

Executive Summary – Enforcement Matter – Case No. 64838

ICU MEDICAL, INC.

RN100952860

Docket No. 2023-1500-MLM-E

Order Type:

1660 Agreed Order

Findings Order Justification:

N/A

Media:

MLM – IHW and MSW

Small Business:

No

Location(s) Where Violation(s) Occurred:

ICU Medical, 3900 Howard Lane, Austin, Travis County

Type of Operation:

Medical supply manufacturing facility

Other Significant Matters:

Additional Pending Enforcement Actions: No

Past-Due Penalties: No

Past-Due Fees: No

Other: N/A

Interested Third-Parties: None

Texas Register Publication Date: August 1, 2025

Comments Received: No

Penalty Information

Total Penalty Assessed: \$53,413

Amount Deferred for Expedited Settlement: \$10,682

Total Paid to General Revenue: \$42,731

Total Due to General Revenue: \$0

Payment Plan: N/A

Compliance History Classifications:

Person/CN - High

Site/RN - High

Major Source: Yes

Statutory Limit Adjustment: N/A

Applicable Penalty Policy: January 2021

Investigation Information

Complaint Date(s): N/A

Complaint Information: N/A

Date(s) of Investigation: November 18, 2022

Date(s) of NOE(s): January 13, 2023

Executive Summary – Enforcement Matter – Case No. 64838

ICU MEDICAL, INC.

RN100952860

Docket No. 2023-1500-MLM-E

Violation Information

1. Failed to provide secondary containment in order to prevent the release of hazardous waste or hazardous constituents to the environment. Specifically, approximately 24,000 gallons of hazardous waste was being stored in an above ground storage tank ("AST") without secondary containment [30 TEX. ADMIN. CODE § 335.112(a)(9) and 40 CODE OF FEDERAL REGULATIONS ("C.F.R.") § 265.193(a)].
2. Failed to label all tanks that accumulate hazardous waste with the words "Hazardous Waste". Specifically, an approximately 24,000-gallon AST was storing hazardous waste and was not labeled with the words "Hazardous Waste" [30 TEX. ADMIN. CODE § 335.53(f) and 40 C.F.R. § 262.17(a)(5)(ii)(A)].
3. Failed to submit a copy of the contingency plan and all revisions to all local emergency responders [30 TEX. ADMIN. CODE § 335.61 and 40 C.F.R. § 262.262(a)].
4. Failed to complete closure and remediation obligations of an industrial hazardous waste facility. Specifically, the Respondent had not satisfied the closure and remediation obligations associated with converting the function of an unregistered approximately 24,000-gallon AST from storing hazardous waste to storing non-hazardous waste [30 TEX. ADMIN. CODE § 335.8(b)].
5. Failed to submit written notification to the Executive Director ("ED") at least 90 days prior to engaging in on-site treatment of medical waste. Specifically, the Respondent had not notified the ED prior to using two autoclave units for the treatment of the medical waste generated at the on-site nursing unit by the August 20, 2022 notification due date [30 TEX. ADMIN. CODE §§ 326.37(a) and 326.39(a)].
6. Failed to conduct hazardous waste determinations and waste classifications. Specifically, inaccurate waste classification documentation was provided for the following waste streams: water contaminated with Bis (2-ethylhexyl) phthalate; demolished process equipment including old poly tanks, piping, and connectors; and Resource Conservation and Recovery Act empty polyethylene drums [30 TEX. ADMIN. CODE §§ 335.503(a) and 335.504 and 40 C.F.R. § 262.11].
7. Failed to label all hazardous waste containers in Satellite Accumulation Areas ("SAAs") with the words "Hazardous Waste". Specifically, one 5-gallon drum in a laboratory SAA was observed without a hazardous waste label [30 TEX. ADMIN. CODE § 335.53(d) and 40 C.F.R. § 262.15(a)(5)].

Corrective Actions/Technical Requirements

Corrective Action(s) Completed:

The Respondent implemented the following corrective measures:

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ICU MEDICAL, INC.

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Docket No. 2023-1500-MLM-E

- a. In lieu of labeling an approximately 24,000-gallon AST with the words "Hazardous Waste", the Respondent removed the hazardous waste from the AST on February 27, 2023;
- b. In lieu of providing secondary containment for the AST, the Respondent removed the hazardous waste from the AST on February 27, 2023;
- c. Submitted a copy of the Facility's contingency plan to all local emergency responders on December 1, 2022;
- d. Submitted written notification to the ED for on-site treatment of medical waste on December 12, 2022;
- e. Submitted complete and accurate waste determination and waste classification documentation for the three waste streams on November 18, 2022; and
- f. Properly labeled the 5-gallon drum in the laboratory SAA on November 18, 2022.

Technical Requirements:

The Order will require the Respondent to:

- a. Within 120 days, properly complete all closure and remediation obligations regarding the unregistered 24,000-gallon AST previously storing hazardous waste;
- b. Within 180 days, prepare and submit a closure report demonstrating proper closure of the unregistered 24,000-gallon AST previously storing hazardous waste; and
- c. Within 195 days, submit written certification to demonstrate compliance with a. and b.

Contact Information

TCEQ Attorney: N/A

TCEQ Enforcement Coordinator: Eresha DeSilva, Enforcement Division, Enforcement Team 3, MC R-12, (512) 239-5084; Michael Parrish, Enforcement Division, MC R-12, (512) 239-2548

Respondent: Brian Michael Bonnell, Chief Financial Officer, ICU MEDICAL, INC., 951 Calle Amanecer, San Clemente, California 92673

Respondent's Attorney: N/A



Penalty Calculation Worksheet (PCW)

Policy Revision 5 (January 28, 2021)

PCW Revision February 11, 2021

DATES	Assigned	17-Jan-2023	Screening	11-Sep-2023	EPA Due	
	PCW	18-Oct-2023				

RESPONDENT/FACILITY INFORMATION

Respondent	ICU MEDICAL, INC. (PCW No. 1 of 2)				
Reg. Ent. Ref. No.	RN100952860				
Facility/Site Region	11-Austin	Major/Minor Source	Major		

CASE INFORMATION

Enf./Case ID No.	64838	No. of Violations	6
Docket No.	2023-1500-MLM-E	Order Type	1660
Media Program(s)	Industrial and Hazardous Waste	Government/Non-Profit	No
Multi-Media	Medical Waste	Enf. Coordinator	Eresha DeSilva
		EC's Team	Enforcement Team 3
Admin. Penalty \$ Limit Minimum	\$0	Maximum	\$25,000

Penalty Calculation Section

TOTAL BASE PENALTY (Sum of violation base penalties)	Subtotal 1	\$65,250
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ADJUSTMENTS (+/-) TO SUBTOTAL 1

Subtotals 2-7 are obtained by multiplying the Total Base Penalty (Subtotal 1) by the indicated percentage.

Compliance History	-10.0%	Adjustment	Subtotals 2, 3, & 7	-\$6,525
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Notes	Reduction for High Performer classification.
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Culpability	No	0.0%	Enhancement	Subtotal 4	\$0
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Notes	The Respondent does not meet the culpability criteria.
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Good Faith Effort to Comply Total Adjustments	Subtotal 5	-\$6,937
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Economic Benefit	0.0%	Enhancement*	Subtotal 6	\$0
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Total EB Amounts	\$624	*Capped at the Total EB \$ Amount
Estimated Cost of Compliance	\$22,610	

SUM OF SUBTOTALS 1-7	Final Subtotal	\$51,788
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OTHER FACTORS AS JUSTICE MAY REQUIRE	0.0%	Adjustment	\$0
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Reduces or enhances the Final Subtotal by the indicated percentage.

