PETITION

Petition to Add Need Determination for One Heart-Lung Bypass Machine in Mecklenburg County

Petitioner

Atrium Health, Inc.
1000 Blythe Boulevard
Charlotte, North Carolina 28203

Greg Bass
Director, Core Market Growth and Business Development
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Statement of Requested Adjustment

Atrium Health, Inc. (Atrium), part of Advocate Health, respectfully petitions the State Health Coordinating Council (SHCC) to add a need for an additional heart-lung bypass machine in Mecklenburg County to the 2026 State Medical Facilities Plan (SMFP).

Lack of Methodology for Heart Lung Bypass Machines

The SMFP does not currently have a methodology to calculate the need for additional machines in a service area. In the 2012 SMFP the need methodology was removed from the Plan and the following section was included to explain the change.

> Notice Regarding Heart-Lung Bypass Machines
>
> Prior to the North Carolina 2012 State Medical Facilities Plan, a section detailing the heart-lung bypass machine need determination methodology and its results for the year followed the open-heart surgery services section. In 2011, the State Health Coordinating Council recommended removal of the heart-lung bypass machine need determination methodology. The primary reason for creating the need determination methodology for heart-lung bypass equipment was to control the expansion of open-heart surgery programs. When the North Carolina certificate of need statute was amended in 1993 to include open-heart surgery programs, there was no requirement to obtain a certificate of need for new operating rooms. Limiting the number of heart-lung bypass machines was determined to be the most effective means of controlling open-heart surgery expansions; however, since 2000, the number of adult open-heart surgeries has dropped steadily. At the same time that open-heart surgery procedures declined, the use of heart-lung bypass machines for other procedures increased across the state. Other procedures include organ transplants, stent repairs, trauma resuscitations, and pacemaker implants. Also, a certificate of need now is required for new operating rooms.
>
> Because limiting the number of heart-lung bypass machines is no longer necessary to control unneeded growth in open-heart surgery programs, and since the machines are used for procedures other than open-heart surgery, the need determination methodology for heart-lung bypass machines has been taken out of the State Medical Facilities Plan. Heart-lung bypass machines are still regulated by the certificate of need statutes, and acquisition of a new or replacement heart-lung bypass machine must be reviewed by the Certificate of Need Section.

In the 2023 SMFP the following language was added regarding the need to file a petition to add a need for an additional heart-lung bypass machine prior to filing a CON application.

The SMFP also does not have a methodology to project need for additional heart-lung bypass machines. Facilities that would like to acquire machines other than a second one for emergency coverage as set forth in Policy AC-6 must submit a summer petition. If the need determination is approved, CON applications submitted for these machines will be subject to the performance standards established in 10A NCAC 14C .1703.

Reasons for the Requested Change

Atrium believes a need determination for an additional heart-lung bypass machine for Mecklenburg County is demonstrated based on the following five factors:

I. Population growth trends
II. Growth in open heart surgery procedures
III. Correction to Atrium Health Pineville (AH Pineville) heart-lung bypass machine inventory
IV. Backup requirements for heart-lung bypass machines
V. Growth in procedures other than traditional open heart surgery that utilize heart-lung bypass machines.

Each of these factors is explained in more detail below to support the need for additional heart-lung bypass machine capacity.

I. Population Growth

Mecklenburg County has been experiencing rapid population growth over the last several years. According to population counts and estimates from the North Carolina Office of State Budget and Management (NCOSBM), population growth in Mecklenburg County over the past five years has been significant with a growth rate of 7.1 percent. The annual growth is forecasted to increase to 8.0 percent between 2025 and 2030 and 7.5 percent between 2030 and 2035.

County	2020	2025	2030	2035
Mecklenburg	1,118,967	1,198,460	1,293,761	1,390,256
% Change		7.1%	8.0%	7.5%

Source: North Carolina Office of State Budget and Management

This level of forecasted growth places Mecklenburg County as the twentieth fastest growing county from 2020 to 2025 and the twelfth fastest growing county for the 2025-2030 and 2030-2035 time periods.

II. Growth in Open Heart Surgery Procedures

Statewide there has been minimal growth in open heart surgeries over the last few years. The table below from the Proposed 2026 SMFP shows the total statewide procedures in 2024 were 10,226, which was a decrease of 1.7 percent from the prior year after an increase in 2023 of 8.0 percent. The statewide total is still lower than the pre-pandemic level of 10,454 procedures in 2019.

License	Facility	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	23-24 % Change
H0031	Atrium Health Cabarrus	214	233	237	245	218	253	235	273	194	239	183	195	337	324	-3.9%
H0042	Atrium Health Pineville	0	132	201	245	186	207	252	225	234	158	159	270	344	425	23.5%
H0011	Atrium Health Wake Forest Baptist	621	612	609	692	696	678	689	758	942	789	866	840	925	825	-10.8%
H0213	Cape Fear Valley Medical Center	233	202	220	218	277	262	292	238	195	162	152	124	139	150	7.9%
H0201	CarolinaEast Medical Center	227	236	202	169	208	221	248	256	331	219	224	222	255	280	9.8%
H0071	Carolinas Medical Center	675	704	820	715	788	818	869	682	751	580	729	777	803	876	9.1%
H0105	CaroMont Regional Medical Center	128	207	230	265	249	260	230	278	240	275	308	268	283	256	-9.5%
H0159	Cone Health	472	471	544	541	485	440	547	627	673	574	405	601	546	420	-23.1%
H0233	Duke Regional Hospital	66	60	75	82	92	124	98	148	151	107	119	97	91	0	-100.0%
H0015	Duke University Hospital	1,013	1,062	1,047	1,066	1,161	1,180	1,095	1,130	1,175	1,090	1,203	1,259	1,286	1,388	7.9%
H0104	ECU Health Medical Center	814	900	842	853	601	677	654	675	767	626	787	805	865	856	-1.0%
H0100	FirstHealth Moore Regional Hospital	293	261	271	329	395	341	351	288	276	235	246	234	228	214	-6.1%
H0053	Frye Regional Medical Center	196	253	246	194	205	239	232	222	172	126	117	177	207	191	-7.7%
H0052	High Point Regional Health System	184	191	150	137	111	111	129	112	123	176	53	19	30	73	143.3%
H0036	Mission Hospital	798	813	848	988	874	950	962	939	1,198	1,051	1,421	1,099	1,254	965	-23.0%
H0221	New Hanover Regional Medical Center	464	473	538	487	486	494	482	480	466	395	378	433	466	375	-19.5%
H0209	Novant Health Forsyth Medical Center	568	514	587	691	626	652	580	635	506	380	442	436	500	512	2.4%
H0010	Novant Health Presbyterian Medical Center	378	381	355	360	391	391	397	406	413	339	434	360	450	500	11.1%
H0065	Rex Hospital	203	346	347	369	460	536	612	602	558	553	567	520	490	550	12.2%
H0064	Southeastern Regional Medical Center	54	52	42	34	44	42	39	44	78	81	56	53	43	41	-4.7%
H0157	University of North Carolina Hospitals	350	391	441	390	407	384	445	430	465	332	354	351	339	451	33.0%
H0199	WakeMed	756	553	499	557	607	554	567	512	546	524	498	487	519	554	6.7%
Total Procedures		8,707	9,047	9,351	9,627	9,567	9,814	10,005	9,960	10,454	9,011	9,701	9,627	10,400	10,226	-1.7%

Annual % Change		3.9%	3.4%	3.0%	-0.6%	2.6%	1.9%	-0.4%	5.0%	-13.8%	7.7%	-0.8%	8.0%	-1.7%

In contrast, Mecklenburg County has been experiencing much higher growth than the state. The table below shows the county experienced a 12.8 percent growth rate in 2024 and a compound annual growth rate of 10.9 percent since 2021. The Mecklenburg County total open heart surgery volume reached 1,597 cases in 2023, the highest volume in the last 20 years, and then grew to 1,801 cases in 2024.

