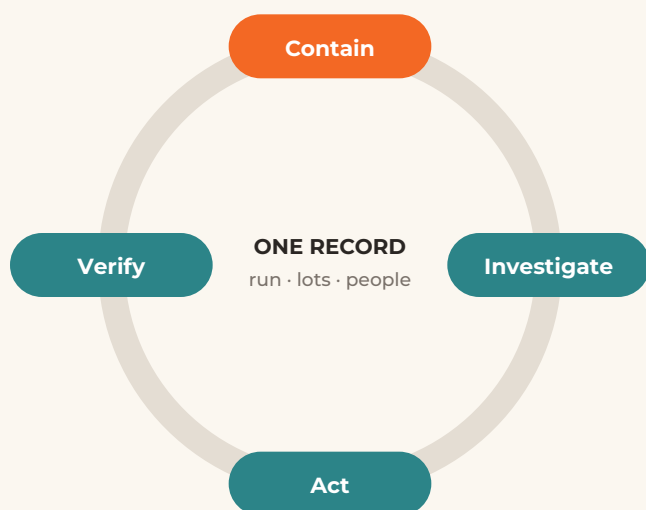
Because the run links to its dispatch records, the affected receiving facilities can be listed from the record. A deviation can be raised from the failed result and linked to the run, lots and dispatches. Notifications can be routed by email or SMS where configured; who must be told, and when, stays with your procedure.

Sources: [1], [3] (linked on pages 30–31)

DECIDE / 04

Fix the cause, not just the run.

Failed syntheses, late starts, monitoring excursions and near misses all have a cost in a short-life business. A connected CAPA loop turns them into fewer repeats.



Contain fast

Hold affected lots and open runs, record the immediate decision and who made it.

Investigate with evidence

Module logs, results, people, equipment status and material lots, all reachable from the run.

Act on the system

Change the instruction, training, maintenance plan or supplier approval, through change control.

Verify it worked

Agree what evidence will show the fix held, and when you will look.

ICH Q9(R1) asks that the level of effort, formality and documentation of quality risk management be commensurate with the level of risk, and highlights that subjectivity should be managed [11]. Size investigations to risk; do not let a minor event and a sterility failure share the same template.

WHERE V5 FITS

Deviations and CAPA link to the run, lot, equipment and people involved, with root-cause workflow, effectiveness checks and change control. AI can suggest a classification or draft an investigation summary for a person to review and edit; it never closes or approves one.

Sources: [3], [5], [11] (linked on pages 30–31)

DECIDE / 05

The right people, trained and independent.

Small teams wear several hats. The guidance still expects some hats never to be worn at once.

Train for the real job

Production, QC and release staff need GMP and radiopharmaceutical-specific training, and everyone in radioactive areas, including cleaning and maintenance, needs suitable additional training [3].

Keep release independent

WHO/IAEA guidance asks that batch release be performed by a responsible person independent of the person carrying out production and QC [5]. Design rosters, permissions and signatures around that.

Instructions in force

Operators should only be able to follow the current approved revision, and should be trained on it before they use it.

WORKED EXAMPLE: COMPETENCE AND SEGREGATION MATRIX

	Synthesis rev 4	Dispensing	QC release tests	Release review
Operator A	Trained	Trained	—	Not permitted
Operator B	Trained	Refresher due	—	Not permitted
QC analyst	—	—	Trained	Not permitted
Reviewer	—	—	—	Trained

WHERE V5 FITS

Document control keeps SOPs and instructions under revision with read-and-understood training. The training and competence matrix can block untrained operators at the kiosk where configured, and role permissions control who can record, review or approve.

Sources: [3], [5] (linked on pages 30–31)

SUSTAIN / 01

Ready equipment is evidence too.

Cyclotron, synthesis modules, hot cells, dispensing systems, activity meters and QC instruments are part of the batch story. Their state on the day belongs in the record.



Qualify and keep qualified

Equipment should be qualified for its intended use. WHO/IAEA guidance names the dose calibrator (activity meter) as needing qualification and regular checks [5].

Plan maintenance

Calendar and usage-based maintenance on modules and hot cells, with parts drawn from stock and the work signed.

