Division of Chemical Health & Safety (DCHAS) of the American Chemical Society (ACS) – Safety Shower and Eyewash Survey and Recommendations for the 2019 Revision of ANSI/ISEA 2358.1

As a stakeholder, and at the recommendation of Dr. Alan Hall, two members of DCHAS were invited on November 2nd by Cristine Z. Fargo (Director, Member and Technical Services) to attend the International Safety Equipment Association (ISEA) Eyewash and Shower Group "kick-off" meeting in Alexandria, VA on December 2, 2016. The DCHAS representatives would provide input to the Eyewash and Shower group for the 2019 revision of ANSI/ISEA 2358.1.

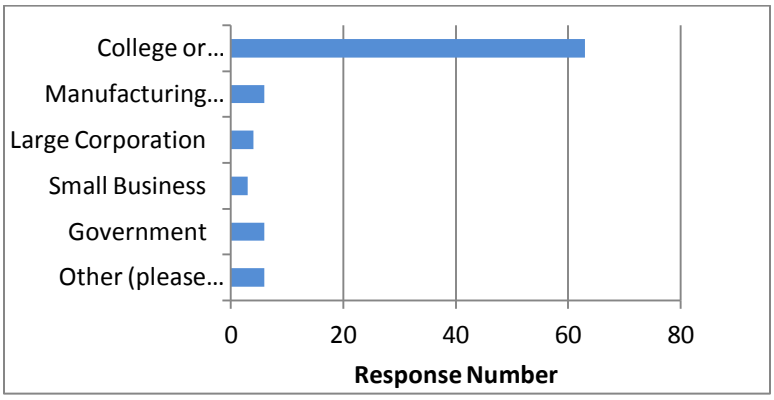
DCHAS welcomes and appreciates the opportunity to participate in the meeting. In order to provide broad user input from DCHAS on the strengths and weaknesses of the standard, our membership was surveyed. Eighty-eight responses (~ 8% of the membership) were completed on the survey which was opened on November 10, 2106 and closed on November 18. The largest number of respondents (71.6%, n=63) were from academic institutions with the remaining participants split fairly evenly between manufacturing, large corporations, small business, and government. Several respondents chose the "other" grouping and their specific organizations were given.

Approximately half (54.6%, n=48) of those that responded were individuals whose primary role was "Environmental Health and Safety Professionals" and about half (51.1%, n=45) of the respondents represented organizations which had more than 1000 employees.

The complete survey results are included below.

2016 DCHAS Complete Survey Results for

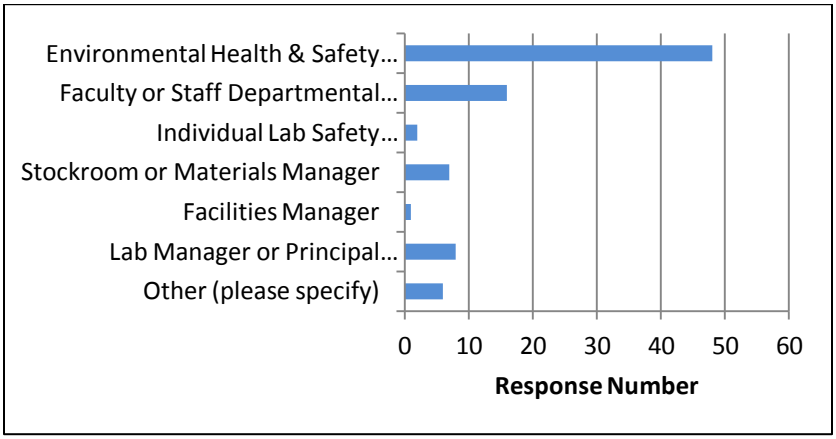
Q1. What type of organization do you represent?



Other (please specify)

1	Retail distributor of safety equipment; former professor
2	Independent School, k-12
3	healthcare facility
4	independent High School
5	BioPharma R and D Facility
6	Consulting Engineers - work in a wide variety of facilities

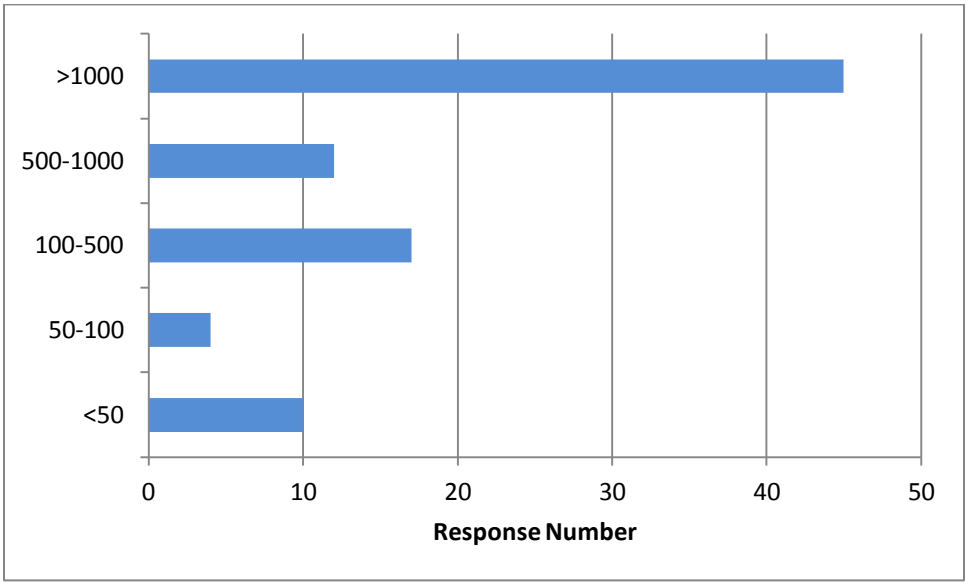
Q2. Please indicate your role in this organization?



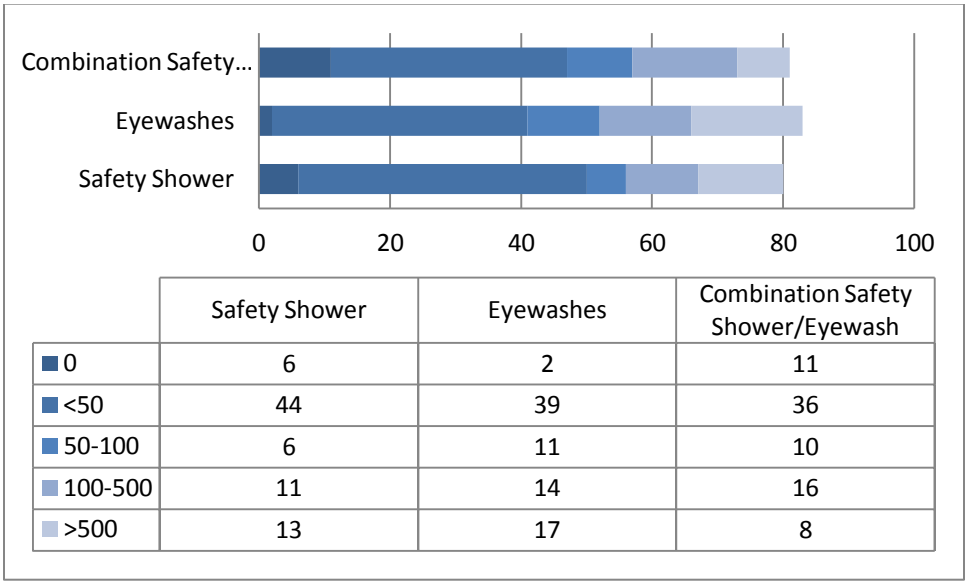
Other (please specify)

1	Owner
2	Director, R&D
3	Supply Value Chain Chemical Management Advisor
4	Environmental Safety and Laboratory Manager
5	teacher, lab manager (high school level), safety officer
6	CHO for college of liberal arts, and chemistry dept. stockroom manager

Q3. How many employees does your organization have?



