

# SEALING SENSE

## The P3-A Equipment Standards

**Q.** How Will the P3-A Equipment Standards Affect You?

**A.** The pharmaceutical industry has frequently cited 3-A sanitary standards (used primarily in dairy and other food processing) when specifying equipment for their processes. Equipment manufacturers with sanitation requirements, pharmaceutical processors and regulators have been working together to create the first end suction centrifugal pump standard expressly for the API (Active Pharmaceutical Ingredient) segment of the pharmaceutical industry.

The new Pharmaceutical 3-A, or P3-A, standards represent the first major expansion of 3-A sanitary standards beyond the food and dairy processing industry. 3-A Sanitary Standards, Inc. (3-A SSI) created the new P3-A standards in accordance with the accreditation requirements of ANSI. The first group of P3-A Standards includes:

- P3-A 001:2008, General Glossary of Terminology Used in Pharmaceutical 3-A Standards
- P2-A 002:2008, Pharmaceutical 3-A Sanitary/Hygienic Standards for Materials for Use in Process Equipment and Systems
- P3-A 003:2008, P3-A End Suction Centrifugal Pumps for Active Pharmaceutical Ingredients

The P3-A standards will assure pharmaceutical equipment buyers, equipment fabricators, contractors and regulatory authorities that equipment is built to specific criteria for API production and cleanliness.

**Q.** What Are the Advantages of These Standards?

**A.** These standards are expected to provide uniform practices for hygienic design, materials of construction and fabrication of equipment within the API industry. Ultimately, the harmonization of equipment, material and design standards should help reduce costs for component suppliers and end-users while providing a clear, more consistent path to equipment design. Part of the cost savings is expected from decreased capital budgeting for specification time and the standardization of equipment design across the industry. Design standards are based on a well-established starting point of current P3-A standards and a third party verification inspection process.

### Third Party Verification

A third party verification inspection program is key to the success of the new standards. Third party inspectors, with