Notes	
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Final Penalty Amount	\$51,788
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STATUTORY LIMIT ADJUSTMENT	Final Assessed Penalty	\$51,788
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DEFERRAL	20.0%	Reduction	Adjustment	-\$10,357
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Reduces the Final Assessed Penalty by the indicated percentage.

Notes	Deferral offered for expedited settlement.
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PAYABLE PENALTY	\$41,431
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Screening Date		Docket No. 2023-1500-MLM-E	PCW
Respondent	ICU MEDICAL, INC. (PCW No. 1 of 2)		<i>Policy Revision 5 (January 28, 2021)</i>
Case ID No.	64838		<i>PCW Revision February 11, 2021</i>
Reg. Ent. Reference No.	RN100952860		
Media	Industrial and Hazardous Waste		
Enf. Coordinator	Eresha DeSilva		

Compliance History Worksheet

>> Compliance History Site Enhancement (Subtotal 2)

Component	Number of...	Number	Adjust.
NOVs	Written notices of violation ("NOVs") with same or similar violations as those in the current enforcement action (<i>number of NOVs meeting criteria</i>)	0	0%
	Other written NOVs	0	0%
Orders	Any agreed final enforcement orders containing a denial of liability (<i>number of orders meeting criteria</i>)	0	0%
	Any adjudicated final enforcement orders, agreed final enforcement orders without a denial of liability, or default orders of this state or the federal government, or any final prohibitory emergency orders issued by the commission	0	0%
Judgments and Consent Decrees	Any non-adjudicated final court judgments or consent decrees containing a denial of liability of this state or the federal government (<i>number of judgments or consent decrees meeting criteria</i>)	0	0%
	Any adjudicated final court judgments and default judgments, or non-adjudicated final court judgments or consent decrees without a denial of liability, of this state or the federal government	0	0%
Convictions	Any criminal convictions of this state or the federal government (<i>number of counts</i>)	0	0%
Emissions	Chronic excessive emissions events (<i>number of events</i>)	0	0%
Audits	Letters notifying the executive director of an intended audit conducted under the Texas Environmental, Health, and Safety Audit Privilege Act, 74th Legislature, 1995 (<i>number of audits for which notices were submitted</i>)	0	0%
	Disclosures of violations under the Texas Environmental, Health, and Safety Audit Privilege Act, 74th Legislature, 1995 (<i>number of audits for which violations were disclosed</i>)	0	0%
Other	Environmental management systems in place for one year or more	No	0%
	Voluntary on-site compliance assessments conducted by the executive director under a special assistance program	No	0%
	Participation in a voluntary pollution reduction program	No	0%
	Early compliance with, or offer of a product that meets future state or federal government environmental requirements	No	0%

Adjustment Percentage (Subtotal 2) 0%

>> Repeat Violator (Subtotal 3)

No

Adjustment Percentage (Subtotal 3) 0%

>> Compliance History Person Classification (Subtotal 7)

High Performer

Adjustment Percentage (Subtotal 7) -10%

>> Compliance History Summary

Compliance History Notes

Reduction for High Performer classification.

Total Compliance History Adjustment Percentage (Subtotals 2, 3, & 7) -10%

>> Final Compliance History Adjustment

Final Adjustment Percentage *capped at 100% -10%

Screening Date		Docket No. 2023-1500-MLM-E		PCW	
Respondent ICU MEDICAL, INC. (PCW No. 1 of 2)		Policy Revision 5 (January 28, 2021)			
Case ID No. 64838		PCW Revision February 11, 2021			
Reg. Ent. Reference No. RN100952860					
Media Industrial and Hazardous Waste					
Enf. Coordinator Eresha DeSilva					
Violation Number 1					
Rule Cite(s)		30 Tex. Admin. Code § 335.112(a)(9) and 40 Code of Federal Regulations ("C.F.R.") § 265.193(a)			
Violation Description		Failed to provide secondary containment in order to prevent the release of hazardous waste or hazardous constituents to the environment. Specifically, approximately 24,000 gallons of hazardous waste was being stored in an above ground storage tank ("AST") without secondary containment.			
		Base Penalty		\$25,000	

>> Environmental, Property and Human Health Matrix

OR		Harm			
	Release	Major	Moderate	Minor	
	Actual				Percent 30.0%
Potential	X				

>> Programmatic Matrix

	Falsification	Major	Moderate	Minor	
					Percent 0.0%
Matrix Notes	Human health or the environment will or could be exposed to pollutants that would exceed levels that are protective of human health or environmental receptors as a result of the violation.				
Adjustment					\$17,500

Violation Events

Number of Violation Events		2	101		Number of violation days	
	daily					
	weekly					
	monthly					
	quarterly	X				
	semiannual					
	annual					
	single event					
		Violation Base Penalty				\$15,000
Two quarterly events are recommended from the November 18, 2022 investigation date to the February 27, 2023 compliance date.						

Good Faith Efforts to Comply

		10.0%	Reduction		\$1,500
		Before NOE/NOV	NOE/NOV to EDPRP/Settlement Offer		
	Extraordinary				
	Ordinary		X		
	N/A				
	Notes	The Respondent came into compliance on February 27, 2023, after the January 13, 2023 Notice of Enforcement ("NOE").			
Violation Subtotal					\$13,500

Economic Benefit (EB) for this violation

Statutory Limit Test	
Estimated EB Amount	\$0
Violation Final Penalty Total	\$12,000
This violation Final Assessed Penalty (adjusted for limits)	
\$12,000	

Economic Benefit Worksheet

Respondent ICU MEDICAL, INC. (PCW No. 1 of 2)
Case ID No. 64838
Reg. Ent. Reference No. RN100952860
Media Industrial and Hazardous Waste
Violation No. 1

Percent Interest	Years of Depreciation
5.0	15

Item Description	Item Cost	Date Required	Final Date	Yrs	Interest Saved	Costs Saved	EB Amount
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Delayed Costs

Equipment				0.00	\$0	\$0	\$0
Buildings				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Engineering/Construction	\$5,000	18-Nov-2022	27-Feb-2023	0.28	\$5	\$92	\$97
Land				0.00	\$0	n/a	\$0
Record Keeping System				0.00	\$0	n/a	\$0
Training/Sampling				0.00	\$0	n/a	\$0
Remediation/Disposal				0.00	\$0	n/a	\$0
Permit Costs				0.00	\$0	n/a	\$0
Other (as needed)				0.00	\$0	n/a	\$0
Notes for DELAYED costs	Estimated delayed cost to remove the hazardous waste from the 24,000-gallon AST. The Date Required is the investigation date, and the Final Date is the date of compliance.						

