

April 26, 2019

Donna Jerry
Senior Health Policy Analyst
Green Mountain Care Board
89 Main Street, Third Floor, City Center
Montpelier, Vermont 05620

Re: Norris Cotton Cancer Center North
1080 Hospital Drive, St Johnsbury, VT
Pharmacy USP 797 / 800 upgrade project

Dear Ms. Jerry,

Dartmouth Hitchcock (D-H) provides cancer treatment at our Norris Cotton Cancer Center – North (NCCC-N) in St. Johnsbury, VT. This facility provides compounded pharmaceutical products as required for patient care. Recent changes to the U. S. Pharmacopeia Convention (USP) standards for sterile and hazardous drug compounding pharmacies require renovations of our facility to meet new requirements. This letter is to provide an overview of that work and to request a jurisdictional determination from the Green Mountain Care Board in regards to Certificate of Need Requirements.

USP standards, chapters 797 and 800, provide enforceable standards for sterile and hazardous drug compounding. USP 797 addresses requirements for non-hazardous sterile compounding. USP 800 addresses the requirements for hazardous sterile compounding. These standards have new requirements that affect the built environment used to compound drugs as well as operational procedures and many other facets of the compounding process. Both USP 797 and USP 800 are considered standards of practice and as such are enforced by the Joint Commission, CMS, the FDA and the state Boards of Pharmacy. All regulated facilities are expected to be in full compliance prior to December 1, 2019.

Our NCCC-N facility is housed at 1080 Hospital Drive in St. Johnsbury. We have a long term lease agreement with Northeastern Vermont Regional Hospital (NVRH) for a portion of the space in the former Ames Department store building. NVRH leases the remainder of the building to other tenants. Our pharmacy at NCCC-N compounds products to be used for cancer treatment on site. The services provided are Hospital Based Ambulatory Services (HBAS).

Our existing pharmacy will not meet the new USP requirements as currently constructed. To address this, D-H has engaged SMRT Architects and Engineers to provide architectural design services and HP Cummings Construction to provide construction services for new clean rooms and associated spaces. This team is doing the same work at our Lebanon, NH facility. The end product will be a new pharmacy area with separate clean rooms and support spaces to produce hazardous and non-hazardous products for cancer treatment. The new pharmacy area will need to be larger in size to provide separation of hazardous and non-hazardous product storage and compounding. Both the hazardous and non-hazardous clean rooms will include space for an additional hood to accommodate the increased cycle time required by the USP (one product at a time plus cleaning) and to allow for redundancy should we experience a problem that won't allow us to use a particular hood.

Because of the need to maintain patient treatment during the project, we looked at two different approaches to the project. The first option considered was to provide a temporary pharmacy on site so that we could demo the

St Johnsbury Pharmacy USP 797 / 800 upgrade project

existing pharmacy and construct the new pharmacy in its place. The logistics to lease, locate and set up a mobile facility for this purpose proved to be cost prohibitive. Also, because many hospitals in the US are doing this same work, the availability of mobile systems is not within our schedule requirements. We also considered building a temporary clean room in other space in the building. Our research showed the cost to build and certify a space that will eventually be demolished did not make sense financially or operationally. Our final decision was to relocate some existing services, construct a new pharmacy in their place, then reconstruct the existing spaces in the old pharmacy footprint. This work will be done in a phased approach, allowing us to complete and certify the new clean room production areas ahead of the December 1, 2019 deadline. Some of the support space renovation work will extend into early 2020, but that necessary work is outside the USP requirements. The plans included with this letter reflect that approach.

The estimated project cost is \$2,250,000. This includes design, construction, equipment, temporary accommodations and misc. other items required to support the work. The overall breakdown of the costs is as follows:

- Design, permitting, temp accommodations: \$ 340,000
- Construction \$1,830,000
- Equipment and furnishings: \$ 80,000
- o Total estimated project cost \$2,250,000

D-H intends to fund the cost of this project thru existing operational revenue. No bonds or other funding sources are anticipated to be required.

The operational cost impact of this project will be minimal. The larger size of the pharmacy space and the ventilation requirements to support the added space will have an impact in energy use, but that is expected to be less than \$10,000/year. Our pharmacy staff is expected to increase by 0.4 employees to accommodate the increased procedure and documentation requirements called for in the regulations. This is expected to have a cost impact of \$28,000/year.

