

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: November 20, 2023

Findings Date: November 20, 2023

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: J-12437-23

Facility: Duke University Hospital

FID #: 943138

County: Durham

Applicant(s): Duke University Health System, Inc.

Project: Cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR)

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Duke University Health Systems, Inc. (hereinafter referred to as “the applicant”) proposes a cost overrun (COR) for previously approved Project ID # J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at Duke University Hospital (DUH).

A certificate of need was issued on June 29, 2020, for Project ID # J-11851-20 and authorized a capital expenditure of \$4,677,999. The current application proposes a capital cost increase of \$1,797,001 over the previously approved capital cost for a total combined capital cost of \$6,475,000.

The applicant does not propose to develop any new health service facility beds, services or equipment for which there is a need determination in the 2023 State Medical Facilities Plan (2023 SMFP) nor does the applicant propose to offer a new institutional health service for which there are any policies in the 2023 SMFP. Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

The applicant states that this cost overrun application is necessary due to increased costs, primarily related to price escalation for construction and equipment, since the issuance of the original certificate of need. The applicant proposes no material change in scope from the originally approved project in this application.

Patient Origin

In Section C, pages 39-40, the applicant states it does not project any changes to patient origin. The application for Project ID #J-11851-20 was found conforming with Criterion (3) with regard to projected patient origin. No changes are proposed in this application which would affect that determination.

Analysis of Need

The following table compares the capital cost approved in Project ID # J-11851-20, the changes proposed in this application, and the new projected capital costs, as reported on Form F.1b in Section Q.

	Previously Approved Capital Expenditures (Project ID #J-11851-20)	Total Combined Proposed Capital Expenditures	Net Increase/(Decrease) in Capital Expenditure (Project ID #J-12437-23)
Construction Contracts	\$1,922,999	\$2,427,025	\$504,026
Architect/Engineering Fees	\$250,000	\$328,200	\$78,200
Medical Equipment	\$2,430,407	\$2,738,857	\$308,450
Non-Medical Equipment	\$50,293	\$296,886	\$246,593
Furniture	\$24,300	\$22,600	-\$1,700
Other (permits/inspection)	\$0	\$39,050	\$39,050
Other (contingency)	\$0	\$622,382	\$622,382
Total Capital Cost	\$4,677,999	\$6,475,000	\$1,797,001

In Section C, page 39, the applicant states that cost overrun application is necessary due to increased costs, primarily related to price escalation for construction and equipment, since the issuance of the original certificate of need. The applicant states the reason behind the increases is primarily related to costs that increased significantly during the COVID-19 pandemic and were known to affect the construction industry in particular. On page 39, the applicant states the following sets forth the specific reasons for the cost increases by line item in Form F.1b:

- Construction/Renovation Contract(s)- Increased due to market cost escalation.
- Architect/Engineering Fees – Updated based on current design proposals. Updated design work was necessary due to the delay in the project to ensure the project design remained operationally and clinically optimal. The resulting design is materially similar to the original design and does not reflect any change in scope of the services to be provided. The architect’s quote reflecting construction costs and fees is included in Exhibit F.1(b).
- Medical Equipment – Updated to reflect latest quotes from vendors, included in Exhibit F.1(b).
- Non-Medical Equipment (technology) –The updated technology costs included the integration costs for the Karl-Storz equipment. These costs were included in the original medical equipment cost estimate but Duke now believes that it is more precise to include them in the technology line item. Any increased costs for integration reflect inflation and not any change in scope or design.
- Furniture- Updated based on current furniture estimates and moving fees.
- Other (utilities, permits, inspections)- Updated to reflect current costs (original expenses may have been included in the construction total; now broken out separately).
- Contingency – This updated budget includes a contingency to account for any additional cost increases going forward.

The information is reasonable and adequately supported because the applicant adequately explains the reasons additional costs are necessary to develop the proposed project.

Projected Utilization

In Section C, page 40, the applicant states it does not project any changes to projected utilization as part of the proposed project. Project ID #J-11851-20 was found conforming with Criterion (3), with regard to projected utilization. No changes are proposed in this application which would affect that determination.

Access to Medically Underserved Groups

In Section C, pages 40, the applicant states it does not project changes to access by medically underserved groups because of the proposed project. The application for Project ID #J-11851-20 adequately demonstrated the extent to which all residents of the area, including underserved groups, were likely to have access to the proposed services. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

In Section E, page 45, the applicant states,

“DUHS is committed to completing this project, as the need for the project originally identified still exists. For the same reasons that is the most effective alternative as set forth in the original application, this remains the most effective alternative to develop this service. While DUHS will continue to make all reasonable efforts to control construction costs, the increased construction and equipment costs reflect national inflationary trends.”

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The applicant does not propose any change to the scope of the project as described in the application for Project ID #J-11851-20.
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. The total combined capital expenditure for this project and Project ID#J-11851-20 is \$6,475,000, an increase of \$1,797,001 over the capital expenditure of \$4,677,999 previously approved in Project ID# J-11851-20.**
 - 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on May 1, 2024.**
 - 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 5. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

Capital and Working Capital Costs

The following table compares the capital cost approved in Project ID# J-11851-20, the changes proposed in this application, and the new projected capital costs, as reported on Form F.1b in Section Q.

