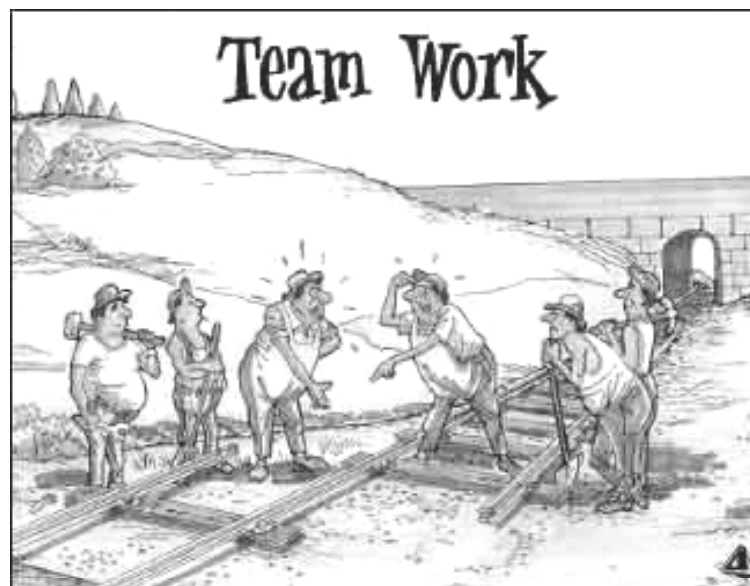


V

# Introduction to Quality Management



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## 1 Introduction

In 1984 WHO published the "Health 2000" programme, and recommended: "By the year 1990 in the healthcare sector of every Member State there should be in place an effective quality assurance system for patient care."

Most countries have incorporated this requirement into their national legislation.

**However, legal regulations alone are no guarantee of success if these are merely regulations decreed by the authorities, since acceptance and motivation are key factors.**



Why do we talk about quality assurance? Is there a danger of a decline in quality? If one has kept abreast of the discussions and reports on treatment mistakes, staff shortages, workshifts, cost pressures, etc, one would have every reason to believe that this was the case. It is perfectly reasonable to query the quality of medical care. Nonetheless, it would be desirable if quality assurance measures were to go beyond preserving the status quo (actual status) and bring about quality improvement as well as enhancement of efficiency, i.e. have a cost-cutting effect,

**In that respect, the term quality management is perhaps more apt to describe just what is involved here, i.e. optimization of medical care by making improvements in structural, organizational, medical, nursing and technical areas.**

## 2 Introduction to quality management

The term quality is often used. We let other people know, for example, where they can buy good sausages, get good customer service, etc.

We praise quality of an unchangingly high standard. “Mr X’s sausages are of a high standard year in, year out.” We criticize poor quality: “The standard of customer service is no longer what it used to be”.

If we go on to discuss this, we soon realize that people apply very different criteria to quality.

One person may deem sausages fresh from the farmer of his choice as being of excellent “quality”, whereas another person bestows this accolade on sausages produced in accordance with the pertinent legal standards.

The term quality entails, of course, not just product quality but also many other criteria, such as price, customer service, etc.

Therefore the term quality must be defined:

### What is quality?

“The quality of a product or a service is determined by the totality of features and characteristics of the product or service that bear on its ability to satisfy the stated and implied needs.” (ISO 8402).

### In other words:

- It is not that which is Expensive and Elaborate that is Quality, but what the customer wants and needs.
- It is not that which I *believe* the customer needs that is decisive – but rather what I *know* the customer needs.
- Quality means the absence of faults (mistakes, errors). That means: it is not the elimination of faulty products at the end of a process that is decisive, but the guiding principle here is to already avoid occurrence of faults as far as possible.

A somewhat more amusing definition:

**Quality is when the customer, and not the product, comes back.**



## What is quality in the hospital?

Only in the recent past, 10-bed rooms were not a quality problem, but today we have other requirements. Although there are no clearly defined quality criteria, one talks about the maternity wards that are currently the “best”, about where one should have hip surgery done or which paediatrician one can trust.



**Assurance of the quality of a medical service is an interdisciplinary task with input from all healthcare workers and is a patient's right.**

Quality in the hospital could be defined as follows:

**Quality means the best possible diagnosis, treatment and care for the patient. The goal must be efficient, adequate and economically feasible patient care.**

## What is quality assurance?

The sausages produced as per ISO 9000 standards or from the farmer remain unchanged. If the sausages taste good to us and the price / performance ratio is in order we are satisfied.