Avoided Costs

ANNUALIZE avoided costs before entering item (except for one-time avoided costs)

Disposal				0.00	\$0	\$0	\$0
Personnel				0.00	\$0	\$0	\$0
Inspection/Reporting/Sampling				0.00	\$0	\$0	\$0
Supplies/Equipment				0.00	\$0	\$0	\$0
Financial Assurance				0.00	\$0	\$0	\$0
ONE-TIME avoided costs				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Notes for AVOIDED costs							

Approx. Cost of Compliance \$5,000

TOTAL \$97

Screening Date	Docket No. 2023-1500-MLM-E	PCW
Respondent ICU MEDICAL, INC. (PCW No. 1 of 2)	<i>Policy Revision 5 (January 28, 2021)</i>	
Case ID No. 64838	<i>PCW Revision February 11, 2021</i>	
Reg. Ent. Reference No. RN100952860		
Media Industrial and Hazardous Waste		
Enf. Coordinator Eresha DeSilva		
Violation Number	2	
Rule Cite(s)	30 Tex. Admin. Code § 335.53(f) and 40 C.F.R. § 262.17(a)(5)(ii)(A)	
Violation Description	Failed to label all tanks that accumulate hazardous waste with the words "Hazardous Waste". Specifically, an approximately 24,000-gallon AST was storing hazardous waste and was not labeled with the words "Hazardous Waste".	
Base Penalty		\$25,000

>> Environmental, Property and Human Health Matrix

OR		Harm			
	Release	Major	Moderate	Minor	
	Actual				Percent 0.0%
Potential					

>> Programmatic Matrix

	Falsification	Major	Moderate	Minor	
		X			Percent 20.0%

Matrix Notes	100% of the rule requirement was not met.
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Adjustment \$20,000

\$5,000

Violation Events

Number of Violation Events	2		101	Number of violation days
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	daily		Violation Base Penalty \$10,000
	weekly		
	monthly		
	quarterly	X	
	semiannual		
	annual		
	single event		

Two quarterly events are recommended from the November 18, 2022 investigation date to the February 27, 2023 compliance date.

Good Faith Efforts to Comply

	10.0%		Reduction	\$1,000
	Before NOE/NOV	NOE/NOV to EDPRP/Settlement Offer		
Extraordinary				
Ordinary		X		
N/A				

Notes	The Respondent came into compliance on February 27, 2023, after January 13, 2023 NOE.
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Violation Subtotal \$9,000

Economic Benefit (EB) for this violation

Estimated EB Amount	\$0	Statutory Limit Test	
		Violation Final Penalty Total	\$8,000
This violation Final Assessed Penalty (adjusted for limits)			\$8,000

Economic Benefit Worksheet

Respondent ICU MEDICAL, INC. (PCW No. 1 of 2)
Case ID No. 64838
Reg. Ent. Reference No. RN100952860
Media Industrial and Hazardous Waste
Violation No. 2

Percent Interest	Years of Depreciation
5.0	15

Item Description	Item Cost	Date Required	Final Date	Yrs	Interest Saved	Costs Saved	EB Amount
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Delayed Costs

Equipment				0.00	\$0	\$0	\$0
Buildings				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Engineering/Construction				0.00	\$0	\$0	\$0
Land				0.00	\$0	n/a	\$0
Record Keeping System				0.00	\$0	n/a	\$0
Training/Sampling				0.00	\$0	n/a	\$0
Remediation/Disposal				0.00	\$0	n/a	\$0
Permit Costs				0.00	\$0	n/a	\$0
Other (as needed)				0.00	\$0	n/a	\$0
Notes for DELAYED costs	Economic Benefit is included in the Economic Benefit Worksheet for Violation No. 1.						

Avoided Costs

ANNUALIZE avoided costs before entering item (except for one-time avoided costs)

Disposal				0.00	\$0	\$0	\$0
Personnel				0.00	\$0	\$0	\$0
Inspection/Reporting/Sampling				0.00	\$0	\$0	\$0
Supplies/Equipment				0.00	\$0	\$0	\$0
Financial Assurance				0.00	\$0	\$0	\$0
ONE-TIME avoided costs				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Notes for AVOIDED costs							

Approx. Cost of Compliance \$0

TOTAL \$0

Screening Date Respondent Case ID No. Reg. Ent. Reference No. Media Enf. Coordinator Violation Number Rule Cite(s) Violation Description	Docket No. 2023-1500-MLM-E ICU MEDICAL, INC. (PCW No. 1 of 2) RN100952860 Industrial and Hazardous Waste Eresha DeSilva <div style="border: 1px solid black; padding: 5px; margin-top: 10px;">30 Tex. Admin. Code § 335.61 and 40 C.F.R. § 262.262(a)</div> <div style="border: 1px solid black; padding: 10px; margin-top: 10px;">Failed to submit a copy of the contingency plan and all revisions to all local emergency responders.</div>	PCW <i>Policy Revision 5 (January 28, 2021)</i> <i>PCW Revision February 11, 2021</i>
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Base Penalty \$25,000

>> Environmental, Property and Human Health Matrix

OR

	Release	Major	Moderate	Minor	
Actual					Percent 30.0%
Potential	X				

>> Programmatic Matrix

Matrix Notes

Falsification	Major	Moderate	Minor	
				Percent 0.0%

Human health or the environment will or could be exposed to pollutants that would exceed levels that are protective of human health or environmental receptors as a result of the violation.

Adjustment \$17,500

\$7,500

Violation Events

Number of Violation Events 1

Number of violation days 13

daily	
weekly	
monthly	
quarterly	
semiannual	
annual	
single event	X

Violation Base Penalty \$7,500

One single event is recommended.

Good Faith Efforts to Comply

Before NOE/NOV
 Extraordinary
 Ordinary
 N/A
 Notes

X	

Reduction \$1,875

The Respondent came into compliance on December 1, 2022, before January 13, 2023 NOE.

Violation Subtotal \$5,625

Economic Benefit (EB) for this violation

Estimated EB Amount \$0

Statutory Limit Test
Violation Final Penalty Total \$4,875

This violation Final Assessed Penalty (adjusted for limits) \$4,875

Economic Benefit Worksheet

Respondent ICU MEDICAL, INC. (PCW No. 1 of 2)
Case ID No. 64838
Reg. Ent. Reference No. RN100952860
Media Industrial and Hazardous Waste
Violation No. 3

Percent Interest	Years of Depreciation
5.0	15

Item Description	Item Cost	Date Required	Final Date	Yrs	Interest Saved	Costs Saved	EB Amount
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Delayed Costs

Equipment				0.00	\$0	\$0	\$0
Buildings				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Engineering/Construction				0.00	\$0	\$0	\$0
Land				0.00	\$0	n/a	\$0
Record Keeping System				0.00	\$0	n/a	\$0
Training/Sampling				0.00	\$0	n/a	\$0
Remediation/Disposal				0.00	\$0	n/a	\$0
Permit Costs	\$1,000	18-Nov-2022	1-Dec-2022	0.04	\$2	n/a	\$2
Other (as needed)				0.00	\$0	n/a	\$0
Notes for DELAYED costs	Estimated delayed cost to submit a copy of the contingency plan to all local responders that may be called upon to provide emergency services. The Date Required is the investigation date, and the Final Date is the date of compliance.						

