

SPC Software Productivity Centre Inc.'s ISO Gap Checklist

Version 1.1

Overview

The ISO Gap Checklist was originally developed by SPC for use in SPC ISO consulting as a means of quickly obtaining an overall impression of how large a gap a software development company has in meeting ISO 9001 requirements. It can also be used to help determine the effort involved in preparing for ISO certification.

The checklist is based on ISO 9000-3, which is a guideline for applying ISO 9001 to the development, supply and maintenance of computer software. Version 1.1 of the checklist complies with the 1991 issue of 9000-3¹.

ISO 9000-3 (1991) contains 22 major clauses or areas. They are as follows:

9000-3 Section#	Section Heading
4.1	Management responsibility
4.2	Quality system
4.3	Internal quality system audits
4.4	Corrective action
5.2	Contract review
5.3	Purchaser's requirements specification
5.4	Development Planning
5.5	Quality Planning
5.6	Design and Implementation
5.7	Testing and Validation
5.8	Acceptance
5.9	Replication, delivery and installation
5.10	Maintenance
6.1	Configuration Management
6.2	Document Control
6.3	Quality Records
6.4	Measurement
6.5	Rules, practices and conventions
6.6	Tools and techniques
6.7	Purchasing
6.8	Included Software Product
6.9	Training

See the ISO 9000-3 Guidelines for an appendix which cross-references the 9000-3 sections with ISO 9001 sections.

For each of the above 22 areas, the ISO Gap Checklist contains a number of questions that are used to determine whether the requirements of that area are met. In addition, suggestions for relevant documentation and reviews are provided.

Using the Checklist

Each page of the checklist provides space for the user to indicate a Yes/No answer to each question, to check off the existence of documentation and reviews, and to write notes. Note that the answers will be subjective as:

- it will be difficult to answer “Yes” to a particular question unless you are certain that your organization has an adequate policy/process/procedure/standard in place and consistently applies it. If you find yourself answering “Yes,but....”, try to determine if the “but” is a significant deviation before allowing yourself to answer “Yes”.
- the documents in use by your organization may not have the same names as those given in the checklist, or your organization’s documents may combine the content of listed documents in different ways. You will have to decide if the intent of the listed documents is covered by your organization’s set of documentation.
- different industries may utilize various differing processes, procedures, and methods to satisfy the ISO requirements.

Make good use of notes to itemize your findings and assumptions, and reasons for them.

Once the answers for a particular area are given, you should “grade” the area as one of the following:

“Grade”	Meaning
Adequate (AD)	Possible pass
Needs Improvement (NI)	Very close to adequate, but missing something
Unacceptable (UN)	Significant amount work needed to improve
Not Covered (NC)	Didn’t review the area
Not Applicable (NA)	Area not applicable to the organization (e.g., some organizations may not have development subcontracted out, etc.)

ISO Gap Analysis

Once you have worked through the answers to each of the 22 areas in the checklist, and graded each area, you will need to summarize your results and identify actions that will improve your organization’s readiness for ISO certification.

References

ISO 9001 (1994), “Quality systems – Model for quality assurance in design, development, production, installation and servicing”

ISO 9000-3 (1991), “Guidelines for the application of ISO 9001 to the development, supply and maintenance of software”

ISO/DIS 9000-3 (1996 Draft), “Guidelines for the application of ISO 9001: 1994 to the development, supply, installation and maintenance of computer software”

¹ There is a more recent issue of ISO 9000-3 which is a draft standard issued in 1996 that aligns ISO 9000-3 with the latest issue of ISO 9001 (1994). An official release of the updated 9000-3 standard is expected in Q1 1998. However, since the ISO Gap Checklist is only to be used to get an initial impression of the current state of readiness and not to guarantee a successful audit for ISO certification, the differences should not affect the usefulness of the checklist as a first step towards ISO certification.

