Can Peracetic Acid Replace Glutaraldehyde?

Peracetic acid (PA) is a liquid chemical germicide used for sterilizing or disinfecting heat sensitive devices. Scientists have been working with this germicide since the turn of the century. Freer and Novy reported on the germicidal action of PA in 1902, but the solution was generally unavailable due to the cost of manufacturing.\(^1\)

When a commercial process was able to economically produce 90 percent hydrogen peroxide, an ingredient necessary in the manufacturing process of PA, a wide variety of uses were introduced. In medical applications, PA has been used to sterilize rooms, equipment, hemodialyzers, and medical, surgical, and dental instruments.\(^3\)

Effectiveness

Why all the excitement? In several studies looking at the comparisons of germicides, PA was found to be the most active against bacterial spores. In one test of 23 agents, the anti microbial activity of PA was the most efficacious against Bacillus thermoacidurans spores, including chlorine-containing compounds.\(^2\)

When compared to a variety of disinfectants PA is the most effective against a wide range of bacteria, mycobacteria, viruses, yeast's and fungi. \(^3\) Studies show PA is more efficacious than hydrogen peroxide, formaldehyde, and glutaraldehyde.\(^3\) Additional advantages are its rapid action, ability to remain effective at low temperatures, and efficacy in presence of organic material. The decomposition products of PA are acetic acid (vinegar), water, and oxygen.

Though the effectiveness of PA as a germicide has been demonstrated, the actual killing mechanism is not well understood. PA may destroy cell membranes by disrupting sulfur and sulphydryl bonds. PA inactivates a catalase that breaks down hydrogen peroxide and may oxidize enzymes that support biochemical transportation across cell membranes, thus causing the cell wall to rupture. PA is known to be a protein denaturant and reportedly destroys pyrogens.\(^2\)

The Use Of PA

PA currently is being used to reprocess heat sensitive medical devices. Expensive, sophisticated, heat sensitive endoscopes used in minimally invasive procedures have increased the need for rapid device reprocessing time. Because many of these devices are incompatible with steam sterilization, and gas or plasma technologies require anywhere from 90 minutes to 12 hours for sterilization to occur, these methods may be unacceptable.

Discussion

PA's perceived advantages may stem from its ability to function in the presence of organic matter. Unlike the inherent tissue fixing properties of glutaraldehyde and formaldehyde, PA is a protein oxidizer. "The sporicidal time-concentration product for glutaraldehyde was 32 times higher and that for formaldehyde was 64 times higher than that for PA against Bacillus anthracis with four percent horse serum at 20 degrees C."\(^3\)

In studies by various investigators the efficacy of PA has been demonstrated in narrow lumens in the presence of serum challenges.\(^4\) Additionally, studies done by Tucker, e.t.al., demonstrate the ability of PA to remove glutaraldehyde fixed protein in lumens.\(^5\)

Both manual and mechanical cleaning processes can be utilized. Manual cleaning is usually reserved for items that cannot be processed mechanically, cannot be immersed or are very delicate. In some facilities manual cleaning is the only process available. Whatever process is used, certain practices are essential to the effectiveness of the cleaning process, disassembly of the device (if recommended by the manufacturer), proper cleaning implement (for manual cleaning), and proper positioning and loading of devices in baskets for mechanical cleaners. This includes loading devices in the proper basket to allow for the detergent and water to reach all surfaces.

Disinfection

The principles of effective disinfection are similar to decontamination. Upon purchase, read the Material Safety Data Sheet (MSDS) for the disinfecting agent being used. Obtain the instructions for proper cleaning and disinfection. Measure the disinfecting agent properly. Always read the label on the container. The label provides important information with regards as to how to measure the disinfectant, what type of water is needed (tap versus distilled water) and how to use the disinfectant.

Good practices in disinfection include wearing proper protective attire, measuring the disinfectant properly, and using proper containers for soaking. Disinfectants are available in concentrates (need to be diluted), pre-mixed or require activation. The MSDS will alert the user if any special protective attire is needed during use.

