4.1

Q- Does top management have to be involved with understanding the organization and its context?

ISO 9001:2015 doesn't stipulate who has to be involved. However, it makes sense to involve top managers, because they usually have a very good grasp of global issues that other employees lack. Also, involving top management helps to reinforce the significance of this important planning activity.

4.2

Q-Where do we draw the line with interested parties?
You could go on and on with this.

The key is how much of an impact they have on your organization. Start with the parties who have a significant effect on your ability to provide conforming products, meet customer requirements, and stay within the law. This is going to include customers, suppliers, subcontractors, employees, regulators, local police, and fire departments. Beyond these high-impact entities, it's up to you how far you want to go with interested parties.

How can we possibly determine the expectations of interested parties? We can't read their minds.
You can't read their minds, but you can ask them. For the important categories of interested parties, ask them what they believe to be their needs and expectations, now and in the future. The more dialogue and communication you have with interested parties, the better off your organization will be.

4.3

Q-Do all of our products and services have to be within the scope of the QMS?

No, your organization determines the QMS scope. That said, the broader the QMS is applied, the more benefit you'll get out of it.

Q-What happened to the requirement for a quality manual?
It no longer exists in ISO 9001:2015. The scope of the QMS must be maintained as

documented information (clause 4.3), and you must define the processes necessary for the QMS (clause 4.4), but these are the only remaining vestiges of the requirement. If you see value in a top-level quality manual, then by all means keep it

4.4

Q-Does all our documentation have to be in a process format, such as a fishbone (cause-and-effect) diagram?

No, you can choose whatever format works best for you. At a high level, you do have to define all the variables shown in subclasses 4.4.1(a–g). An easy and visual way to do this is through a fishbone diagram.

Does sub clause 4.4.2(a) require that we maintain documented information on every process?

No. You have to determine where documentation is necessary.

5.1.1

Q- There are numerous aspects of leadership and commitment that top management must demonstrate in sub clause 5.1.1. Do we have to keep records of top management's compliance?

ISO 9001:2015 doesn't require you to retain documented information (i.e., keep records) of this. If there's a different way of showing that they met the commitments, then that would suffice as evidence. In the absence of records, ask a variety of personnel how the commitments were met and how top management demonstrated leadership. And, of course, ask top management how they demonstrated leadership and commitment over the QMS. Their own words will reveal a lot.

Top management of our organization is the vice president of operations, but she has designated that the plant manager act as top management for ISO 9001:2015 purposes. Is this OK?

No. Top management is whoever leads your organization at the highest levels within the defined QMS scope. This can't be delegated downward

5.1.2

Q- Do I need to do anything specific in this section? It seems like we would satisfy 5.1.2 by implementing other parts of the ISO 9001:2015 standard.

You don't need to do anything specific unless you see the need to do so. This

section of ISO 9001 is often met through achievement of other requirements.

Q-We would like to introduce the concept of internal customers to our employees. Can we do this as part of ISO 9001:2015?

Yes, of course. The concept of internal customers is very powerful, though it's not specifically addressed by ISO 9001:2015.

5.2

Q- How does our quality policy support our strategic direction?

The policy is the uppermost document in your QMS, and it influences other high-level documents. For example, if you have a strategy to design certain products, the quality policy might state that innovation is a key principle. If you have a strategy for building a new facility, the policy might state that growth and/or expansion was important. The quality policy provides a stepping stone to strategic direction and quality objectives.

Q- Do we need to actually say in our quality policy that it will be communicated, understood, applied, and available to interested parties?

Not unless you want to. Those are requirements related to implementing the policy, not commitments that must be stated within the policy.

Q-Does the quality policy has to be signed by top management?

No. There must be some evidence of top management's approval, but this could be demonstrated through meeting minutes, approval of the quality manual or other means.

5.3

Q- Can we use an organizational chart to define responsibility and authority?

Probably not. An organizational chart usually shows reporting relationships and organizational structure, not responsibilities and authorities.

Q-ISO 9001:2015 no longer requires an ISO 9001 management representative. Is it OK if we continue to have one?

