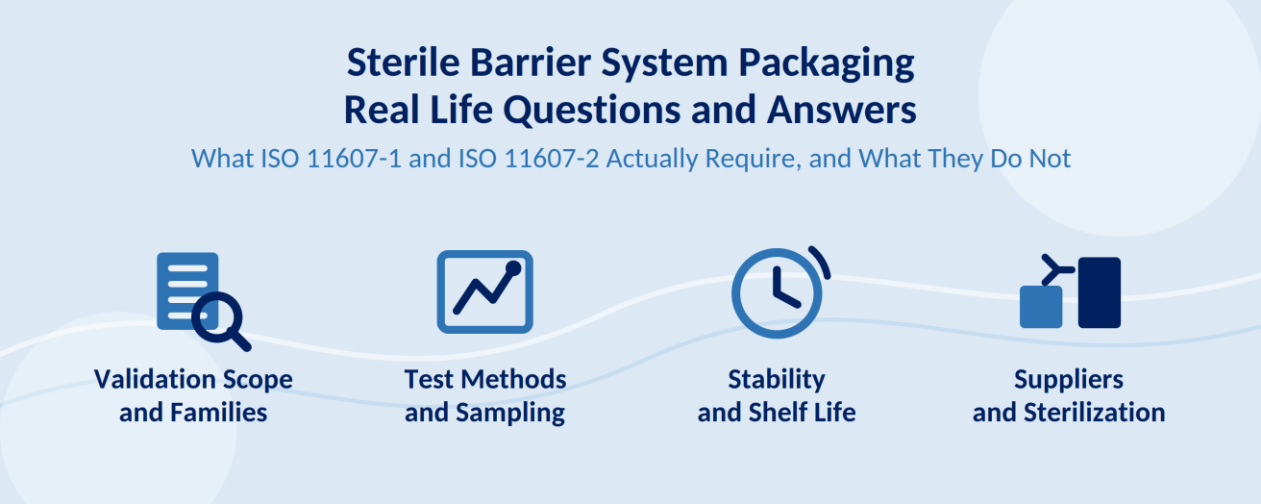
White Paper # 06-2026

Sterile Barrier Packaging: Questions and Answers



This paper takes fourteen real life questions that recur in build, review and audit, and answers each one against the clause that actually governs it. Where the standard is silent, it says so, because knowing where a requirement ends is as useful as knowing where it begins.

Scope. The answers rest on ISO 11607-1:2019 and ISO 11607-2:2019 as amended in 2023, ISO/TS 16775:2021, ASTM F1980-21, ASTM F88, ASTM F1886, ASTM F1929, ASTM F3039 and EN 868-5:2018. Clause numbers are cited throughout so every statement can be traced. This paper explains and applies those documents; it does not reproduce them, and it is not a substitute for the controlled copies.

The Questions

#	Question	Source
	Part A. Validation scope, families and revalidation	
A1	Do different machines, dies, process parameters and package sizes each require separate validation, even when the packaging material is the only thing they share?	ISO 11607-2, 5.1.4; TS 16775, 6.4
A2	When must testing and validation be repeated?	ISO 11607-1, Cl. 9; ISO 11607-2, 5.7
A3	How do we validate a legacy product that was never formally validated?	ISO 11607-2, 5.1.3 Note 2
	Part B. Test methods, acceptance criteria and sampling	
B1	How do you establish a peel test acceptance limit?	ISO 11607-1, 4.4.2, 5.1.9, Cl. 7
B2	Can burst testing replace peel testing for routine release?	TS 16775, 5.6.2.3
B3	How many samples for OQ and PQ, and how do we defend the number?	ISO 11607-1, 4.3; TS 16775, 4.5.2
	Part C. Stability, aging and shelf life	
C1	Must the real-time study start at the same time as the accelerated study, and what is checked in what order?	ISO 11607-1, 8.3; F1980, 4.3
C2	How is humidity integrated into the accelerated aging calculation?	F1980, 6.6 and Appendix X3
C3	Can we extend a shelf life claim using samples already in the chamber?	ISO 11607-1, 8.3; F1980, 7.4, 8.7
	Part D. Suppliers, sterilization and process capability	
D1	What does the supplier's certificate actually cover?	ISO 11607-1, 5.1.1, Cl. 11; TS 16775
D2	We are increasing the gamma dose. What has to be repeated?	ISO 11607-1, 5.3 and 9.3
D3	What process capability index does ISO 11607 require?	ISO 11607-2, 5.4.7; TS 16775, Annex E

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Part A: Validation Scope, Families and Revalidation

A1. Do different machines, dies, parameters and sizes each require separate validation?