### **Quality is unchanging**

Various methods are employed to ensure the standard (level) achieved is maintained, something that calls for continuous control and documentation

### **Quality assurance is a static process**

## What is quality assurance in the hospital?

- 10-bed rooms continue to 10-bed rooms
- disease X cannot be treated successfully
- training remains unchanged

**Quality remains unchanged, we assure the current status**

## What is quality management?

With a "good" sausage, quality assurance may be enough for several years but here, too, it may be necessary to make changes. There could be a change in consumers' taste (for example, children nowadays generally prefer fast food to more conventional alternatives), the laws could change, etc.

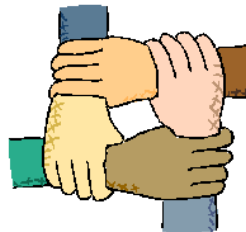
**Quality management is the continuous, planned and well-targeted endeavour to improve a service or a product.**

## What does quality management mean in the hospital?

The best medical care is not going to be very effective if there are delivery problems or maintenance problems, the best cleaning is not going to be very effective – overall – if suitable products are not used.

**Quality management in the hospital entails optimization of medical care by making improvements in structural, organizational, medical, nursing and technical areas. It is important that improvements be based on a reasonable policy so as to be as effective as possible.**

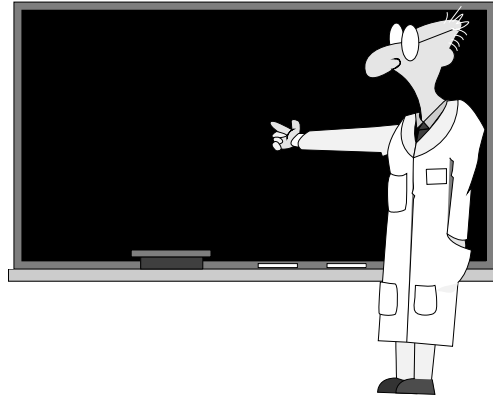
**Quality management calls for commitment from all occupational groups.**



**Quality management never refers to the shortcomings of an individual employee.**



### 3 TERMS RELATED TO THE TOPIC OF QUALITY MANAGEMENT



#### Quality policy

Quality policies are understood to mean an organization's intentions and efforts in respect of quality .

In most cases, quality policies are expressed in general terms:

For example,.

*"People help people": That guiding principle determines the actions of our hospital's employees.*

*It ensures that the around .....inpatients and ..... outpatients treated each year receive the best possible medical, nursing and dignified care: top priority is given to the health, security and satisfaction of the patients.*

*They are also called upon to ensure their actions are carried out in a manner that is economically feasible, environmentally friendly and efficient.*

**How could one define the quality policies of a central sterile supply department?**

## Quality assurance

Quality assurance ensures that quality remains unchanged.

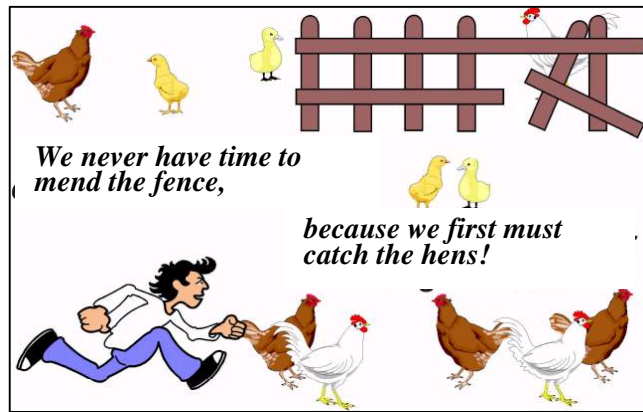
What quality assurance measures are taken for the reprocessing of medical devices?





### Quality management

**Quality management is the continuous planned and well-targeted endeavour to improve a service or a product.**



**What quality management measures can be taken in a central sterile supply department?**

## Audit

An audit is understood to mean a quality check to establish to what extent products or activities meet the predetermined quality requirements.