License	Facility	2019	2020	2021	2022	2023	2024	23-24 % Change	21-24 CAGR
H0042	Atrium Health Pineville	234	158	159	270	344	425	23.5%	38.8%
H0071	Carolinas Medical Center	751	580	729	777	803	876	9.1%	6.3%
H0010	Novant Health Presbyterian Medical Center	413	339	434	360	450	500	11.1%	4.8%
Total Procedures		1,398	1,077	1,322	1,407	1,597	1,801	12.8%	10.9%

Mecklenburg County Annual % Change		-23.0%	22.7%	6.4%	13.5%	12.8%

This high growth creates operational challenges for Atrium's facilities in dealing with increasing complexity of cases, higher acuity patients and longer case times.

III. Correction to Atrium Health Pineville Heart-lung Bypass Machine Inventory.

Atrium operates nine heart-lung bypass machines in Mecklenburg County facilities. During the preparation of this petition, we discovered the heart-lung bypass machines were incorrectly reported on the 2025 Hospital License Renewal Application for AH Pineville. The 2025 form shows only two heart-lung bypass machines on page 11 as shown below.

8-a. Open Heart Surgery

Open Heart Surgery	Number of Machines/Procedures
1. Number of heart-lung bypass machines	2
2. Total annual number of open heart surgery procedures utilizing heart-lung bypass machine	425
3. Total annual number of open heart surgery procedures done without utilizing a heart-lung bypass machine	40

* For questions on this section, contact Healthcare Planning at 919-855-3865.

The correct count is three machines based on the DHSR approval in March 2022 of Atrium's request to replace and relocate a replacement backup heart-lung bypass machine from CMC to AH Pineville. (Please see a corrected licensure form and a copy of the DHSR approval letter in Exhibit 1.) The result of the equipment relocation is six machines at CMC and three machines at AH Pineville.

IV. Backup Requirements for Heart-lung Bypass Machines

The American Society of Extracorporeal Technology Standards has published Guidelines for Perfusion Practice that provides "perfusionists with a framework to guide safe and effective extracorporeal support for their patients." This document is provided in Exhibit 2. Standard 14 on page 20 of the document is titled Level of Readiness for Procedures that may require cardiopulmonary bypass support and includes the following sub-points:

- **Standard 14.1**: Procedures identified preoperatively to be at elevated risk of requiring conversion to a cardiopulmonary bypass procedure shall have a protocol for transition to such procedures.
- **Standard 14.2**: One Perfusionist shall be assigned for each such standby procedure.
- **Standard 14.3:** A heart-lung machine consisting of a sterile extracorporeal set-up and ancillary equipment shall be readily available for the procedure.
- **Standard 14.4:** Assembly and maintenance of circuit shall be regulated according to institutional protocol using aseptic technique.
- **Guideline 14.1:** The level of readiness for utilizing cardiopulmonary bypass during a surgical procedure should be determined through consultation with the surgical team.

The SHCC and the SMFP have long recognized the need for backup heart-lung bypass machines. The SMFP contains Policy AC-6 Heart-Lung Bypass Machines for Emergency Coverage which allows a hospital with an open heart surgery program and only one bypass machine to file a CON application to add a backup machine. As the standards above indicate, a backup machine is still needed even when a hospital has multiple heart-lung bypass machines. While necessary for patient safety, these backup requirements limit the usage of the machines and hinder a provider's ability to meet growing volumes.

Treating pediatric patients is another challenge for providers facing increasing demand. Two of the heart-lung bypass machines at Carolinas Medical Center (CMC) are dedicated to pediatric procedures, one for scheduled procedures and one as a backup. These pediatric machines are specifically made for pediatric patients and cannot be interchanged with adult machines. This leaves four machines for adult procedures on the CMC campus, but one of those must be used as a backup for emergent procedures. AH Pineville operates three heart-lung bypass machines. Two are for scheduled procedures and one is used as a backup. Each of these campuses has been approved to expand expanding operating room capacity. AH Pineville has recently added two operating rooms and there are plans to expand cardiovascular cases in

the next few years. The CMC campus is undergoing a major expansion including nine additional operating rooms that will open within the next two years. These additional operating rooms will be used in part to expand availability for cardiovascular procedures.

V. Growth in Open Heart Procedures, Case Times and Other Procedures Using Heart-lung Bypass Machines at Atrium Health.

As shown in the table below, which was included earlier to document the growth in Mecklenburg County open heart surgery case volumes, the cases are growing fastest at Atrium facilities. AH Pineville grew at a compound annual growth rate (CAGR) of 38.8 percent between 2021 and 2024. CMC had the second highest CAGR of 6.3 percent.

License	Facility	2019	2020	2021	2022	2023	2024	23-24 % Change	21-24 CAGR
H0042	Atrium Health Pineville	234	158	159	270	344	425	23.5%	38.8%
H0071	Carolinas Medical Center	751	580	729	777	803	876	9.1%	6.3%
H0010	Novant Health Presbyterian Medical Center	413	339	434	360	450	500	11.1%	4.8%
Total Procedures		1,398	1,077	1,322	1,407	1,597	1,801	12.8%	10.9%

In addition to the growth in open heart surgery cases, heart-lung bypass machine utilization is also increasing at Atrium facilities in Mecklenburg County due to increases in the machine usage times. Atrium facilities have experienced an increase in average case machine usage in coronary artery bypass graft (CABG) procedures over the last four years with the case times reaching six hours. The case time increase is due to increasing case acuity resulting in decreased capacity for additional procedures.

The number of cases requiring a heart-lung bypass machine on standby has also increased in recent years. Procedures that require a standby machine include transcatheter arterial valve replacement (TAVR), lead extractions, liver bypass, right ventricular assist device (RVAD), extracorporeal membrane oxygenation (ECMO), and hyperthermic intraperitoneal chemotherapy (HIPEC). The total of these cases across Atrium facilities in Mecklenburg County totaled 515 cases in 2024. For example, TAVR procedures/Lead extractions render one machine at the CMC campus blocked every Monday and Wednesday for eight hours meaning the machine cannot be utilized for another procedure. These procedures run a risk of complication that would require emergent use of the heart-lung machine.

Impact of Request/Implications if Petition is Not Approved

As outlined above, approval of this petition will result in the adjusted need for an additional heart-lung bypass machine for Mecklenburg County. Based on historical growth rates and projections, if this petition is not approved it will result in an unnecessary burden on existing providers who lack capacity to treat the growing population and on patients who may experience delays in receiving critical treatments.

Adverse Effects on Population

The approval of this petition would not have any negative effects on the population of Mecklenburg County. The approval of the petition with allow for continued growth in open-heart surgery services and other cases requiring a heart-lung bypass machine and reduce delays in receiving care for critical health conditions.

Alternative Considerations

Atrium considered not filing a petition. However, given the growing number of open heart surgery patients and expanding procedures requiring the use of heart-lung bypass machines this alternative was not acceptable. For Atrium to continue to serve patients in the region who choose to receive their care in one

of our facilities it was determined that the best alternative at this time was to ask the SHCC to add the need determination.

Impact of Proposed Changes on Unnecessary Duplication

The proposed revision will not result in unnecessary duplication of heart-lung bypass machine services in Mecklenburg County and the surrounding area. As demonstrated above, the population is growing, and the procedure growth is high. The addition of an additional machine in 2026 will allow patients to receive critical procedures in a more timely manner.

Proposal's Consistency with the Basic Principles of the SMFP

The addition of a heart-lung bypass machine need determination will ensure quality, access, and value for Mecklenburg County patients. By ensuring an adequate supply of heart-lung bypass machines to meet the growing demand for cardiovascular procedures, patients will have improved access and higher quality care. The low cost to acquire the machines will also positively impact the value of care patients receive.

Summary

Based on the evidence presented above, Atrium believes that the addition of a need for an additional heart-lung bypass machine is essential to meet the needs of the citizens of Mecklenburg County who require the complex medical procedures that can be provided with this technology.

EXHIBIT 1

Atrium Health Pineville Corrected Licensure Form and

DHSR Approval Letter to Replace and Relocate Backup Heart-Lung Bypass Machine

Telehealth/telemedicine is defined by the U.S. Health Resources & Services Administration as "the use of electronic information and telecommunication technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health, and health administration. Technologies include video conferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications."