Short answer. A new machine always requires a new validation. Everything else can usually be bracketed into a family, provided you write the worst-case rationale that ISO 11607-2 clause 5.1.4 requires. Sharing a packaging material is not, on its own, a sufficient basis for grouping.

Clause 5.1.4 permits validation of families: where similar preformed sterile barrier systems and manufacturing processes are validated, a rationale for establishing similarity and identifying the worst-case configuration shall be documented, and at minimum the worst case shall be validated. ISO/TS 16775 clause 6.4 adds the point most often missed. When validating a manufacturing process, the worst-case configuration applies to the sterile barrier system manufacturing process, not to the medical device itself. The device still matters, but as an input to how the process behaves rather than as the object being bracketed.

What changes	Bracketing	What the risk analysis has to consider
Package size, same webs and machine	Usually yes	Both extremes of seal area. Large seal areas can see colder sealing temperatures at the edge of the platen; the smallest seals can be over-sealed in the middle of the equipment, and pressure control may react differently to different areas
Pouch length	Yes	Misalignment risk is greatest for longer pouches, because operators find them harder to handle
Device within a family	Yes	The heaviest and bulkiest product. A bulky device creates folds in the seal; in form-fill-seal a heavy product pulls the bottom web and distorts the flange
Sealing die or tooling	Assess	Different pressure and temperature distribution across the seal land. Treat as a change to a main part of the equipment under 5.7.2
Process parameters	No	Parameters are the output of OQ. A different parameter set is a different window
A second identical machine	IQ no, OQ partly	See the worked example below

The ISO/TS 16775 worked example: a second identical machine

A new machine always requires a new validation. IQ is specific to machine 2, to confirm everything is properly installed and calibrated and the documentation is complete. For OQ, process development can be leveraged from the previous validation, and the bracketing can be simplified where the configuration is identical and the handling risks are understood and controlled.

The manufacturer still challenges machine 2 with the bulkiest product, to prove it seals without folds as machine 1 does, and with the smallest and largest seal areas, to confirm it meets the predetermined specification. During PQ, three lots are run to confirm the process is capable and reproducible. The guidance closes with a caution worth repeating: each situation is unique, and manufacturers should carefully perform their own risk analysis.

A2. When must testing and validation be repeated?

Short answer. When a change compromises the original validation, and whenever a quality or process indicator trends negatively. Both parts also require that the need for revalidation be evaluated and recorded for every change, including changes you conclude need no action.

Source	Trigger
ISO 11607, 9.3	Changes to design, contents, packaging materials or configurations that compromise the original validation and can affect SBS integrity; changes to storage, handling and distribution hazards exceeding those originally applied

Source	Trigger
ISO 11607, 9.3 Note	New packaging materials; raw material changes negatively affecting properties or stability; sterilization process changes; different shipping configurations or distribution methods; market feedback of SBS integrity issues
ISO 11607, 9.5	Minor design changes shall be recorded and can require review of validation status. Multiple minor changes can cumulatively affect it
ISO 11607-2, 5.7.2	Changes to equipment, contents, packaging materials or the packaging process that compromise the original validation
ISO 11607-2, 5.7.2 N1	Raw material changes affecting process variables; change or exchange of a main equipment part; modification or refurbishment; transfer or relocation; negative trends in quality or process control indicators
ISO 11607-2, 5.7.2 N2	Installation of a new piece of equipment is not revalidation. It is new process validation
ISO 11607-2, Annex B.8	Any deviation from desired process performance shall be investigated and the risk analysis reviewed and adapted

On scope, both parts use identical language: the need for revalidation shall be evaluated and recorded, and if the situation does not require all aspects of the original validation to be repeated, the revalidation does not have to be as extensive as the initial validation. Both also carry the same note recommending that design validation be kept separate from process validation, precisely so the revalidation effort can be confined to the aspects really affected.

A3. How do we validate a legacy product that was never formally validated?