Block what is not ready

An instrument out of calibration or overdue for service should be flagged before the run, not discovered in the review.

WHERE V5 FITS

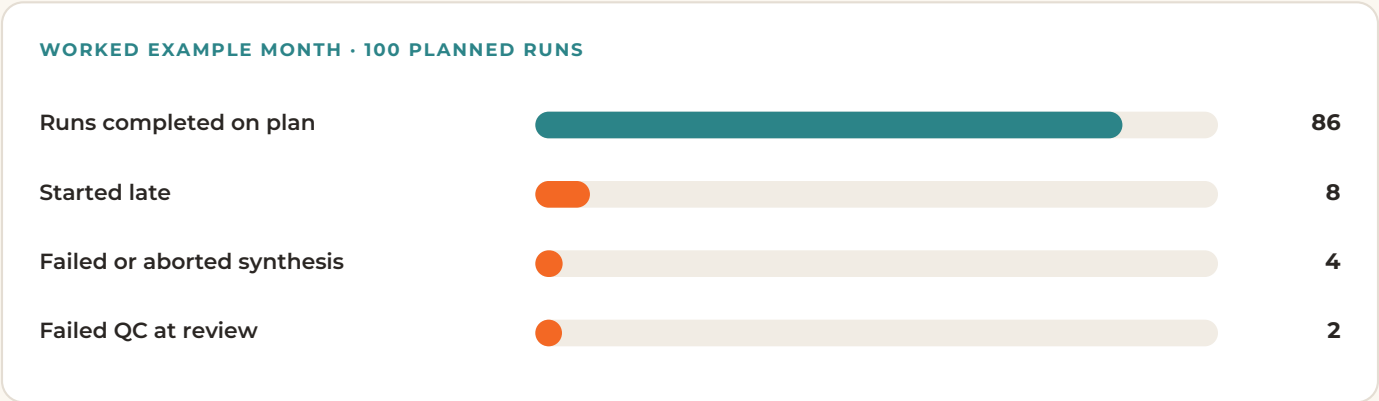
Each module, hot cell and instrument can have an equipment record with calibration schedules, tolerance checks, certificates and planned maintenance. Out-of-calibration instruments can be blocked at the kiosk. Predictive failure analytics are not offered today.

Sources: [3], [5] (linked on pages 30–31)

SUSTAIN / 02

Measure what loses you a delivery.

In a short-life operation, the cost of a lost run is a missed patient appointment or customer, not just scrap. Measure the losses that matter to that.



Choose the denominator

Planned runs, delivered on time, is often more useful than equipment effectiveness alone. Use OEE where a line genuinely runs continuously.

Record the reason

A failed synthesis, late start or QC failure gets a reason from your own list, so the top losses can be ranked from records rather than memory.

Review on a cadence

Bring schedule adherence, failures, deviations and equipment downtime to management review with actions and owners.

WHERE V5 FITS

Reports and dashboards can show completed and failed runs, delays and downtime reasons from the events your team records; maintenance and OEE views are available where your plan includes them. AI forecasting and anomaly detection are coming soon, not available today.

SUSTAIN / 03

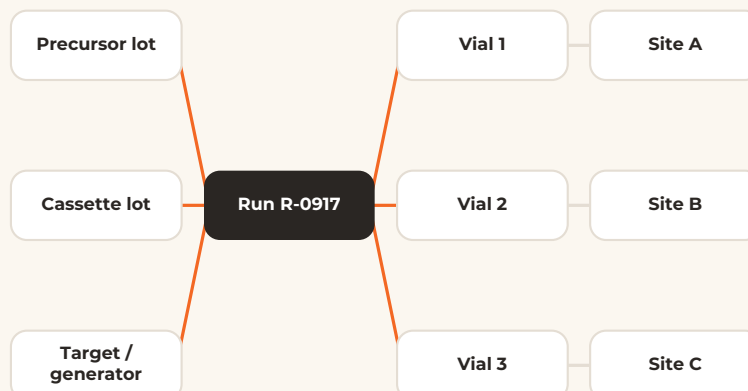
Right label. Whole family tree.

Labels carry information that changes by the minute, and traceability has to follow a run to every container and every receiving site.