SPC ISO GAP ANALYSIS CHECKLIST (Version 1.1)

ISO 9000-3 Clauses	Questions	Possible Documentation	Possible Reviews	Notes
4.1 Management Responsibility	<p>1. Has management defined its policy and objectives to quality?</p> <p>2. Is the quality policy implemented and maintained in the organization?</p> <p>3. Are the responsibilities and authority of all people whose job affects quality defined and documented?</p> <p>4. Are verification activities defined, provided with adequate resources, and assigned trained personnel?</p> <p>5. Is there an assigned management representative who ensures requirements of ISO 9001 are implemented and maintained?</p> <p>6. Is the quality system reviewed by management at defined intervals? Does review include suitability and effectiveness in satisfying quality policy and objectives?</p> <p>7. If the organization acts as a purchaser, is there a purchaser representative responsible for dealing with suppliers on contractual issues?</p> <p>8. Are there regular reviews between purchaser and supplier to cover:</p> <ul style="list-style-type: none"> - conformance to requirements - verification and acceptance test results? 	<p>Quality Policy Statement</p> <p>Quality Manual</p> <p>Quality System Review Records</p> <p>Purchasers Requirements Specification</p> <p>Acceptance Criteria</p> <p>Acceptance Procedures</p> <p>Records of Non-Conformance for products, process, and the quality system</p>	<p>Quality System Review</p> <p>Supplier and Purchaser Joint Reviews</p>	

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4.2 Quality System	<p>1. Does a documented quality system exist which covers all life cycle phases?</p> <p>2. Is the structure of the quality system documents defined in the Quality Manual?</p> <p>3. Does the Quality Manual include references to documented procedures and processes?</p> <p>4. Do documented processes and procedures exist which are consistent with ISO 9001 and corporate quality policy?</p> <p>5. Are how the requirements for quality kept, documented for each software development project (e.g. in a Quality Plan)?</p>	<p>Quality System Documents</p> <p>Quality Manual</p> <p>Quality Processes and Procedures</p> <p>Quality Planning documents (i.e. Quality Plan)</p>		

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<p>4.3 Internal Quality System Audits</p>	<p>1. Are internal quality system audits conducted to determine conformance to the documented quality system and effectiveness of the quality system?</p> <p>2. Does a schedule exist for conducting audits?</p> <p>3. Are audit follow-up actions carried out in accordance with corrective action procedures?</p> <p>4. Are results of audits brought to the attention of the people responsible for the area?</p>	<p>Internal Audit Schedule</p> <p>Internal Audit Procedures</p> <p>Corrective Action Procedures</p> <p>Corrective Action Request</p> <p>Internal Audit Results</p>	<p>Quality System Audit</p>	

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4.4 Corrective Action	1. Do corrective action procedures exist to prevent and record nonconforming products, processes, and quality system? 2. Do the procedures take into account investigating the cause and corrective action needed to prevent? 3. Do the procedures take into account analyzing applicable records and procedures to detect and eliminate potential causes for nonconformance? 4. Do the procedures allow for taking preventative action that corresponds to the risks associated with the nonconformance? 5. Do the procedures include controls to ensure corrective action is taken? 6. Are the procedures followed and maintained?	Corrective Action Procedures Corrective Action Records or Request		

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5.2 Contract Review (by the Supplier)	1. Do procedures for contract review exist? 2. In the absence of written requirements, as a supplier do you accept the responsibility to ensure that all customer requirements are clearly understood and agreed before accepting the order? 3. Are contracts reviewed to ensure: <ul style="list-style-type: none"> - scope and requirements are defined - possible risks are identified - proprietary information is protected - any requirements differing from those in tender are resolved - you have capability to meet contractual requirements - supplier's responsibility with regard to subcontracted work is defined - purchaser has capability to meet contractual requirements? 	Contract Review Procedures Contract Review Records Contract Subcontracts Contract Risks	Contract Review	