Short answer. Retrospectively, using the production history you already hold. ISO 11607-2 clause 5.1.3 Note 2 states that validation of existing products can rely on data from previous validations of existing products, and that such data can be used for determining the tolerances for process parameters.

That note is the legitimate route to closing out a legacy process without pretending it is new. It does not waive the structure: IQ, OQ and PQ are still required in that order under clause 5.1.2, and the process specification of clause 5.1.3 still has to exist.

#	Activity	What history contributes
1	Write the process specification required by 5.1.3: required output, variables and attributes to monitor, parameters for control	Existing work instructions, machine settings, inspection records
2	Perform the Annex B risk analysis on the process as it actually runs	Deviation records, complaint history, process trending
3	Complete IQ on the equipment as installed, including calibration, alarms and firmware versions	Nothing is inherited. Alarms must be challenged, per 5.2.4
4	Establish the process window for OQ	History sets the starting point; the limits must still be challenged, with SBS produced at both
5	Perform PQ over at least three runs at nominal settings	Historical capability supports the sample size rationale
6	Formally approve per 5.5 and place under the monitoring of 5.6	Existing monitoring records become the baseline trend

The trap

The temptation with a legacy process is to substitute a large volume of historical release data for the OQ challenge, on the argument that the process has made good product for years. It has not been shown to make good product at the edges of the window, because it has never been run there. That is exactly the evidence gap OQ exists to close, and it is why clause 5.1.2 keeps the sequence normative even for an existing process.

Part B: Test Methods, Acceptance Criteria and Sampling

B1. How do you establish a peel test acceptance limit?

Short answer. From your own data, and as a two-sided limit. ISO 11607 clause 4.4.2 requires a recorded rationale for acceptance criteria, and that rationale must address both bounds, because the seal has two opposing failure modes.

	Lower bound	Upper bound
Question answered	Will the seal survive everything that happens before use?	Can the user open it cleanly at the point of care?
Evidence that sets it	Distribution performance testing under 8.2; pressure differential during the sterilization cycle; handling and storage; device mass and rigidity	The Clause 7 usability evaluation under real or simulated conditions; clause 5.1.9 d), requiring peel to be continuous and homogeneous without delamination or tearing that affects aseptic presentation
Harm if wrong	Seal opens in transit or during sterilization. Loss of sterility, high severity	Seal will not peel cleanly. The porous web tears, fibers shed onto the sterile field, or the device is dropped
Detectability	Moderate. May be found at incoming inspection or by the user	Low, because the package passes every strength test

A defensible route to the number runs in six steps. Fix the test method completely before generating any data, including the ASTM F88 technique, the grip separation rate, the specimen width, the initial grip separation and the reported statistic. Build the seal-strength curve across the process window during process development. Characterize the distribution across several material lots. Test after sterilization, after aging and after distribution, not only at time zero. Run the usability evaluation and record the force at which clean peel stops. Then set limits the process can meet with capability, and that aged and distributed product still satisfies.

Two things not to do

Do not import the EN 868-5 values into an industrial specification without a rationale. The 1.5 N per 15 mm for steam and 1.2 N per 15 mm for other processes apply to preformed pouches and reels supplied to health care facilities, where the facility makes the final seal. EN 868-5 itself states that for industrial applications different values can be established based on the specific application and on the validation requirements of EN ISO 11607.

Do not set the limit from time-zero data alone. Seal strength commonly rises after sterilization and after aging. A limit set on fresh seals can be comfortably met at time zero and breached at month eighteen, in the direction that makes the package difficult to open. That is the failure mode a one-sided specification cannot catch.

B2. Can burst testing replace peel testing for routine release?

Short answer. No, not as an integrity test. ISO/TS 16775 states plainly that burst testing is more typically used for in-process control and is not considered to be a whole package integrity test.