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COMMENT

December is always a good time to reflect on significant happenings from the past year and to focus our attention on the year ahead. Despite the fact that the Y2K bug has had everyone in a tailspin, some significant developments have taken place during the past year that relate to sterilization and infection prevention.

Firstly the World Symposium for Central Service in Hospitals held in Orlando, Florida highlighted the challenges facing sterilization practice in the new millennium. These included dealing with non-conventional agents such as Prions, cost containment and fundamental issues such as proper pre-cleaning prior to sterilization.

The second significant development of the year has been the progress made in the unification of quality standards. Standards should enable users to determine whether products are suitable for a certain purpose and also to make comparisons between different brands. Unfortunately, each country has developed their own standards over the years, using unique test methods which means that it has been impossible to compare the performance of various products. The problem is compounded further when novel products are launched onto the market which do not have an applicable standard. It was therefore particularly encouraging to see the adoption of EN 868 during May of this year as it harmonized the various existing European standards for Sterilization Packaging materials and systems. The committee work being done on ISO 13683 also forms part of this trend (see article on Parametric Release on Page 3).

The expansion of the Infection Control Society of South Africa (ICASA) into the provinces has been the third significant development of the year. New chapters have been set up in the Eastern Cape, Mpumulanga and the Northern Province during 1999 and this will enable more health care workers to keep up to date with the latest developments in this very important field. All those involved are to be congratulated.

It would be nice to think that entering the 21st Century is somehow going to magic away all the challenges and problems that we presently face and that we will be able to start with a clean slate. Unfortunately, the reality of HIV/AIDS, increasing antibiotic resistance trends and reduced health care budgets will be with us for the foreseeable future. Hopefully, if we look at what has been achieved in medical science during the past 100 years, these problems will be addressed in a cost effective way in the not too distant future.

From our side, we will continue to keep you up to date with all the latest developments in the field of disinfection and sterilization and the launch of our new web site will greatly enhance our ability to get this information to you. Progress is all about communication and working together and I would like to throw down the challenge to all those CSSD Managers out there to get together and form a National Sterilization Society in the new year, as we certainly need one. As part of this challenge, Safmed commits to give you as much support as possible in this endeavour.

In closing, Safmed thanks all its customers for their support during 1999 and look forward to meeting all your needs during the year 2000. We wish you a blessed and safe festive season. Please drive carefully if you are going to be on the roads.

Pat Ayling

Effective disinfection is dependent upon thorough pre-cleaning of the device. The disinfection process requires proper soak/contact time to the disinfectant (follow the manufacturer’s recommendations), proper temperature (for some) and the proper concentration. The soak/contact time should be verified with the use of a timing device or other reliable mechanism. Some disinfectants have test kits that can determine if the solution is still strong enough to disinfect. The solution should be tested at a minimum at the beginning of each day that it is used. Records of such testing should be retained according to the facility policy.

When processing devices for high level disinfection (flexible scopes), devices should be logged into a record that at a minimum, verifies the name of the device, records that the device was cleaned, and the total time in the solution.

Conclusion

Effective sterilization and disinfection begins with proper decontamination. All policies and procedures must be followed at all times. Manufacturer’s instructions for devices should be obtained and made readily available to personnel performing decontamination activities. Always read the label on cleaning and disinfecting agents and follow instructions carefully.

We’ve heard it before, but it bears repeating “if you can’t clean an item you can’t disinfect or sterilize it properly!” That is the essence of good practice.

Summary

The increase in minimally invasive surgery and the need for rapid device reprocessing of critical devices requiring sterilization has led to an increase in the use of PA. The development of increasingly sophisticated device structures raise questions regarding current reprocessing practices. Worker safety and the cost containment climate favouring reusability of devices must be factored with infection prevention issues. Health care personnel need to understand PA’s advantages and applications.

References

Parametric Release

What is parametric release? Why are people talking about it? What do you as a sterilization professional need to know about it?

