

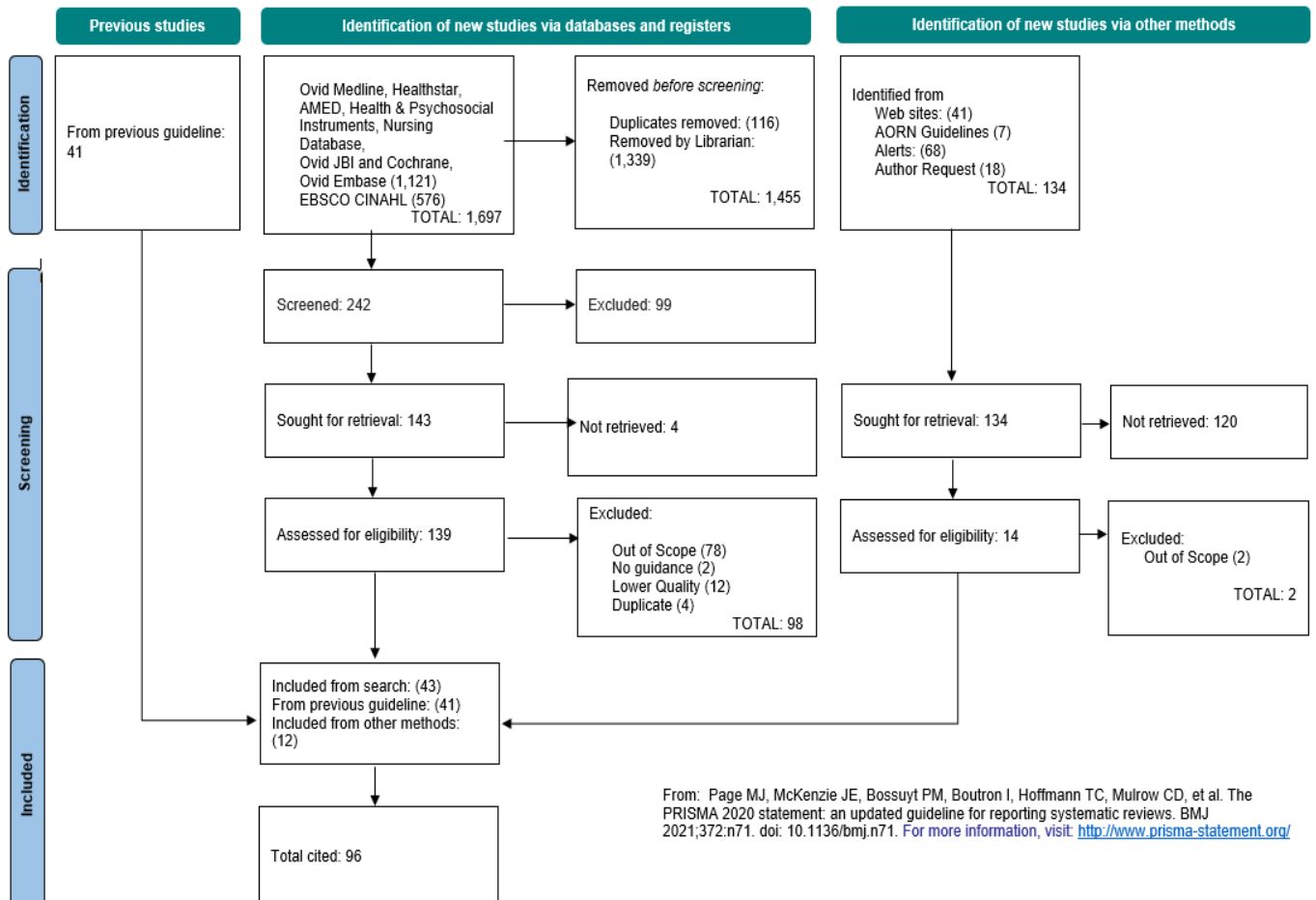
### EVIDENCE REVIEW

The Guideline for Sterilization Packaging Systems was approved by the AORN Guidelines Advisory Board and became effective November 21, 2024.

A medical librarian with a perioperative background conducted a systematic search of the databases Ovid MEDLINE®, Ovid Embase®, EBSCO CINAHL®, and the Cochrane Database of Systematic Reviews. The search was limited to literature published in English from January, 2018 through August, 2023. At the time of the initial search, weekly alerts were created on the topics included in that search. Results from these alerts were provided to the lead author until March, 2024. The lead author requested additional articles that either did not fit the original search criteria or were discovered during the evidence appraisal process. The lead author and the medical librarian also identified relevant guidelines from government agencies, professional organizations, and standards-setting bodies.