Yes, of course. The term "management representative" is gone from ISO 9001:2015, but the responsibilities and authorities are still included

6.1

Q-Do we have to use ISO 31000 or ISO 31010 when addressing risks and opportunities?

No, you're not required to use these guidance documents on risk management, but they might be helpful.

Q-We chose to identify risks and opportunities directly related to our QMS. We didn't include risks related to safety or the environment. Is that OK?

Yes. ISO 9001:2015 states that the risks and opportunities you identify are those needed to give assurance that the QMS can achieve intended results. Since safety and environment are not specifically addressed by the QMS, you don't need to include them. I believe there are benefits to addressing risks in a universal manner, but that decision is yours.

6.2

Q-I understand that ISO 9001:2015 requires quality objectives to be documented, but do the plans for achieving them also have to be documented?

Yes, I would interpret the documentation requirement as applying to the quality objectives and to the plans for achieving them. Document both.

Q- Everyone in our organization has his or her own personal objectives. Does this satisfy ISO 9001:2015 requirements?

Maybe. The intent of this requirement is to determine organizational objectives, not personal objectives. Make sure that you have established objectives on a broader scale (organizational, functional, or departmental). Personal objectives may then stem from the higher level objectives; if that's the way your organization wants to operate.

Q- Can we include our quality objectives in our quality policy?

You can if you want, but it makes more sense to maintain them as separate documents. The objectives are likely to change much more often than the policy.

Q-Can we use profit as a quality objective? Our consultant told us we can't because it has nothing to do with quality.

Yes, you can use profit as a quality objective. Quality is a very broad topic and can

encompass nearly anything the organization does. Profit certainly reflects on the quality of your processes and products

6.3

Q-We have established a change management process, but we're not clear on scope. Does every change we make have to be run through it?

No,of course not. Within your change management process, you should establish criteria for the types of changes that will be considered. Only changes above a certain level (such as a dollar amount, number of people affected, connection to products, or connection to customers) would go through your change management process. I would also keep your process as streamlined and practical as possible. That way, it's not burdensome.

Q-Do we have to keep records of changes and how they were planned?

ISO 9001:2015 doesn't require records (i.e., retained documented information), but it will be more difficult to prove that changes happened without records. Also, the process will be more consistent and effective if it is guided by a form or documented procedure. But you aren't required to keep records or have a documented procedure.

7.1.3

Q-Our organization is located in a rented office. The landlord takes care of all maintenance. What should we do about the infrastructure requirements of ISO 9001:2015?

In the case of an office environment, the office building is likely to be less important than the equipment within the building. Focus on things like the computer system, telephones, and other infrastructure that are needed to produce your products within the office environment. Also make sure you have communicated your building requirements to the landlord

7.1.4

Q-We have a gage that monitors the temperature of our warehouse, which must be maintained at 50° F +/- 10°. Does the gage have to be calibrated?

Yes. Because you've committed to a particular work environment, having accurate readings of that environment is necessary.

Q-The note at the bottom of this section includes a lot of unusual environmental factors: social, psychological, physical. We don't have to consider all these, do we?

No, these are simply given as examples. It's very unlikely that many companies will take environment to those extremes, because the conditions needed for running processes and products don't require consideration.

7.2

Q-The CEO of our company is the owner. We have no ability to make him undergo training, skill building, or anything else. Do we have to establish competency requirements for him?

Yes. Competency requirements must be established for all personnel who affect the performance and effectiveness of the QMS, and the owner and CEO certainly does this

Q-Do training records need to include the signatures of the people who were trained?

There is nothing in ISO 9001:2015 that requires signatures on training records (i.e.,retained documented information). However, there may be internal, statutory, or regulatory requirements that require signatures on training records.

Q-All our employees arrive to the organization fully competent, with significant experience, education, training, and skills. There's no additional training we need to provide. Is that OK?

At the very least, personnel typically need to be trained on the relevant aspects of your organization's QMS. No level of incoming competency will provide this type of information.

Q-Do we have to include temporary workers within our competency process? Some of them are only with us a couple of days.