Check the appropriate box for each service this facility provides or receives via telehealth/telemedicine. A service may apply to more than one category. **Check all that apply.**

Service	Provide service to other facilities via telemedicine	Receive service from other facilities via telemedicine
Emergency Department	☐	☑
Imaging	☑	☑
Psychiatric	☐	☑
Alcohol and/or substance use disorder (other than tobacco cessation) services	☐	☐
Stroke	☐	☑
Other services	☐	☑

Workbook last modified: April 11

8. Specialized Cardiac Services

8-a. Open Heart Surgery

Open Heart Surgery	Number of Machines/Procedures
1. Number of heart-lung bypass machines	3 ~~2~~
2. Total annual number of open heart surgery procedures utilizing heart-lung bypass machine	425
3. Total annual number of open heart surgery procedures done without utilizing a heart-lung bypass machine	40

* For questions on this section, contact Healthcare Planning at 919-855-3865.

8-b. Cardiac Catheterization and Electrophysiology

1. Does this facility provide cardiac catheterization on fixed units or electrophysiology services? Yes

* Cardiac Catheterization procedures (as defined in G.S. § 131E-176 (2g))

Number of units of fixed cardiac catheterization equipment with a CON: 2

* CON Project IDs for fixed equipment:

F-7979-07 covers relocation of 2 units from AH Mercy

* Number of units of legacy fixed cardiac catheterization equipment (i.e., equipment obtained before a CON was required): 1

NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

March 24, 2022

Gary S. Qualls
gary.qualls@klgates.com

No Review

Record #:	**3848**
Date of Request:	March 16, 2022
Facility Name:	Atrium Health Pineville
FID #:	110878
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Relocate a replacement heart/lung bypass machine from Carolinas Medical Center to Atrium Health Pineville
County:	Mecklenburg

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request,** the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective. Please see the Agency's Exempt from Review determination (Record #3847) regarding the replacement of the heart/lung bypass machine being relocated from Carolinas Medical Center to Atrium Health Pineville.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Julie M. Faenza

Julie M. Faenza, Project Analyst

Micheala Mitchell

Micheala Mitchell, Chief

cc. Acute and Home Care Licensure and Certification

NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

March 24, 2022

Gary S. Qualls
gary.qualls@klgates.com

Exempt from Review – Replacement Equipment

Record #:	**3847**
Date of Request:	March 16, 2022
Facility Name:	Carolinas Medical Center
FID #:	943070
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Replace existing heart/lung bypass machine
County:	Mecklenburg

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the newer model LivaNova SRD S5 Heart Lung Perfusion System to replace the LivaNova SRD S5 Heart Lung Perfusion System (ID #48E01770). This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required. Please see the Agency's No Review determination (Record #3848) regarding the change of site of the replacement heart/lung bypass machine from Carolinas Medical Center to Atrium Health Pineville.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Julie M. Faenza

Julie M. Faenza
Project Analyst

Micheala Mitchell

Micheala Mitchell
Chief

cc. Acute and Home Care Licensure and Certification Section, DHSR

K&L GATES

March 16, 2022

Gary S. Qualls
D 919.466.1182
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gary.qualls@klgates.com

Via E-Mail
Micheala Mitchell, Chief
Julie Faenza, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

Re: Replacement Equipment Exemption and Material Compliance / No Review Request for Replacing and Relocating Heart-Lung Bypass Machine from CMHA's CMC Campus to CMHA's Pineville Campus

Dear Ms. Mitchell and Ms. Faenza:

The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health ("CMHA") asks the Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") to make the two rulings described below for its wholly owned facilities and operating divisions, Carolinas Medical Center ("CMC") and Atrium Health Pineville ("AH Pineville").

The Exemption Notice in Part I describes how CMHA will replace one CMHA-owned and operated Heart-Lung Bypass Unit ("Bypass Unit") at CMC with another existing, comparable Bypass Unit at CMC.

The Material Compliance / No Review Request in Part II asks the Agency to confirm that no Certificate of Need ("CON") is required in order for CMHA to relocate that replaced Bypass Unit from one existing CMHA wholly owned facility and operating division to another (i.e., from CMC to AH Pineville). The relocation of this Bypass Unit will not increase CMHA's Bypass Unit complement or the Bypass Unit complement in Mecklenburg County.[1]

[1] We characterize Step 2 as, alternatively, a Material Compliance / No Review Request for the following reasons. Step 2 is most accurately called a Material Compliance Request if the "Old Bypass Unit" being replaced (or its predecessors units) were obtained pursuant to a CON, as opposed to being grandfathered under the CON Law. Because CMHA has owned the Old Bypass Unit (or its predecessors units) so long, CMHA's records do not reflect whether this particular unit originated from a CON or predated CON

A summary of each step is described immediately below. A more detailed description of each step is then provided in Parts I and II below.

Summary of Step #1

1. In Step #1, CMHA seeks a replacement equipment exemption to replace the "Old Bypass Unit" at CMC with a new Bypass Unit (the "Replacement Bypass Unit" or "Replacement Equipment") for under $2 Million. See N.C. Gen. Stat. § 131E-184(a)(7) and 131E-176(22a).

Summary of Step #2

2. CMHA next seeks a material compliance or (in the alternative) a no review determination to relocate the Replacement Bypass Unit to the AH Pineville Campus. The act of relocating the Replacement Bypass Unit does not constitute a "purchase" or "acquisition" since CMHA: (a) owns it when it is located at CMC; and (b) will still own it when it is made operational at AH Pineville.

I. Step #1 -- The Replacement Equipment Exemption.

CMHA first seeks a replacement equipment exemption to replace CMC's "Old Bypass Unit" with the Replacement Bypass Unit. The Old Bypass Unit is a LivaNova S5 Heart Lung Perfusion System. The Replacement Bypass Unit is also the same make and model of LivaNova S5 Heart Lung Perfusion System, just newer. See Exhibit B (cost quote for Replacement Bypass Unit); Exhibit C (brochure for Replacement Bypass Unit); Exhibit D (CON Equipment Comparison Form). CMHA's acquisition of this Replacement Bypass Unit is exempt as described below.

A. Section 184(a)(7) Exemption

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," as provided in N.C. Gen. Stat. § 131E-184(a)(7), set forth below:

> (a) Except as provided in subsection (b), the Department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, which notice includes an explanation of why the new institutional health service is required, for any of the following: .
>
> * * *
>
> (7) To provide replacement equipment.

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requirements for heart-lung bypass machines. For example, 1996 SMFP excerpts show that CMHA already owned and operated seven (7) bypass units at CMC in that reporting year. See Exhibit A.

The CON Law then defines "replacement equipment," as follows:

> "Replacement equipment" means equipment that costs less than two million dollars ($2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. § 131E-176(22a).

Therefore, to qualify for this exemption, the replacement equipment must cost less than $2 Million and be "comparable" to the equipment it replaces and must be "sold or otherwise disposed of when replaced." As described below, CMHA's proposal qualifies for this exemption.

B. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") reads as follows:

> 10A NCAC 14C.0303 REPLACEMENT EQUIPMENT
>
> (a) This Rule defines the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a).
>
> (b) "Currently in use" means that the equipment to be replaced has been used by the person requesting the exemption at least 10 times to provide a health service during the 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section.
>
> (c) Replacement equipment is not "comparable" if:
>
> (1) the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide; or
>
> (2) the equipment to be replaced was acquired less than 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption.

10A N.C.A.C. 14C.0303(c).

CMHA used the Old Bypass Unit at CMC to perform over 30 procedures in FY 2021, thus satisfying Subsection (b). CMHA intends to use the Replacement Bypass Unit for the same health service as the Old Bypass Unit, open heart surgery, thus satisfying Subsection (c)(1). Moreover, the Old Bypass Unit was acquired in 2011, thus satisfying Subsection (c)(2). See Exhibit D. For further equipment comparison points, please refer to Exhibit D (CON Equipment Comparison Chart).

