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Guidelines for the selection of quality management system consultants and use of their services

*Lignes directrices pour la sélection de consultants en systèmes de
management de la qualité et pour l'utilisation de leurs services*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10019 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

Introduction

In the realization of a quality management system, some organizations choose to rely on their own personnel but some use the services of external consultants. The selection of a consultant by an organization is important for ensuring that the resulting quality management system is capable of meeting the organization's planned objectives in the most efficient and effective manner. Even when using the services of a quality management system consultant, the involvement and commitment of the organization's top management are key factors for a quality management system realization.

This International Standard aims to provide guidance on the factors to be taken into consideration when selecting a quality management system consultant. It can be used by organizations in the selection of a quality management system consultant who is able to meet their specific needs, expectations and objectives in the realization of quality management system. It can additionally be used by

- a) quality management system consultants as guidelines to quality management system consulting, and
- b) consulting organizations for the selection of quality management system consultants.

Guidelines for the selection of quality management system consultants and use of their services

1 Scope

This International Standard provides guidance for the selection of quality management system consultants and the use of their services.

It is intended to assist organizations when selecting a quality management system consultant. It gives guidance on the process for evaluating the competence of a quality management system consultant and provides confidence that the organization's needs and expectations for the consultant's services will be met.

NOTE 1 This International Standard is not intended to be used for certification purposes.

NOTE 2 This International Standard addresses the realization of a quality management system but, at the same time, could be used with appropriate adaptation for the realization of any other management systems.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply.

3.1

quality management system realization

process of establishing, documenting, implementing, maintaining and continually improving a quality management system

NOTE Quality management system realization can include the following:

- identifying the processes needed for a quality management system and their application throughout the organization;
- determining the sequence and interaction of the identified processes;
- determining criteria and methods needed to ensure that both the operation and control of the identified processes are effective;
- ensuring the availability of resources and information necessary to support the operation and monitoring of the identified processes;
- monitoring, measuring and analysing the identified processes;
- implementing actions necessary to achieve planned results and continual improvement of the identified processes.

3.2

quality management system consultant

person who assists the organization on quality management system realization, giving advice or information

NOTE 1 The consultant can also assist in realizing parts of a quality management system.

NOTE 2 This International Standard provides guidance on how to distinguish a competent quality management system consultant from one who is not competent.

4 Selection of a quality management system consultant

4.1 Input to the selection process

4.1.1 Organization's needs and expectations

When selecting a quality management system consultant, the organization should identify its needs and expectations of the quality management system consultant, based on its overall objectives for the realization of a quality management system. Top management should be involved in the process of evaluation and selection of the quality management system consultant.

4.1.2 Role of the consultant

The selection process should take into account the role of the quality management system consultant in the quality management system realization (see Annex A). The consultant's role generally includes the following:

- a) assisting the organization to ensure that the design and the implementation of the quality management system is suited to the organization's culture, characteristics, level of education and specific business environment;
- b) illustrating the concepts concerning quality management in a clear and understandable way throughout the organization, paying special attention to the understanding and adoption of quality management principles;
- c) communicating with all relevant individuals, at all levels, involving them actively in the quality management system realization;
- d) advising and supporting the organization in identifying the appropriate processes needed for its quality management system and defining the relative importance, sequence and interaction of those processes;
- e) assisting the organization in identifying needs for documentation essential to ensure the effective planning, operation and control of its processes;
- f) evaluating the effectiveness and efficiency of the quality management system processes to stimulate the organization to look for opportunities for improvement;
- g) assisting in promoting a process approach and continual improvement of the quality management system within the organization;
- h) assisting in identifying the training needs to enable the organization to maintain the quality management system;
- i) assisting the organization, where applicable, to identify the relationship between its quality management system and any other relevant management system (e.g. environmental or occupational health and safety) and facilitate the integration of such systems.

