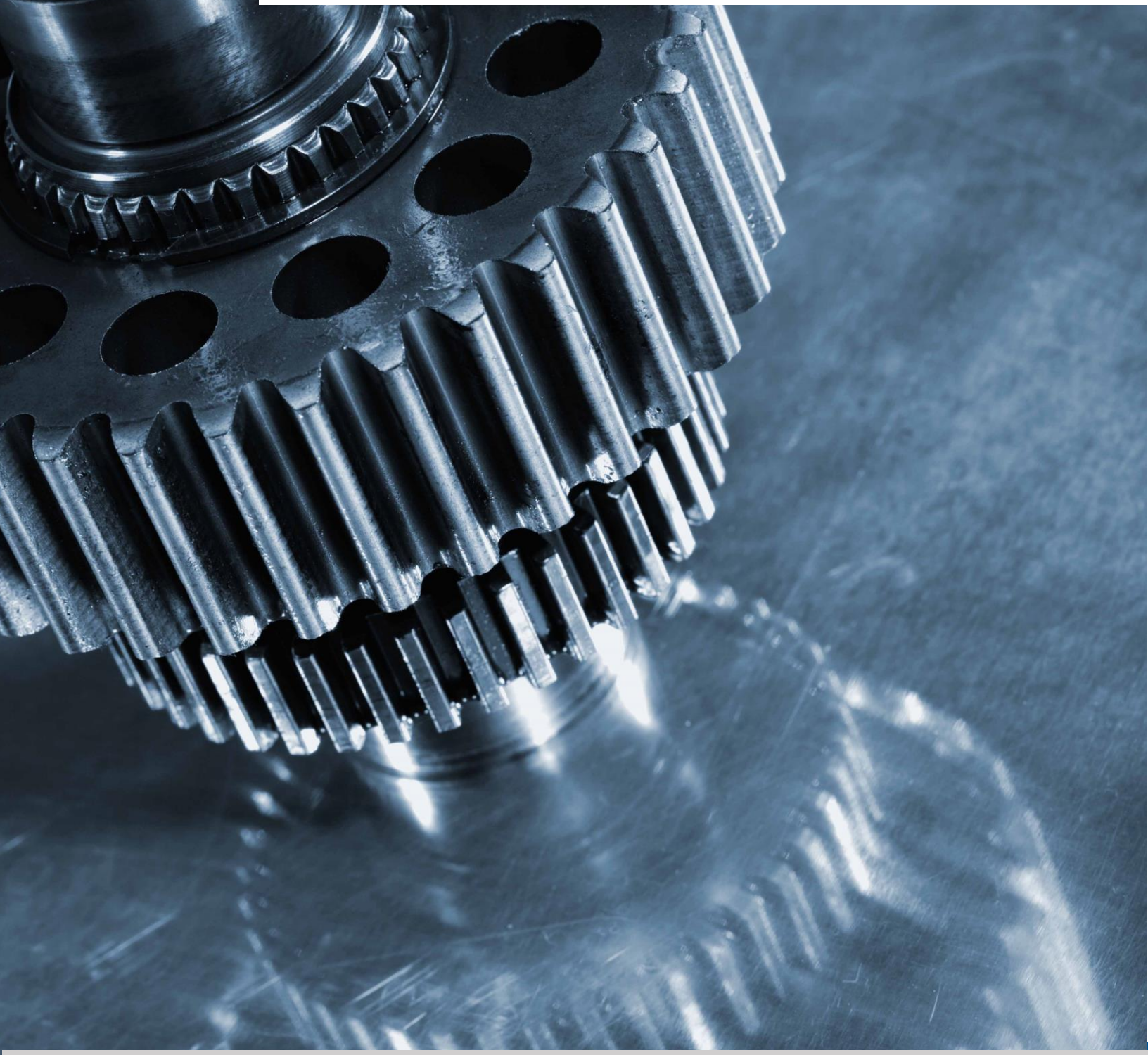
ISO 9001:2015
TRANSITION INFORMATION



ISO 9001:2015 Transition

It Doesn't Need to be Difficult

Whether your organization is transitioning from ISO 9001:2008 to the new ISO 9001:2015, or implementing an ISO 9001 Quality Management System (QMS) for the first time; NSF-ISR is here to help!

