



*The Institute for
Interconnecting
and Packaging
Electronic Circuits*

IPC-QS-95

General Requirements for Implementation of ISO 9000 Quality Systems

IPC-QS-95

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A standard developed by the Institute for Interconnecting
and Packaging Electronic Circuits

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- Show relationship to DFM & DFE
- Minimize time to market
- Contain simple (simplified) language
- Just include spec information
- Focus on end product performance
- Include a feed back system on use and problems for future improvement

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- Inhibit innovation
- Increase time-to-market
- Keep people out
- Increase cycle time
- Tell you how to make something
- Contain anything that cannot be defended with data

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AND PACKAGING
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Users of this standard are encouraged to participate in the
development of future revisions.

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General Requirements for Implementation of ISO 9000 Quality Systems

1.0 SCOPE

This standard explains the requirements for implementing ISO 9000 quality standards, in conjunction with IPC or other product conformance specifications. The standard is applicable, but not restricted, to suppliers and manufacturers of electrical/electronic components, base materials, printed boards, assemblies, equipment and related products.

In addition to encouraging manufacturers to adopt ISO 9000 principles, this standard details the methodology to be used for integrating adherence to performance specification requirements (Section 6), or process control and certification into a relationship with a single third-party auditing authority.

1.1 Purpose The purpose of this document is to clearly identify the various steps that may be followed to model a quality system to ISO 9001, 9002, or 9003 Standards. This is applicable for companies that wish to follow the intent of the ISO 9000 Series Standards or are applying for registration.

1.2 Intent This standard describes the requirements for implementing a quality system which is in compliance to the ISO 9000 Quality Assurance Standards. The standard outlines the strategies and techniques that may be applied for design, manufacture, installation, assembly, testing and/or servicing.

1.3 Interpretation “Shall”, the emphatic form of the verb, is used throughout this standard whenever a requirement is intended to express a provision that is binding per the requirements of the ISO 9000 standards (Section 4) and the IPC. To assist the reader, the word “**shall**” is presented in bold character.

“**Must**” is used as a synonym for “**shall**.”

The words “**should**” and “**may**” are used whenever it is necessary to express non-mandatory provisions.

“**Will**” is used to express a declaration of purpose.

“**Applicable**” reflects mutual agreements between customer and suppliers.

“**Documentation**” is factual or substantial support for statements made.

“**Objective evidence**” is documentation, consisting of facts, in the form of hard copy, computer data, computer algorithms, video, or other media.

“**References**” are intended to clarify and add information, not to be used as auditable criteria. Any reference is noted by the author’s last name, followed by year of publication in parenthesis.

“**Examples**” provide additional information only, and are not to be interpreted as requirements.

1.4 Quality Systems Authentication Authentication of a manufacturer’s or supplier’s Qualification System should be based on the company’s business needs and the requirements of the customer base (internal and external). The ISO 9000 provides guidelines for the selection/implementation of the three standards and should be considered when entering into a third party audit assessment agreement.

The specification(s) to which a manufacturer or supplier must adhere are also an important part of the decision making process. Auditing to authenticate the quality system established within a company verifies that the processes necessary to produce a product or family of products are in place, are properly understood, and adequately documented. At times this documentation is in the form of specifications (customer, industry, international, internal etc.); the auditing function verifies adherence to this documented form of the requirements.

Auditing bodies are referred to as “Registrars” and are the organizations or individuals that have been accredited to conduct ISO 9000 assessments. Specific “Accreditors” exist throughout the world; their function is to establish the appropriate credentials of the registrar(s). Careful consideration should be given to the selection of the registrar, verifying their credentials, their experience in the industry, and their appeal to the customer base.

“Certification” is the authoritative act of documenting compliance with the requirements. These may be to the aspects of the quality systems(s) identified in the ISO standards, or may be to an appropriate performance specification. “Registration” is accomplished when compliance of a company’s quality management system has been demonstrated to the appropriate third party auditing body. In order to obtain registration, the auditor attempts to establish the linkages that the processes stated in the quality standards and specifications are being followed, thus proof of certification may be required.