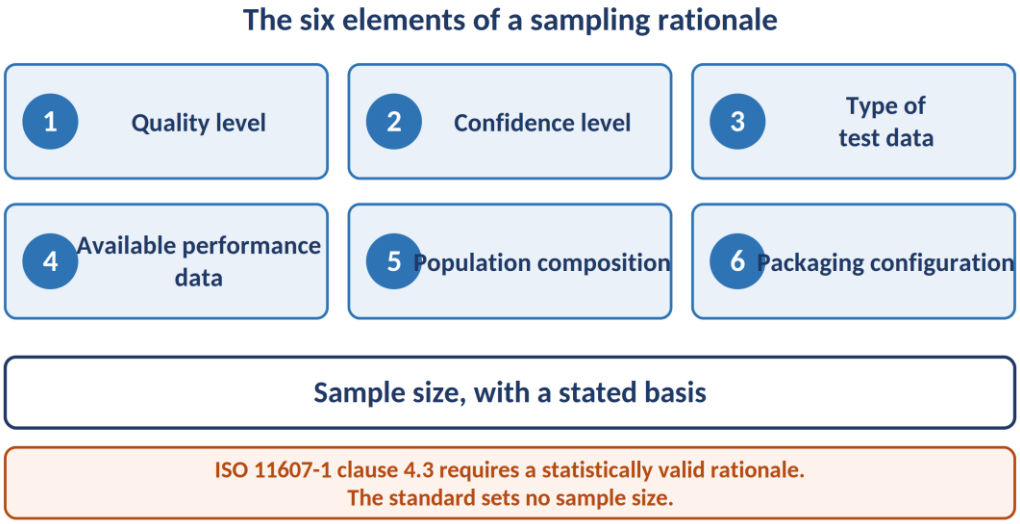
The guidance explains why. Burst testing probes the entire sterile barrier system at once by internally pressurizing the package, which is its attraction. But it does not apply the force equally to all parts of the package, and it necessarily carries more variability in the observed results than seal testing. A weak zone in one seal can be masked by strong seals elsewhere, and the pressure distribution inside an inflating package is not the loading the seal experiences in service.

Method	What it measures	Appropriate use	Not appropriate for
ASTM F88 peel	Force to separate a defined width of seal, plus the failure mode	Specification conformity, OQ limits, PQ capability, trending	Whole-package integrity, since it tests a strip
F1140 / F2054 burst	Pressure at which the package or seal fails, or creep to failure	In-process control and comparative studies	Integrity release testing, or as a substitute for peel strength
F1929 / F3039 dye	Presence and location of a channel through the seal	Integrity verification, validation, investigation	Any quantitative statement about seal strength or leak size

If you intend to use burst as an in-process control, ISO/TS 16775 sets the condition: concurrent seal and burst testing should be performed at the time of validation. That establishes the relationship between the two on your own material and process, so a burst value can be interpreted against the seal strength specification the product is actually released to. Without that study, a burst reading is a number with no established link to the requirement it stands in for.

B3. How many samples, and how do we defend the number?

Short answer. The standard sets no number. ISO 11607-1 clause 4.3 requires sampling plans to be appropriate and based on a statistically valid rationale, and ISO/TS 16775 clause 4.5.2 sets out the six elements that rationale has to address.



Element	What has to be decided, and why it moves the number
Quality level	What quality level is required and is to be proven: an AQL, a percentage of conforming product, a minimum capability index, or another performance metric
Confidence level	Unless 100 % inspection is performed there is always uncertainty. Note that 100 % inspection without uncertainty assumes a fail-safe non-destructive method, and does not ensure 100 % of errors are caught
Type of test data	Attribute data carries far less information than variable data. For the same quality and reliability level, continuous data needs a smaller sample. A grading scale with greater resolution can reduce the sample size
Available performance data	Engineering studies and similar processes give an initial capability estimate. A process expected to run at Cpk 3 needs a smaller sample than one expected at 1.33
Population composition	Samples drawn from a batch differ from units built for the evaluation. Either way they must represent the final process or the settings being evaluated
Packaging configuration	Distribution simulation needs the entire packaging system; sealing process validation may focus only on the sterile barrier system

The question an auditor actually asks

Not "how many did you test?" but "what quality level and confidence level does that number demonstrate, and why is that level right for this device?" A plan stating n = 30 with no quality level, no confidence level and no link to the risk record answers none of that. The same n = 30 described as 95 % confidence at 90 % reliability on attribute data, justified by the severity rating in the packaging risk file, answers all of it.

The cheapest lever is the data type. Converting an attribute check into a measurement, for example recording seal width rather than pass or fail, reduces the sample size needed for the same statistical claim.