Avoided Costs

ANNUALIZE avoided costs before entering item (except for one-time avoided costs)

Disposal				0.00	\$0	\$0	\$0
Personnel				0.00	\$0	\$0	\$0
Inspection/Reporting/Sampling				0.00	\$0	\$0	\$0
Supplies/Equipment				0.00	\$0	\$0	\$0
Financial Assurance				0.00	\$0	\$0	\$0
ONE-TIME avoided costs				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Notes for AVOIDED costs							

Approx. Cost of Compliance \$1,000

TOTAL \$2

Screening Date Respondent Case ID No. Reg. Ent. Reference No. Media Enf. Coordinator Violation Number Rule Cite(s)	Docket No. 2023-1500-MLM-E ICU MEDICAL, INC. (PCW No. 1 of 2) 64838 RN100952860 Industrial and Hazardous Waste Eresha DeSilva <div style="border: 1px solid black; padding: 5px; text-align: center;">4</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">30 Tex. Admin. Code § 335.8(b)</div> <div style="border: 1px solid black; padding: 5px;"> Failed to complete closure and remediation obligations of an industrial hazardous waste facility. Specifically, the Respondent had not satisfied the closure and remediation obligations associated with converting the function of an unregistered approximately 24,000-gallon AST from storing hazardous waste to storing non-hazardous waste. </div>	PCW <i>Policy Revision 5 (January 28, 2021)</i> <i>PCW Revision February 11, 2021</i>																	
Base Penalty		\$25,000																	
>> Environmental, Property and Human Health Matrix																			
OR	Harm Major Moderate Minor																		
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Actual</td> <td style="width: 33%;"></td> <td style="width: 33%;"></td> </tr> <tr> <td>Potential</td> <td style="text-align: center;">X</td> <td></td> </tr> </table>			Actual			Potential	X											
	Actual																		
Potential	X																		
Percent			30.0%																
>> Programmatic Matrix																			
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Falsification</td> <td style="width: 33%;">Major</td> <td style="width: 33%;">Moderate</td> <td style="width: 33%;">Minor</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> </table>			Falsification	Major	Moderate	Minor					Percent	0.0%						
Falsification	Major	Moderate	Minor																
Matrix Notes	Human health or the environment will or could be exposed to pollutants that would exceed levels that are protective of human health or environmental receptors as a result of the violation.																		
Adjustment			\$17,500																
			\$7,500																
Violation Events																			
Number of Violation Events		3	196 Number of violation days																
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>daily</td><td></td></tr> <tr><td>weekly</td><td></td></tr> <tr><td>monthly</td><td></td></tr> <tr><td>quarterly</td><td style="text-align: center;">X</td></tr> <tr><td>semiannual</td><td></td></tr> <tr><td>annual</td><td></td></tr> <tr><td>single event</td><td></td></tr> </table>	daily		weekly		monthly		quarterly	X	semiannual		annual		single event		Violation Base Penalty			\$22,500
daily																			
weekly																			
monthly																			
quarterly	X																		
semiannual																			
annual																			
single event																			
Three quarterly events are recommended from the February 27, 2023 date that the AST storage function changed to the September 11, 2023 screening date.																			
Good Faith Efforts to Comply		0.0%	Reduction		\$0														
	Before NOE/NOV NOE/NOV to EDPRP/Settlement Offer																		
	Extraordinary																		
	Ordinary																		
	N/A	X																	
Notes	The Respondent does not meet the good faith criteria for this violation.																		
Violation Subtotal			\$22,500																
Economic Benefit (EB) for this violation		Statutory Limit Test																	
Estimated EB Amount		\$525	Violation Final Penalty Total		\$20,250														
This violation Final Assessed Penalty (adjusted for limits)			\$20,250																

Economic Benefit Worksheet

Respondent ICU MEDICAL, INC. (PCW No. 1 of 2)
Case ID No. 64838
Reg. Ent. Reference No. RN100952860
Media Industrial and Hazardous Waste
Violation No. 4

Percent Interest	Years of Depreciation
5.0	15

Item Description	Item Cost	Date Required	Final Date	Yrs	Interest Saved	Costs Saved	EB Amount
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Delayed Costs

Equipment				0.00	\$0	\$0	\$0
Buildings				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Engineering/Construction				0.00	\$0	\$0	\$0
Land				0.00	\$0	n/a	\$0
Record Keeping System				0.00	\$0	n/a	\$0
Training/Sampling				0.00	\$0	n/a	\$0
Remediation/Disposal				0.00	\$0	n/a	\$0
Permit Costs				0.00	\$0	n/a	\$0
Other (as needed)	\$4,000	27-Feb-2023	13-Oct-2025	2.63	\$525	n/a	\$525
Notes for DELAYED costs	Estimated delayed cost to prepare and submit a closure report demonstrating proper closure of the AST (\$2,000) and to complete all closure and remediation obligations (\$2,000). The Date Required is the date that the AST storage function changed, and the Final Date is the estimated date of compliance.						

Avoided Costs

ANNUALIZE avoided costs before entering item (except for one-time avoided costs)

Disposal				0.00	\$0	\$0	\$0
Personnel				0.00	\$0	\$0	\$0
Inspection/Reporting/Sampling				0.00	\$0	\$0	\$0
Supplies/Equipment				0.00	\$0	\$0	\$0
Financial Assurance				0.00	\$0	\$0	\$0
ONE-TIME avoided costs				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Notes for AVOIDED costs							

Approx. Cost of Compliance \$4,000

TOTAL \$525

Screening Date	Docket No. 2023-1500-MLM-E	PCW
Respondent	ICU MEDICAL, INC. (PCW No. 1 of 2)	<i>Policy Revision 5 (January 28, 2021)</i>
Case ID No.	64838	<i>PCW Revision February 11, 2021</i>
Reg. Ent. Reference No.	RN100952860	
Media	Industrial and Hazardous Waste	
Enf. Coordinator	Eresha DeSilva	
Violation Number	5	
Rule Cite(s)	30 Tex. Admin. Code §§ 335.503(a) and 335.504 and 40 C.F.R. § 262.11	
Violation Description	Failed to conduct hazardous waste determinations and waste classifications. Specifically, inaccurate waste classification documentation was provided for the following waste streams: water contaminated with Bis (2-ethylhexyl) phthalate ("DOP"); demolished process equipment including old poly tanks, piping, and connectors; and Resource Conservation and Recovery Act empty polyethylene drums.	
Base Penalty		\$25,000

>> Environmental, Property and Human Health Matrix

OR		Harm			
	Release	Major	Moderate	Minor	
	Actual				
	Potential			X	Percent 7.0%

>> Programmatic Matrix

	Falsification	Major	Moderate	Minor	
					Percent 0.0%

Matrix Notes	Human health or the environment will or could be exposed to insignificant amounts of pollutants that would not exceed levels that are protective of human health or environmental receptors as a result of the violation.
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Adjustment	\$23,250
\$1,750	

Violation Events

Number of Violation Events	3	Number of violation days	1
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	daily					
	weekly					
	monthly					
	quarterly					
	semiannual					
	annual					
	single event		X			

Violation Base Penalty	\$5,250
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Three single events are recommended (one event per waste stream).

Good Faith Efforts to Comply

	25.0%	
	Before NOE/NOV	NOE/NOV to EDPRP/Settlement Offer
Extraordinary		
Ordinary	X	
N/A		
Notes	The Respondent came into compliance on November 18, 2022, before January 13, 2023 NOE.	

Violation Subtotal	\$3,938
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Economic Benefit (EB) for this violation

Estimated EB Amount	\$0	Statutory Limit Test	
Violation Final Penalty Total		\$3,413	
This violation Final Assessed Penalty (adjusted for limits)		\$3,413	

Economic Benefit Worksheet

Respondent ICU MEDICAL, INC. (PCW No. 1 of 2)
Case ID No. 64838
Reg. Ent. Reference No. RN100952860
Media Industrial and Hazardous Waste
Violation No. 5

Percent Interest	Years of Depreciation
5.0	15

Item Description	Item Cost	Date Required	Final Date	Yrs	Interest Saved	Costs Saved	EB Amount
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Delayed Costs

Equipment				0.00	\$0	\$0	\$0
Buildings				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Engineering/Construction				0.00	\$0	\$0	\$0
Land				0.00	\$0	n/a	\$0
Record Keeping System				0.00	\$0	n/a	\$0
Training/Sampling				0.00	\$0	n/a	\$0
Remediation/Disposal				0.00	\$0	n/a	\$0
Permit Costs				0.00	\$0	n/a	\$0
Other (as needed)	\$12,600	18-Nov-2022	18-Nov-2022	0.00	\$0	n/a	\$0
Notes for DELAYED costs Estimated delayed cost to conduct complete and accurate waste determinations and waste classifications on three waste streams (\$4,200 per waste stream). The Date Required is the investigation date, and the Final Date is the date of compliance.							

