

CEMETERY AND FUNERAL BUREAU

Final Statement of Reasons

Effective Date

The Cemetery and Funeral Bureau (Bureau) is requesting an “on filing” effective date to align as closely as possible with the statutory implementation date of July 1, 2020 found in Assembly Bill (AB) 967 (Gloria, Chapter 846, Statutes of 2017). This would enable the Bureau to fulfill its primary function of protecting the public from unlicensed hydrolysis facilities. In addition, it will positively affect the state’s environment because hydrolysis is considered an environmentally friendly choice because there are no direct emissions of harmful greenhouse gasses or mercury released to the atmosphere.

Subject Matter of Proposed Regulations:

This final statement of reasons addresses the regulations applicable to alkaline hydrolysis related licensure contained in Article 6, of Division 23, of Title 16 of the California Code of Regulations (CCR), Licensure and regulation of alkaline hydrolysis facilities.

Sections Affected: CCR, Title 16, Division 23, Article 6, Sections 2310, 2311, 2326.05, 2326.1, 2329.1, 2339 & 2370

Updated Information

The Informative Digest and Initial Statement of Reasons are included in the rulemaking file and incorporated as though set forth herein.

The information contained therein is updated as follows:

The Application for Hydrolysis Facility License, form 23-HF (07/20), incorporated by reference, would be cumbersome, unduly expensive and otherwise impractical to publish in the CCR. The form is available on the Bureau’s website and hardcopies are available from the Bureau upon request.

Non-substantive modifications were made to the originally approved text. Below is a description of the modifications that were made to the text.

Section 2326.05

In subdivision (a): Add the word “New” to the newly incorporated Cemetery and Funeral Bureau (bureau) form 23-HF before the date of 07/20.

Section 2326.1

In subdivision (c):

- Changing the word “Bureau” to “bureau”
- Adding the phrase “section 2317.2 of Title 16 of the”
- Changing the word “subsection” to “subdivision”

The Bureau proposes these changes to correct minor inconsistencies in the text and to align for consistency throughout the regulation.

Section 2329.1

Insertion and deletion of text to rephrase the paragraph:

- Replacement of “Title 16, California Code of Regulations, sections 2326.05 and 2326.1(c)” with “sections 2326.05 and 2326.1(c) of Title 16, of the California Code of Regulations.”

The Bureau proposes to rephrase this reference for consistency throughout the regulations.

After consultation with the Office of Administrative Law, the Bureau made certain modifications to the proposed text to enhance clarity.

On March 23, 2021, the Bureau provided 15 days’ notice of the modified text. It received no comments.

The amendments are summarized below:

1. Section 2311(c):

The Bureau struck the second sentence of subdivision (c), stating, “In the event the expenses of the bureau's investigation, computed at the rate of one hundred dollars (\$100) per day per person, exceeds this amount, the applicant shall, within five (5) days after request therefore, deposit such additional sums as deemed necessary by the bureau, provided that the total sum shall not exceed fourteen hundred dollars (\$1,400).”

2. Section 2326.05(c)(1)-(2):

The Bureau replaced “adequacy” with “amount” for clarity in subdivision (c)(2).

The Bureau struck “Such other matters as the bureau may require by written notice to the applicant,” and replaced it with “The relative placement of structures and equipment

in the hydrolysis facility,” to clarify what other matters the Bureau specifically considers.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Comments and/or questions and responses:

The 45-day public comment period began on June 19, 2020 and ended on August 3, 2020. The Bureau did not hold a regulatory hearing.

The Bureau received a letter from Sheetal Singh, Environmental Program Manager, Emergency, Restoration & Waste Management Section of the California Department of Public Health (CDPH). The questions and/or comments, and the Bureau’s responses, are as follows:

Question and/or Comment #1

Section 2310(c)(1) - Each hydrolysis facility shall submit to the bureau annual maintenance records of the hydrolysis chamber for the preceding year with the annual renewal application. The hydrolysis facility license shall not be renewed without proof of annual maintenance of the hydrolysis chamber.

What annual maintenance information will the bureau be requiring/reviewing? Is the maintenance based on what the Operations Manual identifies/outlines? If periodic efficacy testing using biological spore samples is required, would this be considered part of the annual maintenance records?