Yes, you must include all personnel who affect the performance and effectiveness of the QMS. Exactly what the competency requirements are is up to you.

7.3

Q- Do we have to keep records of making employees aware of the quality policy, quality objectives, and the like? We view the awareness activity as being very similar to training.

No. Strictly speaking, ISO 9001:2015 doesn't require records of awareness activities, though it does require records as evidence of competence. It all depends on how you view this activity and what sort of accountability you need

Q-We wrote a communication program, but we've already violated it a couple of times by not performing the communication specified. Is this a potential audit finding?

Yes. If you've made a commitment to perform certain communication activities, then it's a requirement of the QMS. This is especially the case if the commitment is documented.

7.5

Q-Where is the requirement in ISO 9001:2015 that says we have to follow our own procedures?

There is no specific requirement in ISO 9001:2015 that states this. The expectation is that if you write a procedure within the scope of the management system, then you've committed to implementing it.

Q-Even though ISO 9001:2015 doesn't really distinguish between documents and records, we do. Is it OK if we maintain separate procedures for controlling documents and records?

Yes, of course. I expect that many companies will do this.

Do we need top management to review and approve all our documents?

I certainly hope not. There's nothing in ISO 9001:2015 that would require top management to approve all documents. You decide who must approve documents.

Q-We have a lot of job aids and work instructions in our work areas that are impractical to control. People use the information only occasionally. Can we just stamp all of this "For Reference Only"?

No. Either control the job aids and instructions or get rid of them. Stamping something "For Reference Only" does little to prevent personnel from using the

documents to guide their actions and make decisions.

Q-Can we specify two weeks as the retention time for a particular record?
If two weeks is as long as you need to retain a record, then that's your decision. ISO 9001:2015 doesn't provide any guidance on retention times.

8.2.1
Q-We have effective means of communicating with our customers, including a toll-free phone number, website, and frequent meetings. Do we need to document these processes in a procedure?
No, not unless you think it adds value.

8.2.2
Q- Do we have to put all the product requirements in the same place? They won't all fit on our sales order.
You don't have to record all the product requirements in the same place. As long you know what they are and can access them, then there's proof that they were determined

8.2.3
Q-We don't take orders or write contracts with customers. All we do is work against a schedule our home office sends us once a week. Can we exclude the requirement of reviewing product requirements?
No. The schedule represents your product requirements (at least in part) and you must review them.

8.3
Q-Do we need to keep separate records of each stage of design? We would like to combine all of these into a single record, sort of like a "design traveler" that follows a new product through the entire design process.
You can format your design records in whatever way makes sense to you. The record you described sounds like it could work very well.
8.4
Q-Can we evaluate our suppliers though a supplier questionnaire?
Yes, but weigh the value of a questionnaire against other types of criteria.

Questionnaires are often “pencil whipped” by suppliers and seldom reflect meaningful performance of the suppliers.

Q-Do we have to keep records of verifying purchased product?
Yes. Records aren’t specifically required in clause 8.4, but there would be no other way to demonstrate that the verification took place. Also, clause,clause 8.6 requires records of all product releases, which would certainly include purchased products.

8.5.1

Q-ISO 9001:2015 doesn’t even mention work instructions anymore. Does that mean this sort of tool isn’t considered effective?
No, not at all. The fact that ISO 9001:2015 doesn’t mention it reflects the general movement away from prescribing documentation. If you see value in work instructions, then by all means use them. Keep them graphic, concise, and located near the point of use.

8.5.5
Q-Due to the nature of our business, we have no post-delivery activities. In fact, our customers don’t want us to follow up with them for any reason. Do we have to specify post-delivery activities?
No, of course not. This is only applicable if it is needed to achieve product conformity or customer satisfaction.

8.6
Q-We inspect our products, but the record of inspection is shipped with our products to the customer. Is that OK?
No, it’s not OK. How are you going to demonstrate that the inspection took place without a record of some sort? Consider developing a process that enables you to provide data to your customers and maintain proof of required inspections.