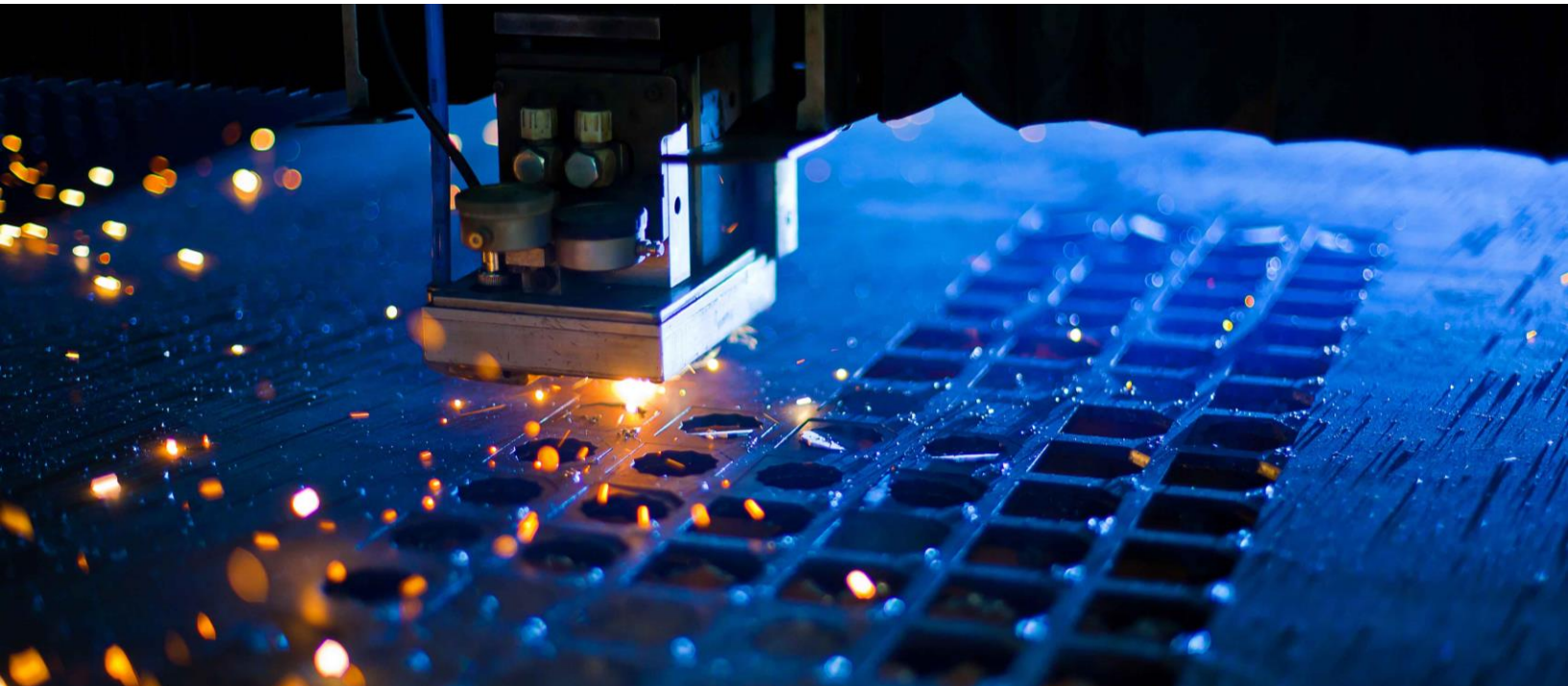
The following information is meant to provide you with a straight forward guide to preparing for a successful transition and implementation for ISO 9001:2015.