C. Cost of the Replacement Equipment

CMHA will incur $193,380.56 in total capital costs to acquire and make operational the Replacement Bypass Unit. See Exhibits B and D. As the brochure in Exhibit C illustrates, this Bypass Unit is relatively small, moveable equipment, which does not require "installation" as would a larger piece of equipment (e.g., MRI scanner). Thus, the capital costs associated with the replacement are far less than the $2 Million threshold in N.C. Gen. Stat. § 131E-176(22a).

D. Disposal of the Old Bypass Unit

CMHA commits to dispose of the Old Bypass Unit and not operate it again in North Carolina. See N.C. Gen. Stat. § 131E-176(22a).

II. Step #2 -- The Material Compliance / No Review Request.

This Material Compliance / No Review Request in Part II asks the Agency to confirm that no CON is required in order for CMHA to relocate the CMHA-owned and operated Replacement Bypass Unit from the CMC Campus to the AH Pineville Campus. As underscored in Part I(C) above, the Replacement Bypass Unit is a relatively small, moveable equipment unit, which does not require "installation" as would a larger piece of equipment. See Exhibits C. Thus, there are no additional relocation costs involved in the relocation from the CMC Campus to the AH Pineville Campus.

Upon relocation, the Replacement Bypass Unit will then be operated as a full-time heart-lung bypass unit at AH Pineville. After the relocation: (a) CMC will have six (6) heart-lung bypass units (five full-time units and one backup unit); and (b) AH Pineville will have three (3) heart-lung bypass units (two full-time units and one backup unit).

There is precedent for the relocation of CON *per se* reviewable equipment from one wholly owned hospital to another wholly owned hospital in the same county (and thus the same service area).

In two September 29, 2017 material compliance and replacement equipment exemption determinations, the Agency approved CMHA to relocate and replace cardiac catheterization equipment from CMHA's University Campus to its CMC Campus. See Exhibit E.

Relatedly, in an August 5, 2015 determination, the Agency approved Novant Health to relocate and replace cardiac catheterization unit from Novant Health Presbyterian Medical Center ("Presbyterian") to Novant Health Matthews Medical Center ("Matthews"). See Exhibit 3 to Exhibit E (Ex. E-3, Bates Nos. 17-18). In requesting the relocation, Novant pointed out that both Presbyterian and Matthews were within the Novant Health corporate family and were both located in Mecklenburg County (and thus the same cardiac cath service area). See Ex. E-4, Bates Nos. 19-24. That Agency analysis fits CMHA here even better than it fit Novant in the foregoing scenario. In the Novant situation, Presby and Matthews were owned by two separate Novant Health subsidiaries, but were under Novant Health ownership at the parent level. Here, CMC and AH Pineville are both operating units of CMHA, with both located in Mecklenburg County. Thus, CMC and AH Pineville are operated within the same entity.

Thus, as with the requests approved in Exhibit E (and discussed above), CMHA's proposed Bypass Relocation Project here is not CON reviewable.

Conclusion

Based on the foregoing information, CMHA asks the Agency to make the following two conclusions:

1. Find that the replacement equipment transaction described in Part I above is exempt from CON review under N.C. Gen. Stat. § 131E-184(a)(7); and

2. Find that relocating the Replacement Bypass Unit from one existing CMHA Mecklenburg County hospital campus to another (not increasing CMHA's Bypass Unit complement) materially complies with the CON for CMC's Old Bypass Unit or is otherwise not reviewable.

We thank you for your consideration of this notice.

Sincerely,

Gary S. Qualls

Gary S. Qualls

EXHIBIT 2

The American Society of Extracorporeal Technology Standards

Guidelines for Perfusion Practice

American Society of ExtraCorporeal Technology

Standards and Guidelines

for Perfusion Practice

The American Society of ExtraCorporeal Technology (AmSECT) has created the following document based on clinical evidence and currently accepted perfusion practices. Perfusionists are the only allied healthcare professionals formally trained and educated in the field of extracorporeal science and whose scope of practice expressly includes the utilization of extracorporeal devices. The document is intended to serve as a useful guide for teams developing institution-specific protocols to improve the reliability, safety, and effectiveness of extracorporeal support services.

Goal Statement

The goal of this project was to provide Perfusionists with a framework to guide safe and effective extracorporeal support care to their patients. AmSECT recommends that clinical teams use this document as a guide for developing institution-specific protocols for patients receiving extracorporeal support.

Approach

In 2011, the AmSECT Board of Directors (BOD) requested the International Consortium for Evidence-Based Perfusion (ICEBP) subcommittee to review and update the Essentials and Guidelines. In 2013, the revision was completed and adopted by the membership, and a report of this work published in the Journal of Extracorporeal Technology (J Extra Corporeal Technol. 2013 Sep;45(3):156-66). In recognition of the developing role of extracorporeal support the BOD requested that the 2013 Standards and Guidelines be updated. The ICEBP undertook this review and shared the suggested revision with the BOD and the perfusion community at AmSECT's conferences in 2014 and 2015. Based on feedback from conference attendees, and further review, the ICEBP submitted a revised document that was approved by the BOD and membership in 2017. As a continuation to improve quality and focus on patient safety the Standards and Guidelines have been updated for 2023. Valuable community feedback from direct emails, four webinars, and an open-text response survey were received and applied towards editing the final document. With these goals in mind, the Standards and Guidelines will continue to be reviewed and updated as necessary or as deemed appropriate by AmSECT's BOD.

This document is aimed for adult perfusion practices. For pediatric patients, please see the AmSECT Standards and Guidelines for Pediatric and Congenital Perfusion Practice document.

The 2023 update includes extensive modifications to existing standards (and their respective guidelines) to enhance their interpretation and use. In addition, the update includes the addition of Standard 19 that focuses on crisis management.

To facilitate the understanding of the Standards and Guidelines, we define important terms used throughout the document. Unless otherwise stated, Standards and Guidelines are written for perfusion services, with the intent to be disseminated and adopted across members of this team.

Definitions:

Standard: Practices, technology and/or conduct of care that institutions shall meet in order to fulfill the minimum requirements for cardiopulmonary bypass.

***Guideline*:** A recommendation that should be considered and may assist in the development and implementation of protocols.

Protocol: An institution-specific written document, derived from professional standards and guidelines, which contains decision and treatment algorithms.

Word Usage:

Shall: In this document, the word shall is used to indicate a mandatory requirement.

Should: In this document, the word should is used to indicate a recommendation.

Surgical Care Team: In this document, the term surgical care team is used to indicate the group surgeon, anesthesiologist, Perfusionist, nurse and technicians.

Supervising Physician: In this document, the term supervising physician is intended to describe the physician responsible, at that given time, for the patient and their hemodynamics.

Continuously: In this document, the word 'continuously' describes an action that occurs without ceasing, whereas the word 'continually' is intended to describe an action that recurs frequently or regularly.

Appendix: The appendices are presented as documents to help with institutional implementation of specified Standards and Guidelines. As such, appendices are meant solely as supporting material.

Special Note:

As noted above, the intent of these Standards and Guidelines for Perfusion Practice are to help healthcare professionals with evidence-based recommendations regarding safe and effective extracorporeal support care for their patients. The Standards and Guidelines do not include all potential options for care, and they are not intended and should not be used as a substitute for the provider's clinical judgment and experience. The responsible provider must make all treatment decisions based upon their independent judgment and the patient's presentation. Although the Standards and Guidelines have been reviewed with significant care, they are provided as is and without liability. AmSECT shall not be liable for any direct, indirect, special, incidental, or consequential damages related to the use or misuse of the information contained herein. AmSECT recognizes that individual medical centers may have local policies that may supersede AmSECT's Standards and Guidelines. Likewise, AmSECT recognizes that some districts or states may have laws that supersede AmSECT's Standards and Guidelines. As a result, Perfusionists practicing within those jurisdictions should comply in all respects with those policies and laws.