Q4. How many of each of these pieces of emergency equipment does your organization have?

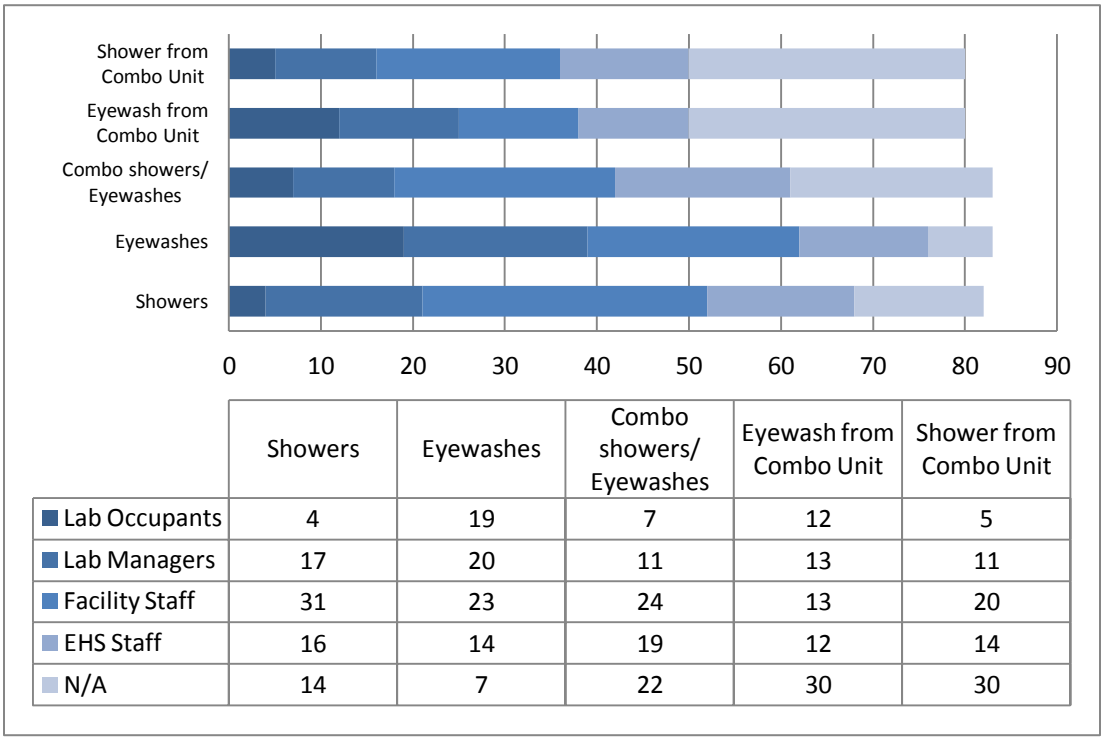


	Safety Shower	Eyewashes	Combination Safety Shower/Eyewash
0	6	2	11
<50	44	39	36
50-100	6	11	10
100-500	11	14	16
>500	13	17	8

Other (please specify)

1	Not applicable currently; we sell. Former university professor
2	Note: we have ~1000 labs, not sure how this breaks down between combo and standalone units, but all labs have some equipment inside or nearby
3	Most of our new labs are equiped with a drench
4	We monitor over 60 facilities of various types and capabilities
5	Dual Head Drench Hose
6	With very few exceptions, all showers are installed with eyewashes

Q5. How many of each of these pieces of emergency equipment does your organization have?

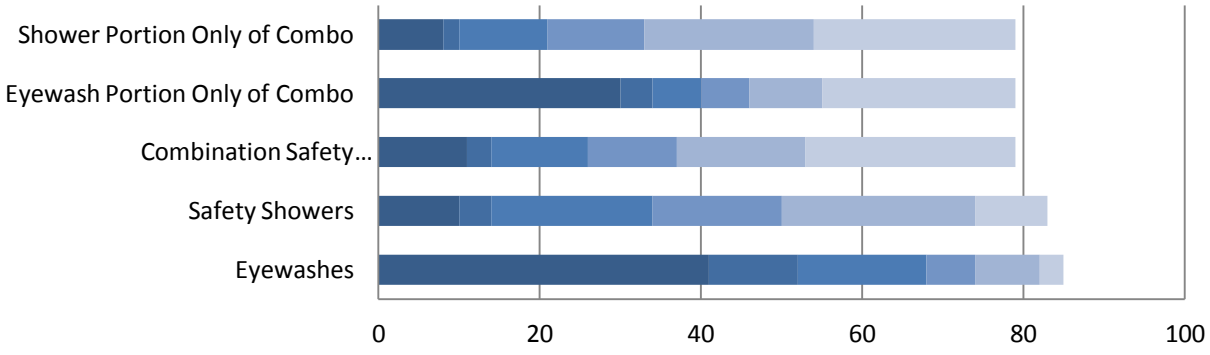


	Showers	Eyewashes	Combo showers/ Eyewashes	Eyewash from Combo Unit	Shower from Combo Unit
Lab Occupants	4	19	7	12	5
Lab Managers	17	20	11	13	11
Facility Staff	31	23	24	13	20
EHS Staff	16	14	19	12	14
N/A	14	7	22	30	30

Other system (please specify)

1	Lab occupants flash emergency eyewashes every two weeks
2	Student employees
3	Annual inspections by facility staff; oversight inspections by ESH and Lab Managers
4	Operations personnel
5	Lab Safety Manager, we have no EHS Dept.
6	Under constant debate, they are not flushed nor inspected as per current ANSI guidelines
7	during semester breaks the custodial staff does it
8	No system in place. If it breaks someone will report it to maintenance.
9	each department on campus is responsible for testing their equipment; responses indicated are for the Science department
10	Lab personnel check eyewashes weekly. EH&S staff checkes them every 6 months, as well, because we don't think they are all checking them weekly. EH&S staff checks all showers and combo units (both parts) because we have the equipment to do so.
11	This is only for one science building; shower/eye wash stations in Facilities and the Art Dept fall under their control.
12	Lab managers= technical staff members
13	Facilities plumbing staff inspects eyewashes and showers to the ANSI standard annually
14	occupants do weekly inspection; Facility Techs do annual check for volume & temperatures
15	EH&S tests annually, lab occupants monthly
16	outsourced to competent contract firm

Q6. How often are these units activated to assure water flow and quality?

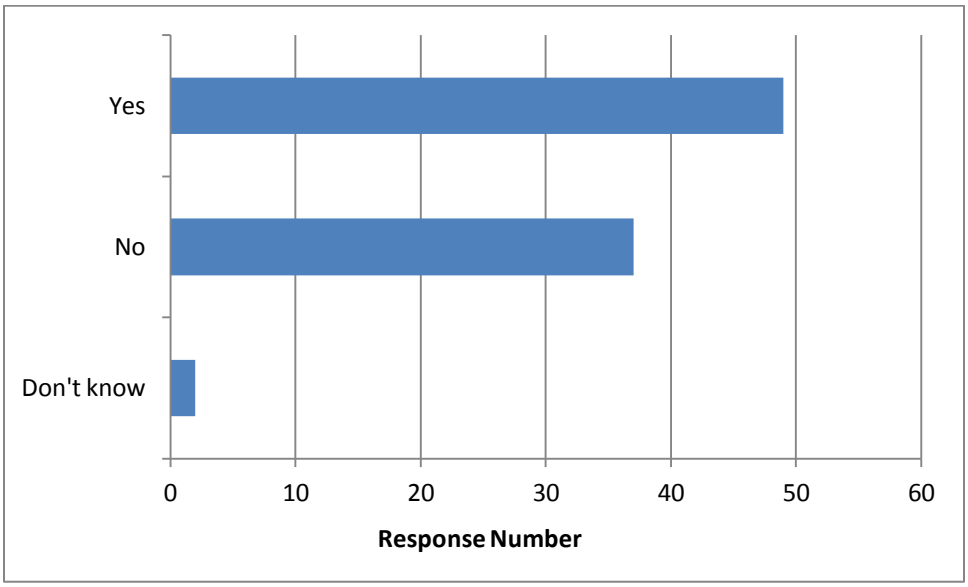


	Eyewashes	Safety Showers	Combination Safety Shower/Eyewash (Both)	Eyewash Portion Only of Combo	Shower Portion Only of Combo
At Least Weekly	41	10	11	30	8
>Weekly but <Monthly	11	4	3	4	2
Monthly	16	20	12	6	11
Several Time per Year	6	16	11	6	12
Annually	8	24	16	9	21
N/A	3	9	26	24	25