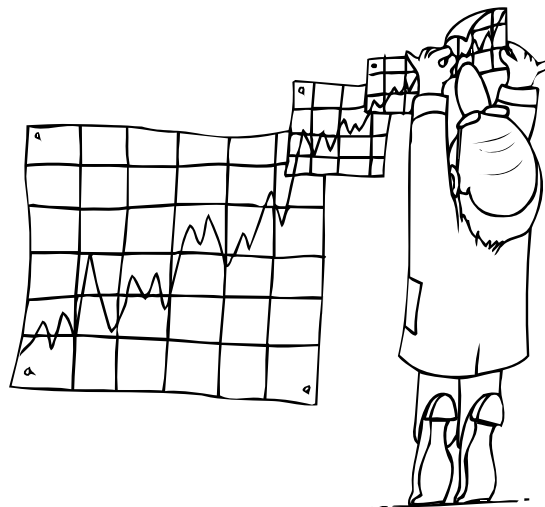
**What should be checked in a central sterile supply department?**

**What is the difference between a quality assurer and a terrorist?  
Terrorists have sympathizers!**

## 4 QUALITY MANAGEMENT PHILOSOPHY



**A quality management system is not a rigid construct within an organization,  
rather it is a dynamic process within the organization aimed at continuous quality  
improvement**



## 5 RESPONSIBILITY FOR QUALITY



Everyone in the organization is the customer of a predefined work process and is, at the same time, the supplier of a subsequent work process.

In other words: we receive e.g. medical devices from the operating room / theatre (OR) and reprocess them for the OR.

Everyone who is a customer expects perfection and is aware that the same perfection is expected of him.

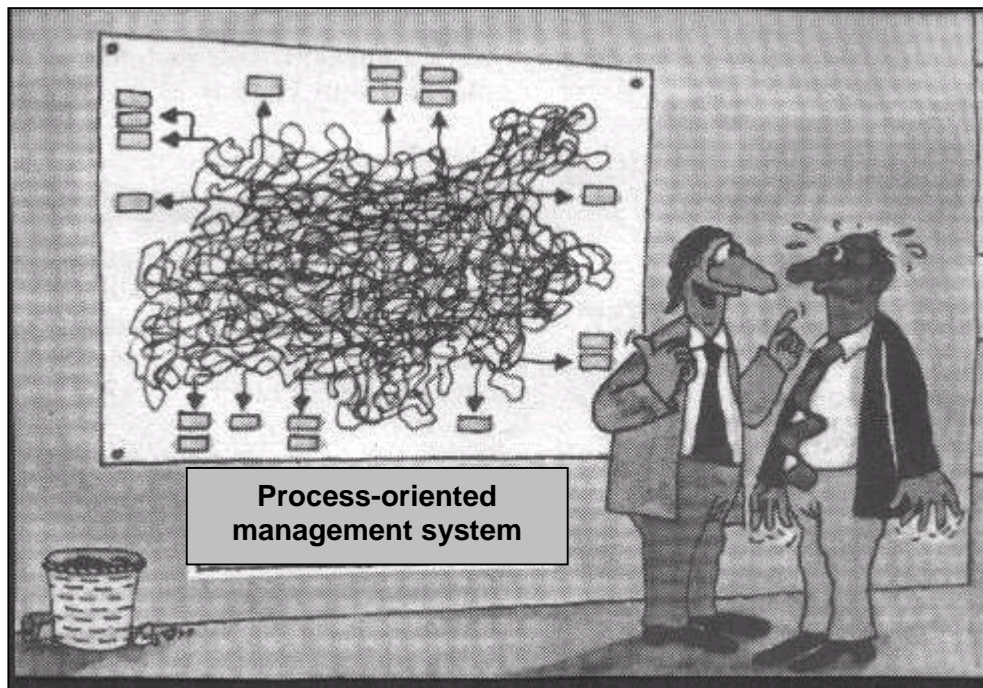
In other words: we expect the OR will supply us with properly arranged sets for reprocessing, the OR expects us to return properly packed sets.

Everyone in the organization directly or indirectly influences the quality of services and of how they are rendered, and is thus responsible for these.

In other words: every individual is important in ensuring that we supply perfect products. A properly packed set is of little use if functional checks are not properly carried out, etc.

**Therefore at the core of quality efforts is each and every staff member!**

## 6 PROCESS MANAGEMENT



Processes are activities that, taken as a whole, create a value for the customer, e.g. warm, healthy food that tastes good to the patient!

In general, these functions are of an overlapping nature and are carried out by an interdisciplinary team, e.g. caring for patients in the healthcare sector.