American Society of ExtraCorporeal Technology

Standards and Guidelines

For Perfusion Practice

February 2023

Standard 1: Development of Institutionally-based Protocols

Standard 1.1: As a mechanism for applying each standard to clinical practice, an institution or service provider shall develop and implement an operating procedure (protocol) for each of the standards.

Standard 1.2: The protocol shall be:

- Approved by the Chair of Cardiac Surgery, or their designee, Director of Perfusion, or equivalent, and other relevant clinical governance committees if available.
- Reviewed and revised annually or more frequently when deemed necessary.

Standard 1.3: Perfusion emergency protocols shall be accessible to help guide the user during an event.[1][2]

Guideline 1.1: Deviation from protocol or intended treatment care plan may be at the discretion of the supervising physician and should be documented in the perfusion record.

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[1] AmSECT Failure Mode and Effects Analysis examples: https://www.amsect.org/page/fmea-archives
[2] OSHA and The Joint Commission. Safety and Health Management Systems and Joint Commission Standards. https://www.osha.gov/sites/default/files/2.2_SHMS-JCAHO_comparison_508.pdf (accessed August 6, 2022)

Standard 2: Qualification, Competency and Support Staff

Standard 2.1: A Perfusionist, who is Board Certified by the American Board of Cardiovascular Perfusion or who demonstrates equivalent qualifications and competency, shall conduct cardiopulmonary bypass procedures.[3]

Standard 2.2: Perfusionist competency shall be assessed annually to evaluate compliance with departmental protocols.

Standard 2.3: The Perfusionist shall attend, participate, and engage in perfusion-related continuing education courses on an annual basis.[4]

Standard 2.4: Support staff shall be available on site to assist the primary Perfusionist during cardiopulmonary bypass procedures.

Standard 2.5: An outline detailing the onboarding process shall be developed in order to ensure new hires are oriented and able to safely perform perfusion related responsibilities, including training with hazardous materials (e.g., radiation or chemotherapy) relevant to work duties. The onboarding process shall be documented and retained upon completion.

Guideline 2.1: An individual graduating from an accredited perfusion education program should complete all requirements for American Board of Cardiovascular Perfusion certification within 3 years of graduation.

Guideline 2.2: A standardized process should be developed and followed to identify, orient, and educate support staff to ensure they have general knowledge of the duties performed by the Perfusionist, flow of the operation and location of primary and ancillary items required during cardiopulmonary bypass procedures. Support staff may include a Perfusionist, nursing, technical, or non- technical staff.

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[3] AmSECT recognizes that individual states may license Perfusionists based on other criteria. These laws supersede this standard.

[4] American Board of Cardiovascular Perfusion, *www.abcp.org/* (accessed March 6, 2021)

Standard 3: Communication

Standard 3.1: A patient-specific management plan for the cardiopulmonary bypass procedure shall be prepared and communicated to the surgical team either during the pre-operative briefing or prior to beginning the procedure.[5]

Standard 3.2: The primary Perfusionist shall use a set handoff protocol (e.g., SBAR-Situation, Background, Assessment, Recommendation) when transitioning the management of the case to a second Perfusionist.[6]

Standard 3.3: The primary Perfusionist shall participate in the post-procedure debrief with the surgical team.

Guideline 3.1: The use of cellular telephone technology in the operating room should be guided by the principles of ST-59 Statement on use of cell phones in the operating room, written by the American College of Surgeons.[7]

Guideline 3.2: Protocol driven communication (e.g., closed loop), should be utilized to acknowledge verbal commands, verify the content, and reduce ambiguity.[8,9,10]

Guideline 3.3 Topics that should be considered during the post-procedure debrief include, but are not limited to, communication, additional training, equipment or disposables issues, post-operative instructions, and safety events.

Guideline 3.4 Deviations from the intended treatment care plan should be appropriately communicated to the supervising physician and documented to allow for changes in the management plan.

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[5] World Health Organization surgical safety checklist and implementation manual. World Health Organization, http://www.who.int/patientsafety/safesurgery/ss_checklist/en/ (accessed March 6, 2021)

[6] The Joint Commission. Hot Topics in Health Care. Transitions of Care: The need for a more effective approach to continuing patient care. http://www.jointcommission.org/assets/1/18/hot_topics_transitions_of_care.pdf (accessed March 6, 2021)

[7] Statement on use of cell phones in the operating room, October 1, 2016. Bulletin of the American College of Surgeons, https://www.facs.org/~/media/files/publications/bulletin/2008/2008%20september%20bulletin.ashx (accessed March 6, 2021)

[8] Wadhera RK, Parker SH, Burkhart HM, Greason KL, Neal JR, Levenick KM, Wiegmann DA, Sundt TM 3rd. Is the "sterile cockpit" concept applicable to cardiovascular surgery critical intervals or critical events? The impact of protocol-driven communication during cardiopulmonary bypass. J Thorac Cardiovasc Surg. 2010 Feb;139(2):312-9. doi: 10.1016/j.jtcvs.2009.10.048. PMID: 20106395.

[9] Whyte S, Cartmill C, Gardezi F, Reznick R, Orser BA, Doran D, Lingard L. Uptake of a team briefing in the operating theatre: a Burkean dramatistic analysis. Soc Sci Med. 2009 Dec;69(12):1757-66. doi: 10.1016/j.socscimed.2009.09.054. Epub 2009 Oct 23. PMID: 19853344.

[10] de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH, Schlack WS, van Putten MA, Gouma DJ, Dijkgraaf MG, Smorenburg SM, Boermeester MA; SURPASS Collaborative Group. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med. 2010 Nov 11;363(20):1928-37. doi: 10.1056/NEJMsa0911535. PMID: 21067384.

Standard 4: Perfusion Record

Standard 4:1: The perfusion record (written and/or electronic) for each cardiopulmonary bypass (CPB) procedure shall be included as part of the patient's permanent medical record. The perfusion records shall be maintained and stored according to institution policy for retaining patient medical records.

Standard 4.2: The record shall include:

- Patient information including demographics and pre-operative risk factors (Appendix A).
- Information sufficient to accurately describe the procedure, personnel, and equipment (Appendix B).
- Patient physiological parameters documented at a frequency determined by institutional protocol (Appendix C).
- Blood gas and anticoagulation monitoring results (Appendix D).
- Signature of the Perfusionist (and all relief Perfusionists) performing the procedure.

Guideline 4.1: The perfusion record should include open text (factual) commentary including supervising physician verbal orders pertinent to the CPB procedure.

Guideline 4.2: The perfusion record should include the signatures of the supervising physician(s) providing oversight for the CPB procedure.

Guideline 4.3: Raw data (e.g., blood flow, pressure and temperature values) contained in electronic perfusion databases should be stored for a time period in accordance with the institution's policy for retaining electronic patient medical records.

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Standard 5: Checklist

Standard 5.1: The Perfusionist shall use a checklist for each cardiopulmonary bypass procedure.[11]

Standard 5.2: Checklists shall be included as part of the patient's permanent medical record.

Guideline 5.1: The Perfusionist should use checklists in a read-verify manner where critical steps that should have been performed are confirmed.[12] Completion of the checklist should be performed by two people, one person being the primary Perfusionist responsible for operation of the heart lung machine during the intra-operative period.

Guideline 5.2: The Perfusionist should utilize a checklist throughout the entire peri-operative period (e.g., set-up, pre-bypass, initial onset of bypass, prior to cessation of bypass, post bypass, and/or any return to bypass).

Guideline 5.3: The Perfusionist should utilize a checklist for other ancillary perfusion services (e.g., autotransfusion, intra-aortic balloon pump, extracorporeal membrane oxygenation).

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[11] Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009 Jan 29;360(5):491-9. doi: 10.1056/NEJMsa0810119. Epub 2009 Jan 14. PMID: 19144931.

[12] Advancing Patient Safety in the U.S. Department of Veterans Affairs. Preoperative Briefing Guide for Use in the Operating Room. Commonwealth Fund Pub. 1477, Vol 9. https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_case_study_2011_mar_1477_mccarthy_va_case_study_final_march_v2.pdf (accessed 02/2023).