ISO 9001 Overview

ISO 9001 Quality Management Systems registration provides a set of uniform requirements for a quality management system. A number of quality management principles including a strong customer focus, support of top management, the process approach and continual improvement form the basis for the standard.

It is very important to understand that your organization's ISO 9001:2008 certification will no longer be valid as of September 14, 2018. As a result, we are encouraging your organization to get started as soon as possible on the transition path to achieving ISO 9001:2015 registration. Our goal is to have all of our clients in a position where their transition audits are completed by June 15, 2018 in order for any corrective actions to be completed, and for the certifications to be processed well before the September 15, 2018 deadline. The standard can be purchased through the NSF Bookstore.

At first glance, the changes introduced in the 2015 version of the Standard may seem to be significant. However, NSF International Strategic Registrations (NSF-ISR) can be your partner in simplifying the approach to implementing ISO 9001:2015.



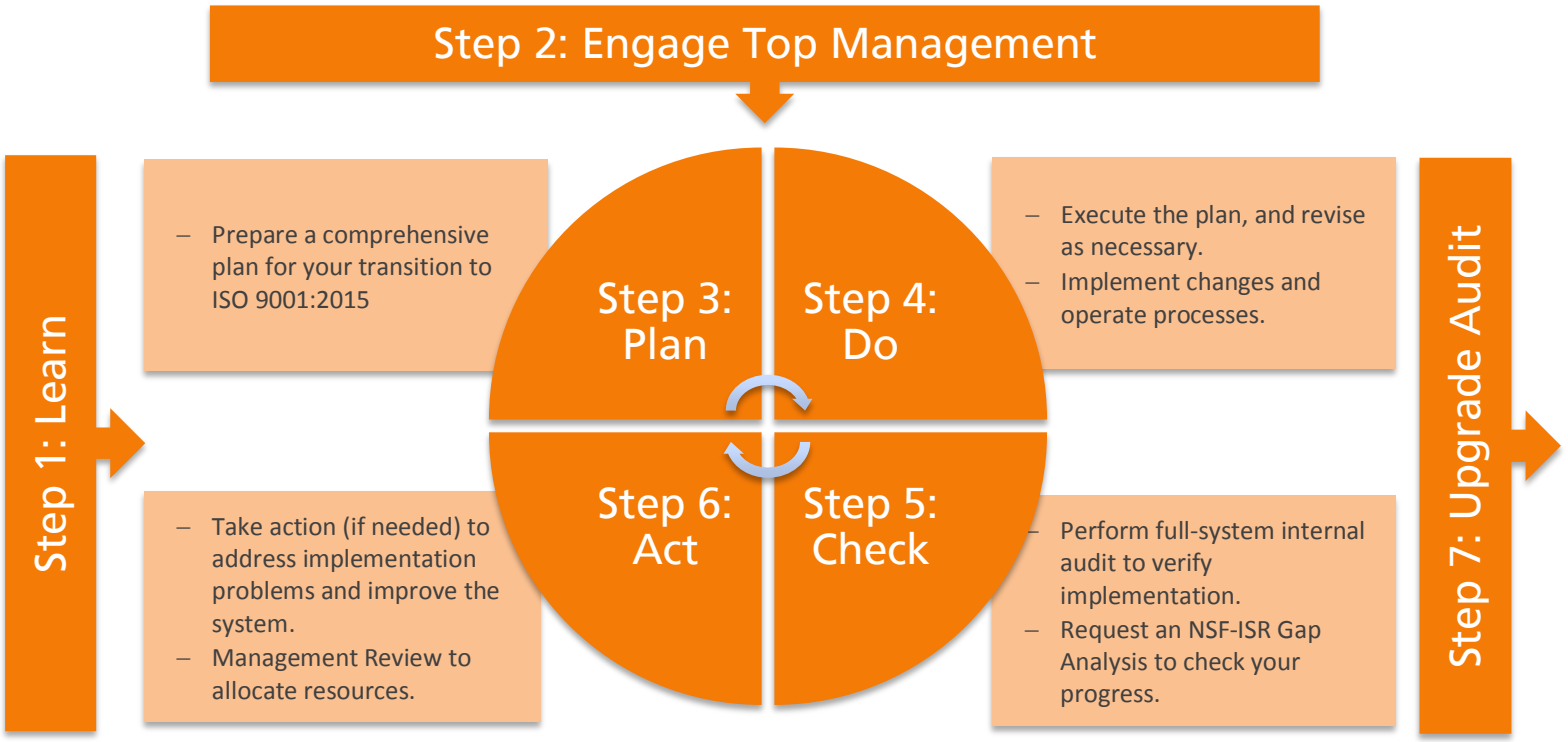
Changes to the Standard

The newly revised ISO 9001:2015 responds to the latest market developments, and is more compatible with other management systems, such as ISO 14001, thanks to an updated, higher-level structure. The new standard is less prescriptive than the previous version; instead focusing on performance through a combination of risk-based thinking and a process approach, as well as employment of the "Plan-Do-Check-Act" cycle at all levels in the organization.

We have outlined 7 Steps that can guide you to a successful transition/ implementation:

1. Learn
2. Engage Top Management
3. Plan
4. Do
5. Check
6. Act
7. Upgrade Audit

The following pages contain a more in-depth explanation of the steps to a successful transition.



Step 1: LEARN

- NSF-ISR has informative materials to help you learn about ISO 9001:2015, all available at www.nsf.org/info/iso-updates.
    - ISO 9001 Webinar Series
    - Online Readiness Assessment
    - Newsletters
    - Upgrade Planner & Comparison Matrix
- Purchase a copy of the ISO 9001:2015 Standard from the NSF Bookstore.
- Review the Standard carefully and make note of the changes in requirements, or changes in approach to other clauses of the Standard.
- NSF-ISR is your partner in this process, and we will continue to add materials to guide our valued clients throughout the transition period (through September 14, 2018). We are here to help you in this step and all of the transition steps that follow.
- Visit www.gftc.ca for more in-depth training offerings.

Step 2: ENGAGE TOP MANAGEMENT

- A fundamental change in the 2015 version of ISO 9001 is the emphasis on Leadership and the Top Management of your organization.
- Traditionally, the QMS development, implementation and maintenance have been the domain of the Quality Management representatives of your organization. This has also required Top Management involvement in the past, but the new version of the Standard has more far-reaching requirements to all facets of your organization.