**Let's name certain occupational groups that have to work together to reach the goal of good (or optimal) patient care:**

Often, working tasks are viewed as separate activities, e.g. my job is to pack instruments. If everyone sees his job as an isolated task and loses sight of the overall process, problems can easily arise. This is true in the case of a department and is much more so in a large interlinked organization such as a hospital.



Even if everyone works well but there is not enough cooperation or no “joined-up thinking”, major problems can occur.

For example, a hospital has employed an award-winning chef, able to produce delicious dishes but, because of the long distances to be covered, the food is cold when it is served to the patients.

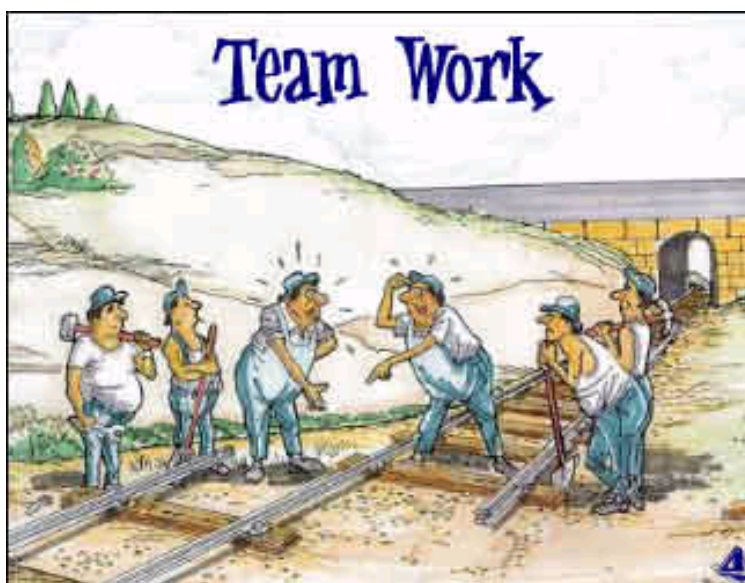
This type of task division where everyone sees only his own job is called functional work division.

Quality assurers would express this as follows:

Work practices are established over many years within areas of competence and are aimed exclusively at meeting their own objectives, even if that is at the cost of other areas of competence.

This principle quickly leads to “tunnel thinking” and to many problems arising at the points of intersection between the various departments and, often, it is very difficult to identify and solve these.

**From the diagram below we can see what happens when everyone works well but in isolation:**



## 7 Process-oriented working – process management



That the award-winning chef is of little use to us if the food is cold when served we have seen above. Now, of course, we could improve the transport system, e.g. purchase suitable trolleys to keep the food warm. That, no doubt, would be great but would it mean that the patient automatically got warm food? Of course not because he might be absent undergoing some prolonged treatment procedure. Now, of course, measures could be taken to eliminate this problem, too, but must the patient himself be satisfied if he is served warm food? Of course not, e.g. on a children's ward pizza and Viennese-style veal cutlets are, no doubt, more popular than award-winning menus. If one wanted to, one could enlist the services of the dietician who would probably not be too happy about the idea of a Viennese-style cutlet.....

Process management is understood to mean the fundamental approach, whereby the entire organization's activities are viewed as a combination of processes or process chains.

The goal here is to assure continuous quality improvement through continuous improvement of the processes involved.

**What must one bear in mind in connection with process management in the central sterile supply department?**

## PROCESS TYPES

We distinguish between the following processes

### MANAGEMENT PROCESSES

**contribute to strategic business management**

Example: budget control, planning medical facilities (e.g. do we need a maternity ward?)