	Previously Approved Capital Expenditures (Project ID #J-11851-20)	Total Combined Proposed Capital Expenditures	Net Increase/(Decrease) in Capital Expenditure (Project ID #J-12437-23)
Construction Contracts	\$1,922,999	\$2,427,025	\$504,026
Architect/Engineering Fees	\$250,000	\$328,200	\$78,200
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Furniture	\$24,300	\$22,600	-\$1,700
Other (permits/inspection)	\$0	\$39,050	\$39,050
Other (contingency)	\$0	\$622,382	\$622,382
Total Capital Cost	\$4,677,999	\$6,475,000	\$1,797,001

In Section C, pages 38-40, the applicant states that cost overrun application is necessary due to increased costs, primarily related to construction and equipment price escalation, since the issuance of the original certificate of need. The applicant states the reason behind the increases is primarily related to costs that increased significantly during the COVID-19 pandemic.

In Section F, pages 53-54, the applicant states there are no startup costs or initial operating expenses associated with this project.

The information provided by the applicant is reasonable and adequately supported based on the reasons described above.

Availability of Funds

In Section F, page 52, the applicant states that the capital cost will be funded as shown in the table below.

SOURCES OF CAPITAL COST FINANCING

TYPE	TOTAL
Loans	
Accumulated Reserves/ Investments or OE *	\$1,797,001
Bonds	
Other (Specify)	
Total Financing	\$1,797,001

*OE = Owner's Equity

Exhibit F.2 (a) a letter dated October 10, 2023, from the interim Chief Financial Officer of Duke University Health System. The letter states DUHS will fund the entire capital costs with

accumulated reserves and commits to using the available accumulated reserves to develop the proposed project. Exhibit F.2 (b) contains Duke University Health System Consolidated Financial Statements and Supplementary Schedules for June 30, 2023 and 2022 the applicant had adequate cash and assets to fund the proposed project. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides appropriate documentation to confirm the availability of the accumulated reserves it plans to use to develop the proposed project.
- In Project ID #J-11851-20, the applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the proposed project, and the applicant does not propose any changes in this cost overrun application which would affect that determination.

Financial Feasibility

In Section F, pages 50-55, the applicant states the financial projections it previously provided in Project ID #J-11851-20 will change, even though the applicant is not proposing a change to the scope of the project, because the facility will now offer services later than originally anticipated and inflation will impact revenues.

On Form F.2b in Section Q, the applicant projects that revenues will exceed operating expenses in the third full fiscal year of the proposed project, as shown in the table below.

Revenues and Operating Expenses Duke University Health System FYs 1-3 (CYs 2026-2028)			
	FY 1 (CY 2026)	FY 2 (CY 2027)	FY 3 (CY 2028)
Gross Revenue (Charges)	\$20,330,28	\$21,163,103	\$22,029,654
Net Revenue	\$6,532,431	\$6,797,120	\$7,070,364
Operating Expenses (Costs)	\$6,718,955	\$6,889,770	\$7,061,331
Net Income/(Loss)	(\$186,523)	(\$92,650)	\$9,032

The applicant provides the assumptions and methodology it uses to project income and operating expenses in Form F.2b in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported because they are based on the projections provided in Project ID#J-11851-20 which have been adjusted for inflation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits of the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

The application for Project ID#J-11851-20 was found conforming with Criterion (6). The applicant does not propose any changes in this cost overrun application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

The application for Project ID #J-11851-20 adequately demonstrated the availability of resources, including health manpower and management personnel to provide the proposed

services, and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

The application for Project ID #J-11851-20 adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system, and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

This applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

A certificate of need was issued on June 29, 2020, for Project ID #J-11851-20 and authorized a capital expenditure of \$4,677,999. The current application proposes a capital cost increase of \$1,797,001 over the previously approved capital expenditure for a total combined capital expenditure of \$6,475,000. The applicant states that cost overrun application is necessary due to increased costs, primarily related to price escalation for construction and equipment, since the issuance of the original certificate of need. The applicant proposes no material change in scope from the originally approved project in this application.

In Section K, pages 63- 65, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant is not proposing to change the scope of the construction or design previously proposed in Project ID #J-11851-20.
- The applicant adequately explains why the increased cost is necessary for the proposed project.
- Project ID #J-11851-20 was conforming with this criterion and this application does not propose any changes which would affect that determination.

In Section K, page 64, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant is not proposing to change the scope of the project as proposed in Project ID #J-11851-20.
- The applicant states it has set aside excess revenues to be able to pay for projects like these without needing to increase costs or charges to patients.
- Project ID #J-11851-20 was conforming with this criterion and this application does not propose any changes which would affect that determination.

In Section B, pages 24 - 26, the applicant identifies and describes any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Project ID # J-11851-20, the Agency determined the applicant adequately demonstrated the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Project ID #J-11851-20, the Agency determined the application was conforming to this criterion. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Project ID #J-11851-20, the Agency determined the applicant adequately demonstrated the extent to which medically underserved populations will be served by the applicant's proposed services. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Project ID #J-11851-20, the Agency determined the applicant adequately demonstrated it would offer a range of means by which a person would have access to its services. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

In Project ID# J-11851-20, the Agency determined the applicant adequately demonstrated that the proposed health services would accommodate the clinical needs of health professionals

training programs in the area. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

The application for Project ID #J-11851-20 was found conforming with Criterion (18a). The applicant does not propose any changes in this cost overrun application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

On Form O in Section Q, the applicant identifies the hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 4 of these types of facilities located in North Carolina.

In Section O, page 74, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents which resulted in a finding of immediate jeopardy at any of the facilities listed on Form O. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in one of these facilities; however, the facility is now back in compliance. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 18 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes a cost overrun for Project ID #J-11851-20 (acquire one unit of angiography equipment for an existing OR to create a hybrid OR) at DUH.

There were no administrative rules applicable to Project ID #J-11851-20, and there are no changes proposed in this application which would affect that determination. Therefore, this criterion is not applicable to this review.