Part C: Stability, Aging and Shelf Life

C1. Must the real-time study start at the same time as the accelerated study?

Short answer. Not literally the same day, but the two must be close together, and real-time must be running before you sell. ISO 11607-1 clause 8.3.4 requires that if accelerated aging is conducted it shall begin within three months of real-time aging unless an alternative rationale has been developed, and that real-time aging shall be started prior to commercialization.

ASTM F1980 states the same principle from the other direction in clause 4.3: to ensure accelerated aging studies represent real-time effects, real-time studies must be conducted in parallel, and must be carried out to the claimed shelf life and performed to their completion.

#	Activity	Why it sits here
1	Sterilize the sample set using the specified process at its limits	ISO 11607 clause 8.1 requires integrity testing on sterilized samples
2	Establish time zero and test the full property set	Time zero is the baseline for every later interval, and F1980 8.7 names it as one accepted basis for the criteria
3	Start the accelerated chamber and the real-time storage, within three months of each other	Clause 8.3.4. Record both start dates in the protocol, not only the accelerated one
4	Run distribution simulation on a separate sample set	Performance and stability testing are separate entities addressing different questions (F1980, 8.4)
5	Test at each accelerated interval against the predetermined criteria	F1980 7.4.4 requires intervals, including time zero, to be defined beforehand
6	Release on the accelerated data, with real time running	Clause 8.3.3: accelerated protocols are sufficient evidence until real-time data are available
7	Test at each real-time interval to the full claimed shelf life	F1980 7.4.11. The accelerated result is confirmed, not replaced

If the real-time data disagrees

ASTM F1980 Appendix X2.7.2 is explicit. If the real-time aging results fail to meet the acceptance criteria, the shelf life must be reduced to the longest shelf life for which real-time testing has been successful. If product has been released to the market at risk based on the accelerated data, a careful review must be performed and documented, and the appropriate action taken.

That action can extend to field notification. This is precisely why the three-month rule exists: the longer the gap between the two studies, the larger the volume of product exposed if they disagree. Under the 2023 amendments this review is also a post-production input to the risk file.

C2. How is humidity integrated into the accelerated aging calculation?

Short answer. It is not part of the calculation at all, and that is the point. ASTM F1980 Appendix X3.2 states that the calculation is based solely on temperature, because an underlying assumption of the Arrhenius equation is that reactant concentrations are essentially constant for a given chemical reaction across a temperature domain. Humidity is a condition you hold steady so that assumption remains true.

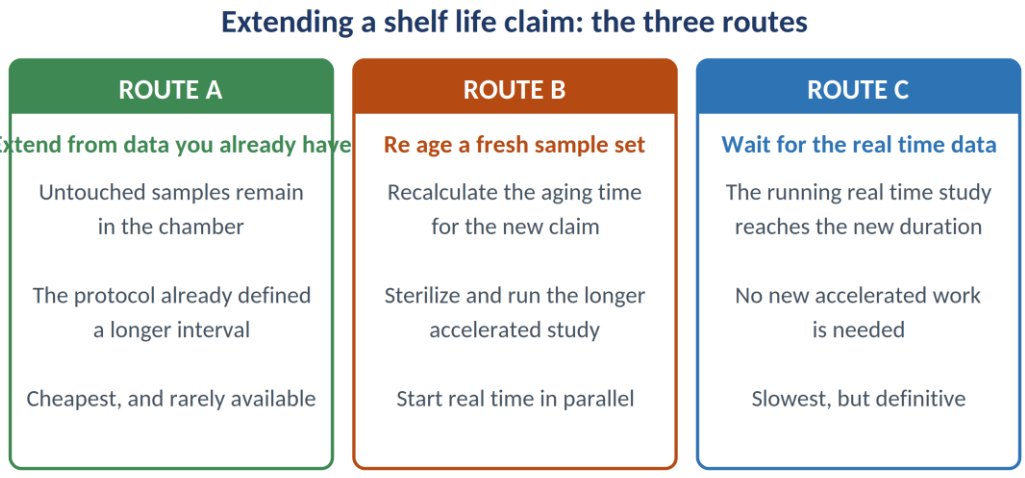
The mechanism matters. For a hydrolysis reaction the effective rate depends on the concentration of water in the polymer matrix raised to the reaction order. To use the Arrhenius equation to predict a rate change across a temperature domain, that water concentration must remain constant. Raising the temperature at fixed absolute humidity drops the relative humidity, dries the polymer, and slows a degradation pathway that will run at full speed on the shelf.