Response to Question and/or Comment #1

The Bureau believes the proposed language, “annual maintenance records” is sufficiently clear and understandable without modification. Given that annual maintenance can be performed in several different levels or services, the Bureau is allowing the licensee to make a business decision and perform the maintenance necessary for the care and upkeep of the chamber to ensure it continues to operate at an optimal level.

As for the periodic efficacy testing using biological spore samples, this issue is outside the Bureau’s purview because the statute did not expressly grant the Bureau authority to review the testing protocols and the results of the hydrolysis chamber to ensure that the chamber continues in the total destruction of pathogenic microorganisms. Business and Professions Code (BPC) section 7639.08(e) requires licensed hydrolysis facilities that discharge hydrolysate to a sewer collection system to submit to the CDPH results of biological indicator spore testing. Accordingly, this issue is within CDPH’s duty to oversee and regulate.

The Bureau has determined that no changes to the text are required.

Question and/or Comment #2

Section 2310(c)(2) - Each hydrolysis facility that discharges hydrolysate to a sewer collection system shall submit to the bureau the current Department of Public Health evaluation with the annual renewal application pursuant to Business and Professions Code section 7639.08(e). The hydrolysis facility license shall not be renewed without proof of the evaluation.

CDPH does not annually evaluate the hydrolysis chamber that discharges hydrolysate to a sewer collection system. This evaluation will only occur once every five years. The hydrolysis facility will not have proof of a current evaluation of their hydrolysis chamber until year five (and that is only for the hydrolysis chambers that discharge to a sewer collection system). CDPH will conduct an evaluation of a specific model a manufacturer wishes to market in California for the treatment of human remains. That initial evaluation is to prove that a specific technology can efficaciously treat pathogenic microorganisms. It is not an evaluation of a hydrolysis facility's specific unit.

Response to Question and/or Comment #2

The Bureau believes the proposed language is sufficiently clear and understandable without any proposed modification. CDPH is tasked with the review and approval of hydrolysis chambers marketed in California for licensed hydrolysis facilities to use for the final disposition of human remains. The Bureau understands that CDPH will issue an approval for the specific chamber to the manufacturer that will then be provided to the hydrolysis facility that purchases that chamber. For hydrolysis facilities that utilize the sewer collection system, this initial approval from CDPH is the current evaluation for the chamber until the facility has been using that chamber for five years and requires a new evaluation.

However, pursuant to BPC section 7639.08(e), a licensed hydrolysis facility is required to submit archived electronic hydrolysis chamber data to the CDPH for evaluation as to whether the chamber continues to destroy pathogens. If the chamber is determined not to destroy pathogens, the Bureau will not renew the license until the hydrolysis facility has remedied the issues. The Bureau understands the evaluation could potentially be outdated depending on when the hydrolysis facility begins operation, but still constitutes being the most current evaluation available to the licensed hydrolysis facility.

The Bureau has determined that no changes to the text are required.

Question and/or Comment #3, Section 2310(c)(2)

There is no mechanism for CDPH to know when an evaluation of a hydrolysis chamber that discharges to a sewer collection system is due for its five-year review.

Response to Question and/or Comment #3

This comment is outside the scope of this rulemaking proposal because the statute did not expressly grant the Bureau authority to establish a process to perform evaluations of hydrolysis chamber that discharges to a sewer collection system. As mentioned above, BPC section 7639.08(e) requires a licensed hydrolysis facility to submit archived electronic hydrolysis chamber data to the CDPH, so it is not CDPH's responsibility to track but is incumbent on the licensee to provide.

The Bureau has determined that no changes to the text are required.

Question and/or Comment #4

Section 2326.05(a)(5) - Approval of hydrolysis chamber issued by the State Department of Public Health.

CDPH assumes that the issued approval the proposed regulations are referring to is the approval letter that CDPH will give to the manufacturer who has received approval that their treatment machine model efficaciously treats pathogenic microorganisms.

Response to Question and/or Comment #4

CDPH is correct in their understanding. The Bureau believes the proposed language is sufficiently clear and understandable without any proposed modification. Under BPC section 7639.08, the Bureau may only grant a hydrolysis facility license to applicants that will employ a hydrolysis chamber approved by the CDPH. As part of the Bureau's application process, the applicant will be required to provide proof of the approval issued by CDPH for the specific hydrolysis chamber they will use to ensure compliance with this section.