2.0 APPLICABLE DOCUMENTS

Unless otherwise specified, the following documents form a part of this standard to the extent specified herein.

2.1 Industry

2.1.1 Institute for Interconnecting and Packaging Electronic Circuits (IPC)¹

IPC-T-50 Terms and Definitions for Interconnecting and Packaging Electronic Circuits.

IPC-PC-90 General Requirements for Implementation of Statistical Process Control

IPC-QL-653 Qualification Requirements for Facilities that Inspect/Test Printed Boards, Components, and Materials

2.1.2 Electronic Industries Association (EIA)²

ANSI/EIA-557-1 Statistical Process Control Guidance for the Selection of Critical Manufacturing Operations for Use in Implementing an SPC System for Passive Components

SP-2768 National Electronic Process Certification Standard

JEDEC Standard No. 19 General Standards for Statistical Process Control

2.1.3 American Society for Quality Control (ASQC)³

ANSI/ASQC A3 Quality Systems Terminology

ANSI/ASQC Q90-1987 Quality Management and Quality Assurance Standard—Guidelines for Selection and Use

ANSI/ASQC Q91-1987 Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing

ANSI/ASQC Q92-1987 Quality Systems—Model for Quality Assurance in Productions and Installation

ANSI/ASQC Q93-1987 Quality Systems—Model for Quality Assurance in Final Inspection and Test

ANSI/ASQC Q94-1987 Quality Management and Quality System Elements—Guidelines

2.1.4 National Electronic Components Quality Assessment System (NECQ)⁴

– Rules of Procedure of the NECQ

– Statement of Surveillance Arrangements (NECQ)

– Bylaws of the Electronic Components Certification Board

– Designated Auditor Approval Procedure

2.1.5 National Institute of Standards and Technology (NIST)⁵

– Malcolm Baldrige National Quality Award Criteria

2.2 Military Specification⁶

MIL-STD-45662 Calibration System Requirements

DoD 5000.51-G Total Quality Management—A Guide for Implementation

2.3 International

2.3.1 International Electrotechnical Commission (IEC)⁷

QC 001001 Basic Rules of the IEC Quality Assessment System for Electronic Components (IECQ)

QC 001002 Rules of Procedure

2.3.2 International Organization for Standards (ISO)⁸

ISO-8402 Quality Vocabulary

ISO-9000 Quality Management and Quality Assurance Standards—Guidelines for Selection and Use

ISO 9001-1987 Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation and Servicing

ISO 9002-1987 Quality Systems—Model for Quality Assurance in Production and Installation

ISO 9003-1987 Quality Systems—Model for Quality Assurance in Final Inspection and Test

ISO 9004-1987 Quality Management and Quality Systems Elements—Guidelines

2.3.3 International Equivalency Because qualification and certification crosses international boundaries, many countries have developed national documents that are equivalent to the quality system standards, i.e. Section 2.1.3 for US compared to Section 2.3.2 for ISO 9000. Table 2–1 shows the equivalency comparison in various countries for the ISO standard series.