Item	Value	Basis
Ambient temperature, T_RT	30 C	Upper limit of the labelled storage range, per F1980 clause 7.2.2
Chamber temperature, T_AA	55 C	Below material transitions and below the 60 C ceiling of clause 7.2.3.2
Q10	2.0	The conservative default of clause 7.3.1
Accelerated aging factor	2.0 raised to (55 minus 30) divided by 10, that is 2.0 to the power 2.5 = 5.657	AAF equation
Two-year claim (730.5 days)	730.5 divided by 5.657 = 130 days	AAT equation
Three-year claim (1095.75 days)	1095.75 divided by 5.657 = 194 days	AAT equation
Five-year claim (1826.25 days)	1826.25 divided by 5.657 = 323 days	AAT equation
Relative humidity	Target 45 to 55 % RH, tolerance plus or minus 5 %	F1980 Appendix X3.3, unless material knowledge warrants otherwise

C3. Can we extend a shelf life claim using samples already in the chamber?

Short answer. Only if the original protocol already defined an interval at the longer duration and untouched samples remain. Otherwise you re-age a fresh set, or you wait for the real-time study to reach the new claim.

ASTM F1980 clause 8.7 requires acceptance criteria to be established prior to any aging testing, accelerated and real-time, and clause 7.4.4 requires the aging test intervals, including time zero, to be defined in the protocol. A sample pulled at an interval never written into the protocol is not covered by the study design, and a sample already opened and tested is consumed.



The constraint that overrides all three routes

The claim can never exceed the longest duration for which real-time testing has been successful. Accelerated data supports the claim in the interim under clause 8.3.3, but if the real-time result at the new duration fails, F1980 Appendix X2.7.2 requires the shelf life to be reduced to the longest successfully tested real-time duration, with a documented review of any product already released.

Part D: Suppliers, Sterilization and Process Capability

D1. What does the supplier's certificate actually cover?

Short answer. Less than most teams assume. ISO/TS 16775 states that suppliers of packaging materials and preformed sterile barrier systems can apply ISO 11607, but their conformity statements are limited to what they can claim, because full conformance is only possible for the completely sealed or closed sterile barrier system validated for a specific device or family of devices. Suppliers should clearly indicate what is covered and what is not.

Preformed sterile barrier system: who validates what

THE SUPPLIER VALIDATES	YOU VALIDATE
Material properties of both webs	The closing seal you make, under Part 2
Microbial barrier of the porous web	IQ, OQ and PQ of your sealing equipment
The three seals they form on a pouch	Suitability for YOUR sterilization cycle
Seal width and strength of those seals	Compatibility with YOUR device
Their own forming and sealing process	Usability for aseptic presentation
Material storage and use by limits	Shelf life of the sterilized package

Full conformance is only possible for the completely sealed sterile barrier system validated for a specific device or family of devices. ISO/TS 16775

Two claims that do not transfer

A certificate of conformity to a part of the EN 868 series is not conformity with ISO 11607-1. Clause 5.1.1 Note 2 states this directly: confirmation of conformity to a part of EN 868 is not sufficient to be in full conformity with ISO 11607-1. Note 1 says only that EN 868 parts can be used to demonstrate conformity with one or more requirements.

Barrier and property data generated on the unconverted web is not data on your converted, sealed, sterilized and aged sterile barrier system. Clause 5.3.3 requires material performance to remain within specified limits after exposure to all the specified sterilization processes, a condition the supplier cannot test on your behalf because they do not own your cycle.

Clause 11 of ISO 11607-1 defines what a supplier must provide with materials and preformed sterile barrier systems placed on the health care market. Use it as the qualification checklist: product identification, intended use and restrictions, the sterilization methods for which the material is suitable, storage and transport conditions, use-by limitations, and the information the user needs to make and verify a seal.

D2. We are increasing the gamma dose. What has to be repeated?

Short answer. The material and package evidence has to be regenerated at the new maximum dose. The process validation under Part 2 is usually untouched, because sealing has not changed.