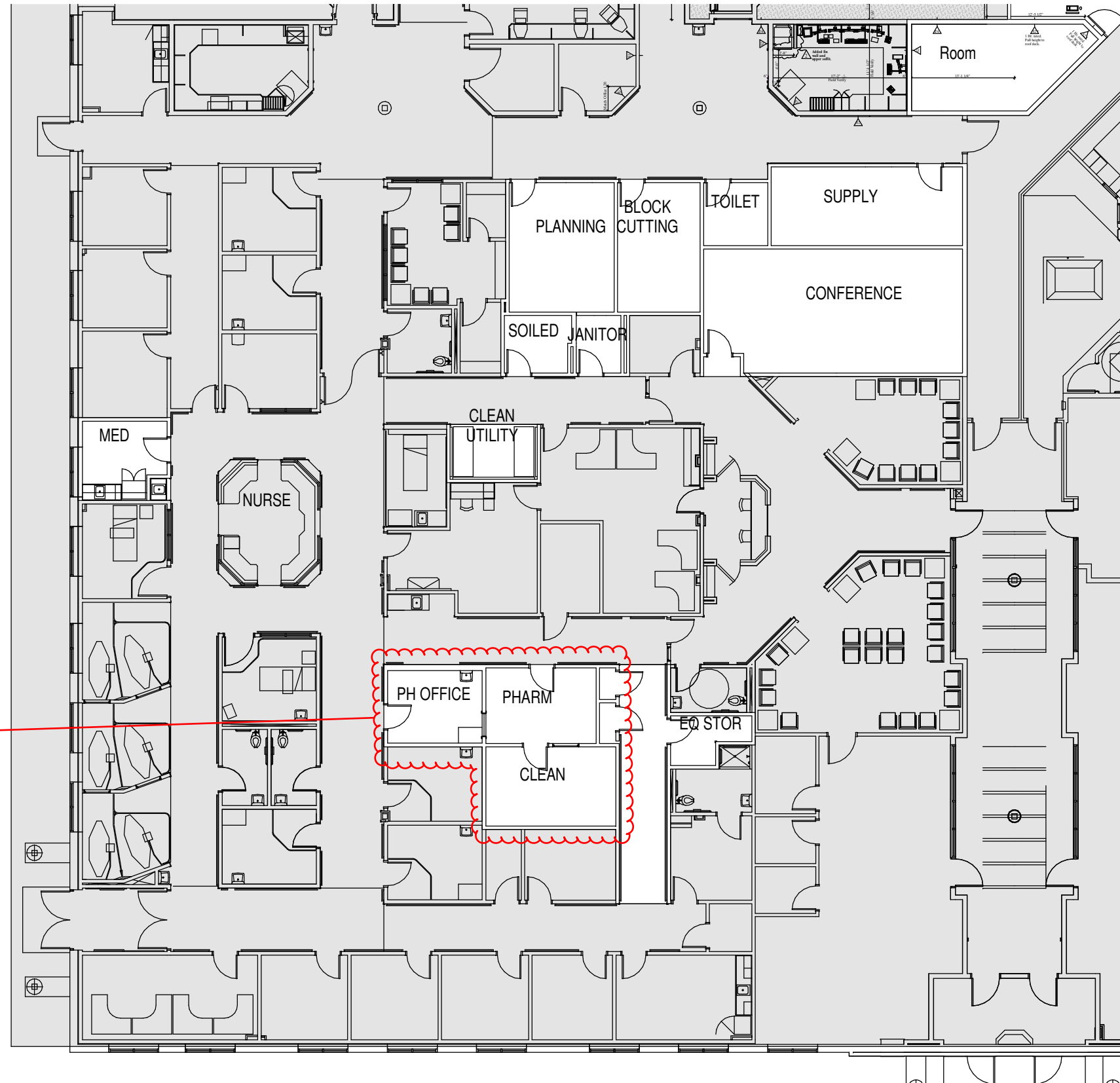
We hope this letter addresses any questions or concerns you have regarding this project. Our design process has taken longer than anticipated due to the time required to evaluate the various construction and schedule options. Due to the regulatory required deadline of December 1, 2019 we ask that this review be expedited as much as practical. We would be glad to meet with you to review the project if / as required. Please contact us at (603) 650-5741 for questions or via email at david.l.stiger@hitchcock.org. Thank you for your consideration and time.