Avoided Costs

ANNUALIZE avoided costs before entering item (except for one-time avoided costs)

Disposal				0.00	\$0	\$0	\$0
Personnel				0.00	\$0	\$0	\$0
Inspection/Reporting/Sampling				0.00	\$0	\$0	\$0
Supplies/Equipment				0.00	\$0	\$0	\$0
Financial Assurance				0.00	\$0	\$0	\$0
ONE-TIME avoided costs				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Notes for AVOIDED costs							

Approx. Cost of Compliance \$12,600

TOTAL \$0

Screening Date Respondent Case ID No. Reg. Ent. Reference No. Media Enf. Coordinator Violation Number Rule Cite(s) Violation Description	Docket No. 2023-1500-MLM-E ICU MEDICAL, INC. (PCW No. 1 of 2) 64838 RN100952860 Industrial and Hazardous Waste Eresha DeSilva 6 30 Tex. Admin. Code § 335.53(d) and 40 C.F.R. § 262.15(a)(5) Failed to label all hazardous waste containers in satellite accumulation areas ("SAAs") with the words "Hazardous Waste". Specifically, one 5-gallon drum in a laboratory SAA was observed without a hazardous waste label.	PCW <i>Policy Revision 5 (January 28, 2021)</i> <i>PCW Revision February 11, 2021</i>
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Base Penalty	\$25,000
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>> Environmental, Property and Human Health Matrix

OR		Harm			
	Release	Major	Moderate	Minor	
	Actual				Percent 0.0%
	Potential				

>> Programmatic Matrix

Matrix Notes		Falsification	Major	Moderate	Minor	
			X			Percent 20.0%
		100 percent of the rule requirement was not met.				

Adjustment	\$20,000
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	\$5,000
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Violation Events

Number of Violation Events	1		1	Number of violation days
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daily					
weekly					
monthly		X			
quarterly					
semiannual					
annual					
single event					

	Violation Base Penalty \$5,000
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	One monthly event is recommended from the November 18, 2022 investigation date to the November 18, 2022 compliance date.
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Good Faith Efforts to Comply

	25.0%			
	Before NOE/NOV	NOE/NOV to EDPRP/Settlement Offer		
Extraordinary				
Ordinary	X			
N/A				

	The Respondent came into compliance on November 18, 2022, before January 13, 2023 NOE.
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Violation Subtotal	\$3,750
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Economic Benefit (EB) for this violation
Statutory Limit Test

Estimated EB Amount	\$0	Violation Final Penalty Total	\$3,250
This violation Final Assessed Penalty (adjusted for limits)			\$3,250

Economic Benefit Worksheet

Respondent ICU MEDICAL, INC. (PCW No. 1 of 2)
Case ID No. 64838
Reg. Ent. Reference No. RN100952860
Media Industrial and Hazardous Waste
Violation No. 6

Percent Interest	Years of Depreciation
5.0	15

Item Description	Item Cost	Date Required	Final Date	Yrs	Interest Saved	Costs Saved	EB Amount
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Delayed Costs

Equipment				0.00	\$0	\$0	\$0
Buildings				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Engineering/Construction				0.00	\$0	\$0	\$0
Land				0.00	\$0	n/a	\$0
Record Keeping System				0.00	\$0	n/a	\$0
Training/Sampling				0.00	\$0	n/a	\$0
Remediation/Disposal				0.00	\$0	n/a	\$0
Permit Costs				0.00	\$0	n/a	\$0
Other (as needed)	\$10	18-Nov-2022	18-Nov-2022	0.00	\$0	n/a	\$0
Notes for DELAYED costs	Estimated delayed cost to properly label the 5-gallon drum in the laboratory SAA with the words "Hazardous Waste". The Date Required is the investigation date, and the Final Date is the date of compliance.						

Avoided Costs

ANNUALIZE avoided costs before entering item (except for one-time avoided costs)

Disposal				0.00	\$0	\$0	\$0
Personnel				0.00	\$0	\$0	\$0
Inspection/Reporting/Sampling				0.00	\$0	\$0	\$0
Supplies/Equipment				0.00	\$0	\$0	\$0
Financial Assurance				0.00	\$0	\$0	\$0
ONE-TIME avoided costs				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Notes for AVOIDED costs							

Approx. Cost of Compliance \$10

TOTAL \$0



Penalty Calculation Worksheet (PCW)

Policy Revision 5 (January 28, 2021)

PCW Revision February 11, 2021

DATES	Assigned	17-Jan-2023	Screening	11-Sep-2023	EPA Due	
	PCW	18-Oct-2023				

RESPONDENT/FACILITY INFORMATION

Respondent	ICU MEDICAL, INC. (PCW No. 2 of 2)				
Reg. Ent. Ref. No.	RN100952860				
Facility/Site Region	11-Austin	Major/Minor Source	Minor		

CASE INFORMATION

Enf./Case ID No.	64838	No. of Violations	1
Docket No.	2023-1500-MLM-E	Order Type	1660
Media Program(s)	Medical Waste	Government/Non-Profit	No
Multi-Media	Industrial and Hazardous Waste	Enf. Coordinator	Eresha DeSilva
		EC's Team	Enforcement Team 3
Admin. Penalty \$ Limit Minimum	\$0	Maximum	\$25,000

Penalty Calculation Section

TOTAL BASE PENALTY (Sum of violation base penalties)	Subtotal 1	\$2,500
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ADJUSTMENTS (+/-) TO SUBTOTAL 1

Subtotals 2-7 are obtained by multiplying the Total Base Penalty (Subtotal 1) by the indicated percentage.

Compliance History	-10.0%	Adjustment	Subtotals 2, 3, & 7	-\$250
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Notes	Reduction for High Performer classification.
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Culpability	No	0.0%	Enhancement	Subtotal 4	\$0
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Notes	The Respondent does not meet the culpability criteria.
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Good Faith Effort to Comply Total Adjustments	Subtotal 5	-\$625
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Economic Benefit	0.0%	Enhancement*	Subtotal 6	\$0
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Total EB Amounts	\$2	*Capped at the Total EB \$ Amount
Estimated Cost of Compliance	\$100	

SUM OF SUBTOTALS 1-7	Final Subtotal	\$1,625
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OTHER FACTORS AS JUSTICE MAY REQUIRE	0.0%	Adjustment	\$0
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Reduces or enhances the Final Subtotal by the indicated percentage.

Notes	
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Final Penalty Amount	\$1,625
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STATUTORY LIMIT ADJUSTMENT	Final Assessed Penalty	\$1,625
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DEFERRAL	20.0%	Reduction	Adjustment	-\$325
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Reduces the Final Assessed Penalty by the indicated percentage.