4.1.3 Evaluation of the competence of the consultant

When evaluating the competence and suitability of a consultant, due consideration should be given to

- a) personal attributes (see 4.2.2),
- b) relevant education (see 4.2.3),
- c) knowledge and skills necessary to meet the organization's overall objectives for the quality management system (see 4.2.3, 4.2.4 and 4.2.5),
- d) work experience (see 4.2.6), and
- e) ethical behaviour (see 4.3).

4.2 Competence of the consultant

4.2.1 General

When selecting a quality management system consultant, the organization should evaluate whether the consultant maintains the competence appropriate to the scope of the consulting services to be provided.

The concept of the competence of a quality management system consultant is illustrated in Figure 1.

NOTE Competence is defined in ISO 9000 as the demonstrated ability to apply knowledge and skills.

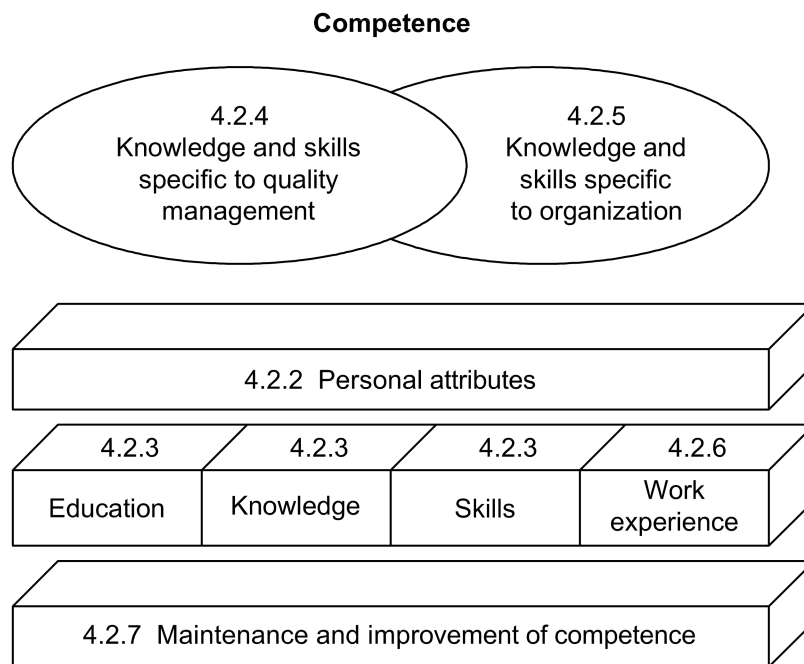


Figure 1 — Concept of competence of a quality management system consultant

4.2.2 Personal attributes

Personal attributes contribute to the successful performance of a quality management system consultant. A quality management system consultant, generally, should be

- a) ethical: fair, truthful, sincere, honest and discreet;
- b) observant: constantly and actively aware of organizational culture and values, physical surroundings and activities;
- c) perceptive: aware of and able to understand the need for change and improvement;
- d) versatile: able to adapt to different situations and provide alternative and creative solutions;
- e) tenacious: persistent, focused on achieving objectives;
- f) decisive: capable of reaching timely conclusions based on logical reasoning and analysis;
- g) self-reliant: able to act and function independently while interacting effectively with others;
- h) communicative: able to listen to, and effectively interface with, all levels of an organization, confidently and with sensitivity to its culture;
- i) practical: realistic and flexible with good time management;

- j) accountable: able to take responsibility for his/her own actions;
- k) facilitative: able to assist an organization's management and employees through the quality management system realization.

4.2.3 Education, knowledge and skills

Quality management system consultants should have the appropriate education needed to acquire the knowledge and skills relevant for the consulting services to be provided. A typical example is provided in Annex B.

NOTE In this context, knowledge and skills are related to generic scholastic ability, such as linguistic ability and knowledge of basic science and humanities.

4.2.4 Knowledge and skills specific to quality management

4.2.4.1 Relevant standards

Quality management system consultants should be able to understand and apply relevant International standards that can affect the organization, such as

- ISO 9000, *Quality management systems — Fundamentals and vocabulary*,
- ISO 9001, *Quality management systems — Requirements*,
- ISO 9004, *Quality management systems — Guidelines for performance improvements*,
- ISO 19011, *Guidelines for quality and/or environmental management systems auditing*, and
- other relevant International Standards as listed in the Bibliography.