- Top Management is considered to be the senior-most person(s) in your organization who are the decision makers.
- Top Management will need to be actively involved in the decision process for determining the scope of the QMS, determining the internal and external factors that influence the performance of your organization's QMS, determining and managing risks, and providing leadership and resources to ensure that the QMS is successfully implemented and maintained.

Step 3: PLAN

- Another of the highlighted revisions is the emphasis on managing change. Since transitioning to the 2015 version of the Standard, or implementing a QMS against these requirements for the first time, represents significant change; it makes a great deal of sense to develop a process to plan for the transition in a fashion consistent with the change.
- Develop a cross-functional, or multi-disciplinary team (including Top Management) to plan out the transition/implementation process.
- Identify key milestones - Assign responsibilities and due dates.
- NSF-ISR has prepared an ISO 9001:2015 Planner and Delta Checklist that can help you identify changes in this standard version. The use of the planning sections are optional, however, the remainder of the document will be necessary in the later steps.
- Hold regular meetings to update progress and plan next steps.
- Have Top Management reviews of progress and continuously improve upon the plan as you progress through the transition.
- A comprehensive plan for transition or implementation may include the following:
    - Complete the NSF-ISR Readiness Tool to help you identify areas where you need to focus. You can utilize the readiness tool multiple times as progress on you journey.
    - Review the current scope of your QMS against the new requirements for defining the scope and revise as necessary.
    - Review and revision of QMS documentation, now referred to "Documented Information" in ISO 9001:2015.
    - Retire any documents and records that are unnecessary, or have become obsolete. Focus on the documents and records required by the Standard, and those specific to your organization, to operate and maintain the QMS effectively and efficiently.
    - Implement any new processes required to meet the new requirements of the Standard, once it is determined the method(s) your organization will use to demonstrate compliance (e.g. Management of risks and opportunities).
    - Perform full-system internal audits to verify the effectiveness of the entire QMS, including the changes your organization has implemented.
    - Take corrective actions where needed.
    - Perform detailed management reviews. Following the requirements of ISO 9001:2015, this is the best method of ensuring that Top Management is engaged and aware of the transition / implementation process. It is also a great forum for resource needs to be determined and allocated to assist the overall QMS.
    - You may wish to request NSF-ISR perform a GAP Analysis to assist you with you planning and readiness.