Notes	Deferral offered for expedited settlement.
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PAYABLE PENALTY	\$1,300
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Screening Date	11-Sep-2023	Docket No.	2023-1500-MLM-E	PCW
Respondent	ICU MEDICAL, INC. (PCW No. 2 of 2)			<i>Policy Revision 5 (January 28, 2021)</i>
Case ID No.	64838			<i>PCW Revision February 11, 2021</i>
Reg. Ent. Reference No.	RN100952860			
Media	Medical Waste			
Enf. Coordinator	Eresha DeSilva			

Compliance History Worksheet

>> Compliance History Site Enhancement (Subtotal 2)

Component	Number of...	Number	Adjust.
NOVs	Written notices of violation ("NOVs") with same or similar violations as those in the current enforcement action (<i>number of NOVs meeting criteria</i>)	0	0%
	Other written NOVs	0	0%
Orders	Any agreed final enforcement orders containing a denial of liability (<i>number of orders meeting criteria</i>)	0	0%
	Any adjudicated final enforcement orders, agreed final enforcement orders without a denial of liability, or default orders of this state or the federal government, or any final prohibitory emergency orders issued by the commission	0	0%
Judgments and Consent Decrees	Any non-adjudicated final court judgments or consent decrees containing a denial of liability of this state or the federal government (<i>number of judgments or consent decrees meeting criteria</i>)	0	0%
	Any adjudicated final court judgments and default judgments, or non-adjudicated final court judgments or consent decrees without a denial of liability, of this state or the federal government	0	0%
Convictions	Any criminal convictions of this state or the federal government (<i>number of counts</i>)	0	0%
Emissions	Chronic excessive emissions events (<i>number of events</i>)	0	0%
Audits	Letters notifying the executive director of an intended audit conducted under the Texas Environmental, Health, and Safety Audit Privilege Act, 74th Legislature, 1995 (<i>number of audits for which notices were submitted</i>)	0	0%
	Disclosures of violations under the Texas Environmental, Health, and Safety Audit Privilege Act, 74th Legislature, 1995 (<i>number of audits for which violations were disclosed</i>)	0	0%
Other	Environmental management systems in place for one year or more	No	0%
	Voluntary on-site compliance assessments conducted by the executive director under a special assistance program	No	0%
	Participation in a voluntary pollution reduction program	No	0%
	Early compliance with, or offer of a product that meets future state or federal government environmental requirements	No	0%

Adjustment Percentage (Subtotal 2) 0%

>> Repeat Violator (Subtotal 3)

No

Adjustment Percentage (Subtotal 3) 0%

>> Compliance History Person Classification (Subtotal 7)

High Performer

Adjustment Percentage (Subtotal 7) -10%

>> Compliance History Summary

Compliance History Notes

Reduction for High Performer classification.

Total Compliance History Adjustment Percentage (Subtotals 2, 3, & 7) -10%

>> Final Compliance History Adjustment

Final Adjustment Percentage *capped at 100% -10%

Screening Date	11-Sep-2023	Docket No. 2023-1500-MLM-E	PCW
Respondent	ICU MEDICAL, INC. (PCW No. 2 of 2)		Policy Revision 5 (January 28, 2021)
Case ID No.	64838		PCW Revision February 11, 2021
Reg. Ent. Reference No.	RN100952860		
Media	Medical Waste		
Enf. Coordinator	Eresha DeSilva		
Violation Number	1		
Rule Cite(s)	30 Tex. Admin. Code §§ 326.37(a) and 326.39(a)		
Violation Description	Failed to submit written notification to the Executive Director at least 90 days prior to engaging in on-site treatment of medical waste. Specifically, the Respondent had not notified the Executive Director prior to using two autoclave units for the treatment of the medical waste generated at the on-site nursing unit by the August 20, 2022 notification due date.		
	Base Penalty	\$25,000	

>> Environmental, Property and Human Health Matrix

OR		Release	Harm		
		Major	Moderate	Minor	
	Actual				
	Potential				
					Percent 0.0%

>> Programmatic Matrix

	Falsification	Major	Moderate	Minor	
		X			
					Percent 10.0%
Matrix Notes	100% of the rule requirement was not met.				
	Adjustment				\$22,500

\$2,500

Violation Events

Number of Violation Events	1	Number of violation days	114
	<div style="display: flex; flex-direction: column; align-items: flex-start;"> <div style="background-color: #d9e1f2; padding: 2px 5px; margin-bottom: 2px;">daily</div> <div style="background-color: #d9e1f2; padding: 2px 5px; margin-bottom: 2px;">weekly</div> <div style="background-color: #d9e1f2; padding: 2px 5px; margin-bottom: 2px;">monthly</div> <div style="background-color: #d9e1f2; padding: 2px 5px; margin-bottom: 2px;">quarterly</div> <div style="background-color: #d9e1f2; padding: 2px 5px; margin-bottom: 2px;">semiannual</div> <div style="background-color: #d9e1f2; padding: 2px 5px; margin-bottom: 2px;">annual</div> <div style="background-color: #d9e1f2; padding: 2px 5px;">single event</div> </div>		
			Violation Base Penalty \$2,500
	One single event is recommended.		

Good Faith Efforts to Comply

	25.0%		
		Before NOE/NOV	NOE/NOV to EDPRP/Settlement Offer
Extraordinary			
Ordinary	X		
N/A			
Notes	The Respondent achieved compliance on December 12, 2022, before the January 13, 2023 Notice of Enforcement.		
	Violation Subtotal		\$1,875

Economic Benefit (EB) for this violation

	Statutory Limit Test
Estimated EB Amount	\$2
	Violation Final Penalty Total \$1,625
This violation Final Assessed Penalty (adjusted for limits) \$1,625	

Economic Benefit Worksheet

Respondent ICU MEDICAL, INC. (PCW No. 2 of 2)
Case ID No. 64838
Reg. Ent. Reference No. RN100952860
Media Medical Waste
Violation No. 1

Percent Interest	Years of Depreciation
5.0	15

Item Description	Item Cost	Date Required	Final Date	Yrs	Interest Saved	Costs Saved	EB Amount
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Delayed Costs

Equipment				0.00	\$0	\$0	\$0
Buildings				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Engineering/Construction				0.00	\$0	\$0	\$0
Land				0.00	\$0	n/a	\$0
Record Keeping System				0.00	\$0	n/a	\$0
Training/Sampling				0.00	\$0	n/a	\$0
Remediation/Disposal				0.00	\$0	n/a	\$0
Permit Costs	\$100	20-Aug-2022	12-Dec-2022	0.31	\$2	n/a	\$2
Other (as needed)				0.00	\$0	n/a	\$0
Notes for DELAYED costs Estimated delayed cost to submit notification to the agency at least 90 days prior to on-site treatment of medical waste generated at the on-site nursing unit using two autoclaves. The Date Required is the date the notification was due, and the Final Date is the date of compliance.							

Avoided Costs

ANNUALIZE avoided costs before entering item (except for one-time avoided costs)

Disposal				0.00	\$0	\$0	\$0
Personnel				0.00	\$0	\$0	\$0
Inspection/Reporting/Sampling				0.00	\$0	\$0	\$0
Supplies/Equipment				0.00	\$0	\$0	\$0
Financial Assurance				0.00	\$0	\$0	\$0
ONE-TIME avoided costs				0.00	\$0	\$0	\$0
Other (as needed)				0.00	\$0	\$0	\$0
Notes for AVOIDED costs							

Approx. Cost of Compliance \$100

TOTAL \$2



Compliance History Report

Compliance History Report for CN605758275, RN100952860, Rating Year 2024 which includes Compliance History (CH) components from September 1, 2019, through August 31, 2024.