Included were research and non-research literature in English, complete publications, and publications with dates within the time restriction when available. Historical studies were also included. Excluded were non-peer-reviewed publications and older evidence within the time restriction when more recent evidence was available. Editorials, news items, and other brief items were excluded. Low-quality evidence was excluded when higher-quality evidence was available, and literature outside the time restriction was excluded when literature within the time restriction was available. Articles identified in the search were provided to the project team for evaluation. The team consisted of the lead author and one evidence appraiser. The lead author and the evidence appraiser reviewed and critically appraised each article using the AORN Research or Non-Research Evidence Appraisal Tools as appropriate. A third appraiser was consulted if there was a disagreement between the lead author and the primary evidence appraiser. The literature was independently evaluated and appraised according to the strength and quality of the evidence. Each article was then assigned an appraisal score. The appraisal score is noted in brackets after each reference as applicable. Each recommendation rating is based on a synthesis of the collective evidence, a benefit-harm assessment, and consideration of resource use. The strength of the recommendation was determined using the AORN Evidence Rating Model and the quality and consistency of the evidence supporting a recommendation. The recommendation strength rating is noted in brackets after each recommendation. See the PRISMA 2020 flow diagram (Figure 1) below for more information about the systematic review and nature of included studies and resources.

**Figure 1: PRISMA 2020 Flow Diagram**



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: <http://www.prisma-statement.org/>

On August 21, 2023, a medical librarian with a perioperative background conducted searches for relevant publications on websites of organizations selected by the author (including government departments). Full details of these supplementary searches is included in the Supplementary Content on the aorn.org web site. These results were also screened by two screeners: the medical librarian, and then the lead author.

On August 17, 2023, a medical librarian with a perioperative background conducted a systematic search of 18 health science databases, the names and date coverage of which are given in Table 1. These results were screened by the medical librarian, and then the lead author.

Table 1: Databases searched and coverage

Database	Coverage
AORN Full Text Journals@Ovid	
Books@Ovid	August 14, 2023
JBI EBP Database	Current to August 09, 2023
EBM Reviews: ACP Journal Club	1991 to July 2023
EBM Reviews: Cochrane Central Register of Controlled Trials	July 2023
EBM Reviews: Cochrane Database of Systematic Reviews	2005 to August 16, 2023
EBM Reviews: Cochrane Clinical Answers	July 2023
EBM Reviews: Cochrane Methodology Register	3rd Quarter 2012
EBM Reviews: Database of Abstracts of Reviews of Effects	1st Quarter 2016
EBM Reviews: Health Technology Assessment	4th Quarter 2016
EBM Reviews: NHS Economic Evaluation Database	1st Quarter 2016
AMED (Allied and Complementary Medicine)	1985 to August 2023
Embase	1974 to 2023 August 16
Health and Psychosocial Instruments	1985 to July 2023
Ovid Healthstar	1902 to 1998, 1999 to June 2023
Ovid MEDLINE(R) ALL	1946 to August 16, 2023
Ovid Nursing Database	1946 to August Week 2 2023
CINAHL Complete via EBSCOhost	1937 to Current

Search strategy development process: The medical librarian referred to a search strategy used for the previous Guideline. A draft search strategy was developed using terms listed in the previous strategy and additional search terms identified from a meeting with the lead author. Using the MeSH Subject Headings database, additional search terms were identified and added to the search strategy. The strategy was limited following the constraints in the eligibility criteria outlined by the lead author.

**Editor's note:** MEDLINE is a registered trademark of the US National Library of Medicine's Medical Literature Analysis and Retrieval System, Bethesda, MD. Embase is a registered trademark of Elsevier B.V., Amsterdam, The Netherlands. CINAHL, Cumulative Index to Nursing and Allied Health Literature, is a registered trademark of EBSCO Industries, Birmingham, AL.