WHO/IAEA LABEL ORIENTATION [5]

- Product name and batch number
- Manufacturer
- Activity in SI units
- Concentration or activity at calibration date/time; volume
- Radioactivity symbol where relevant
- Expiry date and time
- Cautionary statements

Applies in the absence of regulatory authority requirements; your national rules and authorisation take precedence [5].



Print from the record

Print labels from the released data on the run, not by retyping. Reconcile labels issued, used and destroyed.

Trace both ways

From a material lot to every run and site; from a site's complaint back to every material.

Test the trace

Run a mock trace on a schedule and time it. Fix gaps in scanning before a real recall finds them.

WHERE V5 FITS

Label design and printing use data from the record, including GS1-128 barcodes, on configured printers. Lots link at every receipt, use and dispatch, so genealogy can be followed forward or backward. V5 does not calculate activity at calibration time or decay; enter the values from your validated methods.

Sources: [5] (linked on pages 30–31)

SUSTAIN / 04

Dispatch is a handover, not an exit.

Transport of radioactive material has its own law, its own competence and its own documents. Your quality record should link to them, not try to replace them.



Two regimes, one parcel

IAEA SSR-6 (Rev. 2, 2025 edition) underpins international transport rules, transcribed into the UN Model Regulations, the IMDG Code and ICAO Technical Instructions; land transport is national [8]. Check which edition your authority has adopted.

Link the documents

Package, transport documents, consignor and carrier details referenced from the dispatch record so a trace reaches them.

Keep the receiving site

Each dispatch should identify the receiving facility, so a late failure can be communicated quickly.

What software should not pretend to do. Package classification, activity limits, transport index and labelling categories are determined by trained people applying the transport regulations. Annex 3 notes that transport is regulated outside GMP [3][8].

WHERE V5 FITS

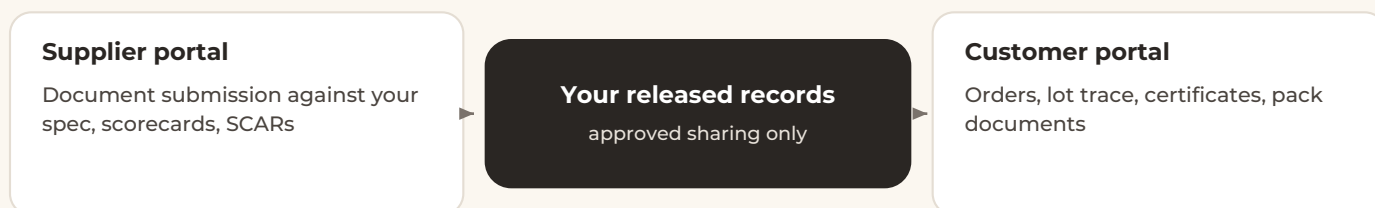
Shipments and dispatch records link back to the run, lots and customer, with documents attached. Recall and withdrawal scope can be listed from those links. V5 does not classify packages or calculate transport index; record the outcomes your trained staff determine.

Sources: [3], [8] (linked on pages 30–31)

SUSTAIN / 05

Share the right records, safely.

Hospitals and customers want certificates, documents and status fast. Suppliers need to send documents against your specification. Both should see only what you choose.



Decide what is shareable

Only released documents and records, never drafts or open investigations. Agree with customers what they receive and when.

Late results

If customers receive a certificate before all results, say so plainly on it, and have a process to send the final status.

Supplier evidence

Let suppliers upload certificates and change notices to the right material, then review them before they count.

WHERE V5 FITS

A portal foundation gives customers and suppliers branded, read-only access to what you approve. Portal scope and permissions depend on configuration; check the current plan comparison for inclusion. Nothing is shared automatically from an open record.

SUSTAIN / 06

Trustworthy records. Honest AI.

Electronic records and signatures need controls, and AI is useful only where a person stays accountable for the result.

Electronic records

21 CFR Part 11 sets criteria for electronic records and signatures in the U.S. [9]; EU Annex 11 covers computerised systems, including risk management, validation, audit trails and data checks [10].