### OPERATIONAL PROCESSES

**contribute directly to the actual work involved**

Example: nursing / medical services

### SUPPORTING PROCESSES

**contribute indirectly to the organization's working activities**

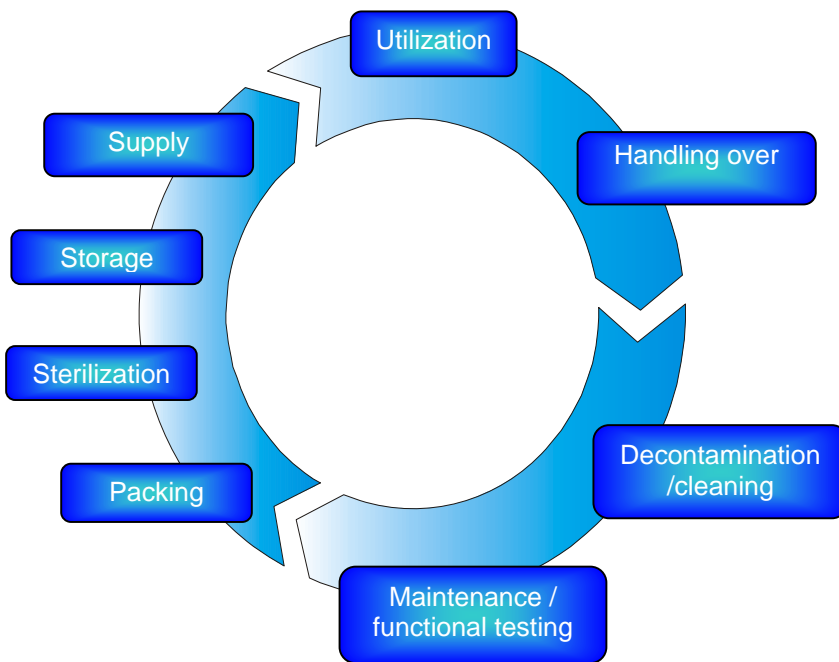
- refer essentially to provision of the requisite materials

Example: sterile instruments

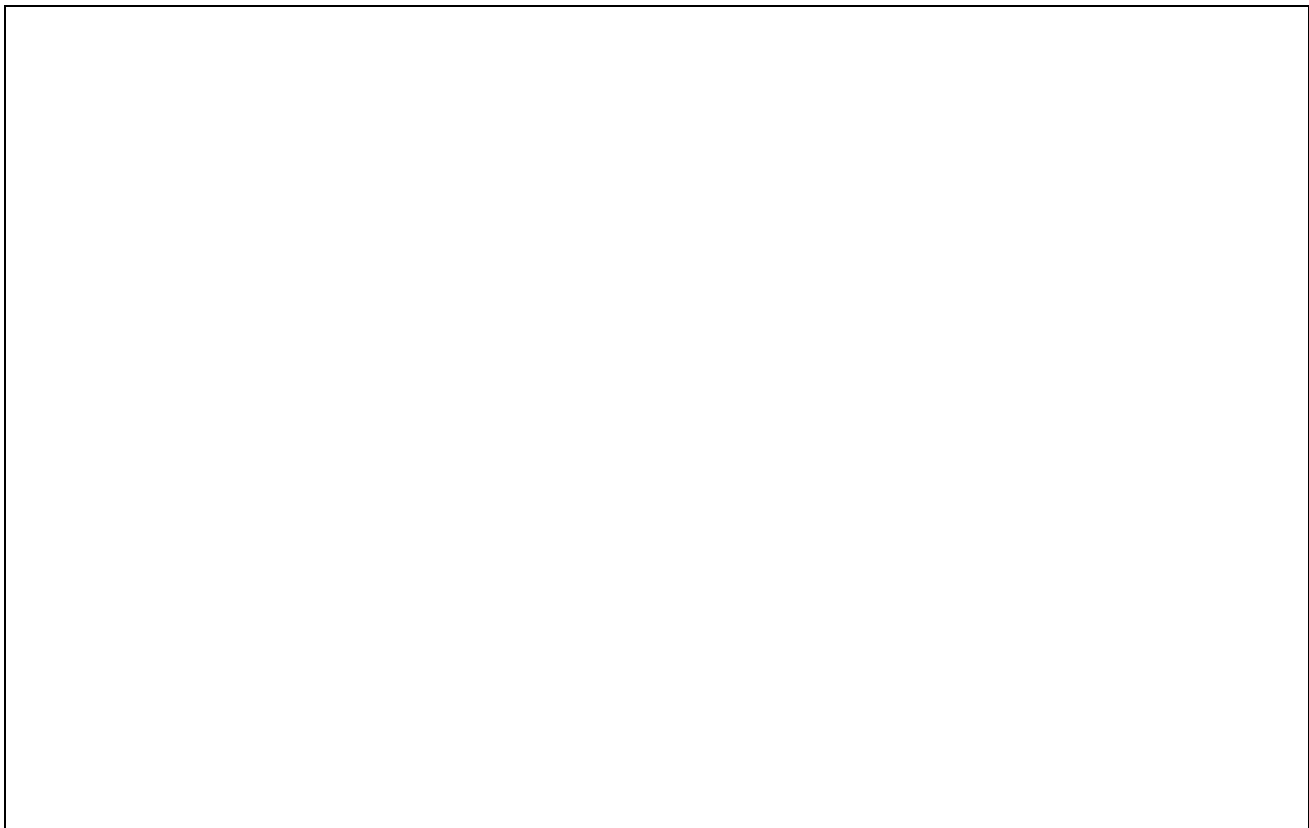


## 8 Medical device circuit

Medical Devices Circuit in the traditional sense:



