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Document Approval

Title/Department	Name	Signature	Date
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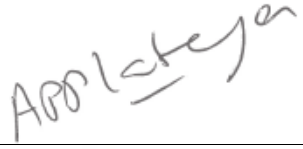
Reviewer	Annedien Plantenga		01-01-2020
Reviewer	Nicole Spieker		01-01-2020

Document History

Version	Date	Summary of the changes
1.0	01-01-2014	This procedure has been prepared in order to define the requirements for standard development.
2.0	01-01-2020	This procedure has been reviewed and updated.

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1. Purpose and Scope

The purpose of this procedure is to outline the process followed in the development of new or modified standards.

This procedure is to be followed by the Standards Development Coordinator and the Standards Development Group.

2. Responsibilities

2.1. The Standards Development Coordinator

It is the responsibility of the Standards Development Coordinator, in consultation with the SafeCare Director, to coordinate the standards development process and to organize and record the proceedings of the Standards Development Group. The Standards Development Coordinator is the chair of the Standards Development Group.

2.2. The Standards Development Group

This Group directs all matters relating to the development of standards, including all steps to be followed in the research, consultation, piloting and acceptance process, until the standards are finally approved by the SafeCare Director.

2.3. SafeCare Director

It is the responsibility of the SafeCare Director to grant final approval to new standards.

3. Related documents

- QA-GEN-005 Procedure for the functioning of the standards development group
- QA-GEN-005_Annex 1 Composition of the SafeCare standards development group

Released versions of the standard operation procedure (SOP) are applicable.

4. Procedure or Process

When the development of new standards or review of consisting standards is contemplated, a proposal must be drawn up and submitted to the SafeCare Director for initial approval.

4.1. Guidelines to be followed in the preparation of a proposal/protocol for the development of new standards

The following aspects should be considered in the proposal.

- The *aim* of the standards development program.
- The *reason* why the particular standards need to be developed
- The *market requirements* and the *opportunities* that will arise from developing and instituting the program. At this point, it could be advantageous to include customer response (if available).
- *Statutory and legal requirements.* Excerpts from relevant laws and regulations should be included to inform the SafeCare Director of the need to include certain standards.
- *Views and requirements of interest groups.* Stakeholders could include experts in the medical, ancillary and legal fields, as well as customer/user groups.
- If necessary, the *inadequacies* of the *current standards* should be discussed.
- The *objectives* of the standards development program as they relate to the standards should be considered. These could include:
  - → Best practice in the particular field as it relates to the standard;
  - → Guidelines to and the assessment of the degree of compliance to the standard.
- *Timeframes* for the project, taking into account the time it may take to get responses from recognized experts and associations.
- *Financial implications.* These should include the cost of:
  - Standard development:
    a) Consultants
    b) Administration
    c) Transport
  - Assessment and decision-making process:
    a) Consultants
    b) Computer Programming
    c) Pilot Program
    d) Surveyor Training
    e) Development of Surveyor Guidelines

4.2. Planning for the development of standards

4.2.1 Guidelines for standards

- Once the standards have been approved for use, they should not be changed substantially for a period of **at least two years**. However, planning for the ongoing development and updating of standards should take place.
- Only the SafeCare Director is empowered to order changes to standards should they be deemed necessary.
- All standards are to be underpinned by the 'Principles for the Development of Health and Social Care Standards, 5th Edition v1.0' of International Society for Quality in Health Care External Evaluation Association (IEEA) (see below).
- When standards development is planned, particular attention must be paid to customer and market needs, resources, regulations and timeframes. This is achieved through:
  - Surveys and networking to establish industry and customer requirements, taking statutory and ethical requirements into account.
- Specialist interest groups should be consulted to identify shortcomings in the current standards where they exist.
- A consultation process with appropriate interest groups must be planned.

4.2.2 The principles the SafeCare standards

The following IEEA principles are the basis of all SafeCare standards.

Standards development	The standards are planned, developed and evaluated through a defined and rigorous process.
Standards measurement	There is a transparent measurement or rating methodology used by organisations and surveyors to aid consistent rating of achievement.
Organisational Role, Planning and Performance	The standards require the assessment of the capacity and efficiency of health and social care organisations.
Safety and Risk	Standards include processes to manage risk and to protect the safety of patients/service users, staff and visitors.
Person-centred Approach	The standards are person-centred, reflect the continuum of care and encourage partnerships between patients/service users and professionals.
Quality Performance	The standards require organisations to evaluate, monitor and improve the quality of services.

4.3. Development of draft standards

4.3.1 Development and Review phase (Phase 1)

- The Standards Development Coordinator coordinates and allocates the activities for the members of the Standards Development Group. Issues that are considered:
  - → Expertise
  - → Experience
  - → Availability
- Feedback from the SafeCare country teams is collected and kept until the SafeCare standards are newly developed or reviewed.
- Current international literature is researched, professional bodies and other professional bodies are consulted for suggested revisions of existing standards or for input into new standards.

A timeframe should be set for the review of current and the development of new standards. Once complete, the draft standard(s) will be circulated to all members of the Standards Development Committee to discuss the suitability of the standard(s) for further development and refinement.

4.3.2 Pilot phase (Phase 2)

These newly developed or reviewed standards and criteria are tested in pilot healthcare facilities and are further adapted to meet the specific needs of the healthcare facilities in Africa.

During the pilot phase, these standards and criteria are tested in pilot healthcare facilities to ensure their suitability for the healthcare facilities in Africa. This is done in the following way:

- The Standards Development Group decides how and when to pilot the standards and, in collaboration with the executive unit, sets up the process.
- Senior assessors meet to study the new standards and assist with the planning of standard piloting process.
- Prior to piloting, meetings of senior assessors are held to clarify any doubts regarding the interpretation of standards and criteria and the assessment process.
- Pilot sites are identified and the facilities are evaluated against the draft standards.
- Following the validation of the draft standards, modifications are made as required and the adapted standards piloted again. Piloting with subsequent modifications is repeated until consensus is reached by the surveyors as to the suitability of the standards.

4.3.3 Approval phase (phase 3)

In the approval phase (phase 3), the standards are presented to the Standards Development

Group. This Standards Development Group evaluates the standards in terms of patient and staff safety, legality and efficiency. If satisfied, The Standards Development Group recommends to the SafeCare Director that the standards be accepted. The standards are then taken into full service until the next review round. The required information and documentation, regarding the new or updated (reviewed) standards are shared with all the certified SafeCare assessment users.

4.4. Ongoing revision of standards

A mechanism is in place to ensure that health service providers, facilitators and surveyors are encouraged to make recommendations for change to the standards as required.

These recommendations are collected and reviewed on an ongoing basis. Standards are revised when the circumstances demand.

These changes (if not substantial) are made in a copy of the standards kept on electronic file and named 'Standard in the Process of Change', which, when a review process is initiated, can be considered by the Standards Development Group in the development of future revisions of the standards.

5. Flowchart

Not applicable