The Bureau received a comment outside the comment periods. The Bureau received an email from Patricia Gail Tucker. On March 16, 2021.

Comment: Ms. Tucker questioned the accuracy of a specific statement found on the Notice on page 6, "California is ranked at 76.5 percent in cremations as of 2018, and it is projected to increase to 74.2 percent by 2023."

Response to Comment:

The Bureau discovered a transposition error in the statement. The statement should read, "California is ranked at 67.5 percent in cremation as of 2018, and it is projected to increase to 74.2 percent by 2023." The source relied upon for this statistical data is listed in the Initial Statement of Reason, Underling Data section.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or would be as effective and less burdensome to affected private persons than the adopted regulations or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Fiscal Impact

The Bureau anticipates approximately 15 applicants will initially apply for licensure in year one of implementation and 2 per year thereafter. Licensees will be required to renew annually.

The Bureau indicates initial and renewal licensing workload will include a 3-hour onsite inspection of each hydrolysis facility conducted by a Field Representative, 7 hours of workload performed by an Associate Governmental Program Analyst, and 1 hour of audit workload performed by an Associate Management Auditor.

Hydrolysis Facility License Workload

Registration and License Type	Applicants Per Year	Years Ongoing										Total			
		1	2	3	4	5	6	7	8	9	10				
Hydrolysis Facility License	15/2	15	2	2	2	2	2	2	2	2	2	2	2	2	33
Hydrolysis Facility Initial License															
Inspection Workload - Field Representative* (3 hours)		\$9,480	\$1,264	\$1,264	\$1,264	\$1,264	\$1,264	\$1,264	\$1,264	\$1,264	\$1,264	\$1,264	\$1,264	\$1,264	\$20,856
Licensing Workload - Associate Governmental Program Analyst** (7 hours)		\$3,645	\$486	\$486	\$486	\$486	\$486	\$486	\$486	\$486	\$486	\$486	\$486	\$486	\$8,019
Audit Workload - Associate Management Auditor*** (1 hour)		\$1,470	\$196	\$196	\$196	\$196	\$196	\$196	\$196	\$196	\$196	\$196	\$196	\$196	\$3,234
Total Initial Costs:		\$14,595	\$1,946	\$1,946	\$1,946	\$1,946	\$1,946	\$1,946	\$1,946	\$1,946	\$1,946	\$1,946	\$1,946	\$1,946	\$32,109
Hydrolysis Facility Initial License	Various	-	15	17	19	21	23	25	27	29	31				207
Inspection Workload - Field Representative* (3 hours)		-	\$9,480	\$10,744	\$12,008	\$13,272	\$14,536	\$15,800	\$17,064	\$18,328	\$19,592	\$20,856	\$22,120	\$23,384	\$130,824
Licensing Workload - Associate Governmental Program Analyst** (7 hours)		-	\$3,645	\$4,131	\$4,617	\$5,103	\$5,589	\$6,075	\$6,561	\$7,047	\$7,533	\$8,019	\$8,505	\$8,991	\$50,301
Audit Workload - Associate Management Auditor*** (1 hour)		-	\$1,470	\$1,666	\$1,862	\$2,058	\$2,254	\$2,450	\$2,646	\$2,842	\$3,038	\$3,234	\$3,430	\$3,626	\$20,286
Enforcement-related costs per licensee (\$205 per license)		-	\$3,075	\$3,485	\$3,895	\$4,305	\$4,715	\$5,125	\$5,535	\$5,945	\$6,355	\$6,765	\$7,175	\$7,585	\$42,435
Total Renewal Costs:		-	\$17,670	\$20,026	\$22,382	\$24,738	\$27,094	\$29,450	\$31,806	\$34,162	\$36,518	\$38,874	\$41,230	\$43,586	\$243,846
Total Initial and Renewal Costs:		\$14,595	\$19,616	\$21,972	\$24,328	\$26,684	\$29,040	\$31,396	\$33,752	\$36,108	\$38,464	\$40,820	\$43,176	\$45,532	\$275,955

*Field Representative (approximately \$79 per hour)
 **Associate Governmental Program Analyst (approximately \$86 per hour)
 ***Associate Management Auditor (approximately \$98 per hour)
 Enforcement Costs (\$2,750,000)/licensee Population (13,400) = \$205 per licensee