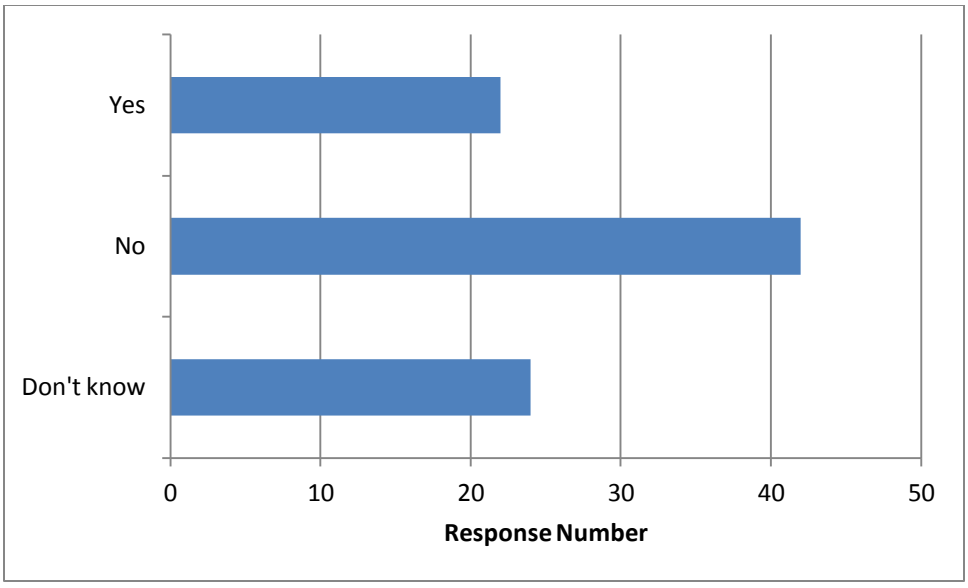
Other (please specify)

1	Quarterly
2	Labs are asked to flush sink contained systems weekly
3	We try for weekly, but sometimes don't achieve this
4	Official testing 1x per year; local flushing varies by area
5	Not flushed as per current guidelines. 6 No system in place.
7	Facilities staff inspect eyewashes and shower to the ANSI standard annually
8	These are not for flow rate only to flush for quality. Ours have never been quantitatively tested for flow rate.
9	these are inspected annually by EHS staff. However, the area workers do activate some of them. This is different all over campus as to how often. Eyewashes are more likely to be activated on a regular basis due to ease and no need for special equipment.

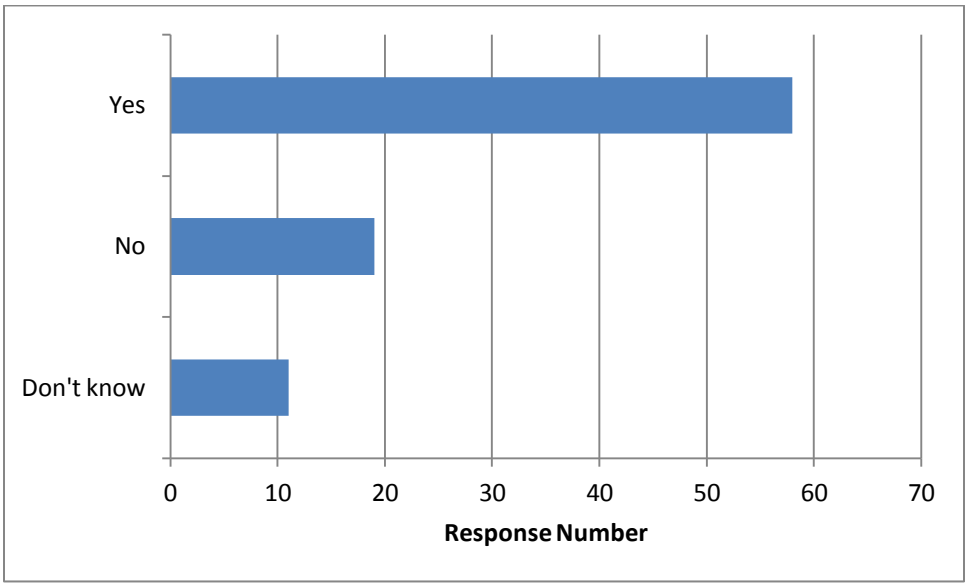
Q7. Does your facility have safety showers installed in hallways outside the laboratory door?



Q8. Does your EHS department support the installation of new safety showers in hallways outside a laboratory?



Q9. Do your laboratory incident reports indicate if a safety shower was used?

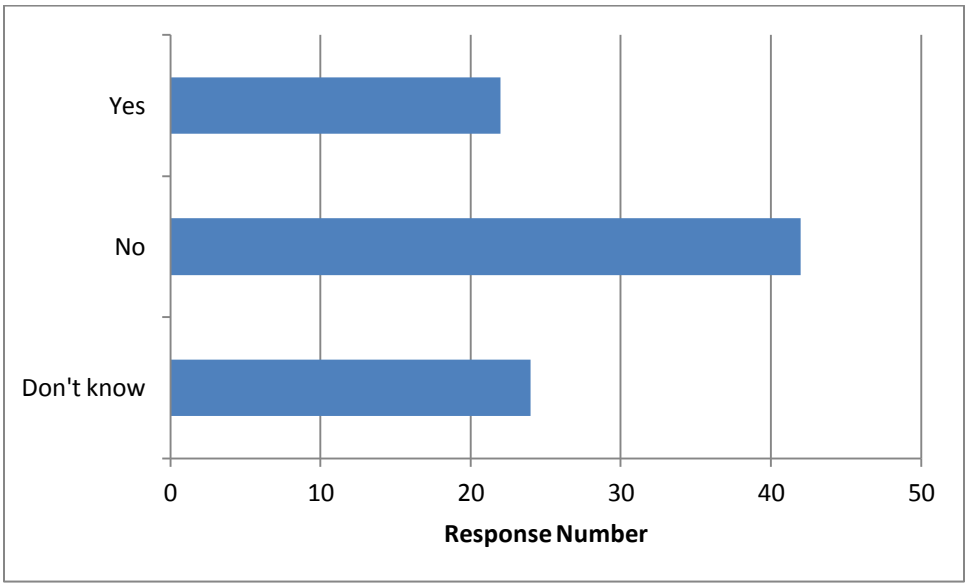


If "yes", how often was the use of an eyewash or safety shower reported in an emergency in the last ten years?