#### Search Strategies

Ovid (Medline, Cochrane, and Embase)

31	remove duplicates from 30	1170
30	limit 29 to primary source	2151
29	limit 28 to original articles	2151
28	limit 27 to humans	2151
27	limit 26 to yr="2018 -Current"	2151
26	limit 25 to medline records	10892
25	limit 24 to human	10899
24	limit 23 to english language	16059
23	limit 22 to embase records	19037
22	limit 21 to cochrane library	19259
21	3 or 5 or 13 or 16 or 17 or 20	19887
20	18 and 19	585
19	6 or 9	382510
18	Prions/ai, ip, st or exp Prion diseases/ or ("Transmissible dementias" or "Transmissible Spongiform Encephalopathies" or "Prion Protein Diseases" or "Prion-Associated Disorders" or "Prion-Induced Disorder").ti,ab,kw.	50954
17	Phacoemulsification/ae, is, st, sn and ("Toxic anterior segment syndrome" or "TASS").ti,ab,kw.	26
16	14 and 15	324
15	6 or 8 or 10	173999
14	(burns or scald\$ or "thermal injury").ti,ab,kw.	135650
13	6 and 12	10566
12	7 or 8 or 9 or 10 or 11	5445527
11	exp "quality assurance, health care"/ or ("clinical quality measures" or "sterility assurance levels" or "user validation" or "process challenge" or "quality assurance testing").ti,ab,kw. or (sterilization adj1 (efficacy or monitoring or quality)).ti,ab,kw. or ((performance or operational or installation) and qualification).ti,ab,kw.	5049160
10	(steris or sterrad or medivator).ab,dm,mf. or ("tabletop sterilizer" or autoclave or "vacuum sterilizer" or (reconcil\$ and "conflicting manufacturer instructions") or ((biological or chemical) and in\$ator)).ti,ab,kw. or "reagent strips".de,sh,hw. or "indicators and reagents".de,sh,hw.	94202

9	("ethylene oxide" or "peracetic acid" or steam or "hydrogen peroxide" or ozone).de,sh,hw. or ("hydrogen peroxide" and (vapo* or gas or "gas plasma")).ti,ab,kw. or "liquid chemical sterilants".ti,ab,kw. or "disinfectant agent".ti,ab,kw.	308570
8	("immediate use" and (flash or steam) and steriliz\$) or "wet tray" or IUSS).ti,ab,kw.	461
7	((("sterilizer load" and (weight or configuration)) or ((load\$ and sterilizer) or "mixed loads") or "load release").ti,ab,kw.	451
6	((sterilization and (modalities or parameters or cycle)) or (("sterile processing" or "instrument processing" or "central services") and department) or ((moist or dry or wet) and heat) or ("gravity displacement" or "dynamic air cycles" or prevacuum or "steam flush pressure pulse" or "satellite processing" or "sterilization and disinfection" or "terminal sterilization")).ti,ab,kw. or exp sterilization/ or sterilization/mt, st or "instrument sterilization".ti,ab,kw.	81120
5	1 and 4	1228
4	exp "Health Disparate, Minority and Vulnerable Populations"/ or ("medically underserved area".mp. or "social determinants of health".de,sh,hw.) or ("medically underserved population" or "Minority Populations").ti,ab,kw.	266463
3	1 and 2	7506
2	"surgical instruments".de,sh,hw. or "surgical instruments"/mi, vi, st, sn	42424
1	("Bacterial adhesion" or biomaterial or Biofouling or bioburden).ti,ab,kw. or exp "Postoperative Complications"/ or exp "Intraoperative Complications"/ or exp "equipment contamination"/ or exp biofilms/	

EBSCOhost (CINAHL)

S22	S3 OR S5 OR S13 OR S16 OR S17 OR S20 Limiters - Publication Date: 20180101-20230831; English Language; Peer Reviewed; Exclude MEDLINE records; [Include] Human	596
S21	S3 OR S5 OR S13 OR S16 OR S17 OR S20	7,575
S20	S18 AND S19	153
S19	S6 OR S9	18,673
S18	( (MH "Prion Diseases+") OR (MH "Prions/AI/ST/AE") ) OR "Transmissible dementias" OR "Transmissible Spongiform Encephalopathies" OR "Prion Protein Diseases" OR "Prion-Associated Disorders" OR "Prion-Induced Disorder"	2,195
S17	(MH "Phacoemulsification/AE/ST/SN") OR "Toxic anterior segment syndrome" OR "TASS"	440