Validate your use

Software can be designed to support compliance. Your validated state comes from your own risk-based validation of how you use it [10][11].

Audit trail you read

Review audit trails as part of routine review where risk warrants, not only after an incident.

AI CAN HELP

- Read certificate values from a photo for a person to confirm
- Draft instructions from an uploaded SOP for approval
- Suggest a deviation classification or draft a summary
- Explain a run's audit trail in plain language
- Find records and screens faster

AI NEVER

- Releases a lot, run or product
- Signs a record or closes a deviation
- Calculates activity, decay, dose or transport index
- Decides which regulations apply to you
- Predicts failures today (forecasting is coming soon)

WHERE V5 FITS

Electronic signatures designed for 21 CFR Part 11, a tamper-evident audit trail and an IQ/OQ/PQ validation pack are available where your plan includes them; every plan can view the audit log. AI features require configured provider access and their outputs need human review.

Sources: [9], [10], [11] (linked on pages 30–31)

APPLY / 01

Evidence map.

A one-page way to check that every theme a reviewer or inspector may ask about has an owner and a record. Adapt the rows to your scope.

THEME	TYPICAL EVIDENCE	WHERE IT LIVES IN V5	OWNER
Scope and rules	Scope statement, applicable frameworks, product list	Controlled documents	Quality unit
Suppliers	Approval, specification, audits, certificates	Supplier qualification, receiving	Quality + purchasing
Materials	Receipt, status, expiry, storage, issue	Lots, status, locations, FEFO	Stores
Master records	Approved revision, change assessment	Formulas, instructions, change control	Quality + production
Execution	Signed steps, lots used, module output, exceptions	Kiosk run record	Production
Aseptic evidence	Monitoring, integrity, simulations, gowning	Lab results, sensors, training	QC + production
QC	Samples, methods, results, OOS	Lab & QC	QC
Release	Staged decisions with signatures	QA review queue, e-signatures	Qualified person
Failures and CAPA	Deviations, notifications, investigations	Deviations, CAPA	Quality unit
People	Training, competence, independence	Document control, skills matrix, roles	Quality + managers
Equipment	Qualification, calibration, maintenance	Equipment, calibration, maintenance	Engineering
Labels and trace	Label data, reconciliation, genealogy	Labels, lot genealogy	Production + quality
Dispatch	Dispatch record, transport documents, receiver	Shipments with documents	Dispatch
Data integrity	Audit trail review, validation	Audit trail, validation pack	Quality + IT

Plan inclusion varies; some areas need Professional or Enterprise. Confirm against the current plan comparison before you scope a project.

WORKSHEET 01

Map your release procedure.

Work through this with the people who release product today. Mark Yes, Partly or No, then note the gap.

	YES	PARTLY	NO
Framework named The procedure states which framework applies and uses its terms (e.g. final release with sterility exception, or staged QP certification).	☐	☐	☐
Stages defined Each release stage is named, with who may perform it and what must be complete before it.	☐	☐	☐
Results classified Every test is classed as required before a stage or allowed later, with justification.	☐	☐	☐
Independence The releasing person is independent of production and QC for that batch, as your framework expects.	☐	☐	☐
Open results owned Late results have a named owner, due time and escalation path.	☐	☐	☐
Failure pathway A late failure triggers recorded notification of receiving facilities and an investigation.	☐	☐	☐
Records linked The release record links to batch record, results, deviations and dispatches.	☐	☐	☐
Signatures Signatures record name, meaning, date and time, and cannot be applied for someone else.	☐	☐	☐
Equipment malfunction If a test cannot be completed because of equipment failure, the special pathway (if any) is defined and limited.	☐	☐	☐
Review and test The procedure is reviewed on a schedule and rehearsed with a mock failure.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Run readiness.

A pre-run check the floor and QC can share. Adapt it to your products; keep it short enough to be used at 04:30.