1	During my professional career I've seen them used several times in academia.
2	six to 7 times
3	3
4	3
5	no records due to department turnover
6	probably 5 or fewer
7	For 7 -9 answer is not really YES (it is not NO)... it is more like Sometimes...
8	None
9	Never
10	One incident involving use of an eyewash station.
11	3-5 times
12	My best educated guess is less than 5%.
13	Safety shower: less than 10 times Eyewash: around 20 times
14	0
15	Cannot say an exact number! However when an incident/accident involves hazardous material, the eyewash or shower or both are used.
16	The showers have not been used in the last 10 years for an emergency situation. The eyewash units have been used twice for an emergency situation.
17	20-25 estimate
18	1
19	none
20	There has not been a reported incident of chemical splash or spill that required the use of

	a safety shower.
21	I do not have access to this data.
22	Has not been required
23	once
24	Eyewash: not more than 5 times in 10 years. Shower: none in last ten years.
25	We don't have EHS person and faculty no longer have forms to fill out when something goes wrong.
26	Zero
27	shower - 0 eye wash - 5
28	~5
29	Never
30	Once
31	1 time
32	Never
33	Only about 2-3 times that we are aware of.
34	2-3 times
35	If the event involved employee using a EW or SS it would be included in the investigation report 100% of the time.
36	twice
37	We have not had an incident yet!
38	0

Q10. Do the requirements of the current American National Standard for Emergency Eyewash and Shower Equipment ANSI/ISEA Z358.1-2014 meet your organization's needs?



If "No", please indicate what changes you would like to see in the standard here.

1	Generally, for an academic environment, yes. However, there are several issues that should be addressed in this revision. 1. Manufacturers should not be able to self-certify compliance with the Standard. This should be independently certified by an accredited third party. 2. The standard is currently vague on the scope of the spray patterns. The diameter of the pattern and height from the floor at a given pressure should be specifically outlined as given in current European requirements. 3. The standard should specifically bar manufacturers from labeling single use 16 oz and 32 oz bottles (and similar devices that do not meet the standard requirements) as "Emergency Eye/Face Wash" units which implies that they meet requirements they do not. The standard already covers these as "Personal Wash Units" and they should be labeled as such. I have seen businesses that require an ANSI-compliant eyewash attempt to satisfy their compliance with these insufficient methods.
2	Change monthly testing of a safety shower to twice yearly.
3	The requirements are too strict and require too much for older laboratories to be upgraded.
4	Weekly flushes of showers is not sustainable and we do not have the man-hours to devote to this.
5	Standard should require they be plumbed to sanitary sewer. It is the only way to get the #($*$& architects, engineers and "value" contractors to do this and prevent other safety hazards arising from hundreds of gallons of water on the floor. EPA has clearly stated this is de minimis and not a waste.
6	Couldn't get our persons responsible for the implementation of these standards to respond in time for this email
7	Weekly flushing of eyewashes seems excessive
8	Need more specifics about quantities of chemicals that require a shower. What does hazardous materials really mean?
9	Of course!
10	We have various contractors globally with differing regional regulations and guidance. ANSI standards go a long way in helping other regions be more protective than they might be.
11	Newly installed units are not connected to drain piping. The connection to drain needs to be more than a recommendation if it's going to cost money.
12	The requirement for weekly activation of showers is far too frequent.
13	Building a new facility that will meet standards Occupancy in Fall of 2018.
14	Requires testing too often with little support for doing so. We do not have the personnel to do it as often as recommended.
15	Weekly activation of both the eyewash and shower is just not feasible. We don't have dedicated staff to test this equipment and it's a real burden on research staff to accomplish.
16	We activate our showers weekly instead of monthly, simply because of time constraints. Eyewashes get activated weekly.
17	Evidence that weekly testing/flushing is needed?
18	I am only answering at the departmental level. The standards are okay for us as far as testing goes for flushing.
19	Periodic flow requirements are too frequent.
20	I would like to see an easier way for the eyewashes and safety showers to get tested. Part of our problem is that our university does not have floor drains so it is hard to test the equipment.
21	Does not address drainage, alarms
22	It needs guidance on special installations, such as where there are accessibility and space concerns.
23	Shower testing frequency is not practical

Q11. Do you have any other comments on the impact of ANSI standards for safety showers for your organizations?

Responses Date

1	ADA compliance is a serious issue, particularly in academia. The standard's travel distance is 55' in 10 seconds, but this is for an able-bodied person, not a wheelchair user or blind person. If a workstation is designated specifically for special physical needs persons, the emergency equipment should be located immediately adjacent to the work area.
2	No
3	No!
4	We appreciate them.
5	Slip and electrical hazards may be posed during use. Insurance companies are refusing to cover water damage from safety shower malfunctions when there are no floor drains. My guess is that insurance companies will also refuse to cover damages from chemicals that may be released into drains during the use of safety showers.
6	most of the showers and eyewashes are in shop settings, not lab settings, and I don't know whether the standards are ok for those settings either.
7	My only concern is a trivial one. We have safety shower/eyewash stations that are alarmed with audio and visual. Is this a new trend?
8	None.
9	We have needed safety officer for a decade but administration doesn't agree. In colleges, administration is often the problem.
10	The requirement for tempered water needs to be modified or removed. The warm water element creates the potential for a hazardous situation in dead legs. And yes the requirement for weekly flushing would eliminate this, but the reality is that in a lab environment the practice of weekly flushing can be difficult and is rarely done. Also, anecdotally, many areas of the country have water temperatures that would fall easily into an expanded temperature range without tempering. We've also seen problems with tempering valves failing to a full hot position (noticed during annual testing), a very bad situation. Just some thoughts for consideration.
11	please make it clear what specific tests need to be conducted and recorded - weekly, monthly, annually. Be specific to eye wash / showers / drench hose units. thanks
12	Please note that the answer to #7 is not the norm for our campus but I have see one safety shower outside a door on campus.
13	We flush eyewash stations weekly.
14	Better advice on what "tepid" water is and when a mixing valve might be required. Stronger language about no obstructions for access (eyewash/showers in hallways). Language about ADA access would also be helpful.
15	no
16	It would be nice to have drain standards for showers.
17	Tepid water requirements are not always followed.

Similar results noted between the CSHEMA and DCHAS surveys[1]

Even though the CSHEMA survey focused primarily on showers in academic institutions some general similarities were found in the responses between the CSHEMA and DCHAS survey.

- Both surveys indicated that more than half (CSHEMA, 53.2%; DCHAS, 65.9%) of the respondent's use incident reports that indicate whether or not a safety shower was used.
- EHS only supported the installation of new showers in hallways about 25% of the time (CSHEMA, 23.4%; DCHAS, 25.0%).
- In general, the most selected activation period for testing showers to assure water flow and quality either was either monthly (CSHEMA, 21.3%; DCHAS, 24.1%) or annually (CSHEMA, 55.3%; DCHAS, 28.9%).
- In general it seems that EHS and facilities personnel performed shower inspections (CSHEMA, 89.4%; DCHAS, 53.4%). The wording variation on this question possibly affected comparison of the two surveys.
    - **CSHEMA:** Who does the annual safety shower inspection?
    - **DCHAS:** Who conducts inspections of this equipment?

On both surveys a similar question was asked about the current version of ANSI/ISEA Z358.1-2014 and significant variance was noted. Less than 10% of the respondents on the CSHEMA survey felt that the standard met their needs, while nearly 50% of the DCHAS respondents felt that the 2104 version met their needs.

CSHEMA: Do the requirements of the current American National Standard for Emergency Eyewash and Shower Equipment ANSI/ISEA Z358.1-2014 fulfills the institutions need. Y/N

Yes, 8.5%

DCHAS: Do the requirements of the current American National Standard for Emergency Eyewash and Shower Equipment ANSI/ISEA Z358.1-2014 meet your organization's needs?

Yes, 49.4%

[1] The CSHEMA percentages were estimated from the bar graphs in their report. The CSHEMA report may be obtained from Markus Schaufele, MS, CSP, Director, Standards, Compliance and Emergency Planning - Office for Research Safety (ORS), ORS Web site http://www.research.northwestern.edu/ors/

Common Themes Observed in DCHAS Survey Text Reponses

Many potentially useful comments were received on the DCHAS survey – particularly on Questions 10 and 11. As your group prepares for the 2019 revision, we would ask that all valid comments given be evaluated for consideration in the next version of the shower and eyewash standard. Below we discuss several recurring themes that were noted.

