

Safety & Compliance

with the Shandon Excelsior™

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U.S. Accrediting & Monitoring Agencies:

- **CAP** (College of American Pathologists)
- **OSHA** (Occupational Safety and Health Administration)
- **FDA** (Food and Drug Administration)

European Monitoring Agencies:

- **IVDD** (In Vitro Diagnostics Directive)

CAP: Laboratory General Checklist (August 2002)

– **Question GEN.70700**

Is there a defined program to reduce the volume of hazardous waste that is generated by the laboratory?

When using the Shandon Excelsior Reagent Rotation Concept, you will only need to change reagents once the Specific Gravity reaches its set point. Once the set point is reached, the 1st alcohol, the 1st Xylene, and the 1st Wax will be discarded. Then a new alcohol, xylene, and wax can be added into the new positions. This will leave only three reagents to discard versus the average ten to fourteen that most laboratories are discarding with other instruments. This cuts the volume of hazardous waste to more than half for this particular instrument.

– **Question GEN.70816**

Is there a defined ergonomics program, designed to prevent musculoskeletal disorders (MSDs) in the workplace through prevention and engineering controls?

With Shandon Excelsior's In-Process Rotation your technicians will no longer need to move reagent bottles to and from a pouring or discarding area. The technician can remove the cap off of a commercially available reagent and place the container into an exchange position. The machine will fill and discard as prompted by the user. There is no more lifting heavy bottles to fill or discard reagents.

– **Question GEN.72100**

Are storage areas and/or rooms where volatile solvents are used adequately ventilated?

The Shandon Excelsior Storage Cabinet is built to similar specifications of a Flammable Cabinet. It is ventilated through a potassium permanganate filter as well as a charcoal filter (with capabilities for vent adapters instead of the use of filters). There is a spill containment area at the bottom of the storage area as well as lockable doors which are standard for all flammable cabinets.

CAP: Anatomic Pathology Checklist (July, 2001)

– **Question ANP.22400**

Where appropriate, are tissue and slide processing temperatures defined and monitored?

With Shandon Excelsior's Disk Drive and Print Options, you will be able to print and store procedures, times, and temperatures, as well as a variety of other options. With the Temperature Status Printout, and the Temperature History Printout you will have documentation to support your answer to this question.

– **Question ANP.23100**

Are solutions changed at regular intervals?

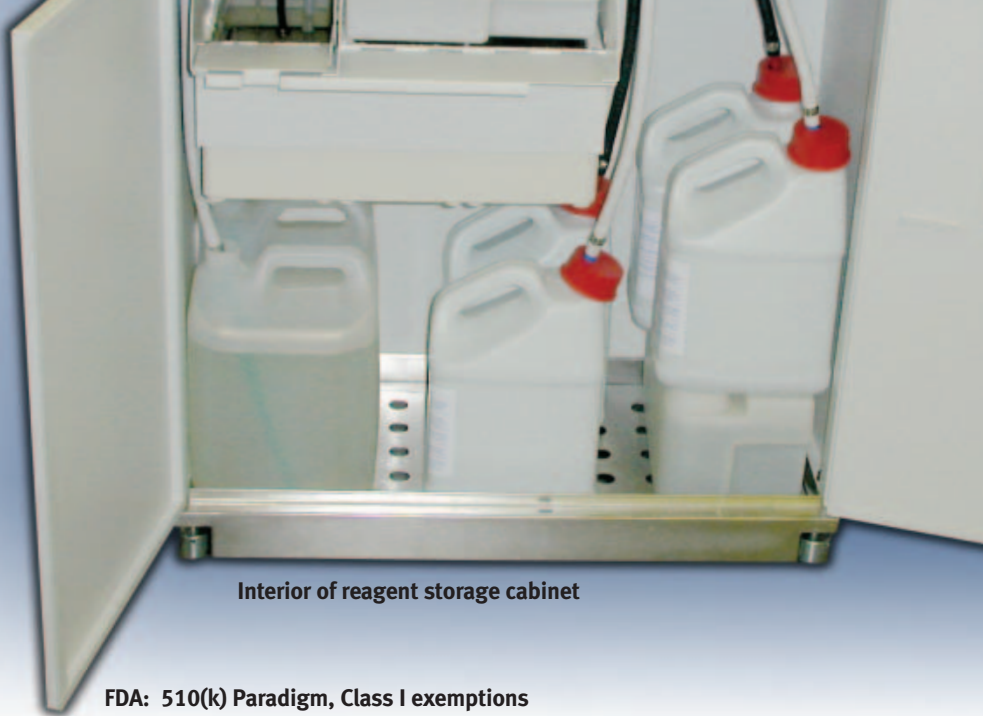
Shandon Excelsior's Disk Drive and Print Options will help to document the rotation processes that have been performed and at what point they were performed. This will show what reagents have been changed or need to be changed and when. Using the Quality Control Status Printout, and the Quality Control History Printout you will have the documentation to support your answer to this question. The Software monitors usage (by Specific Gravity, amount of uses, Cassette counting, or days of the week), and alerts you to acknowledge the situation so corrective action can be taken or override to continue operation. Whatever action you take will be documented in the event logs.