Customer, Respondent, or Owner/Operator:	CN605758275, ICU MEDICAL, INC.	Classification:	HIGH	Rating:	0.00
Regulated Entity:	RN100952860, ICU MEDICAL	Classification:	HIGH	Rating:	0.00
Complexity Points:	14	Repeat Violator:	NO		
CH Group:	14 - Other				
Location:	3900 HOWARD LANE, AUSTIN, TRAVIS COUNTY, TEXAS 78728-6515				
TCEQ Region:	REGION 11 - AUSTIN				
ID Number(s):					
AIR NEW SOURCE PERMITS	PERMIT 40904	AIR NEW SOURCE PERMITS	ACCOUNT NUMBER TH0174A		
AIR NEW SOURCE PERMITS	AFS NUM 4845300064	AIR NEW SOURCE PERMITS	REGISTRATION 83617		
AIR NEW SOURCE PERMITS	REGISTRATION 132149	EDWARDS AQUIFER	PERMIT 11-00080901		
EDWARDS AQUIFER	PERMIT 11-94072801	EDWARDS AQUIFER	PERMIT 11-96121901		
EDWARDS AQUIFER	PERMIT 11-96121901A	EDWARDS AQUIFER	PERMIT 11-08042801		
EDWARDS AQUIFER	PERMIT 11-11121401	EDWARDS AQUIFER	PERMIT 11-15042801		
EDWARDS AQUIFER	PERMIT 11-15032701	EDWARDS AQUIFER	PERMIT 11001190		
STORMWATER	PERMIT TXR05ES81	WASTEWATER	PERMIT 2E0000235		
AIR EMISSIONS INVENTORY	ACCOUNT NUMBER TH0174A	POLLUTION PREVENTION PLANNING	ID NUMBER P03142		
INDUSTRIAL AND HAZARDOUS WASTE	EPA ID TXD012660999	INDUSTRIAL AND HAZARDOUS WASTE	SOLID WASTE REGISTRATION # (SWR) 34010		
Compliance History Period:	September 01, 2019 to August 31, 2024	Rating Year:	2024	Rating Date:	09/01/2024
Date Compliance History Report Prepared:	May 01, 2025				
Agency Decision Requiring Compliance History:	Enforcement				
Component Period Selected:	May 01, 2020 to May 01, 2025				
TCEQ Staff Member to Contact for Additional Information Regarding This Compliance History.					
Name:	Eresha DeSilva	Phone:	(512) 239-5084		

Site and Owner/Operator History:

- | | |
|--|-----|
| 1) Has the site been in existence and/or operation for the full five year compliance period? | YES |
| 2) Has there been a (known) change in ownership/operator of the site during the compliance period? | NO |

Components (Multimedia) for the Site Are Listed in Sections A - J

A. Final Orders, court judgments, and consent decrees:

N/A

B. Criminal convictions:

N/A

C. Chronic excessive emissions events:

N/A

D. The approval dates of investigations (CCEDS Inv. Track. No.):

Item 1	March 24, 2023	(1894249)
Item 2	March 26, 2024	(1981499)
Item 3	March 14, 2025	(2061039)

E. Written notices of violations (NOV) (CCEDS Inv. Track. No.):

A notice of violation represents a written allegation of a violation of a specific regulatory requirement from the commission to a regulated entity. A notice of violation is not a final enforcement action, nor proof that a violation has actually occurred.

N/A

F. Environmental audits:

N/A

G. Type of environmental management systems (EMSs):

N/A

H. Voluntary on-site compliance assessment dates:

N/A

I. Participation in a voluntary pollution reduction program:

N/A

J. Early compliance:

N/A

Sites Outside of Texas:

N/A

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY



IN THE MATTER OF AN
ENFORCEMENT ACTION
CONCERNING
ICU MEDICAL, INC.
RN100952860

§ BEFORE THE
§ TEXAS COMMISSION ON
§ ENVIRONMENTAL QUALITY
§

AGREED ORDER DOCKET NO. 2023-1500-MLM-E

I. JURISDICTION AND STIPULATIONS

On _____, the Texas Commission on Environmental Quality ("the Commission" or "TCEQ") considered this agreement of the parties, resolving an enforcement action regarding ICU MEDICAL, INC. (the "Respondent") under the authority of TEX. HEALTH & SAFETY CODE ch. 361 and TEX. WATER CODE ch. 7. The Executive Director of the TCEQ, through the Enforcement Division, and the Respondent together stipulate that:

1. The Respondent owns and operates a medical supply manufacturing facility located at 3900 Howard Lane in Austin, Travis County, Texas (the "Facility"). The Facility involves or involved the management of industrial and hazardous waste ("IHW") and municipal solid waste ("MSW") as defined in TEX. HEALTH & SAFETY CODE ch. 361.
2. The Executive Director and the Respondent agree that the TCEQ has jurisdiction to enter this Order pursuant to TEX. WATER CODE §§ 7.002, 7.051, and 7.073, and that the Respondent is subject to TCEQ's jurisdiction. The TCEQ has jurisdiction in this matter pursuant to TEX. WATER CODE § 5.013 because it alleges violations of TEX. HEALTH & SAFETY CODE ch. 361 and the rules of the TCEQ.
3. The occurrence of any violation is in dispute and the entry of this Order shall not constitute an admission by the Respondent of any violation alleged in Section II ("Allegations"), nor of any statute or rule.
4. An administrative penalty in the amount of \$53,413 is assessed by the Commission in settlement of the violations alleged in Section II ("Allegations"). The Respondent paid \$42,731 of the penalty and \$10,682 is deferred contingent upon the Respondent's timely and satisfactory compliance with all the terms of this Order. The deferred amount shall be waived only upon full compliance with all the terms and conditions contained in this Order. If the Respondent fails to timely and satisfactorily comply with any of the terms or requirements contained in this Order, the Executive Director may demand payment of all or part of the deferred penalty amount.
5. The Executive Director and the Respondent agree on a settlement of the matters alleged in this enforcement action, subject to final approval in accordance with 30 TEX. ADMIN. CODE § 70.10(a). Any notice and procedures, which might otherwise be authorized or required in this action, are waived in the interest of a more timely resolution of the matter.

6. The Executive Director may, without further notice or hearing, refer this matter to the Office of the Attorney General of the State of Texas ("OAG") for further enforcement proceedings if the Executive Director determines that the Respondent has not complied with one or more of the terms or conditions in this Order.
7. This Order represents the complete and fully integrated agreement of the parties. The provisions of this Order are deemed severable and, if a court of competent jurisdiction or other appropriate authority deems any provision of this Order unenforceable, the remaining provisions shall be valid and enforceable.
8. This Order shall terminate five years from its effective date or upon compliance with all the terms and conditions set forth in this Order, whichever is later.
9. The Executive Director recognizes that the Respondent implemented the following corrective measures at the Facility:
 - a. In lieu of labeling an approximately 24,000-gallon above ground storage tank ("AST") with the words "Hazardous Waste", the Respondent removed the hazardous waste from the AST on February 27, 2023;
 - b. In lieu of providing secondary containment for the AST, the Respondent removed the hazardous waste from the AST on February 27, 2023;
 - c. Submitted a copy of the Facility's contingency plan to all local emergency responders on December 1, 2022;
 - d. Submitted written notification to the Executive Director for on-site treatment of medical waste on December 12, 2022;
 - e. Submitted complete and accurate waste determination and waste classification documentation for the three waste streams on November 18, 2022; and
 - f. Properly labeled the 5-gallon drum in the laboratory Satellite Accumulation Area ("SAA") on November 18, 2022.

II. ALLEGATIONS

During an investigation at the Facility conducted on November 18, 2022, an investigator documented that the Respondent:

1. Failed to provide secondary containment in order to prevent the release of hazardous waste or hazardous constituents to the environment, in violation of 30 TEX. ADMIN. CODE § 335.112(a)(9) and 40 CODE OF FEDERAL REGULATIONS ("C.F.R.") § 265.193(a). Specifically, approximately 24,000 gallons of hazardous waste was being stored in an AST without secondary containment.
2. Failed to label all tanks that accumulate hazardous waste with the words "Hazardous Waste", in violation of 30 TEX. ADMIN. CODE § 335.53(f) and 40 C.F.R. § 262.17(a)(5)(ii)(A). Specifically, an approximately 24,000-gallon AST was storing hazardous waste and was not labeled with the words "Hazardous Waste."