	DONE	N/A
Plan confirmed Run, product, revision, planned dispatch time and receiving sites.	☐	☐
Materials All critical lots released, in date and at the point of use.	☐	☐
Cassette and reagents Correct type and lot for this product and revision.	☐	☐
Room and environment Clearance signed, monitoring in limits, access restricted to qualified people.	☐	☐
Module and hot cell Calibration and maintenance current; previous-run remnants cleared.	☐	☐
QC ready Instruments qualified and available; sample plan and methods prepared.	☐	☐
People Operator trained on this revision; reviewer available for the planned stage.	☐	☐
Labels and dispatch Label data source ready; transport documents and courier confirmed.	☐	☐
Contingency What happens if the run fails or starts late, and who decides.	☐	☐

NOTES AND OWNERS

WORKSHEET 03

Ask to see it work.

Questions for any software demonstration. Ask the vendor to show each one with your product, not a slide.

	SHOWN	PARTLY	NOT SHOWN
Release stages Show our staged release with required and later results on one run.	☐	☐	☐
Open results Show a sterility result entered two days later, and who sees it.	☐	☐	☐
Late failure Show the list of receiving facilities for a failed run, from the record.	☐	☐	☐
Status at use Scan an expired or held lot at the step and show what happens.	☐	☐	☐
Revision control Change an instruction; show runs in progress keep the old revision.	☐	☐	☐
Equipment Show an instrument out of calibration being flagged before a run.	☐	☐	☐
Independence Show that a person who ran production cannot release that run, if configured.	☐	☐	☐
AI limits Show certificate extraction waiting for a person to confirm.	☐	☐	☐
Audit trail Show who changed a result and why, and export it.	☐	☐	☐
Export Export a complete run record for an inspector or customer.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

Roll out in phases.

Start where the value is visible and the risk is contained. Validate as you go; do not switch a release process over a weekend.

PHASE 1
Foundations

Scope, roles, controlled documents, training records, equipment register with calibration and maintenance.

PHASE 2
Materials

Suppliers, specifications, receiving with quarantine, status and expiry, labels for incoming lots.

PHASE 3
Run record

Master records, kiosk execution for one product, QC results on the run, parallel with your current record.

PHASE 4
Decide

Release stages, open-result tracking, deviations and CAPA, after validation of the intended use.

PHASE 5
Connect

Dispatch links, genealogy, mock recalls, portals, performance review.

Validation runs through every phase. Agree intended use, risk and test evidence before each phase goes live, following Annex 11 or your local equivalent and your own procedures [10][11]. V5 offers a validation pack where your plan includes it; your validation remains yours.

WORKSHEET 04

Find your first improvement.

Score each area today: E evidenced, P partial, G gap. Start with the gap that costs you deliveries or sleep.

	E	P	G
Supplier approval and specifications Approved list, specs, certificate checks	☐	☐	☐
Receiving, status and expiry Quarantine, release for use, blocking at the scan	☐	☐	☐
Master records and change One approved revision, impact assessment	☐	☐	☐
Run record Signed steps, lots used, module output, exceptions	☐	☐	☐
Aseptic and environmental evidence Monitoring, integrity, simulations	☐	☐	☐
QC results and open results Required vs later, owners, due times	☐	☐	☐
Release decisions Stages, signatures, independence	☐	☐	☐
Late failures and notification Scope from record, rehearsed	☐	☐	☐
Deviations and CAPA Linked, sized by risk, effectiveness checked	☐	☐	☐
Equipment readiness Calibration, maintenance, flagged before runs	☐	☐	☐
Labels, genealogy and dispatch Printed from record, mock trace timed	☐	☐	☐
Data integrity Audit-trail review, validation of use	☐	☐	☐

NOTES AND OWNERS

APPLY / 03

A fair evaluation in four weeks.

A practical way to test any system with your own people and one real product, without touching your released records.

WEEK 1

Agree the product, the release procedure and the five questions that matter most. Load one master record and its materials.

WEEK 2

Run the record end to end with test data: receipt, run, QC results including one late result, review stages.

WEEK 3

Break it on purpose: expired lot, out-of-calibration instrument, failed late result, revision change mid-week.

WEEK 4

Review with QC, production and the releasing person. Decide what to validate, what to change and what not to do.

Rules for the evaluation. Use test data only. Keep your current release process live until a validated change is approved. Record what was shown, not what was promised.

ASK V5

“We make [products] for [customers or sites] under [framework]. Our hardest moment is [e.g. late results after dispatch]. Which workflows should we evaluate first?”