Q-We’re in a service industry, and we have customers sign off at the end of the project that all requirements are fulfilled. Can we use this as our release of product and services?
Yes, that would work. You’re free to specify who performs release of services and

how it's accomplished.

Q- Our employees do a quick visual inspection of products before they're shipped. Do we need to keep records of this?
Yes. If this is product verification you have deemed necessary, then records are required. Find a simple and transparent way of capturing the record

8.7
Q-We manufacture a product that requires a number of adjustments and tweaks before it meets requirements. Do we have to consider the product nonconforming while we're working to bring it into specification?
No. The product isn't at a point where it's expected to meet requirements. Identify the formal verification points in your process. That's where control of nonconforming outputs will definitely apply.

Q-We use customer feedback as a way to identify nonconforming service. We don't make and inspect a tangible product, so we feel this is one of the best ways to identify problems. Will this work?
Yes. Applying these requirements to a service organization will take some creativity, and this sounds like a perfectly reasonable way to do it. Keep in mind that your internal checks of service work might also identify nonconformities.

9.1.2

Q-Can we use our complaint program to satisfy the customer satisfaction requirements?
You can use it, but it can't be your only method of capturing customer feedback. Since ISO 9001:2015 requires you to monitor customer perceptions, there must be a proactive aspect to your feedback to ensure the full range of possible perceptions.

Q-There's nothing proactive about waiting for customers to complain. Do we have to capture feedback from internal customers?
The intent of this requirement is to capture the feedback of customers outside the scope of your management system. This could be another branch of your company or a different firm altogether. You don't have to capture customer feedback between departments within your organization unless you see value in

9.1.3

Q- All the items that must be analyzed and evaluated are already part of our management review. Do we have to invent new ways of analyzing this information?

No. ISO 9001:2015 doesn't specify how or where the analysis and evaluation will take place. Management review sounds like an especially good way to get the job done.

Q-Are we required to classify our internal audit nonconformities as major or minor, like certification bodies do?

No. Treating all audit nonconformities as being equally important can remove a lot of controversy and confusion from the audit process.

Q-Do we have to use checklists during our internal audit?

No. There's nothing in ISO 9001:2015 that requires checklists for internal audits. Checklists could provide evidence that audits took place, though. They could also help guide the activities of less-experienced auditors.

Q- Do we have to audit our internal audit process?

Yes, you're required to audit all aspects of your management system, including your internal audit process.

9.3

Q- Our general manager is frequently out of town and it's very difficult to schedule management review. Can he delegate someone to attend management review on his behalf?

No. Your management review process must involve top management. Perhaps you could explore creative ways of involving the general manager in management review when he is out of town.

Q-Does management review have to be an actual meeting, or can we have a virtual meeting via teleconference or webinar?

Management review doesn't have to be an actual meeting. As long as you cover the required inputs and outputs, you can conduct management review in any way you see fit.

Q-We would like to address different inputs of management review in different meetings. For example, process performance and product

conformity are subjects we talk about in our weekly staff meeting. Customer feedback gets addressed at our monthly roundtable. Will this approach meet ISO 9001:2015 requirements?
Yes. You can structure your management review in any way that makes sense to you, as long as it involves top management

10.2
Q-We have a separate procedure for each type of corrective action. We have one for supplier corrective actions, one for audit corrective actions, and another for customer complaints. Is this OK?
Yes. Structure your corrective action process in whatever way makes the most sense to you.

Q-Some of our corrective actions have been open for over half a year because they involve capital investments. Is it OK for them to remain open so long?
Yes. As long as you're making progress on the actions and updating the records, there's no problem at all

10.3
Q-Do we need to establish a stand-alone continual improvement program?
No, there is no need to establish a stand-alone continual improvement program. As long as you're using your other improvement processes correctly (quality objectives, internal audits, analysis and evaluation, corrective actions, and management review), then together they constitute your continual improvement process.

Q-Can we use our lean enterprise program to satisfy the continual improvement requirements of ISO 9001:2015?

Yes, of course. Use whatever tools and processes work best in your unique situation