Standard 6: Safety Devices

Standard 6.1: Pressure monitoring of the arterial line, cardioplegia delivery systems and venous reservoir (when augmented venous drainage is utilized) shall be employed during cardiopulmonary bypass procedures.

- The pressure monitor shall be either servoregulated to control the arterial/cardioplegia pump or to allow interruption to the arterial/cardioplegia flow.
- The pressure monitor shall include an audible and visual alarm.

Standard 6.2: A bubble detector shall be employed during cardiopulmonary bypass procedures.

- The gross/macro bubble detector shall be used to control the arterial pump or to allow interruption of the arterial blood flow.
- The detector system shall include an audible and visual alarm and be positioned according to manufacturer instructions for use to enable timely identification and action.

Standard 6.3: A level sensor shall be employed during cardiopulmonary bypass procedures utilizing a (hard-shell) reservoir.

- The level sensor shall be either servoregulated to control the arterial pump or to allow interruption of the arterial blood flow.
- The level sensor shall include an audible and visual alarm and be positioned according to manufacturer's instructions to allow an appropriate reaction time and a safe operational volume.

Standard 6.4: Temperature monitoring of the arterial outflow from the oxygenator shall be employed during cardiopulmonary bypass procedures.

- The temperature sensor shall include an audible and visual alarm to prevent high arterial outlet temperatures.[13]

Standard 6.5: An arterial-line filter, external or integrated, shall be employed during cardiopulmonary bypass procedures.

Standard 6.6: A one-way valve in the vent line shall be employed during cardiopulmonary bypass procedures.

Standard 6.7: A method for retrograde flow avoidance when using a centrifugal pump shall be employed during cardiopulmonary bypass procedures.

- Examples of retrograde avoidance systems may include the following:
  - One-way flow valves
  - Hard stop detent controls to prevent accidental reduction in pump speed
  - Electronically activated arterial line clamps
  - Low speed visual and audible alarm.

Standard 6.8: An anesthetic gas scavenge line shall be employed whenever inhalation agents are introduced into the circuit during cardiopulmonary bypass

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[13] Engelman R, Baker RA, Likosky DS, Grigore A, Dickinson TA, Shore-Lesserson L, Hammon JW. The Society of Thoracic Surgeons, The Society of Cardiovascular Anesthesiologists, and The American Society of ExtraCorporeal Technology: Clinical Practice Guidelines for Cardiopulmonary Bypass—Temperature Management during Cardiopulmonary Bypass. J Extra Corpor Technol. 2015 Sep;47(3):145-54. PMID: 26543248.

procedures.

Standard 6.9: Hand cranks shall be readily available during cardiopulmonary bypass procedures.

Standard 6.10: A back-up gas supply shall be available during cardiopulmonary bypass procedures.

Standard 6.11: The cardiopulmonary bypass machine shall have a backup power source that allows for uninterrupted power supply during cardiopulmonary bypass procedures.

Guideline 6.1: A ventilating gas oxygen analyzer should be employed during cardiopulmonary bypass procedures.

Guideline 6.2: A level sensor should be employed during cardiopulmonary bypass procedures utilizing a soft-shell reservoir.

- The level sensor should be either servoregulated to control the arterial pump or to allow interruption of the arterial blood flow.
- The level sensor should include an audible and visual alarm and be positioned according to manufacturer's instructions to allow an appropriate reaction time and a safe operational volume.
- The use of an air bubble detector distal to the outlet can be used utilized as a surrogate level detector.

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Standard 7: Monitoring[14]

Standard 7.1: Patient arterial blood pressure shall be monitored continuously during cardiopulmonary bypass procedures.[15]

Standard 7.2: Arterial line pressure shall be monitored continuously during cardiopulmonary bypass procedures.

Standard 7.3: Arterial blood flow shall be monitored continuously at a point in the cardiopulmonary bypass circuit where it accurately reflects the flow delivered to the patient during cardiopulmonary bypass procedures (e.g., distal to intra-circuit shunts).

Standard 7.4: Cardioplegia dose, delivery method, line pressure (antegrade), coronary sinus pressure (retrograde) and ischemic intervals shall be monitored continually during cardiopulmonary bypass procedures.

Standard 7.5: Patient and device temperatures shall be monitored continually during cardiopulmonary bypass procedures.

- Patient (e.g., nasopharyngeal, rectal, bladder, esophageal)
- Heart lung machine (arterial, venous and cardioplegia)
- Heater cooler (H20 temperature)

Standard 7.6: Blood gas analyses shall be monitored continually or at regular intervals during cardiopulmonary bypass procedures (Appendix D).

Standard 7.7: Hematocrit (or hemoglobin) shall be monitored continually during cardiopulmonary bypass procedures.

Standard 7.8: Oxygen fraction and gas flow rates shall be monitored continually during cardiopulmonary bypass procedures.

Standard 7.9: The percentage of venous line occlusion of the venous occluder shall be monitored continually during CPB.[16]

Standard 7.10 Venous oxygen saturation shall be monitored continually during cardiopulmonary bypass procedures.

Guideline 7.1: Carbon dioxide removal should be monitored continually during cardiopulmonary bypass procedures.

Guideline 7.2: Arterial oxygen saturation should be monitored continually during cardiopulmonary bypass procedures.

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[14] To be performed in conjunction with Standard 3.
[15] Here, and throughout this document, 'continuously' describes an action that occurs without ceasing, whereas the word 'continually' is intended to describe an action that recurs frequently or regularly.
[16] Monitoring of the venous line occluder only applies if a venous line occluder is being utilized.

Guideline 7.3: The following patient pressures should be monitored during cardiopulmonary bypass procedures:

- Central venous pressure and/ or
- Pulmonary artery blood pressure, if available

Guideline 7.4: Continuous in-line blood gas monitoring should be used during cardiopulmonary bypass procedures.

Guideline 7.5: Cerebral oximetry should be used during cardiopulmonary bypass procedures.

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Standard 8: Anticoagulation

Standard 8.1: The Perfusionist, in collaboration with the supervising physician, shall define the intended anticoagulation management algorithm, including:

- Acceptable target and range for activated clotting time (ACT), considering relevant factors that include the variability in ACT measurement attributed to the measuring device's performance characteristics.[17]
- Monitoring and treating the patient's anticoagulation status before, during, and after the cardiopulmonary bypass period at a determined frequency.
- Patient-specific initial heparin dosage using one of the following methods:
  - Weight
  - Dose Response Curve (automated or manual)
  - Blood Volume
  - Body Surface Area
- Preparing alternative means of anticoagulation for when heparin is not suitable.

Guideline 8.1: Anticoagulation monitoring should include the testing of ACT. Additional monitoring tests may include:

- Heparin level measurement (e.g., heparin/protamine titration or unfractionated heparin level)
- Partial Thromboplastin Time
- Thromboelastograph
- Thrombin Time
- Anti Xa

Guideline 8.2: Additional doses of anticoagulant during cardiopulmonary bypass procedures should be determined by using an appropriate anticoagulation test.[18]

Guideline 8.3: Heparin reversal management strategy should aim to limit over-exposure to protamine and should be confirmed by ACT and/or heparin/protamine titration.

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[17] Shore-Lesserson LJ, Baker RA, Ferraris V, Greilich PE, Fitzgerald DJ, Roman P, Hammon J. STS/SCA/AmSECT Clinical Practice Guidelines: Anticoagulation during Cardiopulmonary Bypass. Ann Thorac Surg. 2018 Feb;105(2):650-662. doi: 10.1016/j.athoracsur.2017.09.061. PMID: 29362176.