Start a 7-day free trial, no card required, or ask V5 on v5ultimate.com.

WHERE V5 FITS

Try V5 with your own product in a trial workspace using test data. The assistant can answer questions about features and plans; it does not give regulatory advice.

SOURCES

Keep the evidence close.

Primary sources behind this guide, checked October 2026. Click a title to open the publisher's page. Always confirm the current version for your products and markets.

- | | | |
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https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-212 | BINDING U.S. REGULATION |
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https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pe... | FDA GUIDANCE (NON-BINDING) |
| [3] | <u>European Commission, EudraLex Vol 4 Annex 3: Manufacture of Radiopharmaceuticals (2008, in operation 1 Mar 2009)</u>
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| [6] | <u>PIC/S Guide to GMP PE 009-17, Annexes (25 Aug 2023)</u>
https://picscheme.org/en/publications | PIC/S GMP GUIDE |
| [7] | <u>EANM Radiopharmacy Committee, Guideline on cGRPP for small-scale preparation (EJNMMI Radiopharm Chem 6:8, 2021)</u>
https://link.springer.com/article/10.1186/s41181-021-00123-2 | PROFESSIONAL GUIDELINE (VOLUNTARY) |

SOURCES

Sources, continued.

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| [9] | <u>U.S. eCFR, 21 CFR Part 11: Electronic Records; Electronic Signatures</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11 | BINDING U.S. REGULATION |
| [10] | <u>European Commission, EudraLex Vol 4 Annex 11: Computerised Systems (2011)</u>
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| [13] | <u>Health Canada, GMP Annex 3B, PET radiopharmaceuticals (GUI-0071, 4 Feb 2026)</u>
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| [14] | <u>TGA, Complying with the PIC/S Guide to GMP (PE009-17 adopted 1 Sep 2025; updated 1 Sep 2025)</u>
https://www.tga.gov.au/products/medicines/manufacturing/manufacture-medicin... | TGA ADOPTION NOTICE |
| [15] | <u>U.S. NRC, Medical product manufacturing and distribution licensing toolkit (10 CFR 32.72; Part 35 is separate)</u>
https://www.nrc.gov/materials/miau/product-manufac/med-toolkit | U.S. NRC LICENSING GUIDANCE |

How to read the status labels. Binding regulation is law in its jurisdiction. Guidance interprets law and is how inspectors read it, but its legal force depends on the jurisdiction. Professional guidelines are voluntary unless an authority adopts them. EU GMP guidance applies through national medicines law; PIC/S members adopt the PIC/S guide nationally.

SCOPE AND LIMITS

What this guide is, and is not.

This guide is practical orientation for evaluating operations and software. It is not legal or regulatory advice and does not list every requirement that applies to you. Requirements differ for PET drug manufacture, commercial radiopharmaceuticals, investigational products, hospital radiopharmacy, research sites and by country. Your quality unit and regulatory advisers decide what applies.

V5 capability statements reflect the V5 product reference reviewed on 1 October 2026. Some capabilities depend on plan, configuration, devices and permissions. AI demand and yield forecasting and process anomaly detection are coming soon and are not available today. V5 does not calculate activity, decay, dose or transport index, does not make clinical or release decisions, and does not by itself make you compliant or validated.

Regional scope. Part 212 covers PET drugs only, and the FDA guide's USP <823> reference is a 2009 edition. Radioactive-material licensing (NRC 10 CFR 32.72 or an Agreement State) is separate from Part 35 medical use [15]. Canada's Annex 3A excludes positron emitters, which follow Annex 3B with its own documented conditions [13]. Australia adopted PIC/S PE009-17 on 1 Sep 2025 [14]. EU Annex 3 separates controlled distribution from authorisation for use, and the revised Annex 19 (applicable 24 Sep 2026) affects reference samples, so this guide prints no retention periods [3][12]. UK and other regions need their own review.

Photography is staged and was created for this guide; everyone shown wears full protective clothing. Run numbers, times and charts are worked examples, not customer data or results.



Short half-lives. Complete records. Clear decisions.

See radiopharmaceutical workflows at v5ultimate.com

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