1. IPC Inc., 2215 Sanders Road, Northbrook, Illinois 60062-6135

2. EIA c/o, Global Engineering Documents, 1990 M Street N.W., Washington, D.C. 20036

3. ASQC, 310 West Wisconsin Ave., Milwaukee, Wisconsin 53203

4. NECQ—c/o ECCB Secretariat, 2001 Pennsylvania Ave., N.W., 9th Floor, Washington, DC 20006

5. NIST—Office of Quality Programs, Building 101, Room A537, Gaithersburg, MD 20899

6. DoD—Standardization Documents Order Desk Building 4D, 700 Robbins Ave., Philadelphia, PA 19111-5094

7. IEC—1 Rue de Varembe, Case Postale 56, CH-1211 Geneve 20, Switzerland

8. ISO—3 Rue de Varembe, Case Postale 56, CH-1211 Geneve 20, Switzerland

Standards Body (country)	Quality Management and Quality Assurance Standards: Guidelines for Selection and Use	Quality Systems Model for Quality Assurance in Design Development, Production, Installation, and Servicing	Quality Systems Model for Quality Assurance in Production and Installation	Quality Systems Model for Quality Assurance in Final Inspection and Test	Quality Management and Quality System Elements: Guidelines
ISO CEN/CENELEC	ISO 9000: 1987 EN 29000	ISO 9001: 1987 EN 29001	ISO 9002: 1987 EN 29002	ISO 9003: 1987 EN 29003	ISO 9004: 1987 EN 29004
Identical					
Australia	AS 3900	AS 3901	AS 3902	AS 3903	AS 3904
Austria	O Norm EN 29000	O Norm EN 29001	O Norm EN 29002	O Norm EN 29003	O Norm EN 29004
Belgium	NBN-EN 29000	NBN-EN 29001	NBN-EN 29002	NBN-EN 29003	NBN-EN 29004
Brazil	NB 9000: 1990	NB 9000: 1990	NB 9000: 1990	NB 9000: 1990	NB 9000: 1990
Canada	—	—	—	—	CSA Q420- 87
Chile	NCH-ISO9000	NCH-ISO 9001	NCH-ISO-9002	NCH-ISO-9003	NCH-ISO 9004
Colombia	ICONTEC-ISO 9000	ICONTEC-ISO 9001	ICONTEC-ISO 9002	ICONTEC-ISO- 9003	ICONTEC-ISO 9004
Cuba	NC-ISO 9000	NC-ISO 9001	NC-ISO 9002	NC-ISO 9003	NC-ISO 9004
Cyprus	CYS ISO 9000	CYS ISO 9001	CYS ISO 9002	CYS ISO 9003	CYS ISO 9004
Czechoslovakia	CSN ISO 9000	CSN ISO 9001	CSN 9002	CSN ISO 9003	CSN ISO 9004
Denmark	DS/ISO 9000	DS/ISO 9001	DS/ISO 9002	DS/ISO 9003	DS/ISO 9004
Finland	SFS-ISO 9000	SFS-ISO 9001	SFS-ISO 9002	SFS-ISO 9003	SFS-ISO 9004
France	NF-EN 29000	NF-EN 29001	NF-EN 29002	NF-EN 29003	NF-EN 29004
Germany	DIN ISO 9000	DIN ISO 9001	DIN ISO 9002	DIN ISO 9003	DIN ISO 9004
Greece	ELOT EN 29000	ELOT EN 29001			
Hungary	MI 18990 - 1988	MI 18991 - 1988	MI 18992 - 1988	MI 18993 - 1988	MI 18994 - 1988
Iceland	IST ISO 9000: 1987	IST ISO 9001: 1987	IST 9002: 1987	IST 9003: 1987	IST 9004: 1987
India	IS 14000: 1988	IS 14001: 1988	IS 14002: 1988	IS 14003: 1988	