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5.4 Development Planning	<p>1. Is there a development plan for each software development?</p> <p>2. Does the development plan include:</p> <ul style="list-style-type: none"> - project definition and objectives - team structure, responsibilities - use of sub-contractors and resources - defined development process or methodology (i.e. phases) - schedule of tasks and deliverables - identification of related plans - progress control - organizational responsibilities - interfaces between different groups - verification plan for phase outputs <p>3. Is the development plan updated as the project progresses?</p> <p>4. Is the development plan reviewed and approved?</p> <p>5. Does the development plan identify methods for development (i.e. rules, practices, tools, techniques)?</p> <p>6. Does the development plan identify a Configuration Management (CM) plan?</p> <p>7. Are there planned project progress reviews?</p> <p>8. Are inputs and outputs for each development phase defined?</p> <p>9. Is each output verified and verified prior to submittal to CM?</p>	<p>Development Plan</p> <p>Configuration Management Plan*</p> <p>Quality Plan*</p> <p>Test Plan*</p> <p>Methods*</p> <p>Verification Plans*</p> <p>Progress Review Records</p> <p>Verification Results</p> <p>(*if in separate documents other than Development Plan)</p>	<p>Progress Reviews</p> <p>Plan Reviews</p>	

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<p>5.5 Quality Planning</p>	<p>1. Is there a quality plan and is it updated as the development progresses?</p> <p>2. Is the quality plan reviewed and agreed upon by all organizations involved?</p> <p>3. Does the quality plan include:</p> <ul style="list-style-type: none"> - quality objectives - input and output criteria for each phase - verification and validation activities - planning of test and V&V activities - responsibilities for quality activities - defect control and corrective action 	<p>Quality Plan (Note it may be included in or combined with other plans; i.e. Resource Plan, Development Plan).</p>	<p>Quality Plan Review</p>	

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5.6 Design and Implementation	<p>1. Are there procedures and guidelines to ensure the design and implementation activities are carried out in a disciplined manner?</p> <p>2. Is there a defined design methodology and is it followed?</p> <p>3. Are implementation rules, such as naming conventions and programming guidelines defined and followed?</p> <p>4. Is the method of implementation and use of implementation tools appropriate to satisfy purchaser requirements?</p> <p>5. Are internal technical reviews held throughout design and implementation to ensure requirements are met and methods are followed?</p> <p>6. Are known deficiencies resolved or risk-assessed prior to proceeding with the next phase of development?</p>	<p>Design procedures and guidelines</p> <p>Implementation procedures and guidelines</p> <p>Technical Review Records</p>	<p>Technical Reviews</p>	

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5.8 Acceptance	<p>1. Is acceptance criteria defined, documented, and agreed upon between the supplier and purchaser?</p> <p>2. Is there a documented agreement between the purchaser and the supplier for handling problems detected during the acceptance test?</p> <p>3. Did the acceptance planning include identification of resources, hardware and software environments, and schedule?</p>	<p>Acceptance Plan</p> <p>Acceptance Test Procedures</p> <p>Acceptance Test Criteria</p> <p>Acceptance Test Results and Records (Problem Records)</p>		

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<p>5.9 Replication, delivery and installation</p>	<p>1. Prior to replication and delivery is consideration given to number of copies, media type, documentation, copyright, masters, and obligations?</p> <p>2. Are the copies of product verified for correctness and completeness?</p> <p>3. Has installation planning taken into account schedules, access to facilities, personnel availability, access to purchaser's equipment and systems, validation of the installation, and a formal procedure for approval of each installation?</p>	<p>Replication Procedure</p> <p>Delivery Procedure</p> <p>Installation Procedure</p> <p>Installation Plan</p>		

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5.10 Maintenance	<p>1. If maintenance is required by the contract, have maintenance procedures been developed and followed?</p> <p>2. Are the items to be maintained (i.e. programs, data, specifications, documents) clearly specified in the contract?</p> <p>3. Has the maintenance plan been defined and agreed upon by the supplier and the purchaser beforehand.</p> <p>4. Are software changes carried out during maintenance made following the development procedures, as far as possible? Are all changes documented in accordance with the procedures for document control and CM?</p> <p>5. Do maintenance records include:</p> <ul style="list-style-type: none"> - problem requests - requests for assistance - responsibilities for responding - priorities - corrective action results - statistical data <p>6. Are there documented and agreed upon procedures for releasing new versions of the software?</p>	<p>Maintenance Procedures</p> <p>Maintenance Plan</p> <p>Maintenance Records and Reports</p> <p>Upgrade and Release Procedures</p>		