In addition, the consultant should have knowledge of other standards that are necessary for the consulting services.

NOTE Typical examples include

- a) sector-specific standards,
- b) measurement control systems standards,
- c) accreditation standards,
- d) conformity assessment standards,
- e) product standards,
- f) dependability management standards, and
- g) standards related to safety aspects.

Quality management system consultants should also have knowledge of the ISO guidance documents developed as part of the ISO 9000 family introduction and support package^[16].

4.2.4.2 National and international certification/registration and accreditation systems

Quality management system consultants should have general knowledge of

- a) the standardization, certification and accreditation systems at national and international level, and the requirements for certification for such systems (e.g. ISO/IEC Guide 62), and
- b) the processes and procedures for national certification of products, systems and personnel.

4.2.4.3 General quality management principles, methodologies and techniques

Quality management system consultants should have knowledge of, and be able to apply, appropriate quality principles, methodologies and techniques. The following list indicates such fields where the consultant's experience and ability may be valuable:

- a) quality management principles;
- b) continual improvement tools and techniques;
- c) appropriate statistical techniques;
- d) auditing methodologies and techniques;
- e) principles for economics of quality;
- f) team work techniques;
- g) PDCA (Plan-Do-Check-Act) methodology;
- h) policy deployment methodology;
- i) process mapping techniques;
- j) problem solving techniques;
- k) techniques for monitoring customer/employee satisfaction;
- l) brainstorming techniques.

4.2.5 Knowledge and skills specific to the organization

4.2.5.1 Statutory and regulatory requirements

Knowledge of statutory and regulatory requirements relevant to the organization's activities and to the consultant's scope of work is essential for quality management system consulting. However, quality management system consultants should not be expected to have experience of the application of this knowledge prior to initiating their services.

Relevant knowledge in this area should typically include the statutory and regulatory requirements for the organization's product as required by, for example, ISO 9001.

4.2.5.2 Product, process and organizational requirements

Quality management system consultants should have a reasonable knowledge of the organization's products, processes and customer expectations prior to initiating their consulting services, and should understand the key factors relevant to the product sector in which the organization operates.

They should be able to apply this knowledge as follows:

- a) to identify the key characteristics of the organization's processes and related products;
- b) to understand the sequence and interaction of the organization's processes and their effect on meeting product requirements;
- c) to understand the terminology of the sector in which the organization operates;
- d) to understand the nature of the structure, functions and relationships within the organization;
- e) to understand the strategic linkage between business objectives and competence resource needs.

4.2.5.3 Management practices

Quality management system consultants should have knowledge of relevant management practices to understand how the quality management system integrates and interacts with the overall management system

of the organization, including its human resources, and how it will be deployed to secure the goals and objectives of the organization.

In some cases, additional competencies can be required to meet the organization's needs, expectations and overall objectives for its quality management system, such as business and strategic planning, risk management, and business improvement tools and techniques (see Annex B).

4.2.6 Work experience

The quality management system consultant should have relevant work experience in managerial, professional and technical aspects of the consultant services to be provided. This work experience can involve the exercise of judgement, problem solving and communication with all interested parties (see Annex B).

Verifiable references to past work experience and achievements are important and should be made available to the organization.

The consultant's relevant experience can include a combination of some or more of the following:

- a) practical work experience;
- b) experience in management;
- c) experience in quality management;
- d) experience in quality management system auditing;
- e) experience in implementing a quality management system, in one or more of the following capacities:
 - 1) providing consultant services;
 - 2) as a quality management system management representative;
 - 3) performing a function related to the management of quality.

4.2.7 Maintenance and improvement of competence

The quality management system consultant should maintain and improve competence through means such as additional work experience, auditing, training, continuing education, self study, coaching, attending professional meetings, seminars and conferences or other relevant activities.