Ireland	IS/ISO 9000	IS/ISO 9001	IS/ISO 9002	IS/ISO 9003	IS/ISO 9004/
Israel	SI 2000: 1990	SI 2001: 1990	SI 2002: 1990	SI 2003: 1990	SI 2004: 1990
Italy	UNI/EN 29000 - 1987	UNI/EN 29001 - 1987	UNI/EN 29002 - 1987	UNI/EN 29003 - 1987	UNI/EN 29004 - 1988
Japan	JIS Z 9900- 1991	JIS Z 9901 - 1991	JIS Z 9902 - 1991	JIS Z 9903 - 1991	JIS Z 9904 - 1991
Malaysia	MS-ISO 9000 - 1991	MS-ISO 9001 - 1991	MS-ISO 9002 - 1991	MS-ISO 9003 - 1991	MS-ISO 9004 - 1991
Netherlands	NEN-ISO 9000	NEN-ISO 9001	NEN-ISO 9002	NEN-ISO 9003	NEN-ISO 9004
New Zealand	NZS 9000: 1990	NZS 9001: 1990	NZS 9002: 1990	NZS 9003: 1990	NZS 9004: 1990
Norway	NS- ISO 9000: 1988	NS-ISO 9001: 1988	NS-ISO 9002	NS-ISO 9003	NS-ISO 9004
Pakistan	PS: 3000: 90	PS: 3001: 90	PS: 3002: 90	PS: 3003: 90	PS: 3004: 90
Philippines	PNS ISO 9000: 1989	PNS ISO 9001: 1989	PNS ISO 9002: 1989	PNS ISO 9003: 1989	PNS ISO 9004: 1989
Poland	ISO 9000	ISO 9001	ISO 9002	ISO 9003	ISO 9004
Portugal	EM 29000	EM 29001	EM 29002	EM 29003	EM 29004
Romania	RS ISO 9000	RS ISO 9001	RS ISO 9002	RS ISO 9003	RS ISO 9004
Russian Federation		Gost 40.9001-88	ISO 40.9002 -88	ISO 40.9003 - 88	—
Singapore	SS 308 Part 0: 1988	SS 308 Part 1: 1988	SS 308 Part 2: 1988	SS 308 Part 3: 1988	SS 308 Part 4: 1988
South Africa	SABS 0157: Part 0	SABS 0157: Part 1	SABS 0157: Part II	SABS 0157: Part III	SABS 0157: Part IV
Spain	UNE 66 900	UNE 66 901	UNE 66 902	UNE 66 903	UNE 66 904
Sweden	SS-ISO 9000: 1989	SS-ISO 9001: 1989	SS-ISO 9002: 1989	SS-ISO 9003: 1989	SS-ISO 9004: 1989
Switzerland	SN EN 29000: 1990	SN EN 29001: 1990	SN EN 29002: 1990	SN EN 29003: 1990	SN EN 29004: 1990
Tanzania	TZS 500: 1990	TZS 501: 1990	TZS 502: 1990	TZS 503: 1990	TZS 504: 1990
Thailand	TISI ISO 9000	TISI ISO 9001	TISI ISO 9002	TISI ISO 9003	TISI ISO 9004
Trinidad and Tobago	TTS 1 65 400: 1988	TTS 1 65 401: 1988	TTS 1 65 402: 1988	TTS 1 65 403: 1988	TTS 1 65 404: 1988
Tunisia	NT 110.18-1987	NT 110.19-1987	NT 110.20-1987	NT 110.21-1987	NT 110.22-1987
United Kingdom	BS 5750: 1987: Pt 0	BS 5750: 1987: Pt 1	BS 5750: 1987: Pt 2	BS 5750: 1987: Pt 3	BS 5750: 1987: Pt 0
USA	ANSI/ASQC Q90	ANSI/ASQC Q91	ANSI/ASQC Q92	ANSI/ASQC Q93	ANSI/ASQC Q94
Yugoslavia	JUS - ISO 9000	JUS - ISO 9001	JUS ISO 9002	JUS - ISO 9003	JUS - ISO 9003
Zimbabwe	SAZ 300	SAZ 301	SAZ 302	SAZ 303	SAZ 304
Equivalent					
China	GB/T 10300.1 - 88	GB/T 10300.2 - 88	GB/T 10300.3 - 88	GB/T 10300.4 - 88	GB/T 10300.5 - 88
Jamaica		JS 167: Part 1: 1990	JS 167: Part 2: 1990	JS 167: Part 3: 1990	
Venezuela	CEVENIN 3000	CEVENIN 3001	CEVENIN 3002	CEVENIN 3003	CEVENIN 3004