*(Continued on page 57)*

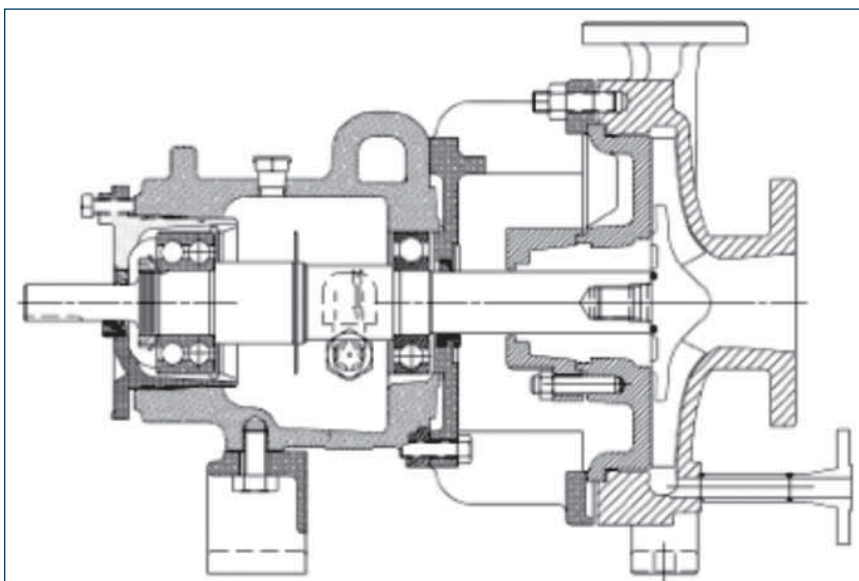


Figure 1. Cross section of pump conforming to Standard P3-003 2008

**Table 1. Features of pump standards P3-A-003 and B 73.1**

P3-A 003	ASME B.73.1
Enclosed impellers are NOT permitted.	Impellers of open, semi-open and closed designs are optional.
The impellers shall be installed on the shaft in a manner to isolate the product from the threads.	Impeller may be keyed or threaded to the shaft with rotation to tighten. Shaft threads and keyways shall be protected so they will not be wetted by the pumped liquid.
Metals shall be specified by the user from metals listed in P3-A-002 ( <i>Sanitary/Hygienic Standards for Materials Use in Process Equipment and Systems</i> ). Only the grade is specified, not the ASTM Standard designation.	Materials of Construction should be available in D1 (A395); Carbon Steel (A216, WCB); 316SS (A744, CF8M); Alloy 20 (A744, CN7M); and Other.
Lubricants for use during assembly shall meet the requirements of P3-A-002, paragraph C8.	Does not address assembly lubricants so suppliers may use a wide variety of products.
Allows cast surface finish but allows customer to specify improved finish.	Does not address surface finish.
Nonmetals require that materials be suitable for cleaning cycles and meet GRAS requirements.	Does not address elastomers.
P3-A addresses non-product contact surfaces and prohibits painting of alloy parts.	Does not address non-product contact surfaces and allows painting of alloy parts.
Requires product contact surfaces to be accessible for cleaning and draining. Requires drainability of the seal chamber. Addresses drainability of internal angles and prohibits threads on product contact surfaces.	Does not address drainability or cleanability.
Annex A (normative) is a P3-A specific data sheet that adds cleanability, sanitations and product contact surface finish requirements and deletes unneeded B73.1 options.	Appendix A (Nonmandatory) contains a detailed three page data sheet.
Annex C addresses engineering design and the technical construction file required for authorization of the P3-A symbol.	Paragraph 7 defines minimum required documentation. Includes basic drawings and instruction manual. The customer can request other data.
The primary product mechanical end face seal shall be sanitary in design with all product contact parts demountable and accessible for inspection and cleaning.	Not covered.
Metal bellows seals, split seals and packing shall not be used. Seals with set screws on product contact surfaces are not allowed.	Not covered.
Seals with single spring designs that reside on the product side may only be used if manual cleaning methods requiring pump disassembly are utilized.	Not covered.
Seals shall be capable of momentary dry running. The end user specifies details of such occurrences.	Not covered.
In liquid lubricated seal arrangements, the buffer/barrier fluid used in dual seal arrangements shall be provided by the owner/user. The design of the outboard sealing chamber, piping circuit and reservoir shall allow for draining and change of the buffer/barrier fluid to reduce particulates, prevent degradation of the fluid lubricating properties and manage biological degradation of some buffer/barrier fluids.	Not covered.

**Table 1. Features of pump standards P3-A-003 and B 73.1 (cont.)**

Seal chambers shall be a tapered bore design that will allow for complete draining of the pumped product in an assembled state. Seal chambers shall not contain threaded connections on product contact surfaces.	<ul style="list-style-type: none"> <li>• Allows for seal chambers or a stuffing box.</li> <li>• Allows for seal chambers that can be either cylindrical or tapered bore designs.</li> <li>• Allows for packing and has dimensional data for cylindrical seal chambers.</li> <li>• Contains stuffing box design details.</li> <li>• Allows space for packing.</li> <li>• Allows for tapped openings on surfaces that can be product contact surfaces.</li> </ul>
Seal chambers and/or gland plates shall be designed such that the seal chamber and piping system, if supplied, is self-venting during start-up and operation.	Allows for manual venting.
Seal chambers shall not contain throat bushings.	Allows for throat bushings.
The pump manufacturer provides seal chambers.	Not covered.
All product contact surfaces in the seal chamber and gland plate shall be cast or machined. Machined surfaces shall have a maximum surface roughness of 63 Ra. Specific surface finishes other than the stated above shall be specified on the data sheet.	Allows surface finish of 250 Ra minimum or as cast on the tapered bore surface.

### Fluid Sealing Association

*Sealing Sense* is produced by the **Fluid Sealing Association** as part of our commitment to industry consensus technical education for pump users, contractors, distributors, OEMs and reps. *This month's Sealing Sense was prepared by FSA Member Bill Adams.* As a source of technical information on sealing systems and devices, and in cooperation with the **European Sealing Association**, the FSA also supports development of harmonized standards in all areas of fluid sealing technology. The education is provided in the public interest to enable a balanced assessment of the most effective solutions to pump technology issues on rational total Life Cycle Cost (LCC) principles.