1. The need for better guidance with regard to ADA requirements.

As stated in Question 11, Comment 1, the travel time for a person with a mobility or vision impairment may be affected. It would be helpful if the 2019 revision included some guidance with regard to this issue and others for alignment with ADA requirements. To this end, we are providing specific comments in a separate document, titled "ICC ANSI A117.1-2009" (Appendix A). Also provided as a separate hard copy is ANSI/ISEA Z358.1 – 2014 with comments and suggestions that seek to align the standard better with accessibility requirements. The authors of Appendix A and the comments in ANSI/ISEA Z358.1 – 2014 are:

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2. The need for requirements regarding floor drains for showers.

As indicated by Comments 5, 11, and 20, on Question 10 and Comments 5 and 16 on Question 11, it would help those of us who have to convince administrators, architects, and engineers when designing labs where chemicals are used that floor drains are the best option for protecting the infrastructure of the building and prevent them from being "value engineered" out.

The EPA has provided language addressing the issue of shower water into the drain in a 1997 Correspondence between COLBY & NANCE, L.L.P and the EPA (Appendix B)[2]. In this correspondence, Peter W. Colby of COLBY & NANCE, L.L.P. sites 40 C.F.R. 261.3(a)(2)(iv)(D):

> The separate regulations defining hazardous waste contain an exclusion for "de minimis losses" of a listed commercial chemical product that occur when the listed product is used as a raw material or produced in a manufacturing process, so long as the de minimis quantities are discharged to the sewer system. 40 C.F.R. 261.3(a)(2)(iv)(D). The regulations state that de minimis losses include spills from normal material handling operations such as the transfer of materials, leaks from pipes or process equipment, sample purgings, and discharges from safety showers and rinsing and cleaning of containers and personal safety equipment.

To this, the EPA responds:

> Your statement concerning the applicability of the de minimis exemption under 40 CFR 261.3(a)(2)(iv)(D) to plant wash down water may be correct. The exemption applies to discarded commercial chemical products or chemical intermediates listed in §261.33 from manufacturing operations in which the materials are used as raw materials or are produced in the manufacturing process. The regulatory language in §261.3(a)(2)(iv)(D) provides several examples of de minimis losses envisioned by the regulatory exemption. Please remember the facility's discharge of wastewater must be subject to regulation under Section 402 or 307(b) of the Clean Water Act to qualify for this exemption. Also, please be aware that if the facility's wastewater treatment system leaks before the wastewater reaches the headworks of the treatment system, the leaked material is classified as a §261.33 material. In addition, while the de minimis amount is not quantified in the regulatory language, large material losses would void the de minimis quantity exemption.

In some instances, the lack of drains impedes testing of showers. If the EPA has not changed their guidance on "de minimis" release with regard to shower and eyewash effluent (see http://ohioepa.custhelp.com/app/answers/detail/a_id/332/~/emergency-safety-shower-discharging-into-a-sanitary-sewer), then Including provisions, at least for locations that meet the OSHA definition of a "laboratory", in the 2019 revision such as:[3]

- **Eyewash effluent be discharged to plumbing, except where prohibited by the receiving POTW; and**

[2] This letter may be located at: https://yosemite.epa.gov/OSW/rcra.nsf/ea6e50dc6214725285256bf00063269d/fe5517867b1011158525670f006c2c92 and is in RCRA Online (https://yosemite.epa.gov/osw/rcra.nsf/how+to+use?OpenForm), linked from EPA's Resource Conservation and Recovery Act information site, https://www.epa.gov/rcra. RCRA includes: selected ORCR Correspondence letters and memoranda (SOCs), RCRA Permit Policy Compendium guidance documents (RPPCs), and Monthly Call Center Report Q&As (MRQs). This location information is from personal correspondence with Leah McEwen, Cornell Chemistry Librarian.

[3] Personal communication with Mary Margaret Cavanaugh, IH, Appalachian State University, Boone, NC.

- **A floor drain be located underneath safety showers, with slanted flooring to help contain the effluent, except where prohibited by the receiving POTW**

would be helpful.

3. The need for flexibility in testing intervals on flow and quality based on risk and environmental impact.

Whereas the burden of testing primarily falls to the EHS personnel in organizations that may have up to 1000 laboratories or no EHS department, current weekly testing can be simply unmanageable. On Question 10, ten out of 23 comments received are about testing frequency (Comments 2, 4, 7, 12, 14, 15, 16, 17, 19 and 23).

Comment 11 on Question 11 asksing for clarification between flushing for quality and water availability and quantitatively testing for flow on pattern specific to each type of unit seems particularly of relevant. The environmental impact of testing thousands of showers weekly in drought stricken areas can be significant.

We would recommend that testing intervals be based more on risk after considering the hazards present and the environmental impact. The organization should have an option of doing a written risk assessment for the monthly vs. weekly testing. Specific quantitative evidence for testing intervals is needed.

4. Additional comment trends noted.

- There were significant comments on the use of "tepid" water. Comments 10, 14, and 17 on Question 11 address concerns about this topic. More specific guidance on existing units would be welcomed. Mixing valves can fail as noted in Comment 10 on Question 11.

  In addition to Comments received during the survey, the following comment was received by email from a DCHAS member.

  > Tepid water - the cost of using tepid water has proven to be a barrier to getting eyewashes & showers installed at all. I'd like to see the committee consider making tepid water a requirement only where the climate is not well controlled For example, outdoors and indoor areas that have no heat or are kept below a certain temperature.

- The usefulness/necessity of alarms on showers and eyewashes

Conclusion

The Division of Chemical Health and Safety of the American Chemical Society recognizes the importance of emergency showers and eyewashes in areas where chemical hazards exist. We also understand the importance of having clear guidance for stakeholders in ANSI/ISEA 2358.1. We appreciate this group's consideration of our report as they proceed with the 2019 revisions.

Moving forward, the ISEA group working on this may wish to also seek input for the 2019 revision from additional stakeholder Divisions of the ACS such as:

Business Development & Management (BMGT)
Chemical Education (CHED)
Chemistry & the Law (CHAL)
Environmental Chemistry (ENVR)
Industrial & Engineering Chemistry (I&EC)
Professional Relations (PROF)
Small Chemical Businesses (SCHB)

Respectfully Submitted

Appendix A – ICC ANSI A117.1 - 2009

ICC ANSI A117.1 – 2009

Applicable sections for cross reference to Improve Access to Safety Showers and Eyewash Stations

Link to ICC ANSI A117.1 – 2009:
https://law.resource.org/pub/us/code/ibr/ansi.a117.1.2009.pdf
Link to 2010 ADA Standards for Accessible Design:
https://www.ada.gov/regs2010/2010ADAStandards/2010ADAStandards_prt.pdf

305 Clear Floor Space

305.1 General. A clear floor space shall comply with Section 305.

305.2 Floor Surfaces. Floor surfaces of a clear floor space shall comply with Section 302. Changes in level are not permitted within the clear floor space.

EXCEPTION: Slopes not steeper than 1:48 shall be permitted.

305.3 Size. The clear floor space shall be 48 inches (1220 mm) minimum in length and 30 inches (760 mm) minimum in width.

305.4 Knee and Toe Clearance. Unless otherwise specified, clear floor space shall be permitted to include knee and toe clearance complying with Section 306.

305.5 Position. Unless otherwise specified, the clear floor space shall be positioned for either forward or parallel approach to an element.

305.6 Approach. One full, unobstructed side of the clear floor space shall adjoin or overlap an accessible route or adjoin another clear floor space.

305.7 Alcoves. If a clear floor space is in an alcove or otherwise confined on all or part of three sides, additional maneuvering clearances complying with Sections 305.7.1 and 305.7.2 shall be provided, as applicable.

305.7.1 Parallel Approach. Where the clear floor space is positioned for a parallel approach, the alcove shall be 60 inches (1525 mm) minimum in width where the depth exceeds 15 inches (380 mm).

305.7.2 Forward Approach. Where the clear floor space is positioned for a forward approach, the alcove shall be 36 inches (915 mm) minimum in width where the depth exceeds 24 inches (610 mm).