Continual professional development should be contingent upon the organization's needs, the provision of quality management system consulting services, standards and any other relevant requirements.

NOTE This can be achieved through membership and proven continued personal development with a relevant professional body, organization or institute with regulatory or disciplining powers.

4.3 Ethical considerations

The organization should consider the following ethical issues when selecting a quality management system consultant. The consultant should

- a) avoid or declare any conflict of interest that affects the work to be carried out,
- b) maintain the confidentiality of information provided by or acquired from the organization,
- c) maintain independence from quality management system certification/registration or accreditation bodies,
- d) maintain impartiality in the organization's selection of certification/registration bodies,
- e) provide realistic cost estimates for the consulting services rendered,
- f) not create unnecessary dependence on their services, and
- g) not offer services where the consultant does not have the necessary competence.

5 Use of the quality management system consultant's services

5.1 Consultant's services

The organization may use consulting services to assist in one or more of the following activities within a quality management system realization (see A.2):

- a) definition of objectives and requirements;
- b) initial evaluation;
- c) planning;
- d) design and development;
- e) implementation;
- f) evaluation;
- g) ongoing training and maintenance;
- h) improvement.

5.2 Contract for consultant's services

Organizations should ensure that they have a contract with the quality management system consultant that clearly defines the scope of work (including outputs), has realistic milestones and is cost-effective for the organization (see A.1). When entering into a contract, activities such as the following (see A.2) should be considered:

- a) setting agreed contract objectives that are specific, measurable, achievable, realistic and time-limited;
- b) setting out a detailed contract plan with agreed milestones and outputs;
- c) communicating the plan to all interested parties;
- d) identifying the training needs of relevant employees so they can perform the ongoing evaluation, maintenance and improvement of the quality management system;
- e) implementing the plan;
- f) monitoring and evaluating the effectiveness of the plan and implementing contingent actions, as appropriate;
- g) ensuring the agreed milestones are met or redefined;
- h) defining a process to approve the outcomes of the contract.

Meetings should be held to evaluate the progress in implementing the system and the performance of the consultant. At each of these meetings, progress in terms of the plan and the budget for quality management system realization activities should be reviewed. Documented progress reports should be submitted to the top management.

5.3 Useful considerations for consultant's services

In the process of using quality management system consulting services, the organization should consider the following:

- a) the resulting system should not generate unnecessary administration and documentation;
- b) the success of a quality management system depends mainly on the involvement and commitment of top management and not on the consultant alone;
- c) the organization should assign a staff member (usually the person who will eventually ensure that the quality management system is maintained) to coordinate and monitor the consultant's activities;

- d) employees are involved at all levels, in order to integrate the quality management system within the organization's overall operations;
- e) the consultant should be empowered to interact with the organization's management and employees at all levels in order to appraise the organization's processes;
- f) even if quality management system consulting was in response to contractual or market requirements, there is an opportunity to use the realized quality management system as an effective and efficient management tool;
- g) there is a potential for the quality management system to provide a basis for continual improvement of the organization's performance;
- h) the consulting services should be compatible with the organization's culture, the competence of its employees, and existing processes and/or documentation.

Annex A (informative)

Typical activities of quality management system consultants

A.1 Initial evaluation and preparation of a proposal

A.1.1 Initial evaluation and establishment of a contract should typically include the following:

- a) identification of the organization's needs, requirements and objectives as presented by its top management;
- b) initial evaluation of the organization's identified needs, requirements and objectives with respect to
 - 1) relevant customer requirements,
 - 2) conformity with relevant standard requirements,
 - 3) compliance with relevant statutory and regulatory requirements,
 - 4) present managerial and operational methods, and
 - 5) establishing the difference between the organization's current situation and the identified objectives to be achieved;
- c) documentation of the activities needed to achieve conformity of the quality management system with the needs, requirements and objectives as stated in a) and established by b) 4);
- d) preparation and presentation of a proposal for the realization of the activities, as defined in c), to top management as the basis for the contract.