ISO 11607-1 clause 5.3.1 requires demonstration that materials, preformed sterile barrier systems and sterile barrier systems are suitable for the specified sterilization processes, cycle parameters and process limits. A dose range is a process limit. Evidence generated at 25 kGy says nothing about behavior at 40 kGy, because radiation damage in polymers is cumulative and dose dependent, and clause 9.3 lists sterilization process changes explicitly among the revalidation triggers.

Element	Repeat?	Reasoning
Material property set	Yes, at the new maximum	Tensile, tear, elongation and burst all shift with dose. Polypropylene embrittles through chain scission
Seal strength and failure mode	Yes	Peel behavior shifts with dose. Check both bounds of the two-sided limit, not only the minimum
Seal and package integrity	Yes	Embrittled material can develop pinholes and edge cracks absent at the lower dose
Microbial barrier	Assess	Usually stable, but confirm if the porous web is near its dose limit
Stability and aging	Yes, bridge or repeat	Aging now starts from a differently damaged material
Distribution performance	Assess	Repeat if the property change alters puncture or drop performance
Usability evaluation	Assess	Repeat if peel force or failure mode changed materially
ISO 11607-2 IQ, OQ, PQ	No	The forming and sealing process is unchanged; nothing in 5.7.2 is triggered

The principle generalizes: identify which process limit moved, then regenerate the evidence that depends on it. A longer steam exposure moves the thermal limit and threatens seal strength and wet strength. A change in EO cycle humidity or aeration time moves the residual limit and threatens ISO 10993-7 conformity. A move from gamma to electron beam at the same nominal dose changes the dose rate and the dose gradient, and ISO 11607-1 gives no basis for assuming the two are equivalent.

D3. What process capability index does ISO 11607 require?

Short answer. None. Neither part of ISO 11607 states a numeric capability target. Clause 5.4.7 of ISO 11607-2 requires only that the process be under control and capable of consistently producing products according to predetermined requirements. The widely quoted figure of 1.33 comes from ISO/TS 16775, which is guidance, not from the standard.

The distinction matters in an audit. A finding that a process fails to meet Cpk 1.33 is a finding against your own internal acceptance criterion, not against ISO 11607. Conversely, meeting Cpk 1.33 does not by itself demonstrate conformity with clause 5.4.7, because that clause requires control as well as capability, and the two are separate claims evidenced in different ways.

Cpk	Sigma level	Process yield	Nonconforming per million	Verdict
0.33	1	68.27 %	317 311	Not acceptable
0.67	2	95.45 %	45 500	Not acceptable
1.00	3	99.73 %	2 700	Marginal
1.33	4	99.99 %	63	Target
1.67	5	99.9999 %	1	Better
2.00	6	About 100 %	0.002	Best

What to do when the target is not met

ISO/TS 16775 gives both the reasoning and the remedy. To maximize capability it is useful to achieve a minimum of variability while keeping the specification window as large as reasonable or possible, and the specifications themselves must be validated, meaning that within those limits seal integrity is assured and the package withstands sterilization and the hazards of transport, distribution and storage.

If the minimum desired Cpk is not obtained, analyze the process, keeping in mind that excessive variation always has a source. The candidates named are material thickness variation, deviations in temperature and flatness across the sealing surfaces, and temperature controllers with excessive fluctuation. Multiple material lots, enough to give a representative view of expected variation, should be used to check robustness before entering formal validation activities.

Closing: Five Positions Worth Holding

- **The standard sets no numbers where teams assume it does.** No sample size, no capability index, no industrial seal strength floor. What it requires in each case is a recorded rationale.
- **A supplier certificate is a component claim, not a system claim.** Full conformance is only possible for the completely sealed sterile barrier system validated for a specific device or family.
- **Accelerated aging is interim evidence.** Real time governs, must start within three months, and must be running before commercialization.
- **Seal strength and seal integrity answer different questions.** Burst answers neither on its own, and is not a whole package integrity test.
- **Since the 2023 amendments, every criterion traces to a risk record.** Acceptance criteria, sampling plans and monitoring frequencies all need that thread, or the file is non-conforming on its face.

IETQAN Conformity and Certification
11 Al-Ahram St. – Heliopolis 11341
Cairo – Egypt
www.ietqan.com ietqan@ietqan.com