306 Knee and Toe Clearance

306.1 General. Where space beneath an element is included as part of clear floor space at an element, clearance at an element, or a turning space, the space shall comply with Section 306. Additional space

shall I not be prohibited beneath an element, but shall not be considered as part of the clear floor space or turning space.

306.2 Toe Clearance.

306.2.1 General. Space beneath an element between the floor and 9 inches (230 mm) above the floor shall be considered toe clearance and shall comply with Section 306.2.

306.2.2 Maximum Depth. Toe clearance shall be permitted to extend 25 inches (635 mm) maximum under an element.

306.2.3 Minimum Depth. Where toe clearance is required at an element as part of a clear floor space complying with Section 305, the toe clearance shall extend 17 inches (430 mm) minimum beneath the element.

306.2.4 Additional Clearance. Space extending greater than 6 inches (150 mm) beyond the available knee clearance at 9 inches (230 mm) above the floor shall not be considered toe clearance.

306.2.5 Width. Toe clearance shall be 30 inches (760 mm) minimum in width.

306.3 Knee Clearance.

306.3.1 General. Space beneath an element between 9 inches (230 mm) and 27 inches (685 mm) above the floor shall be considered knee clearance and shall comply with Section 306.3.

306.3.2 Maximum Depth. Knee clearance shall be permitted to extend 25 inches (635 mm) maximum under an element at 9 inches (230 mm) above the floor.

306.3.3 Minimum Depth. Where knee clearance is required beneath an element as part of a clear floor space complying with Section 305, the knee clearance shall be 11 inches (280 mm) minimum in depth at 9 inches (230 mm) above the floor, and 8 inches (205 mm) minimum in depth at 27 inches (685 mm) above the floor.

306.3.4 Clearance Reduction. Between 9 inches (230 mm) and 27 inches (685 mm) above the floor, the knee clearance shall be permitted to be reduced at a rate of 1 inch (25 mm) in depth for I each 6 inches (150 mm) in height.

306.3.5 Width. Knee clearance shall be 30 inches (760 mm) minimum in width.

308 Reach Ranges

308.1 General. Reach ranges shall comply with Section 308.

308.2 Forward Reach.

308.2.1 Unobstructed. Where a forward reach is unobstructed, the high forward reach shall be 48 inches (1220 mm) maximum and the low forward reach shall be 15 inches (380 mm) minimum above the floor.

308.2.2 Obstructed High Reach. Where a high forward reach is over an obstruction, the clear floor space complying with Section 305 shall extend beneath the element for a distance not less than the required reach depth over the obstruction. The high forward reach shall be 48 inches (1220 mm) maximum above the floor where the reach depth is 20 inches (510mm) maximum. Where the reach depth exceeds 20 inches (510 mm), the high forward reach shall be 44 inches (1120 mm) maximum above the floor, and the reach depth shall be 25 inches (635 mm) maximum.

308.3 Side Reach.

308.3.1 Unobstructed. Where a clear floor space complying with Section 305 allows a parallel approach to an element and the edge of the clear floor space is 10 inches (255 mm) maximum from the element, the high side reach shall be 48 inches I (1220 mm) maximum and the low side reach shall be 15 inches (380 mm) minimum above the floor.

EXCEPTION: Existing elements that are not I altered shall be permitted at 54 inches (1370 mm) maximum above the floor.

308.3.2 Obstructed High Reach. Where a clear floor space complying with Section 305 allows a parallel approach to an element and the high side reach is over an obstruction, the height of the obstruction shall be 34 inches (865 mm) maximum above the floor and the depth of the obstruction shall be 24 inches (610 mm) maximum. The high side reach shall be 48 inches (1220 mm) maximum above the floor for a reach depth of 10 inches (255 mm) maximum where the reach depth exceeds 10 inches (255 mm), the high side reach shall be 46 inches (1170 mm) maximum above the floor for a reach depth of 24 inches (610 mm) maximum.

EXCEPTION: At washing machines and clothes dryers, the height of the obstruction shall be permitted to be 36 inches (915 mm) maximum above the floor.

309 Operable Parts

309.1 General. Operable parts required to be accessible shall comply with Section 309.

309.2 Clear Floor Space. A clear floor space complying with Section 305 shall be provided.

309.3 Height. Operable parts shall be placed within one or more of the reach ranges specified in Section 308.

309.4 Operation. Operable parts shall be operable with one hand and shall not require tight grasping, pinching, or twisting of the wrist. The force required to activate operable parts shall be 5.0 pounds (22.2 N) maximum.

EXCEPTION: Gas pump nozzles shall not be required to provide operable parts that have an activating force of 5.0 pounds (22.2 N) maximum.

602 Drinking Fountains

602.1 General. Accessible drinking fountains shall comply with Sections 602 and 307.

602.2 Clear Floor Space. A clear floor space complying with Section 305, positioned for a forward approach to the drinking fountain, shall be provided. Knee and toe space complying with Section 306 shall be provided. The clear floor space shall be centered on the drinking fountain.

EXCEPTIONS: 1. Drinking fountains for standing persons.

2. Drinking fountains primarily for children's use shall be permitted where the spout outlet is 30 inches (760 mm) maximum above the floor, a parallel approach complying with Section 305 is provided and the clear floor space is centered on the drinking fountain.

602.3 Operable Parts. Operable parts shall comply with Section 309.

602.4 Spout Outlet Height. Spout outlets of wheelchair accessible drinking fountains shall be 36 inches (915 mm) maximum above the floor. Spout outlets of drinking fountains for standing persons shall be 38 inches (965 mm) minimum and 43 inches (1090 mm) maximum above the floor.

602.5 Spout Location. The spout shall be located 15 inches (380 mm) minimum from the vertical support and 5 inches (125mm) maximum from the front edge of the drinking fountain, including bumpers. Where only a parallel approach is provided, the spout shall be located 31 / 2 inches (90 mm) maximum from the front edge of the drinking fountain, including bumpers.

602.6 Water Flow. The spout shall provide a flow of water 4 inches (100 mm) minimum in height. The angle of the water stream from spouts within 3 inches (75 mm) of the front of the drinking fountain shall be 30 degrees maximum, and from spouts between 3 inches (75 mm) and 5 inches (125 mm) from the front of the drinking fountain shall be 15 degrees maximum, measured horizontally relative to the front face of the drinking fountain.

608.2.2 Standard Roll-in-type Shower Compartments. Standard roll-in-type shower compartments shall comply with Section 608.2.2.

608.2.2.1 Size. Standard roll-in-type shower compartments shall have a clear inside dimension of 60 inches (1525 mm) minimum in width and 30 inches (760 mm) minimum in depth, measured at the center point of opposing sides. An entry 60 inches (1525 mm) minimum in width shall be provided.

608.2.2.2 Clearance. A clearance of 60 inches (1525 mm) minimum in length adjacent to the 60- inch (1525 mm) width of the open face of the shower compartment, and 30 inches (760 mm) minimum in depth, shall be provided.

Appendix B – ICC ANSI A117.1 – 2009

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

July 24, 1997

Mr. Peter W. Colby
Colby and Nance, L.L.P.
1001 G Street, NW, Suite 400 East
Washington, DC 20001

Dear Mr. Colby:

Thank you for your letter to Rick Brandes of January 23, 1997, in which you asked for a regulatory determination on the status of certain manufacturing wastes. Specifically, you wanted to know: 1) if warfarin tablets subject to "dissolution testing" are considered hazardous wastes, 2) if fragments from integrity testing of tablets are considered hazardous waste, 3) if certain wash down water is exempt from the mixture rule; 4) the regulatory status of disposable gloves and other personal protective equipment; 5) the status of wastewater from the cleaning of gloves and protective equipment, and 6) if air filters removed from the ventilation system in the manufacturing process are considered hazardous waste.