A.1.2 Contracts should include, in clear language, clauses concerning

- a) the scope of the quality management system consulting activity,
- b) planning of quality management system realization activities,
- c) the consultant's and the organization's commitment, role, responsibilities and outputs,
- d) commitment of the organization's internal resources,
- e) the organization's costs needed to support the consultant's activities,
- f) methods for monitoring
- g) how changes to the contract will be managed,
- h) confidentiality,
- i) applicable standards,
- j) milestones /delivery dates,
- k) terms of payment, and
- l) the time frame.

A.2 Example of the realization of a quality management system

See Table A.1. Table A.2 gives an example of implementation support.

Table A.1 — Quality management system realization activities

| Description of activity | Responsibility |
|--|--|
| 1. Information to top management of the main requirements of the relevant quality management system standard, and the roles of the organization and the consultant in quality management system design and development. | Consultant |
| 2. Analysis of the needs and expectations of the organization's customers and other interested parties. NOTE The results of the initial evaluation are generally used a) to establish the organization's strengths and weaknesses, opportunities and threats, b) to understand and help to define its quality policy and objectives, c) as a basis for planning the quality management system, d) to assess the availability of the resources needed to implement the quality management system, e) as a basis for initial auditing, and f) for the establishment of measurable objectives. | Organization's top management (consultant can provide assistance) |
| 3. Appointment of a management representative and the establishment of definitions of policy, objectives and commitments for quality. Reference of such objectives to appropriate levels and functions within the organization. | Organization's top management (consultant can provide assistance) |
| 4. In-depth analysis of organizational structure, processes, channels of communication and existing interfaces. Identification of the processes and responsibilities needed to achieve the quality objectives. Definition of sequence and interactions among such processes. | Management representative and consultant, with the cooperation of the persons in charge of the various functions within the organization |
| 5. Set up of a plan for defining the quality management system architecture and for identifying and developing the procedures needed for the quality management system. To assess the progress and quality of the implemented actions, appropriate milestones should be defined within the plan. The assessments may refer to a) consistency between what has been prepared and developed and the contractual objectives, b) work progress, and c) satisfaction of the organization (with regard to the services provided by the quality management system consultant). | Management representative and consultant |
| 6. Review of the results of the analysis carried out and of the plan prepared in advance. | Organization's top management and consultant |
| 7. Identification of internal resources needed to achieve the organization's quality objectives. | Organization (consultant can provide assistance) |
| 8. Training of the persons responsible for developing activities for the quality management system realization, and of the organization's other personnel ("facilitators") involved. | Management representative and consultant |

Table A.1 — Quality management system realization activities *(Continued)*

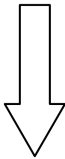
| Description of activity | Responsibility |
|---|---|
| 9. Identification and definition of processes, interrelation of processes and preparation of the necessary procedures, including procedures for record maintenance. | Management representative (consultant can provide assistance). |
| 10. Alignment of interrelated processes and relevant procedures to avoid any inconsistencies, gaps and overlaps. | Management representative and consultant. |
| 11. Elaboration of the final version of the quality manual. | Management representative (consultant can provide assistance). |
| 12. Training of all personnel involved with the quality management system. | Consultant and management representative, or management representative with the consultant's assistance. Training can also be delivered by other competent providers. |
|  | |
| Implementation of the quality management system. | Organization (consultant can provide assistance) |
| NOTE Above the arrow, the activities of the consultant stop. After the arrow, there is a start-up of the implementation of the quality management system by the organization. | |

Table A.2 — Implementation support for the quality management system

| Description of activity | Responsibility |
|--|---|
| 1. Training of internal auditors, emphasizing auditing concepts, audit question development and audit report preparation and other required training | Consultant (or other providers of training appointed by the organization) |
| 2. Development of a programme for internal audits. | Management representative and consultant |
| 3. Participation in an initial series of internal audits, together with internal auditors, to provide them with additional training (including writing audit reports and reports of nonconformities) and assistance in the formalization of detected nonconformities and their causes. | Consultant |
| 4. Assisting top management in conducting effective management review meetings. | Consultant |
| 5. Assisting with any implementation difficulties, focusing on corrective action and preventive actions including nonconformities detected as a result of an audit. | Consultant |
| 6. Continual improvement of the implementation process. | Organization's top management (consultant can provide assistance) |
| 7. Information about certification issues, if required, including pre-assessment or readiness audit. | Consultant |

