

Information Bulletin – March 27, 2008

National Emissions Standards for Hospital Ethylene Oxide Sterilizers EPA Final Rule 40 CFR 63, Subpart W W W W W Federal Register, Volume 72, No. 248, December 28, 2007 pp.73611- 73625

SUMMARY:

Hospital Central Service Managers should find that compliance with the EPA emissions control rule is consistent with sterilizer recordkeeping standards set forth by ANSI/AAMI.¹ Hospitals may comply with the EPA's new rule in one of two ways:

1. The hospital may install an ethylene oxide emission control device and operate it in accordance with state or local regulations, as well as the manufacturer's recommended procedures. This is already practiced by hospitals in localities that mandate control of ethylene oxide emissions.

OR

2. By a management practice to run fully loaded ethylene oxide sterilizers. However, hospitals may run a partially loaded sterilizer in "medically necessary circumstances" to protect patient health (e.g. to meet surgical schedules). The Central Service Manager or the sterilizer technician must note on the record for each sterilizer cycle whether the sterilizer has been run with a full load or not, and note that it was medically necessary when the sterilizer has been run with a partial load.

The Rule stipulates by what dates the hospital must comply. Compliance is demonstrated by providing the EPA and the local authorities, as appropriate, with an Initial Notice of Compliance Status [INOCs]; and by keeping sterilizer records for up to five years, of which two years must be onsite.

In the EPA INOCs form, hospitals will need to state the annual amount of ethylene oxide used [Line 4] of the Form]. Attached for your convenience are tables that will help Oxyfume® sterilant users determine the amount of ethylene oxide used.

NOTE: As of 12-31-2007, most hospitals use Oxyfume 2002, not Oxyfume 2000, sterilant gas.

¹ Association for the Advancement of Medical Instrumentation. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*. ANSI/AAMI ST41:1999. Arlington, VA: AAMI, 1999. American National Standard. p. 34, 7.2.2 Sterilizer records.

IMPORTANT NOTICE: This communication is provided for informational purposes only and is not intended and should not be construed as legal or compliance advice. Readers should not treat this summary as a substitute for reading the regulation adopted by the U.S. Environmental Protection Agency and are encouraged to consult with legal or regulatory advisors concerning their particular circumstances and questions of compliance.

Use this table to determine the Total Actual Annual Ethylene Oxide Usage at your facility. Report the number of lbs. on line 4 of the form for Initial Notification Compliance Status as required for 40 CFR 63 subpart W W W W W

**Total Actual Annual Ethylene Oxide Usage
for facilities that use: Oxyfume® 2002 Sterilant Gas**

Number of Cylinders Used Each Year.	Pounds, (Lbs.) EO Used Each Year	Number of Cylinders Used Each Year.	Pounds, (Lbs.) EO Used Each Year	Number of Cylinders Used Each Year.	Pounds, (Lbs.) EO Used Each Year
1	14	26	351	51	689
2	27	27	365	52	702
3	41	28	378	53	716
4	54	29	392	54	729
5	68	30	405	55	743
6	81	31	419	56	756
7	95	32	432	57	770
8	108	33	446	58	783
9	122	34	459	59	797
10	135	35	473	60	810
11	149	36	486	61	824
12	162	37	500	62	837
13	176	38	513	63	851
14	189	39	527	64	864
15	203	40	540	65	878
16	216	41	554	66	891
17	230	42	567	67	905
18	243	43	581	68	918
19	257	44	594	69	932
20	270	45	608	70	945
21	284	46	621	71	959
22	297	47	635	72	972
23	311	48	648	73	986
24	324	49	662	74	999
25	338	50	675	75	1,013

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**Total Actual Annual Ethylene Oxide Usage
for facilities that use: Oxyfume® 2000 Sterilant Gas**

Number of Cylinders Used Each Year.	Pounds, (Lbs.) EO Used Each Year	Number of Cylinders Used Each Year.	Pounds, (Lbs.) EO Used Each Year	Number of Cylinders Used Each Year.	Pounds, (Lbs.) EO Used Each Year
1	12	26	302	51	592
2	23	27	313	52	603
3	35	28	325	53	615
4	46	29	336	54	626
5	58	30	348	55	638
6	70	31	360	56	650
7	81	32	371	57	661
8	93	33	383	58	673
9	104	34	394	59	684
10	116	35	406	60	696
11	128	36	418	61	708
12	139	37	429	62	719
13	151	38	441	63	731
14	162	39	452	64	742
15	174	40	464	65	754
16	186	41	476	66	766
17	197	42	487	67	777
18	209	43	499	68	789
19	220	44	510	69	800
20	232	45	522	70	812
21	244	46	534	71	824
22	255	47	545	72	835
23	267	48	557	73	847
24	278	49	568	74	858
25	290	50	580	75	870

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