A little background information is essential in order to answer these questions. For quite some time now, the standard setting bodies of Europe, Canada, and the United States have been working together to harmonize each country’s standards for sterilization in health care facilities into a single standard. This standard would be applicable to both industry and health care facilities. The advantages of doing so are far reaching. From an industry perspective, having one standard to comply with would make it very easy to bring products to a larger marketplace. From a CSSD Manager’s perspective, one standard would provide a global language for communication of sterilization issues, questions, and concerns.

The American National Standards Institute (ANSI), the Canadian Standards Association (CSA) in Canada, and countries belonging to the European Union have been working with the International Organization for Standardization (ISO) to achieve this goal. ISO is a worldwide federation of national standards bodies. While one might think that ISO is an acronym for the organization, it is not. “ISO” is a name derived from the Greek word “isos” and means “equal”.

The ISO Technical Committee 198, Sterilization of Health Care Products is administered by the Association for the Advancement of Medical Instruments (AAMI) and is composed of a number of working groups with representatives from several countries. The ISO TC 198 Working Group 3 is responsible for the development of the ISO document entitled “Requirements for Validation and Routine Control - Industrial Moist Heat Sterilization, ISO 11134.” In 1993, this document was adopted as an American National Standard and became known as “ANSI/AAMI/ISO 11134-93.”

This document does not cover moist heat sterilization in health care facilities. Nor does it cover the quality assurance system that is necessary to control all stages of manufacture that take place in a CSSD. It does contain principles that may be useful to those departments.

During development of this standard, the U.S. Delegation felt that a separate document would simplify and segregate those practices from ISO 11134 that would be applicable to health care facilities. Thus, “ISO 13683 Sterilization of health care products - Requirements for validation and routine control of moist heat sterilization in health care facilities” was born.

It is this document that is generating all the talk about parametric release.

The two key words in the title of this document are validation and control. It is these two words that a CSSD Manager must focus on. Sterilization, as defined in ISO 13683, is a “Validated process used to render a product free of all forms of viable micro-organisms.” A sterilization system, as defined in the standard, is the “Total of procedures and equipment, including sterilization needed to render a possibly soiled or contaminated product sterile and safe for use.”

As you can see, the first statement addresses validation and the second one concerns control. In order to comply with this ISO standard, a CSSD Manager must develop a quality system that can identify all critical aspects of a process and then establish control. This ensures that the process is completely reproducible, from cleaning and decontamination, to preparation and load configuration, to the actual sterilization cycle.

So how does one go about achieving this? The components of the sterilization system help to guide the CSSD Manager’s activities. The components are:

• Cleaning and decontamination • Inspection • Assembly • Packaging • Loading • Exposure to the sterilization conditions • Unloading • Storage • Distribution • Documentation

Immediate release of the product based on physical process data is known as parametric release. Physical monitoring of the process confirms that the critical parameters established during the validation of the cycle have been maintained or achieved.

Parametric release is the end result of a quality system that controls and monitors every step in the process. It also enables the CSSD Manager to declare, with confidence, that a product is sterile based on physical and chemical process data rather than on the basis of sample testing or biological results. Consequently, biological monitoring will not be used and chemical indicators will act only as through put indicators.

There are two distinct instances when validation of a sterilizer needs to take place: when commissioning a new sterilizer and, initially, to validate a sterilizer that has already been in operation.

The CSSD Manager will need to complete three steps in sequence. These steps are:

- The installation qualification - is it to the manufacturer’s specifications?
- The operational qualification - does it work to specification when a load is in the chamber?
- The performance qualification - requires that the sterilization process be reproducible.