Table 2-1 Quality Assurance Standards

3.0 GLOSSARY, TERMS, DEFINITIONS

The definition of terms shall be in accordance with IPC-T-50 and the following. A list of acronyms for organization, manufacturing, and assessment programs can be found in Appendix B.

3.1 Applicant The manufacturer/supplier making application for registration.

3.2 Benchmark A standard by which something can be judged.

3.3 Capability The natural variation of the process due to common causes.

3.4 Certification The authoritative act of documenting compliance with requirements. The requirements can relate to personnel, processes, products, organizations and services. (Certification should not be confused with registration, see 3.48).

3.5 Certification Product/Sample An example of the product that is examined, tested and recorded.

3.6 Certified Process A process that, through demonstration and validation, has been determined to produce product capable of consistently achieving or exceeding requirements.

3.7 Characteristic A distinguishing feature of a process or its output on which variable or attribute data can be collected.

3.8 Concession Waiver Written authorization to use or release a quantity of material, components or stores already produced but which do not conform to the specified requirements.

3.9 Critical Pertaining to that which significantly impacts product quality and/or reliability.

3.10 End-Product Parameter A parameter which characterizes the product at the finished product stage. This may be piece parts, subassemblies and/or assemblies.

3.11 Defect The nonfulfillment of intended usage requirements.

3.12 Design Review A formal, documented, comprehensive and systematic examination of a design to evaluate the design requirements and the capability of the design to meet these requirements and to identify problems and propose solutions.

3.13 Designated Auditor An organization or individual that has been evaluated in accordance with a Designated Auditor Approval Procedure and has met all the requirements for performing qualification or certification audits.

3.14 Grade An indicator of category or rank related to features or characteristics that cover different sets of needs for products or services intended for the same functional use.

3.15 In-Process Product Parameter A parameter which characterizes the product prior to the finished product stage.

3.16 Inspection Activities such as measuring, examining, testing, gauging one or more characteristics of a product or service and comparing these with specified requirements to determine conformity.

3.17 Inspection/Test Facility An organization whose services are available to other organizations or groups within a system and which has the facilities and capability to carry out inspection/test measurements, and evaluations on electronic components, materials, or products in accordance with their specifications. Inspection/test facilities covered by this document shall be either of the following:

3.17.1 Commercial/Independent Inspection/Test Facility A facility that provides commercially available inspection/testing services and which is independent of a component/material manufacturer.

3.17.2 Internal Inspection/Test Facility A facility managed by the applicant or participating company. The inspection/test facility may be on site or off site.

3.18 Inspection/Test Facility Certification An approval granted to an inspection/test facility when it has been established that the facility procedures and control methods indicate the capability for inspection/testing components, materials or products to fulfill the requirements of the relevant specification. Any location that performs inspection or testing for end-product acceptance to a specific specification shall be considered part of the facility.

3.19 Metrics A measurement of performance.

3.20 Manufacturer The individual or company responsible for the procurement of materials and components, as well as all assembly process and verification operations necessary to ensure full compliance of assemblies to this standard.

3.21 Nonconformity The nonfulfillment of specified requirements.

3.22 Objective Evidence Information that can be verified, based on factors obtained through observation, measurement, test or other means. This may be documentation, agreed to between user and manufacturer, in the form of hard copy, computer data, computer algorithms, video, or other media.

3.23 Parameter A measurable characteristic of a product or process.

3.24 Participating Company A company that has been evaluated and approved in accordance with the system and has met all requirements.

3.25 Process The combination of people, equipment, materials, methods and environment that produce output (product or service). A repeatable sequence of activities with measurable inputs and outputs.

3.26 Process Characterization The determining of relationships between process parameters and process outputs or product characteristics.

3.27 Process Parameter A measurable characteristic of a process which impacts product performance but may not be measured on the product.

3.28 Process Potential The capability of a parameter over a brief period of time.

3.29 Product The output of a process.

3.30 Product Certification An approval granted to a manufacturer's component, material, or product signifying that the specific item meets all the requirements of the relevant specification and the item may be listed on a Qualified Products List (QPL).

3.31 Product Liability; Service Liability A generic term used to describe the responsibility of a manufacturer or supplier to make restitution for loss related to personal injury, property damage or other harm caused by a product or service.

3.32 Production Permit; Deviation Permit Written authorization, prior to production or before provision of a service, to depart from specified requirements for a specified quantity or for a specified time.

3.33 Proficiency The capability to perform tasks in accordance with the requirements and verification procedures detailed in this standard.

3.34 Purchaser The recipient of products (including services) delivered by the supplier.

3.35 Qualified Products List (QPL) A list components, materials, or products that have been certified or approved under a qualification system. In some cases (IECQ) the list may contain manufacturers, labs and distributors.

3.36 Qualification The process of demonstrating whether an entity is capable of meeting or exceeding the specified requirements.