[18] In patients requiring longer cardiopulmonary bypass (CPB) times (>2 to 3 hours), maintenance of higher and/or patient- specific heparin concentrations during CPB may be considered to reduce hemostatic system activation, reduce consumption of platelets and coagulation proteins, and to reduce blood transfusion. (Class IIb, Level of evidence B). Reference: Society of Thoracic Surgeons Blood Conservation Guideline Task Force, Ferraris VA, Brown JR, Despotis PMID: 21353044

Standard 9: Gas Exchange

Standard 9.1: Gas exchange shall be maintained during cardiopulmonary bypass support procedures according to protocol, accounting for individual patient needs

Standard 9.2: Indexed Oxygen delivery and consumption calculations shall be utilized to evaluate and optimize gas exchange.[19,20,21,22,23]

- Oxygen Delivery: $DO_2i = 10 \times CI \times CaO_2$
- Oxygen Consumption: $VO_2i = 10 \times CI \times (CaO_2 - CvO_2)$

Where:
CaO_2 (arterial oxygen content) = $(Hb \times 1.36 \times SaO_2) + (0.0031 \times PaO_2)$, and
CvO_2 (mixed venous oxygen content) = $(Hb \times 1.36 \times SvO_2) + (0.0031 \times PvO_2)$
CI = cardiac index
Hb = hemoglobin
SaO_2 = arterial oxygen saturation
PaO_2 = partial pressure of oxygen in arterial blood
SvO_2 = venous oxygen saturation
PvO_2 = partial pressure of oxygen in venous blood

Guideline 9.1: Point-of-Care testing should be considered to provide accurate and timely information for blood gas analysis.[24]

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[19] de Somer F, Mulholland JW, Bryan MR, Aloisio T, Van Nooten GJ, Ranucci M. O2 delivery and CO2 production during cardiopulmonary bypass as determinants of acute kidney injury: time for a goal-directed perfusion management? Crit Care. 2011 Aug 10;15(4):R192. doi: 10.1186/cc10349. PMID: 21831302; PMCID: PMC3387634.
[20] Newland RF, Baker RA, Woodman RJ, Barnes MB, Willcox TW; Australian and New Zealand Collaborative Perfusion Registry. Predictive Capacity of Oxygen Delivery During Cardiopulmonary Bypass on Acute Kidney Injury. Ann Thorac Surg. 2019 Dec;108(6):1807- 1814. PMID: 31238029.
[21] Newland RF, Baker RA. Low Oxygen Delivery as a Predictor of Acute Kidney Injury during Cardiopulmonary Bypass. J Extra Corpor Technol. 2017 Dec;49(4):224-230. PMID: 29302112; PMCID: PMC5737422.
[22] Ranucci M, Johnson I, Willcox T, Baker RA, Boer C, Baumann A, Justison GA, de Somer F, Exton P, Agarwal S, Parke R, Newland RF, Haumann RG, Buchwald D, Weitzel N, Venkateswaran R, Ambrogi F, Pistuddi V. Goal-directed perfusion to reduce acute kidney injury: A randomized trial. J Thorac Cardiovasc Surg. 2018 Nov;156(5):1918-1927.e2. PMID: 29778331.
[23] Ranucci M, Romitti F, Isgro G, et al. Oxygen delivery during cardiopulmonary bypass and acute renal failure after coronary operations. Ann Thorac Surg 2005;80:2213-20. PMID: 16305874.
[24] Nichols, JH. Laboratory Medicine Practice Guidelines. Evidence-based practice for point-of-care testing. American Association for Clinical Chemistry Press. 2006. https://www.aacc.org/science-and-research/practice-guidelines/point-of-care-testing (accessed December 4, 2022)

Standard 10: Blood Flow

Standard 10.1: Target blood flow rates shall be determined prior to cardiopulmonary bypass according to protocol.

Standard 10.2: The Perfusionist shall work closely with the supervising physician to maintain targeted blood flow rate during cardiopulmonary bypass procedure.

Guideline 10.1: Appropriate blood flow rate should be determined by evaluation of:

- Acid base balance
- Anesthetic level
- Arterial blood pressure
- Cerebral oximetry
- Lactate burden
- Oxygen delivery and consumption (refer to Standard 9.2 for formula)
    - Venous pO2
    - Arterial pO2
    - Hemoglobin concentration
    - Arterial oxygen saturation
- Temperature
- Venous oxygen saturation

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Standard 11: Blood Pressure

Standard 11.1: The Perfusionist, in collaboration with the surgical care team, shall define and communicate the intended treatment algorithm for blood pressure management prior to cardiopulmonary bypass procedures, including acceptable ranges for blood pressure.[25]

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[25] In many circumstances, the supervising physician may direct the perfusionist to modify the intended blood pressure management to address circumstances occurring during the cardiopulmonary bypass procedure.

Standard 12. Protamine and Cardiotomy Suction

Standard 12.1: Cardiotomy suction shall be discontinued at the onset of protamine administration to avoid clotting within the cardiopulmonary bypass circuit.

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Standard 13: Blood Management

Standard 13.1: The Perfusionist shall utilize the timely and collaborative application of evidence-based medical and surgical concepts (see Guideline 13.1) designed to maintain hemoglobin concentration, optimize hemostasis, and minimize blood loss in an effort to improve patient outcome.[26]

Standard 13.2: The Perfusionist shall minimize the cardiopulmonary bypass circuit size to reduce prime volume.[20]

Standard 13.3: The Perfusionist shall calculate and communicate to the surgical team prior to initiating cardiopulmonary bypass, a patient's predicted post-dilutional hemoglobin or hematocrit to allow time to prepare alternative strategies or changes to the care plan.

Guideline 13.1: Blood management efforts should include the following.[20, 27]

- Participate in pre-operative briefings (discussions) with the surgical care team (Standard 3.1) regarding transfusion strategies and target hematocrit values.
- Participation in a multidisciplinary blood management team.
- Minimize hemodilution by:
    - Ultrafiltration
    - Matching the size of the cardiopulmonary bypass circuit to the size of the patient
    - Autologous priming of cardiopulmonary bypass circuit, including retrograde arterial and/or venous antegrade priming
    - Biocompatible coating on the surface of all cardiopulmonary bypass circuitry
    - Perioperative blood cell recovery, cardiopulmonary bypass, and reinfusion
    - Cardiopulmonary bypass circuit blood salvage at the end of the procedure

Guideline 13.2: Laboratory and Point-of-Care hemostasis monitoring should be utilized to minimize blood loss. Monitoring may include:

- International normalized ratio
- Partial Thromboplastin time

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[26] Society of Thoracic Surgeons Blood Conservation Guideline Task Force, Ferraris VA, Brown JR, Despotis GJ, Hammon JW, Reece TB, Saha SP, Song HK, Clough ER; Society of Cardiovascular Anesthesiologists Special Task Force on Blood Transfusion, Shore-Lesserson LJ, Goodnough LT, Mazer CD, Shander A, Stafford-Smith M, Waters J; International Consortium for Evidence Based Perfusion, Baker RA, Dickinson TA, FitzGerald DJ, Likosky DS, Shann KG. 2011 update to the Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists blood conservation clinical practice guidelines. Ann Thorac Surg. 2011 Mar;91(3):944-82. doi: 10.1016/j.athoracsur.2010.11.078. PMID: 21353044.

[27] Task Force on Patient Blood Management for Adult Cardiac Surgery of the European Association for Cardio-Thoracic Surgery (EACTS) and the European Association of Cardiothoracic Anaesthesiology (EACTA), Boer C, Meesters MI, Milojevic M, Benedetto U, Bolliger D, von Heymann C, Jeppsson A, Koster A, Osnabrugge RL, Ranucci M, Ravn HB, Vonk ABA, Wahba A, Pagano D. 2017 EACTS/EACTA Guidelines on patient blood management for adult cardiac surgery. J Cardiothorac Vasc Anesth. 2018 Feb;32(1):88-120. doi: 10.1053/j.jvca.2017.06.026. Epub 2017 Sep 30. PMID: 29029990.

- Prothrombin time
- Thrombin time
- Thromboelastography/Thromboelastometry
- Platelet count
- Platelet function analysis
- Fibrinogen

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Standard 14: **Level of Readiness for Procedures that may require cardiopulmonary bypass support**

Standard 14.1: Procedures identified preoperatively to be at elevated risk of requiring conversion to a cardiopulmonary bypass procedure shall have a protocol for transition to such procedures.

Standard 14.2: One Perfusionist shall be assigned for each such standby procedure.