CSSD staff will need to develop loading protocols, review the types of loads commonly processed, and classify them into types or families of continued on pg.3
more than placing your initials on
that performance qualification is much
loads are demonstrated. You can see
acceptable limits of product mix across
table loads are quantified, and that
maximum and minimum accept-
meters with micro biological lethality,
there be a correlation of physical para-
process for that load configuration is
replicate cycles, the steam sterilization
slight variances) for three sequential
same (with some allowance for
ations within the sterilizer and load were
If it can be demonstrated that condi-
tions within the sterilizer and load were
same. Mixed loads will require a range
of temperature sensors in the cham-
ber and one in the drain.
If it can be demonstrated that condi-
tions within the sterilizer and load were
the same (with some allowance for
slight variances) for three sequential
replicate cycles, the steam sterilization
process for that load configuration is
said to be validated.
Performance qualification requires that
there be a correlation of physical param-
ters with micro biological lethality,
that maximum and minimum accep-
table loads are quantified, and that
acceptable limits of product mix across
loads are demonstrated. You can see
that performance qualification is much
more than placing your initials on the
printout to indicate that you have
reviewed the cycle and determined
that time and temperature, measured
at intervals at the chamber drain,
were achieved.
Re-validation is required when there
have been changes to the sterilization
cycle, changes in packaging or loading,
changes in material, and any addition
of new medical devices.
The whole subject of Parametric
Release is a very complex one. The
purpose of this review is to give you an
idea of what it is all about and what it
will mean to the Manager of a Central
Service Department in North America
if it becomes the standard. We will
have to wait and see whether South
Africa decides to follow this route.
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notes sponsored by 3M Health Care.
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continued from pg2

like products. This exercise will
provide a map or footprint to consist-
tently and uniformly load the sterilizer
carts so that the same result can be
achieved every time.
Homogenous loads are easier to vali-
date because they are consistently the
same. Mixed loads will require a range
of measurements using a minimum of
five temperature sensors in the cham-
ber and one in the drain.
If it can be demonstrated that condi-
tions within the sterilizer and load were
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Mrs. Therese Morife from the
Northern Province Department of
Health and Welfare, is the 1999
recipient of the Bob Cassel award.
This award is made annually by the
Gauteng Infection Control Society
to the person that achieves the
highest number of points in the
criteria listed below, as voted by
his/her peers.

1. The promotion of infection control
beyond the workplace.

2. Demonstrated education in
infection control both in the
workplace and the Gauteng
Infection Control Society.

3. Has provided support to other
infection control personnel.

4. Has provided support to other
professionals interested in
infection control.

5. Has demonstrated knowledge
and an innovative approach to
infection control.

6. Has realised professional growth
in infection control.

Previous recipients of this award include :

• Ms. G. Sharp  • Dr. A. Duse
• Mrs. J. Pearse  • Dr. D. Durrheim
• Mrs. J. Soester  • Mrs. S. Roberts
• Mrs. C. Park  • Mrs. D. Hlatshwayo

Steri-view Online

This month sees the launch of the
electronic version of Steri-view as part
of a major redesign of Safmed’s web
site. Quite where this will take
Steri-view remains to be seen.
Although the new service will be based
on the printed publication, Steri-view
Online will undoubtedly develop a life
of its own.

Looking for information on something
specific in sterilization? Read an
article in Steri-view that you wish you
had kept? Are you loathe to hoard piles
of back issues, even of your favourite
newsletter? Well, most of the articles
we have ever written have been safely
stored and can be accessed with the
click of a mouse on our web site.
Simply set our search engine to find
exactly what you are looking for.

How to view the Safmed Web site

Assuming that you already have
Internet access, start your web browser
and type the web address
http://www.safmed.co.za in the URL
(unique resource locator). This should
take you to Safmed’s home page, from
where navigation is simply a matter of
following the links. Select Library and
then choose “Current edition of Steri-
view” or “Browse through all issues of
Steri-view” from the menu, depending
on whether you want something from
the latest edition or an earlier one.
Alternatively you can search the
database by topics or keywords. You’ll
be returned a list of links to articles
containing the word or phrase you
searched for.

For best results, the Safmed web
site requires versions 4 or higher
of either Internet Explorer or
Netscape Navigator. Java should be
enables in the browser. Also the
display properties on the desk top
of your computer should be set to
800 x 600 pixels.