The **Mechanical Seal Division** of the FSA is one of six with a specific product technology focus. As part of their educational mission they develop publications such as the *Mechanical Seal Handbook*, a primer intended to complement the more detailed manufacturer's documents produced by the member companies. This document served as the basis for joint development of the more comprehensive *Hydraulic Institute* publication: *Mechanical Seals for Pumps: Application Guidelines*. Joint FSA/ESA publications such as the *Seal Forum*, a series of case studies in pump performance, are another example as is the *Life Cycle Cost Estimator*, a web-based software tool for determination of pump seal total Life Cycle Costs. The *Sealing Systems Matter* initiative also was launched to support the case for choosing mechanical seals

that optimize life cycle cost, reliability, safety and environmental compliance.

The following members of the **Mechanical Seal Division** sponsor this *Sealing Sense* series:

- Advanced Sealing International (ASI)
- Ashbridge & Roseburgh Inc.
- A.W. Chesterton Co.
- CoorsTek
- Daikin America, Inc.
- DuPont Performance Elastomers LLC
- EagleBurgmann Industries LP
- Flex-A-Seal, Inc.
- Flowsolve Flow Solutions Div. - Seal Group
- Garlock Sealing Technologies
- Greene, Tweed & Co./Palmetto, Inc.
- Industrias Vago de Mexico SA de CV
- John Crane
- KC America
- Latty International S.A.
- Metallized Carbon Corp.
- Morgan AM&T
- Nippon Pillar Corp. of America
- Parker Hannifin – Seal Group
- PPC Mechanical Seals
- SEPCO - Sealing Equipment Products Co.
- SGL Technic Polycarbon Division

(Continued from page 54)

3-A SSI credentials, will conduct an on-site inspection to ensure that equipment conforms to the P3-A standards. Based on the inspection report and license application to 3-A SSI, a P3-A symbol will be licensed to the equipment manufacturer to convey that specific models or types of equipment conform to the new standard.

**Q.** How Does a P3-A Pump Vary From an ASME/B73.1 Pump?

**A.** Pumps specified to the ANSI accredited ASME B73.1 Standard are typically employed in the chemical process industry (CPI). Standard B 73.1 is a dimensional and feature focused specification primarily directed to ensure dimensional interchangeability and operational reliability. Design features of the new P3-A standard for end suction centrifugal pumps modify those of the B 73.1 pumps to maintain product integrity and ensure effective in-process sanitation and cleanability.

Key differences between pumps specified to the new P3-A standard and B73.1 are shown in Table 1 (on pages 55-56).

## Conclusion

The introduction of the new series of standards for active pharmaceutical ingredients contributes to the pharmaceutical industry's efforts to improve the economy and efficiency of the entire manufacturing process and maintain the strict requirements of hygienic design and cleanability throughout their production process. This in turn will help ensure the reliability of products from that important industry. These new standards address the unique requirements of process equipment essential to product manufacturing.

For copies of these new P3-A Standards, visit the 3-A SSI website at [www.3-a.org](http://www.3-a.org) and click on Purchase 3-A Standards or contact Tim Rugh at 703-790-0295.

**Next Month:** *How can I extend the performance range of standard cartridge mechanical seals?*

*We invite your questions on sealing issues and will provide best efforts answers based on FSA publications. Please direct your questions to: [sealingsensequestions@fluidsealing.com](mailto:sealingsensequestions@fluidsealing.com).*

P&S

# ATLANTA '09

Destination for the Global Poultry Industry

January 28-30, 2009

Georgia World Congress Center / Atlanta, Georgia, USA

## SHOW PROGRAMS

**Pet Food Regulatory and Technical Conference:**

January 27 - 28

**Animal Agriculture Environmental Sustainability Summit:**

January 27 - 28

**U.S. Poultry & Egg Association's Poultry Issues Program:**

January 29

**AFA's Improving Profitability in Feed Manufacturing Program:**

January 29

**NPFDA/USPOULTRY Market Intelligence Forum:**

January 30

For detailed information on these programs go to [www.ipe09.org](http://www.ipe09.org)

More than 20,000 attendees from over 100 countries



circle 125 on card or go to [psfreeinfo.com](http://psfreeinfo.com)