We have considered the views expressed in your letter and provide the following response based on a general principal: in interpreting the hazardous waste regulations at 40 CFR 261.33, EPA takes the position that a point exists in the manufacturing process in which an operator creates either a commercial chemical product or manufacturing intermediates. When these chemicals meet a listing description under 40 CFR 261.33, any discard of these materials (including these materials captured on filters or mixed with other wastes) are considered hazardous wastes and must be handled accordingly.

Under 40 C.F.R. 261.33, EPA may list as RCRA hazardous wastes various materials associated with chemical products that become hazardous wastes if and when they are discarded or are intended to be discarded. Acutely hazardous chemical product wastes are listed in section 261.33(e) and are known as "P-wastes." Other hazardous chemical product wastes are known as "U-wastes" and are listed at section 261.33(f). Not all P or U listed substances wherever found, however, are RCRA chemical product hazardous wastes. A particular substance is a P or U waste only if, before discard, it is the sole active ingredient in a "commercial chemical product or manufacturing chemical intermediate." See 40 C.F.R. 261.33(a) through (f).

The term "commercial chemical product or manufacturing chemical intermediate" is interpreted in the "Comment" in 40 C.F.R. 261.33(d). The term refers to a chemical "manufactured or formulated for a commercial or manufacturing use" which consists of the commercially pure or technical grades of the chemical and "all formulations in which the chemical is the sole active ingredient." This is distinguished from a chemical contained in a manufacturing process waste. Process wastes are generated

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prior to the creation of the product or intermediate and may be listed as F or K wastes under EPA's listing system.

Once a commercial product or manufacturing intermediate is created, a RCRA hazardous waste is generated when any of the materials related to the product (as described in section 261.33(a) through (f)) is discarded, or intended to be discarded. Because all the activities in your letter describe discarded materials in one form or another, if a commercial chemical product or manufacturing intermediate containing warfarin as its sole active ingredient has been created before any of the activities you describe, the waste must be treated as a RCRA hazardous waste unless an exemption can be found. Further, your description of your client's operation as one in which warfarin is not manufactured, but rather is simply processed into products from warfarin manufactured at another site, suggests all waste not otherwise exempted would qualify as hazardous because the warfarin enters the operation as a commercial chemical product.

In your letter, you characterize waste from dissolution testing (i.e., placing tablets in a distilled water solution and observing the results) and integrity testing (crushing or breaking tablets into fragments) as manufacturing process waste and/or used commercial chemical products. This interpretation is incorrect. Once the product is manufactured, then the listing of a commercial chemical product under 40 CFR 261.33 attaches. As a practical matter, the crushed or dissolved waste would be expected to have the same sort of composition and pose the same sort of threats when discarded as would the untested commercial product and thus must be managed as a hazardous waste listed under 40 CFR 261.33.

Your statement concerning the applicability of the de minimis exemption under 40 CFR 261.3(a)(2)(iv)(D) to plant wash down water may be correct. The exemption applies to discarded commercial chemical products or chemical intermediates listed in §261.33 from manufacturing operations in which the materials are used as raw materials or are produced in the manufacturing process. The regulatory language in §261.3(a)(2)(iv)(D) provides several examples of de minimis losses envisioned by the regulatory exemption. Please remember the facility's discharge of wastewater must be subject to regulation under Section 402 or 307(b) of the Clean Water Act to qualify for this exemption. Also, please be aware that if the facility's wastewater treatment system leaks before the wastewater reaches the headworks of the treatment system, the leaked material is classified as a §261.33 material. In addition, while the de minimis amount is not quantified in the regulatory language, large material losses would void the de minimis quantity exemption.

As for wastewater from the cleaning of protective equipment, the regulatory language of §261 .3(a)(2)(iv)(D) includes "discharges from... rinsing and cleaning of personal safety equipment..." Again, if the cleaning was done on the facility's site and the discharge of wastewater met the requirements for exemption above, the wastewaters would be exempt from the mixture rule.

With respect to the equipment, itself, the analysis should begin with an evaluation of whether the substance that comes in contact with the equipment consists of small amounts of the actual formulated commercial chemical product or manufacturing intermediate (not manufacturing process wastes). If this is the case, the discarded equipment is debris (a "manufactured object" as described at 40 CFR section 268.2(g)) containing a listed hazardous waste—discarded product or intermediate. It, therefore, must be managed as a hazardous waste until it no longer "contains" the hazardous waste. See 57 FR 958 at 986 (Jan. 9, 1992).

There is no explicit exemption for discarded equipment contaminated with de minimis losses from manufacturing operations. However, the contaminated equipment could be washed to the point that it is

considered to no longer "contain" the hazardous waste. This interpretation is based on the fact that the equipment would qualify as hazardous debris under 40 CFR sections 268.2(g) and (h). Under section 261.3(f)(1) it would not be subject to regulation as a hazardous waste if it is washed using one of the technologies described in section 268.45, Table 1. See, in particular, physical and chemical extraction technologies.

Whether air filters from the manufacturing process that contain warfarin should be managed and disposed as nonhazardous waste depends on site-specific details. We would suggest you review the specific circumstances with the appropriate State agency. As we understand your letter, warfarin is released as it is prepared in a separate, sealed-off area. Air filters used in the chemical production of a commercial chemical product or manufacturing intermediate meeting a P or U listing prior to creation of such product or intermediate are considered manufacturing process wastes which do not fall within the listing under 40 CFR 261.33. However, once the material starts to met the listing description as the commercial chemical product or manufacturing chemical intermediate, the particles of warfarin, or of formulations meeting a P or U listing description captured by the filters, still constitute the listed commercial chemical product subject to regulation as hazardous waste, when disposed. The air filters are also subject to regulation as hazardous waste when disposed because they would constitute a solid waste mixed with a listed hazardous waste. The air filters, however, like the personal safety equipment, may also be able to qualify as hazardous debris and may be washed to remove the hazardous waste.

The specifics of how your situation apply to the principles stated above should be reviewed by applicable State Agencies. Please check with the State in which your client's facility is located with respect to the application of general principles to the specific circumstances at your facility and to make sure that other restriction do not apply.

Thank you for your inquiry. If you have any additional questions on this topic, please call Rick Brandes of my office at (703)308-8871.

Sincerely,

David Bussard, Director Hazardous Waste Identification Division

COLBY & NANCE, L.L.P.
1001 0 Street, NW., Ste. 400 East
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January 23, 1997

Mr. Richard Brandes
Chief, Waste Identification Branch
OSWER (5304-W)
United States Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Re: Request for Classification of Manufacturing Waste

Dear Mr. Brandes:

We represent a drug company that is manufacturing a product whose sole active ingredient is warfarin sodium. Currently, the manufacturer manages and disposes of all warfarin-containing waste that is generated through compounding and laboratory operations as RCRA hazardous waste. However, based on our analysis of the federal regulations, it appears that several of the waste streams need not be managed as hazardous. We would appreciate learning the Agency's position as to whether the waste streams discussed below must be managed as hazardous under EPA's RCRA regulations.

DISCUSSION

The product at issue contains between .45% and 4.5% warfarin sodium (depending on the dose) as its sole active ingredient, and will be marketed under the name "warfarin". Accordingly, there is no question that the finished product qualifies as a hazardous waste under 40 C.F.R. 261.33(e) ("commercial chemical product") when it is disposed of for being off-specification or otherwise in a manner that falls within the listing. Likewise, the active ingredient warfarin sodium, which is purchased by our client for use in the formulation of the drug, is a commercial grade chemical that falls within the listing in 40 C.F.R. 261.33(e) when it is disposed of in accordance with the terms of the listing.

The issue on which we are seeking guidance is whether certain wastes containing warfarin which are generated in the quality assurance/quality control process or in the compounding process fall within the commercial chemical product listing. Of course we are aware that even if these waste streams do not fall within the commercial chemical product listing, they may fall within some other listing or may exhibit a hazardous characteristic. However, we are not seeking the Agency's position on any other such issues in this letter.