S16	S14 AND S15	2,984
S15	S6 OR S8 OR S10	291,492
S14	burns OR scald* OR "thermal injury"	36,982
S13	S6 AND S12	3,554
S12	S7 OR S8 OR S9 OR S10 OR S11	1,202,288
S11	(MH "Quality of Health Care+") OR "clinical quality measures" OR "sterility assurance levels" OR "user validation" OR "process challenge" OR "quality assurance testing" OR ( sterilization N1 (efficacy or monitoring or quality) ) OR ( (performance or operational or installation) and qualification )	948,027
S10	( (MH "Indicators and Reagents") OR (MH "Reagent Strips") ) OR AB ( steris or sterrad or medivator ) OR ( "tabletop sterilizer" or autoclave or "vacuum sterilizer" ) OR ( (reconcil* and "conflicting manufacturer instructions") ) OR ( (biological or chemical) and in*ator )	278,600
S9	( (MH "Ethylene Oxide") OR (MH "Hydrogen Peroxide") ) OR ozone OR "peracetic acid" OR ( "hydrogen peroxide" and (vapo* or gas or "gas plasma") ) OR "liquid chemical sterilants" OR "disinfectant agent"	5,322
S8	("immediate use" and (flash or steam) and steriliz*) or "wet tray" or IUSS	76
S7	( "sterilizer load" and (weight or configuration) ) OR ( (load\$ and sterilizer) or "mixed loads" ) OR "load release"	40
S6	( (MM "Sterilization and Disinfection+") ) OR "instrument sterilization" OR ( sterilization and (modalities or parameters or cycle) ) OR ( ("sterile processing" or "instrument processing" or "central services") and department ) OR ( (moist or dry or wet) and heat ) OR ( "gravity displacement" or "dynamic air cycles" or prevacuum or "steam flush pressure pulse" or "satellite processing" or "sterilization and disinfection" or "terminal sterilization" )	13,959
S5	S1 AND S4	119
S4	( (MH "Medically Underserved Area") OR (MH "Social Determinants of Health") OR (MH "Healthcare Disparities") ) OR ( medically underserved population" or "Minority Populations" )	33,539
S3	S1 AND S2	439
S2	(MM "Surgical Instruments")	2,260

S1 ( (MH "Postoperative Complications+") OR (MH "Intraoperative Complications+") ) OR "equipment contamination" OR ( biofilms OR "Bacterial adhesion" or biomaterial or Biofouling or bioburden ) 164,808

Web Searches// All searches conducted in 2023

9/1: Not in early retrievals; unable to find on current FDA site. Moved to rejected per AW teams message.

8/29: 1] Searched google.com for OSHA. 2] Chose first result after seeing it spelled out correctly. 3] In "Topics" drop down menu, chose "Healthcare" under the "By Sector" heading. 4] Scrolled to "Other Hazards" box, and clicked "More". 5] Under "Chemicals" heading, chose result, saved for author screening. (x4)

8/29: 1] Searched google.com for OSHA. 2] Chose first result after seeing it spelled out correctly. 3] In "Topics" drop down menu, chose "Healthcare" under the "By Sector" heading. 4] Scrolled to "Other Hazards" box, and clicked "More". 5] Under "Chemicals" heading, chose "29 CFR 1910.1047." 6] Clicked link for "eCFR". 7] Saved for author screening. (Clicked "Published edition" as saved resource.)

8/29: 1] Searched google.com for OSHA. 2] Chose first result after seeing it spelled out correctly. 3] In "Topics" drop down menu, chose "Healthcare" under the "By Sector" heading. 4] Scrolled to "Other Hazards" box, and clicked "More". 5] Under "Chemicals" heading, chose "Hospitals", which brought me to OSHA's "Hospitals eTool". 6] Under "Modules" drop down menu, chose "Surgical Suite." 7] Followed link for "peracetic acid" in first paragraph, which brought me to an entry in the "Occupational Chemical Database." 8] Saved for author screening.

8/25: 1] Searched google.com for NIOSH. 2] Chose first result after seeing it's from the CDC. 3] Scrolled to "Workplace Safety and Health Topics" heading and chose "Chemicals" subheading. 4] Browsed alphabetical list of results 5] Chose result, saved for author screening.

8/25: 1] Searched google.com for NIOSH. 2] Chose first result after seeing it's from the CDC. 3] Scrolled to "Workplace Safety and Health Topics" heading and chose "Chemicals" subheading. 4] Browsed alphabetical list of results 5] Under "Related NIOSH Resources" heading, chose "Search for ethylene oxide." 6] Browsed results 7] Chose result, saved for author screening. (x2)

8/24: 1] Searched google.com for NIOSH. 2] Chose first result after seeing it's from the CDC. 3] Scrolled to "Workplace Safety and Health Topics" heading and chose "Chemicals" subheading. 4] Browsed alphabetical list of results 5] Chose result, saved for author screening.