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6.1 Configuration Management	<p>1. Is there a configuration management system which:</p> <ul style="list-style-type: none"> - identifies versions of software items - identifies product components - identifies build status - controls simultaneous updates - identifies and tracks changes resulting from a change request? <p>2. Does the configuration plan include responsibilities, CM activities, CM tools and techniques, and timing of when items are brought under CM control?</p> <p>3. Is there a mechanism and procedure which enables software items and related specifications, tools, software, hardware, and files to be uniquely identified throughout the entire software life cycle?</p> <p>4. Is there a documented mechanism to identify, document, review and authorize changes to software items under CM? Is it followed always?</p> <p>5. Are affected personnel notified of the software changes?</p> <p>6. Is the status of software items and change requests reported on?</p>	<p>Configuration Management Plan</p> <p>Configuration Management Procedures</p> <p>Identification and Traceability Procedures</p> <p>Change Control Procedures</p> <p>Change Request Records</p> <p>Configuration Status Reporting Procedures</p>	<p>Review of Change Requests</p>	

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6.2 Document Control	<p>1. Are quality system documents, planning documents, and product documents controlled?</p> <p>2. Do procedures exist to control document approval and issue?</p> <p>3. Are changes to controlled documents reviewed and approved?</p> <p>4. Are the current versions of documents identifiable by a master list or document control procedures?</p>	Document Control Procedures	Review of Document Changes	

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6.3 Quality Records	<p>1. Are there procedures for the identification, filing, maintenance, and disposition of quality records?</p> <p>2. Are quality records identifiable by product?</p> <p>3. Are the quality records stored in such a way that damage and loss is minimized?</p> <p>4. Are retention times of records determined and recorded?</p>	<p>Quality Record Procedures</p> <p>List of Quality Records</p>		

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6.4 Measurement	<p>1. Are product metrics collected and used to manage the development?</p> <p>2. Are product defects measured and reported?</p> <p>3. Is remedial action taken if metric levels exceed established target levels?</p> <p>4. Are improvement goals established in terms of the metrics?</p> <p>5. Are process metrics collected to measure the effectiveness of the development process in terms of schedule and in terms of fault prevention and detection?</p>	Procedures for Measurement		

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<p>6.5 Rules, practices and conventions</p>	<p>1. Do rules, practices, and conventions exist for the processes of the quality system?</p> <p>2. Are they followed?</p> <p>3. Are the rules, practices, and conventions reviewed and revised, when required?</p>	<p>Rules, practices, and conventions</p>	<p>Review of rules, practices, and conventions</p>	

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6.7 Purchasing	<p>1. Are sub-contractors elected on their ability to meet the subcontract and quality requirements?</p> <p>2. Are records of acceptable sub-contractors established and maintained?</p> <p>3. Do the sub-contracts include requirements for validation and acceptance of the sub-contracted work?</p> <p>4. Are purchased products checked for conformance to specified requirements?</p> <p>5. Do purchase orders clearly identify the product?</p> <p>6. Are purchase orders reviewed to ensure adequacy of specified requirements?</p>	<p>Records of Acceptable Sub-contractors</p> <p>Sub-contract</p> <p>Validation and Acceptance Requirements for Sub-contracted Work (in Sub-contract)</p> <p>Purchase Order</p> <p>Purchasing Procedures</p>	<p>Review of Sub-contractor Performance</p> <p>Review of Purchase Orders Prior to Release</p>	

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6.8 Included Software Product	<p>1. Do procedures exist for validation, storage, protection, and maintenance of included software from an external source, such as third party or purchaser?</p> <p>2. Are purchaser-supplied software found unsuitable for use recorded and reported to the purchaser?</p>	<p>Procedures for validation, storage, protection, and maintenance of included software</p> <p>Records of Unacceptable Purchaser-Supplied Software</p>		

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6.9 Training	<p>1. Are training needs identified according to a procedure?</p> <p>2. Is training conducted for all personnel performing work related to quality?</p> <p>3. Personnel performing specific tasks should be qualified on the basis of appropriate education, training, and/or experience, as required.</p> <p>4. Are records kept of personnel training and experience?</p>	<p>Training Plan</p> <p>Training Procedures</p> <p>Training Records</p>		