QUALITY ASSURANCE/QUALITY CONTROL WASTE

1. Dissolution Laboratory Waste

As a part of its quality control procedures under FDA requirements, the manufacturer routinely tests samples of the finished warfarin tablets to determine how fast they will dissolve after ingestion. Dissolution testing is accomplished by placing tablets in distilled water for a standard period of time and observing the results. After the testing is completed, laboratory personnel dispose of the test solution of water and drug ingredients, currently as hazardous waste.

According to our understanding of the commercial chemical product listing, this waste does not fall within the listing. The commercial chemical product listing is limited to a manufactured product that is disposed of under specific circumstances listed in the regulations, including when the waste is off-specification, contaminated, or spilled. See 40 C.F.R. 261.33(a)-(d). The listing does not encompass every waste, "such as a manufacturing process waste", that contains the listed chemical. 40 CFR 261.33(d) *(comment)*. Here, the residue produced by a quality control is essentially a manufacturing process waste, and its disposal does not fall into any of the categories in the listing regulation. Therefore, the waste should not be considered hazardous under the commercial chemical product listing.

Moreover, although the listing regulation does not state that the commercial chemical product must be "unused", EPA has interpreted the listing as being limited to "unused chemicals". *Nitroglycerin Pills as Commercial Chemical Products,* September 1993 Monthly RCRA Hotline Report. Under the facts set out above, testing should be considered the equivalent of use, since the manufacturer has deliberately altered the product physically or chemically in order to serve a specific goal. Thus, the dissolution laboratory waste should not be considered to be within the commercial chemical product listing, and can be discharged to the local sewer system.

2. Integrity Testing Waste

The manufacturer also conducts physical integrity testing for quality control purposes. The manufacturer selects a sample of tablets and subjects them to controlled pressure in order to determine how well they will withstand physical chipping and breaking. When the test is completed, the manufacturer disposes of the resulting dust and fragments as hazardous waste.

Just as with the waste generated by dissolution testing, the disposal of this waste does not fall within any of the categories specified in the commercial chemical product listing. Likewise, the dust and fragments are analogous to a used or spent product, since they have been used for the intended purpose of quality control. Therefore, the waste from integrity testing should not be considered to be within the commercial chemical product listing.[i]

MANUFACTURING WASTE

Waste that is generated in the process of manufacturing warfarin tablets for sale presents different issues. The basic process is simple; the warfarin sodium is blended with various inert ingredients (primarily lactose, starch and water) and the mixture is physically converted to granular form. The granules are dried and then compressed into tablets. Three main waste streams are generated: (1) washdown water containing residues of

warfarin and other drug ingredients, which is generated by cleaning machinery, containers, implements, and manufacturing rooms, (2) disposable gloves, gowns, and other personal equipment used by employees in the manufacturing area, all of which contain traces of warfarin, and (3) airborne dust that is collected in air filters, which are periodically replaced and discarded.

1. Washdown Water

The commercial chemical product listing specifies that not all manufacturing process wastes containing chemicals on the list are thereby rendered hazardous. 40 C.F.R. 261.33(d) *(comment)*. However, the listing itself gives no guidance as to which types of process waste, if any, are to be considered hazardous.

The separate regulations defining hazardous waste contain an exclusion for "de minimis losses" of a listed commercial chemical product that occur when the listed product is used as a raw material or produced in a manufacturing process, so long as the de minimis quantities are discharged to the sewer system. 40 C.F.R. 261.3(a)(2)(iv)(D). The regulations state that de minimis losses include spills from normal material handling operations such as the transfer of materials, leaks from pipes or process equipment, sample purgings, and discharges from safety showers and rinsing and cleaning of containers and personal safety equipment.

This exclusion should apply to washdown water generated in the manufacture of warfarin when the wastewater is disposed of through the sewer system, as this waste constitutes a "de minimis" loss from manufacturing. Moreover, the waste falls clearly within EPA's rationale for the regulatory exclusion:

> These small losses of raw materials, products or intermediates are often disposed of by draining or washing them into the wastewater treatment system. This typically is a reasonable and practical means of disposing of these lost materials. Segregating and separately managing them often would be exceedingly expensive and may not be necessary because the small quantities can be assimilated and treated in the wastewater treatment system.

46 Fed. Reg. 56582, 56586 (November 17,1981). In addition, the Agency has noted, because these losses constitute waste of a valuable product, the manufacturer has a strong incentive to minimize the amount that is lost.

Here, despite the efforts of the manufacturer to minimize waste, the washdown water still contains small quantities of warfarin. The washdown water is currently collected and disposed of as hazardous waste at considerable expense. However, since the small amounts of warfarin found in the washdown water fall within this regulatory exclusion, the manufacturer should be allowed to modify its procedures and dispose of the washdown water through floor drains or otherwise into the sewer system.

2. Disposable Gloves and Other Personal Equipment

According to the regulatory exclusion discussed above, wastewater generated from cleaning gloves, gowns, and other reusable personal equipment would be excluded from the commercial chemical product listing if the wastewater were discharged to the sewer. 40 C.F.R. 261.3(a)(2)(iv)(D). In this case, as a result of FDA requirements, the manufacturer uses disposable gloves and other protective equipment to avoid any risk of contaminating the product. As a result, instead of generating wash water, the manufacturing process generates dry disposable materials that contain traces of warfarin.

Disposable gloves and other personal equipment with traces of warfarin should be subject to management and disposal as nonhazardous solid waste. As a practical matter, this is appropriate because the waste presents the same minimal threat to human health and the environment as the de minimis losses discussed above. Because of the way the waste is generated and the manufacturer's incentive to minimize the lost product, the waste will contain very small amounts of the listed commercial chemical product. Moreover, when the waste is landfilled, the traces of warfarin will soon be diluted or broken down into other substances, just as when wastewater containing trace amounts of product is discharged to the sewer system.

There are at least two ways to analyze this issue under the regulations. First, the waste (defined as "disposable personal protective equipment containing traces of warfarin") can simply be deemed to fall outside the commercial chemical product listing. The waste is not a "commercially pure grade of the chemical" nor a formulation in which the chemical is the sole active ingredient", nor does it fall within any of the other categories enumerated in 40 C.F.R. 261.33. Under this analysis, the waste is simply not a listed hazardous waste, and no exclusion is required.

This issue also could be analyzed under EPA's "contained-in policy". Under this analysis "debris", including clothing and other manufactured items that are being disposed of may be considered hazardous if it contains hazardous waste (here, the traces of warfarin). If the debris were considered potentially hazardous under the contained-in policy, then the state regulatory agency would have the option of determining whether the specific waste stream should in fact be considered hazardous, based on either site-specific or contaminant specific concentration levels. Under this scenario, then, the applicable state agency would have the ultimate decision making authority as to whether the waste should be managed as hazardous. On these facts, the agencies should allow the waste to be managed as non hazardous.

3. **Air Filters**

The area in which the warfarin is manufactured is sealed off from the remainder of the facility, and has a separate ventilation system. The air is continually filtered to remove any impurities, including traces of warfarin that may have become airborne during the manufacturing process. The air filters are periodically removed from the ventilation system and disposed of.

The air filters should be analyzed in essentially the same way as the disposable gloves and other personal protective items. The simplest approach would be to determine that the filters fall outside the commercial chemical product listing. An alternative would be to analyze the filters under the contained-in policy, so that the applicable state agency would determine whether they need to be managed as hazardous waste. In either case, based on the particular facts involved here, the air filters should be managed and disposed of as nonhazardous solid waste.

CONCLUSION

We would appreciate hearing EPA's interpretation of the RCRA regulations as they apply to these issues. If you need further information, please do not hesitate to call me. Thank you for your assistance.

[i] If EPA concurs in this conclusion, the integrity testing waste will be sent for incineration along with all the other nonhazardous pharmaceutical waste that the manufacturer generates.