Standard 14.3: A heart-lung machine consisting of a sterile extracorporeal set-up and ancillary equipment (Ref: Appendix B) shall be readily available for the procedure.

Standard 14.4: Assembly and maintenance of circuit shall be regulated according to institutional protocol using aseptic technique.[28]

Guideline 14.1: The level of readiness for utilizing cardiopulmonary bypass during a surgical procedure should be determined through consultation with the surgical team.

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[28] Considerations when pre-priming medical devices. The Joint Commission. https://www.jointcommission.org/standards/standard-faqs/hospital-and-hospital-clinics/infection-prevention-and-control-ic/000002338/?p=1 (accessed March 20, 2022)

Standard 15: Staffing and On-call

Guideline 15.1: The “n+1” staffing model should be utilized at all times, where “n” equals the number of operating/procedure rooms in use at any given time at a single site. [29]

Guideline 15.2: An on-call Perfusionist should be present and clinically ready for unscheduled and emergency procedures within 60 minutes of being called.

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[29] Generally, the minimum safe number of perfusion staff: defined as N + 1, where N equals the number of operating/procedure rooms in use at any given time at a single site. (Ref: UK Code of Practice https://assets.website-files.com/5da4ad68b9d5374c5a54c71d/5da742c4b9d497537544e0b7_SCPS-%20CODE%20OF%20PRACTICE%20-%202019.pdf; accessed March 6, 2021).

Example: If three operating/procedure rooms are concurrently in use then the minimum safe number of clinical perfusionists available to cover this level of activity is deemed to be four. Non-qualified staff members (e.g., students or staff who have not completed training adequate to meet the requirements of the activity) must not be included in calculating the minimum safe number of staff.

Standard 16: Duty Hours

Standard 16.1: In order for the Perfusionist to ensure proper provision of care, he/she shall receive an adequate rest period between scheduled work hours.[30]

Guideline 16.1: The Perfusionist should receive a minimum of 8 hours of rest period for every 16-hour consecutive work period.

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[30] 10.0 Tiredness and European Working Time Directive (EWTD). The Society of Clinical Perfusion Scientists of Great Britain and Ireland *and* The College of Clinical Perfusion Scientists of Great Britain and Ireland Standards of Practice Document https://assets.website-files.com/5da4ad68b9d5374c5a54c71d/5da743ffa1b0aaa1cb7351e0_SCPS%20-%20Standards%20Of%20Practice%20-%202019.pdf (accessed December 4, 2022)

Standard 17: Quality Assurance and Improvement

Standard 17.1: The Perfusionist shall actively participate in both institutional and departmental quality assurance and improvement programs, and safety reporting systems.

Standard 17.2 The Perfusionist shall collect data concerning the conduct of perfusion via a clinical registry or database to advance quality and safety.[31,32]

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[31] Warren CS, DeFoe GR, Groom RC, Pieroni JW, Groski CS, Morse CB, Connors EM, Lataille PJ, Ross CS, Likosky DS; Northern New England Cardiovascular Disease Study Group. Variation in arterial inflow temperature: a regional quality improvement project. J Extra Corpor Technol. 2011 Jun;43(2):58-63. PMID: 21848173; PMCID: PMC4680024.
[32] Baker RA, Newland RF, Fenton C, McDonald M, Willcox TW, Merry AF; Perfusion Downunder Collaboration. Developing a benchmarking process in perfusion: a report of the Perfusion Downunder Collaboration. J Extra Corpor Technol. 2012 Mar;44(1):26-33. PMID: 22730861; PMCID: PMC4557436.

Standard 18: Maintenance

Standard 18.1: The Perfusionist shall ensure that equipment used in the conduct of cardiopulmonary bypass is properly maintained and functioning, including cleaning and disinfecting

Standard 18.2: Preventive maintenance on perfusion equipment shall be performed by appropriately trained and qualified manufacturer technicians, representatives, or Bio-Medical technicians. Regularly scheduled maintenance shall be documented by the perfusion department and/or Bio-Medical engineering staff. The interval of such maintenance shall be consistent with manufacturer recommendations, applicable external accrediting agency guidelines and institutional requirements.

Standard 18.3: The organization shall follow a protocol for perfusion equipment failures.[33]

Standard 18.4: Appropriate backup perfusion supplies and equipment shall be readily available.

Standard 18.5: The organization shall follow a protocol for acknowledging and addressing perfusion equipment notices (e.g., recalls, warnings, and advisories).

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33 New CMS & Joint Commission Regulations on Medical Equipment Maintenance: Taking the Smart Approach to Compliance. ABM Healthcare Support Services. https://info.abm.com/New-CMS-Joint-LP.html (Accessed March 6, 2021)

Standard 19: Crisis Management

Standard 19.1: The perfusionist shall participate in a collaborative effort to implement an actionable crisis management plan for unforeseen circumstances that may prohibit the ability to perform standard duties.[34][35]

Guideline 19.1: Alternate vendors for vital equipment should be identified in order to address supply chain interruptions.

Guideline 19.2: Alternate storage and staging areas should be identified in the event primary/routine areas are compromised.

Guideline 19.3: Perfusionist should have a working knowledge of the infrastructure of the institution in order to identify operating room facilities that are suitable for cardiopulmonary bypass procedures when routine surgical suites are unavailable.

Guideline 19.4: Clinical personnel should have a procedure for patient evacuation and potential support for patients committed to cardiopulmonary bypass while evacuations are in progress.

Guideline 19.5: Clinical expertise, education, and proper role assignment should be considered if Perfusion staff repurposing is required.

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[34] Preparedness for Specific Types of Emergencies. Centers for Disease Control and Prevention. https://emergency.cdc.gov/planning/ (accessed March 6, 2021).

[35] Crisis management plans should be reviewed and approved by the Chairman of Cardiac Surgery, or their designee, Director of Perfusion, or equivalent, and other relevant clinical governance committees if available. See Standard 1.2.

Relevant Publications

American Society of Extra-Corporeal Technology. Perfusion practice survey, September, 1993. *Perfusion Life* 1994; **11**: 42–45.

American Society of Extra-Corporeal Technology. Guidelines for perfusion practice. *Perfusion Life* 1995; **12**: 20–22.

American Society of Extra-Corporeal Technology. Members accept essentials; approve revised code of ethics. *Perfusion Life* 1993; **10**: 14.

Kurusz M. Standards of practice in perfusion. *Perfusion* 1994; **9**: 211–15.

Aaron G Hill, Mark Kurusz. Perfusion Standards and Practice. *Perfusion* 1997; 12:251-255.

2019 EACTS/EACTA/EBCP guidelines on cardiopulmonary bypass in adult cardiac surgery. Wahba A, Milojevic M, Boer C, De Somer FMJJ, Gudbjartsson T, van den Goor J, Jones TJ, Lomivorotov V, Merkle F, Ranucci M, Kunst G, Puis L; Eur J Cardiothorac Surg. 2019; 57: 210-251.

The Society of Clinical Perfusion Scientists of Great Britain and Ireland *and* The College of Clinical Perfusion Scientists of Great Britain and Ireland

- Standards of Practice Document. https://global-uploads.webflow.com/5da4ad68b9d5374c5a54c71d/5da4ad68b9d537cbe854ca4a_Recommended%20Standards%20Of%20Monitoring%20During%20Cardiopulmonary%20By Pass.pdf (Accessed May 15, 2023)
- Codes of Practice Document. https://global-uploads.webflow.com/5da4ad68b9d5374c5a54c71d/5da4ad68b9d537fd6654c82a_SCPS%20-%20Good%20Practice%20Guide.pdf (Accessed May 15, 2023)

The Australian and New Zealand College of Perfusion.

- ANZCP Code of Ethical Practice. (https://anzcp.org/wp-content/uploads/2020/06/ANZCP-IT-Code-of-Ethical-Practice.pdf Accessed May 15, 2023)
- ANZCP Code of Professional Conduct. (https://anzcp.org/wp-content/uploads/2022/02/ANZCP-Code-of-Professional-Conduct-Final-Approved-21022022.pdf Accessed May 15, 2023)