Annex B (informative)

Evaluation of quality management system consultants

B.1 Example of education and work experience for a quality management system consultant

The organization can use the education and work experience given in Table B.1 as a model when selecting quality management system consultants. This table is only an example, it is not appropriate in all circumstances, and may depend on the scope of the quality management system realization activities. In some cases, additional competencies may be required (see 4.2).

Table B.1 — Education and work experience of a quality management system consultant

| Work experience segments (see Note 1) | Education and work experience ^a | | |
|--|---|--|--|
| | Complexity of quality management system realization | | |
| | -- | | + -- |
| Total work experience | Fewer years may be applicable | 4 years for people who have graduated from a university (see Note 2), or 6 years for people who have graduated from secondary education (see Note 3) | More years may be applicable |
| Work experience in quality management | Fewer years may be applicable | At least 2 years | More years may be applicable |
| Experience in the implementation of a quality management system | Fewer implementations may be applicable | Completed at least three quality management system implementations with adequate participation | More implementations may be applicable |
| ^a Education and experience specified are not requirements and are not intended for certification purposes. Organizations can decide to use them as requirements. | | | |
| NOTE 1 It is essential that the experience of the consultant be relevant to the quality management system realization. | | | |
| NOTE 2 University (higher) education is a part of the national education system and comes after the secondary level education with a duration of at least 3 years. | | | |
| NOTE 3 Secondary education is a part of the national education system and comes after the primary or elementary level, but that is completed prior to entering the degree level education. | | | |

B.2 Evaluation of consultant's references

The evaluation should be based on the examination of objective evidence and can include the following:

- a) references from previous assignments;
- b) publication of books and articles dealing with the management of quality;
- c) references about professional ethics;
- d) quality management system documentation developed by the consultant;
- e) interviews with organizations that have used the consultant's services;
- f) length of time of assignments over which the consultant's professional experience was acquired;
- g) experience with, and knowledge of, similar organizations;
- h) consultant's professional certifications and qualifications;
- i) interviews with the consultant to evaluate competence.

Bibliography

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- [2] ISO 9004, *Quality management systems — Guidelines for performance improvements*
- [3] ISO 10002, *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations*
- [4] ISO 10005, *Quality management systems — Guidelines for quality plans*
- [5] ISO 10006, *Quality management systems — Guidelines for quality management in projects*
- [6] ISO 10007, *Quality management systems — Guidelines for configuration management*
- [7] ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*
- [8] ISO/TR 10013, *Guidelines for quality management system documentation*
- [9] ISO/TR 10014, *Guidelines for managing the economics of quality*
- [10] ISO 10015, *Quality management — Guidelines for training*
- [11] ISO/TR 10017, *Guidance on statistical techniques for ISO 9001:2000*
- [12] ISO 19011, *Guidelines for quality and/or environmental management systems auditing*
- [13] ISO/IEC Guide 62, *General requirements for bodies operating assessment and certification/registration of quality systems*
- [14] *Selection and use of ISO 9000* (brochure)
- [15] *Quality management principles and guidelines on their application* (brochure)
- [16] ISO 9000, *Introduction and Support Package* (obtainable from the official ISO/TC 176 website <http://isotc176sc2.elysium-ltd.net> and <http://www.iso.org>)
 - Guidance on ISO 9001:2000, subclause 1.2 'Application'
 - Guidance on the documentation requirements of ISO 9001:2000
 - Guidance on the terminology used in ISO 9001:2000 and ISO 9004:2000
 - Guidance on the process approach to quality management systems
- [17] ISO Handbook: *ISO 9001 for Small Businesses — What to do (Advice from ISO/TC 176)*

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