– **Question ANP.23150**

Is the temperature of the paraffin baths checked regularly and recorded?

Temperatures of the paraffin baths on the Shandon Excelsior are regulated and controlled by the Shandon Excelsior Software. Should an issue arise where the temperature of the paraffin should go above or below the set point an alarm will sound to notify the user of the situation. During normal use, the paraffin temperature can be monitored and documented on an Event Log from the Print Options or directly on screen.

With the Shandon Excelsior™ the risk of repeatedly moving reagent bottles to be filled and drained is eliminated. You will no longer have to bend down to install or remove the reagent bottles from their docking area.



Interior of reagent storage cabinet

OSHA: 29 CFR 1910.106 Flammable and Combustible Liquids

— **1910.106 (a)(31)**

Ventilation as specified in this section is for the prevention of fire and explosion. It is considered adequate if it is sufficient to prevent accumulation of significant quantities of vapor-air mixtures in concentration over one-fourth of the lower flammable limit.

The Storage Cabinet in the Shandon Excelsior is vented to meet the above OSHA criteria. You have the option to have the fumes filtered through Potassium Permanganate and Charcoal filters, or through a vent adapter (aimed toward a ventilated hood).

OSHA: Ergonomics—Suggested guidelines for the prevention of MSDs (Musculoskeletal Disorders)

— **Ergonomics**

Ergonomics is the science of fitting the job to the workers. Ergonomics is also the practice of designing equipment and work tasks to conform to the capability of the worker, it provides a means for adjusting the work environment and work practice to prevent injuries before they occur.

• **Potential Hazards:**

1. Repetitive Motion
2. Motion done in an awkward posture
3. Lifting heavy objects
4. Distance to be moved

With the Shandon Excelsior, the risk of repeatedly moving reagent bottles to be filled and drained is eliminated. You will no longer have to bend down to install or remove the reagent bottles from their docking area. Since minimal amounts of reagents will have to be changed at any given time, there will be minimal lifting required. Also, since the Shandon Excelsior does its own filling and draining of reagents, you will not have to remove waste to a waste receptacle (simply cap the waste bottle) and you will not have to pour reagents to fill (simply uncap a commercial reagent bottle). The Shandon Excelsior will do the rest.

FDA: 510(k) Paradigm, Class I exemptions

— **Medical Device Amendments of 1976**

The FDA exempted 574 generic types of Class I devices from the requirement of pre-market notification, unless the device is intended for the use that is of substantial importance in preventing impairment to human health or presents a potential unreasonable risk of illness or injury.

The Shandon Excelsior falls into the Class I Medical Device Exemptions, as do the other Tissue Processors that we currently offer. The Shandon Excelsior has been designed to meet the following agency approvals: **CE Mark, UL, CSA, and IEC 1010.**

FDA: 21 CFR Part 11 (March 20, 1997)

— **Electronic Records; Electronic Signatures; Final Rule**

The criteria for acceptance by FDA, under certain circumstances, of electronic records, or electronic signatures.

The Shandon Excelsior does not fall into the FDA's part 11 ruling. This instrument is not used for direct testing and resulting of patient specimens (as would a chemistry analyzer).

IVDD: Shandon Excelsior is compliant with the In Vitro Diagnostic Directive 98/79/EC in advance of Dec 7, 2003 when it becomes active.

References

College of American Pathologist; *Anatomical Pathology Checklist*; July, 2001; pg. 35-36, 41; www.cap.org/html/checklist_html/cklst007p.html.

College of American Pathologist; *Laboratory General Checklist*; August 2002; pg. 97-99, 114; www.cap.org/html/checklist_html/cklst01.html.

Occupational Safety & Health Administration, U.S. Department of Labor; *Hospital e Tool: Healthcare Wide Hazards Module—Ergonomics*; pg. 1,4; www.osha.gov/SLTC/hospital_etoold/hazards/ergo/ergo.html.

Occupational Safety & Health Administration, U.S. Department of Labor; *Regulations (Standards- 29 CFR) Flammable and Combustible Liquids-1910.106*; pg. 6 www.osha.gov/pls/oshaweb/owadispl.show_document?p_table=STANDARD

U.S. Food and Drug Administration, Center for Devices and Radiological Health; *The New 510K Paradigm- Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications—Final Guidance*; March 20, 1998; pg. 4; www.fda.gov/cdrh/ode/parad510.html.

U.S. Food and Drug Administration, Department of Health and Human Services-Federal Register; *21 CFR Part 11- Electronic Records; Electronic Signatures; Final Rule*; March 20, 1997; Vol. 62, No. 54, pg. 13430.