Step 4: DO

- Once established, the Plan should be put into action to implement changes to the requirements of the Standard.
- It is important to ensure that as the QMS evolves into a system that is compliant with ISO 9001:2015, your organization will need to ensure continued compliance with the requirements of ISO 9001:2008 in order to maintain your certification through the transition process. Fortunately, fundamental QMS requirements are present in both versions of the Standard, so it is expected that your organization will continue to operate its processes for the following, and other important QMS processes unique to your organization:
    - Corrective actions
    - Customer Satisfaction
    - Control of nonconforming product
    - Process control
    - Internal audits
    - Management review
- Determine and confirm a date for your Upgrade Audit to be conducted by NSF-ISR.

Step 5: CHECK

- At this stage, your organization is getting close to the time for NSF-ISR to perform your transition audit. If you haven't done so already, you should confirm your Upgrade Audit dates with NSF-ISR Lead Auditor and Account Manager.
- As mentioned in Step 3, your plans should include comprehensive internal audits. NSF-ISR Lead Auditor will need to confirm that you have performed a full-system internal audit and management review to the ISO 9001:2015, before we can proceed with your Upgrade Audit.
- Your internal audit will verify all of the hard work you put into preparing and executing your implementation plan.

Step 6: ACT

- Any resulting internal audit corrective actions will need to be closed, and the details reviewed at management review in order to demonstrate that your organization's efforts have paid off, and you are ready for NSF-ISR to validate this at an Upgrade Audit.
- In situations where there were significant findings from the internal audit, your Top Management should consider having another round of internal audits and management review, once the previous corrective actions have been implemented and taken effect.
- Top Management will also need to confirm that resources for the maintenance of the QMS are adequate, or if changes are necessary.

Step 7: UPGRADE AUDIT

- NSF-ISR will be performing your Upgrade Audit as a Recertification Audit. This means that once successfully completed, and any resulting CARs are closed, we will be able to grant your organization with an ISO 9001:2015 certificate. This begins a new, full three-year cycle!
- All Upgrade Audits need to be completed well in advance of the September 14, 2018. This will ensure that your certification can be processed before the 2008 version of Standard expires. Let us help you plan your organization's Upgrade Audit accordingly.
- Your NSF-ISR Lead Auditor or Account Manager will provide you with a copy of the ISO 9001:2015 Planner and Delta Checklist. We will need your organization to complete this form to provide a final check of your readiness of your QMS for the Upgrade Audit.
- Your NSF-ISR Lead Auditor will perform the Upgrade Audit onsite, and verify the information your organization provided on the form in the previous step.
- The NSF-ISR audit process will not change at the Upgrade, although we will need to make sure that your organization's QMS includes, and is compliant with all of the requirements of ISO 9001:2015, especially the changes, or "Deltas" between the 2008 and 2015 versions.