This is the medical device circuit as we know it in the traditional sense. We must now think about everything that has to be borne in mind if one were to see the instrument circuit as a process



## 9 What is needed for functional quality management?

- Structure

To function well, a central sterile supply department needs a manager, deputy manager(s) and staff.

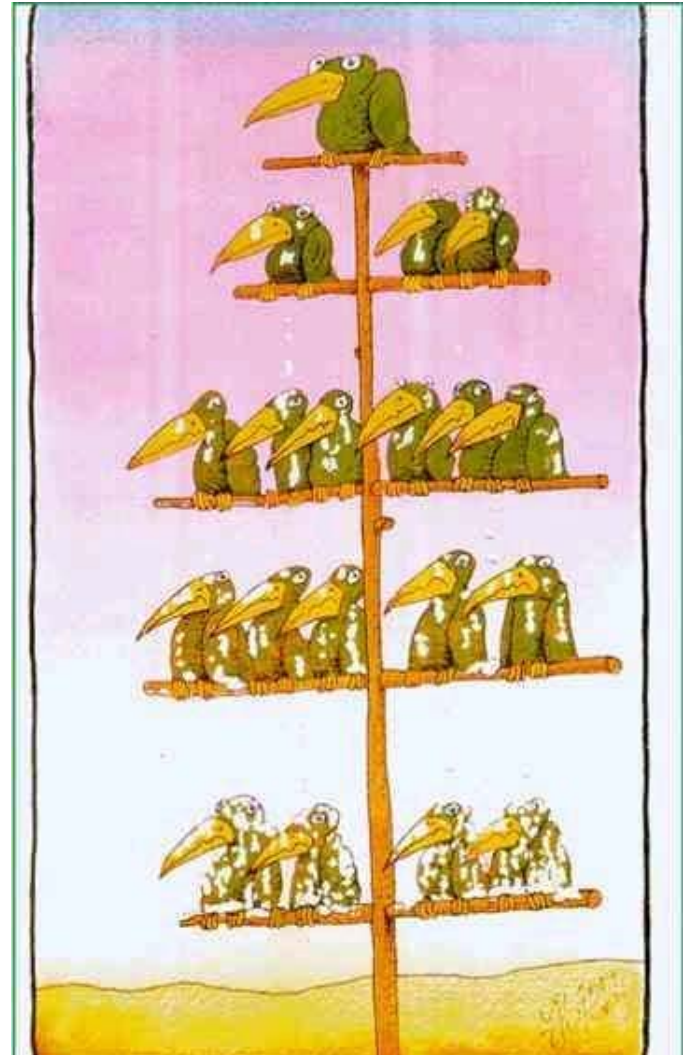
In general, the structure is illustrated in the form of organigrams (see fig. on the right)

- Training

But the structure is of little benefit to us if staff are not well trained. That this is something known even to the bird population is shown in the figure below:



How to  
shit on  
people



In many countries special training courses are run for medical device reprocessing. In other countries, they must still be set up. But in-house training courses, training on WDs, Sterilizers, etc. by the manufacturer or distributor must not be neglected either.

The content of training courses should be documented. Well-run establishments plan their training courses in detail so that all employees receive training within a certain time frame. Likewise for new employees there is a clearly defined training schedule.

- Duties and responsibilities



Each staff member must be aware of his duties and responsibilities. Ideally, these should be set out in writing. In a well-run medical device reprocessing unit, e.g. the name of the person authorized to release batches is specified in writing and the supervisor is reassured that this person is also capable to doing so.

A situation should not arise whereby, for example, during a night shift the person who happens to be on duty starts a program without being properly trained.