3. Failed to submit a copy of the contingency plan and all revisions to all local emergency responders, in violation of 30 TEX. ADMIN. CODE § 335.61 and 40 C.F.R. § 262.262(a).
4. Failed to complete closure and remediation obligations of an IHW facility, in violation of 30 TEX. ADMIN. CODE § 335.8(b). Specifically, the Respondent had not satisfied the closure and remediation obligations associated with converting the function of an unregistered approximately 24,000-gallon AST from storing hazardous waste to storing non-hazardous waste.
5. Failed to submit written notification to the Executive Director at least 90 days prior to engaging in on-site treatment of medical waste, in violation of 30 TEX. ADMIN. CODE §§ 326.37(a) and 326.39(a). Specifically, the Respondent had not notified the Executive Director prior to using two autoclave units for the treatment of the medical waste generated at the on-site nursing unit by the August 20, 2022 notification due date.
6. Failed to conduct hazardous waste determinations and waste classifications, in violation of 30 TEX. ADMIN. CODE §§ 335.503(a) and 335.504 and 40 C.F.R. § 262.11. Specifically, inaccurate waste classification documentation was provided for the following waste streams: water contaminated with Bis (2-ethylhexyl) phthalate ("DOP"); demolished process equipment including old poly tanks, piping, and connectors; and Resource Conservation and Recovery Act empty polyethylene drums.
7. Failed to label all hazardous waste containers in SAAs with the words "Hazardous Waste", in violation of 30 TEX. ADMIN. CODE § 335.53(d) and 40 C.F.R. § 262.15(a)(5). Specifically, one 5-gallon drum in a laboratory SAA was observed without a hazardous waste label.

III. DENIALS

The Respondent generally denies each allegation in Section II ("Allegations").

IV. ORDERING PROVISIONS

NOW, THEREFORE, THE TEXAS COMMISSION ON ENVIRONMENTAL QUALITY ORDERS that:

1. The Respondent is assessed a penalty as set forth in Section I, Paragraph No. 4. The payment of this penalty and the Respondent's compliance with all of the requirements set forth in this Order resolve only the allegations in Section II. The Commission shall not be constrained in any manner from requiring corrective action or penalties for violations which are not raised here. Penalty payments shall be made payable to "TCEQ" and shall be sent with the notation "Re: ICU MEDICAL, INC., Docket No. 2023-1500-MLM-E" to:

Financial Administration Division, Revenue Operations Section
Attention: Cashier's Office, MC 214
Texas Commission on Environmental Quality
P.O. Box 13088
Austin, Texas 78711-3088

2. The Respondent shall undertake the following technical requirements:

- a. Within 120 days after the effective date of this Order, properly complete all closure and remediation obligations regarding the unregistered 24,000-gallon AST previously storing hazardous waste, in accordance with 30 TEX. ADMIN. CODE § 335.8.
- b. Within 180 days after the effective date of this Order, prepare and submit a closure report demonstrating proper closure of the unregistered 24,000-gallon AST previously storing hazardous waste, in accordance with 30 TEX. ADMIN. CODE § 335.8 to:

Remediation Division, MC127
Texas Commission on Environmental Quality
P.O. Box 13087
Austin, Texas 78711-3087

- c. Within 195 days after the effective date of this Order, submit written certification, and include detailed supporting documentation including photographs, receipts, and/or other records to demonstrate compliance with Ordering Provision Nos. 2.a and 2.b. The certification shall be signed by the Respondent and shall include the following certification language:

"I certify under penalty of law that I have personally examined and am familiar with the information submitted and all attached documents, and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations."

The certification shall be submitted to:

Enforcement Division, MC 149A
Texas Commission on Environmental Quality
P.O. Box 13087
Austin, Texas 78711-3087

with a copy to:

Waste Section Manager
Austin Regional Office
Texas Commission on Environmental Quality
P.O. Box 13087
Austin, Texas 78711-3087

3. All relief not expressly granted in this Order is denied.
4. The duties and provisions imposed by this Order shall apply to and be binding upon the Respondent. The Respondent is ordered to give notice of this Order to personnel who maintain day-to-day control over the Facility operations referenced in this Order.

5. The Executive Director may grant an extension of any deadline in this Order or in any plan, report, or other document submitted pursuant to this Order, upon a written and substantiated showing of good cause. All requests for extensions by the Respondent shall be made in writing to the Executive Director. Extensions are not effective until the Respondent receives written approval from the Executive Director. The determination of what constitutes good cause rests solely with the Executive Director. Extension requests shall be sent to the Enforcement Division at the address listed above.
6. This Order, issued by the Commission, shall not be admissible against the Respondent in a civil proceeding, unless the proceeding is brought by the OAG to: (1) enforce the terms of this Order; or (2) pursue violations of a statute within the Commission's jurisdiction, or of a rule adopted or an order or permit issued by the Commission under such a statute.
7. This Order may be executed in separate and multiple counterparts, which together shall constitute a single instrument. Any page of this Order may be copied, scanned, digitized, converted to electronic portable document format ("pdf"), or otherwise reproduced and may be transmitted by digital or electronic transmission, including but not limited to facsimile transmission and electronic mail. Any signature affixed to this Order shall constitute an original signature for all purposes and may be used, filed, substituted, or issued for any purpose for which an original signature could be used. The term "signature" shall include manual signatures and true and accurate reproductions of manual signatures created, executed, endorsed, adopted, or authorized by the person or persons to whom the signatures are attributable. Signatures may be copied or reproduced digitally, electronically, by photocopying, engraving, imprinting, lithographing, electronic mail, facsimile transmission, stamping, or any other means or process which the Executive Director deems acceptable. In this paragraph exclusively, the terms: electronic transmission, owner, person, writing, and written, shall have the meanings assigned to them under TEX. BUS. ORG. CODE § 1.002.
8. The effective date of this Order is the date it is signed by the Commission. A copy of this fully executed Order shall be provided to each of the parties.

SIGNATURE PAGE

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

For the Commission

Date

Krista Mello-Jurack

09/07/2025

For the Executive Director

Date

I, the undersigned, have read and understand the attached Order. I am authorized to agree to the attached Order, and I do agree to the terms and conditions specified therein. I further acknowledge that the TCEQ, in accepting payment for the penalty amount, is materially relying on such representation.

I also understand that failure to comply with the Ordering Provisions, if any, in this Order and/or failure to timely pay the penalty amount, may result in:

- A negative impact on compliance history;
- Greater scrutiny of any permit applications submitted;
- Referral of this case to the OAG for contempt, injunctive relief, additional penalties, and/or attorney fees, or to a collection agency;
- Increased penalties in any future enforcement actions;
- Automatic referral to the OAG of any future enforcement actions; and
- TCEQ seeking other relief as authorized by law.

In addition, any falsification of any compliance documents may result in criminal prosecution.

Brian M. Bonnell

6/9/2025

Signature

Date

Brian Michael Bonnell

CFO

Name (Printed or typed)

Title

Authorized Representative of
ICU MEDICAL, INC.

☐ If mailing address has changed, please check this box and provide the new address below:

Instructions: Send the original, signed Order with penalty payment to the Financial Administration Division, Revenue Operations Section at the address in Ordering Provision 1 of this Order.