Clause-by-Clause Comparison: ISO 9001:2015 and ISO 9001:2008

ISO 9001:2015 CLAUSE	EQUIVALENT ISO 9001:2008 CLAUSE
1 Scope	**1 Scope**
2 Normative Reference	**2 Normative Reference**
3 Terms and Definitions	**3 Terms and Definitions**
4 Context of the Organization	**N/A**
4.1 Understanding the organization and its context	None (previously found under 1.1)
4.2 Understanding the needs and expectations of interested parties	None (previously found under 1.1)
4.3 Determining the scope of the quality management system	None (previously specified under 4.2.2)
4.4 Quality management system and its processes	4.1
5 Leadership	**N/A**
5.1 Leadership and commitment	5.1, 5.2
5.2 Policy	5.3
5.3 Organizational roles, responsibilities and authorities	5.5.1
6 Planning	**N/A**
6.1 Actions to address risks and opportunities	None (new requirement, but borrows ideas found in 8.5.3, 5.4.2 and 7.1)
6.2 Quality objectives and planning to achieve them	5.4.1
6.3 Planning of changes	5.4.2
7 Support	**N/A**
7.1 Resources	6.1
7.1.1 General	6.1
7.1.2 People	6.2
7.1.3 Infrastructure	6.3
7.1.4 Environment for the operation of processes	6.4
7.1.5 Monitoring and measuring resources	7.6
7.1.6 Organizational knowledge	None
7.2 Competence	6.2
7.3 Awareness	6.2
7.4 Communication	5.5.3
7.5 Documented Information	4.2.3, 4.2.4
7.5.1 General	4.2.3, 4.2.4
7.5.2 Creating and Updating	4.2.3, 4.2.4
7.5.3 Control of Documented Information	4.2.3, 4.2.4
8 Operation	**N/A**
8.1 Operational planning and control	7.1
8.2 Requirements for products and services	7.2
8.2.1 Customer communication	7.2.3

Clause-by-Clause Comparison, *continued:*

ISO 9001:2015 CLAUSE	EQUIVALENT ISO 9001:2008 CLAUSE
8.2.2 Determination of requirements related to products and services	7.2.1
8.2.3 Review of requirements related to products and services	7.2.2
8.2.4 Changes to requirements for products and services	7.2.2
8.3 Design and development of products and services	7.3
8.3.1 General	None (although the ideas behind this requirement are rooted in clause 7.3 at large)
8.3.2 Design and development planning	7.3.1
8.3.3 Design and development inputs	7.3.2
8.3.4 Design and development controls	7.3.4, 7.3.5, 7.3.6
8.3.5 Design and development outputs	7.3.3
8.3.6 Design and development changes	7.3.7
8.4 Control of externally provided processes, products and services	7.4.1
8.4.1 General	7.4.1
8.4.2 Type and extent of control	7.4.1, 7.4.3
8.4.3 Information for external providers	7.4.2
8.5 Production and service provision	7.5.1, 7.5.2
8.5.1 Control of production and service provision	7.5.1, 7.5.2
8.5.2 Identification and traceability	7.5.3
8.5.3 Property belonging to customers or external providers	7.5.4
8.5.4 Preservation	7.5.5
8.5.5 Post-delivery activities	7.5.1, 7.2.1
8.5.6 Control of changes	4.2.3, 5.4.2, 7.3.7
8.6 Release of products and services	8.2.4
8.7 Control of nonconforming outputs	8.3
9 Performance evaluation	**N/A**
9.1 Monitoring, measurement, analysis and evaluation	8.1, 8.2
9.1.1 General	8.1, 8.2
9.1.2 Customer satisfaction	8.2.1
9.1.3 Analysis and evaluation	8.4
9.2 Internal audit	8.2.2
9.3 Management review	5.6
10 Improvement	**N/A**
10.1 General	8.3, 8.5
10.2 Nonconformity and Corrective Action	8.3, 8.5.2
10.3 Continual Improvement	8.5.1

We hope that this transition guide is helpful as your organization transitions to the new ISO 9001:2015 Quality Management Standard.

Whether you are currently registered and would like to gain efficiency by consolidating your audits, or are looking to newly register, we have the tools and knowledge you need to succeed. NSF-ISR is a leader in management systems registrations and can provide the latest information to clients on updates to the standard. We work with clients to ensure they fully understand the requirements and timing of the standard changes.

Through webinars, email updates, web content, presentations, and white papers, NSF-ISR is here to ensure that customers are equipped with the tools they need for registration. Our knowledgeable auditors are trained and our systems calibrated for ISO 9001:2015.

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