8/24: 1] Searched google.com for NIOSH. 2] Chose first result after seeing it's from the CDC. 3] Scrolled to "Workplace Safety and Health Topics" heading and chose "Chemicals" subheading. 4] Browsed alphabetical list of results 5] Chose "Glutaraldehyde", browsed additional resources, saved for author screening. (x2)

8/24: 1] Searched google.com for NIOSH. 2] Chose first result after seeing it's from the CDC. 3] Scrolled to "Workplace Safety and Health Topics" heading and chose "Chemicals" subheading. 4] Browsed alphabetical list of results 5] Under "Selected Publications" heading, chose "NIOSHTIC-2 search results on Glutaraldehyde." 6] Browsed results 7] Chose result, saved for author screening.

8/24: 1] Searched google.com for NIOSH. 2] Chose first result after seeing it's from the CDC. 3] Scrolled to "Workplace Safety and Health Topics" heading and chose "Chemicals" subheading. 4] Browsed alphabetical list of results 5] Under "Related NIOSH Resources" heading, chose "NIOSHTIC-2 search results for hydrogen peroxide." 6] Browsed results 7] Chose result, saved for author screening. (x3)

8/24: 1] Searched google.com for NIOSH. 2] Chose first result after seeing it's from the CDC. 3] Scrolled to "Workplace Safety and Health Topics" heading and chose "Chemicals" subheading. 4] Browsed alphabetical list of results 5] Under "Related NIOSH Resources" heading, chose "NIOSHTIC-2 search results on Glutaraldehyde." 6] Browsed results 7] Chose result, saved for author screening. (x9)

8/24: 1] Searched google.com for ATSDR. 2] Chose first result after seeing it's from the CDC. 3] Saved for author screening.

8/24: 1] Searched google.com for ATSDR. 2] Chose first result after seeing it's from the CDC. 3] Scrolled to "Toxicological Profiles" box 4] Scrolled to "A-Z Index of Tox Profiles" 5] Chose result, saved for author screening. (x2)

8/24: 1] Searched google.com for ATSDR. 2] Chose first result after seeing it's from the CDC. 3] Scrolled to "Toxic Substances Portal" box 4] Scrolled to "Toxicological and Health Professionals" box 5] Under heading for "Resources for Toxicological and Health Professionals", chose "Minimal Risk Levels (MRL)" 6] Under heading for "Minimal Risk Levels (MRLs) – For Professionals", chose "List of ATSDR MRLs." 7] Chose result, saved for author screening.

8/21: From google.com, navigated to epa.gov. 2] From Laws & Regulations drop-down menu, chose "Guidance." 3] Chose "A-Z Web Topics Published." 4] Browsed to result, saved for author screening. (x4)

8/21: From google.com, navigated to epa.gov. 2] From Laws & Regulations drop-down menu, chose "By Business Sector." 3] From the "Find more Sectors" list on the right, chose "Healthcare & Social Assistance (NAICS 62)." 4] Scrolled to "Medical Waste"; saved for author screening. (x2)

8/21: Searched google.com for "sterilization site:epa.gov". 2] chose second option from results. 3] Saved result for author screening. (x2)

8/21: Used google.com to search for "iarc"; chose first result for International Agency for Research on Cancer, and within that, the subheading for "Monographs." 2] Scrolled down to "View List of Monographs." 3] Browsed results. 4] Saved result for author review.

8/21: Used google.com to search for "iarc"; chose first result for International Agency for Research on Cancer, and within that, the subheading for "Monographs." 2] Scrolled down to "View List of Monographs." 3] At the top of the page, in "Look for..." I entered "hydrogen peroxide." 4] Saved result for author review.

8/21: Used google.com to search for "iarc"; chose first result for International Agency for Research on Cancer, and within that, the subheading for "Monographs." 2] Scrolled down to "View List of Monographs." 3] At the top of the page, in "Look for..." I entered "ethylene oxide." 4] Saved result for author review.

## PUBLICATION HISTORY

- Originally published February 1983, AORN Journal.
- Revised November 1988, February 1992.
- Revised November 1995; published May 1996, AORN Journal.
- Revised and reformatted; published December 2000, AORN Journal.
- Revised 2006; published in Standards, Recommended Practices, and Guidelines, 2007 edition.
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- Revised September 2013 for online publication in Perioperative Standards and Recommended Practices.
- Minor editing revisions made in November 2014 for publication in Guidelines for Perioperative Practice, 2015 edition.
- Evidence ratings revised in Guidelines for Perioperative Practice, 2018 edition, to conform to the current AORN Evidence Rating Model.
- Revised 2019 for online publication in Guidelines for Perioperative Practice.
- Revised 2024 for online publication in Guidelines for Perioperative Practice.
- **Scheduled for review: 2029.**