3.37 Quality The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.

3.38 Quality Assurance All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

3.39 Quality Audit A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

3.40 Quality Control The operational techniques and activities that are used to fulfill requirements for quality.

3.41 Quality Loop; Quality Spiral Conceptual model of interacting activities that influence the quality of a product or service in the various stages ranging from the identification of needs to the assessment of whether these needs have been satisfied.

3.42 Quality Management That aspect of the overall management function that determines and implements the quality policy.

3.43 Quality Plan A document setting out the specific quality practices, resources and sequence of activities relevant to a particular product, service, contract or project.

3.44 Quality Policy The overall quality intentions and direction of an organization as regards quality, as formally expressed by top management.

3.45 Quality Surveillance The continual monitoring and verification of the status of procedures, methods, conditions, processes, products and services, and analysis of records in relation to stated references to ensure that specified requirements for quality are being met.

3.46 Quality System The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

3.47 Quality System Review A formal evaluation by management of the status and adequacy of the quality system in relation to quality policy and new objectives resulting from changing circumstances.

3.48 Registration Demonstrated compliance of a company's quality management system to ISO 9001, 9002, 9003 or an equivalent national standard, as determined by an accredited third party auditing body.

3.49 Reliability The ability of an item to perform a required function under stated conditions for a stated period of time. The term "reliability" is also used as a reliability characteristic denoting a probability of success or a success ratio.

3.50 Scope of Registration The scope of an assessment which is determined by the company's declared range of products or services. (See 6.1)

3.51 Specification The document that prescribes the requirements with which the product or service has to conform. May include a detailed set of requirements to be satisfied by a product, a material, or a process indicating, whenever appropriate, the procedure by means of which it may be determined whether the given requirements are satisfied.

3.52 Standard A technical specification or other document, available to the public, drawn up with the cooperation and consensus or general approval of all interests affected by it, based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits and approved by a body recognized on the national, regional, or international level.

3.53 Subcontractor The organization which provides products (including services) to the supplier.

3.54 Supplier The organization to which the requirements of ISO 9001, ISO 9002, or ISO 9003 apply.

3.55 Traceability The ability to trace the history, application or location of an item or activity, or similar items or activities, by means of recorded identification.

3.56 Testing Laboratory A laboratory suitable to perform the certification examination and testing. Laboratories covered by this document shall be either of the following:

3.57 Commercial/Independent Laboratory A laboratory that provides commercially available testing services.

3.58 Internal Laboratory A laboratory managed by an applicant.

3.59 User The individual, company or agency responsible for the procurement of electrical/electronic hardware, and who has the authority to define the class of equipment, any variation or restrictions to the requirements of this standard, and is the originator/custodian of the contract detailing these requirements. *Note:* For any one situation, an organization can, in addition to being the supplier, also be a purchaser, and/or a subcontractor at the same time.

4.0 INTRODUCTION TO ISO 9000 ELEMENTS

The ISO 9000 standards establish requirements for the quality systems of companies. They do not refer to the technical specifications of products but instead to the systems that produce the products, providing confidence that the products consistently have the quality that customers expect. They are generic standards in that they apply to all products and industries, but ISO 9000 is designed to complement industry-specific product standards for quality assurance.

A quality management system should be oriented towards reduction, elimination and prevention of quality deficiencies. Each element (or requirement) in a quality management system will vary in importance from one type of activity to another and from one product or service to another. In order to achieve maximum effectiveness, and to satisfy customer expectations, it is essential that the quality management system be appropriate to the type of activity and the product or service being offered.

This section provides assistance in understanding and applying the key aspects of ISO 9000 elements. Integration of the appropriate specifications are detailed in Section 6.0.

4.1 Management Responsibility Management responsibility in supporting the Quality Management System shall be described.

4.1.1 A quality policy shall be established and communicated to all employees.

- The quality policy should be expressed in language which is easy to understand.
- The quality policy should be relevant to the organization, its other policies, the products or services provided, and the organization's people.
- Management should demonstrate commitment visibly and actively on a continuing basis.

4.1.2 The responsibility and authority for establishing quality shall be defined.

- Adequate authority should be delegated to individuals to allow them to carry out their designated responsibilities. They should have clear understanding of their defined authority and freedom and designated channels to take action.