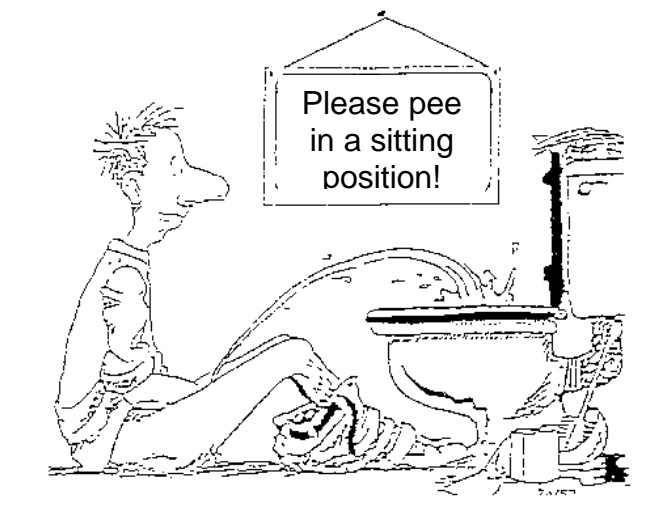
- Operating procedures

Operating procedures have been known to us for centuries in the form of cookery recipes. And really, operating procedures – often known as standard operating procedures (SOPs) – are nothing more than cookery recipes. Operating procedures clearly specify e.g. how a disinfectant solution is to be prepared or what action is needed following needlestick injuries.



Operating procedures are intended as a means of ensuring that all employees will discharge the same activity in exactly the same manner. Because only by doing so can we ensure that the quality is also in order.

**Specimen standard operating procedure – see Annex**



## 10 Documentation

### News from the quality assurance front



*These files can be destroyed Ms Schmalbach!*

*Oh, but to be on the safe side, first make a copy of each one!*

So that we can prove that we have performed our duties correctly, we need to document a number of things, i.e. put them into writing. For example, documented (record) batch release.

- Maintenance plan and checks

Well-run establishments will, of course, also have maintenance plans; they must overhaul their machinery at regular intervals and document this.

- Mistakes (errors)

Any mistakes made are recorded in well-run establishments. This is done not to find the person responsible for the mistake, but rather to think about how mistakes can be avoided in future.

*Whoever works makes mistakes.*  
**AVOID MISTAKES!**



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| <b>Hospital<br/>Specimen</b> | <b>STANDARD OPERATING<br/>PROCEDURE</b>                          | <b>Doc. No:</b>       | <b>AA-XY</b> |
|                              |  |                       |              |
|                              | <b>Title: Preparation of a surface<br/>disinfectant solution</b> | <b>Revision:</b>      | <b>00</b>    |
|                              |  | <b>Valid as from:</b> |              |

## **11 Annex: Specimen Standard Operating Procedure**

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|          |                  |                      |

|                  | Name | Date | Signature |
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| <b>Hospital Specimen</b> | <b>STANDARD OPERATING PROCEDURE</b>                          | Doc. No:       | AA-XY |
|                          |  |                |       |
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## 1. Purpose

This standard operating procedure describes the preparation of surface disinfectants for XY area

## 2. Scope / work place

Specify the area where the solution is to be prepared and used

## 3. Terms

ml = millilitre

l = litre

## 4. Competences

Specify who is responsible for this task

## 5. Procedure

As a standard practice, a 0.5 % solution is to be prepared.

Other concentrations are specified for certain application areas by the suitably qualified nurse on duty

### 5.1 Receptacles

- ◆ Cleaning basin, green, from the cleaning trolley
- ◆ Disinfectant (5 l container with dosing pump)
- ◆ Dosing beaker, small, with precise graduations (markings)

### 5.2 Method

- The solution must be freshly prepared each morning
- Dosing table is stuck inside the cabinet above water tap in the "Unclean Disposal" room
- Fill 8 l water (cool) into the basin (markings on inside rim of basin)
- Then dose the disinfectant with the dosing pump into the small measuring beaker
- Check that it is exactly 40 ml
- Now add the 40 ml to the water

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### ***5.3 Application***

The solution may only be used for one day  
 An already-used cloth must never be dipped into the solution  
 Surfaces are wiped off moist

### **6. Personnel protection**

When preparing the solution gloves, orofacial mask and goggles must be worn.  
 Gloves must always be worn when applying the solution  
 Each staff member shall be briefed on the hazards posed by working materials  
 Each staff member shall be familiar with first aid measures, based on the safety data sheet.

### **7. Troubleshooting**

Check the expiry date  
 After accidents or near accidents, take the action outlined in the valid service instructions of the respective institution.

### **8. Additional documentation**

Hygiene (infection control) policy  
 Service instructions  
 Safety data sheet