Sincerely,



David Stiger
Director Project Management
Mary Hitchcock Memorial Hospital

Enclosures as noted

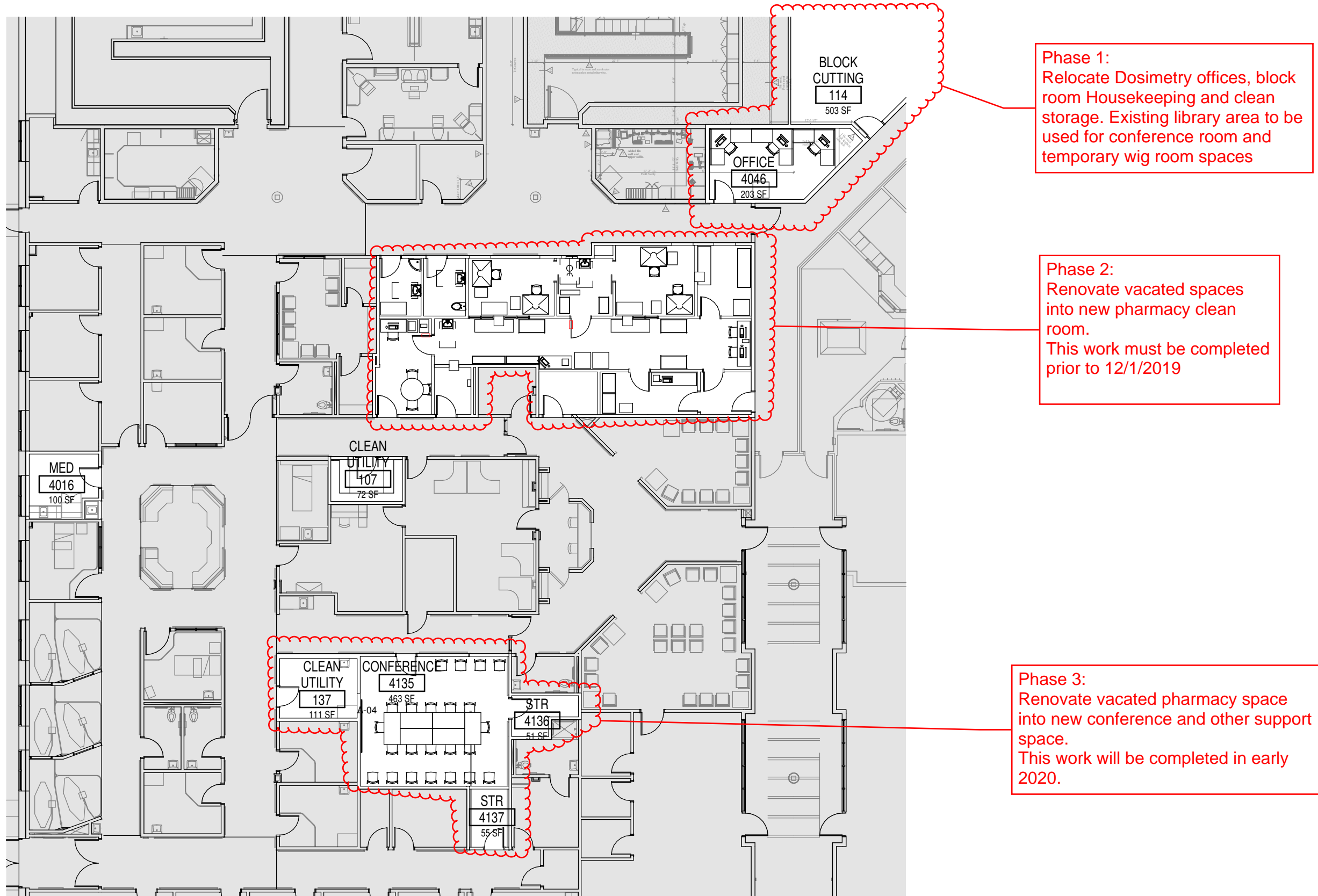


Existing Pharmacy

Existing Plan
DHMC ST JOHNSBURY PHARMACY
DARTMOUTH HITCHCOCK
1080 Hospital Drive
St Johnsbury, VT

4/12/19
1/16" = 1'-0"

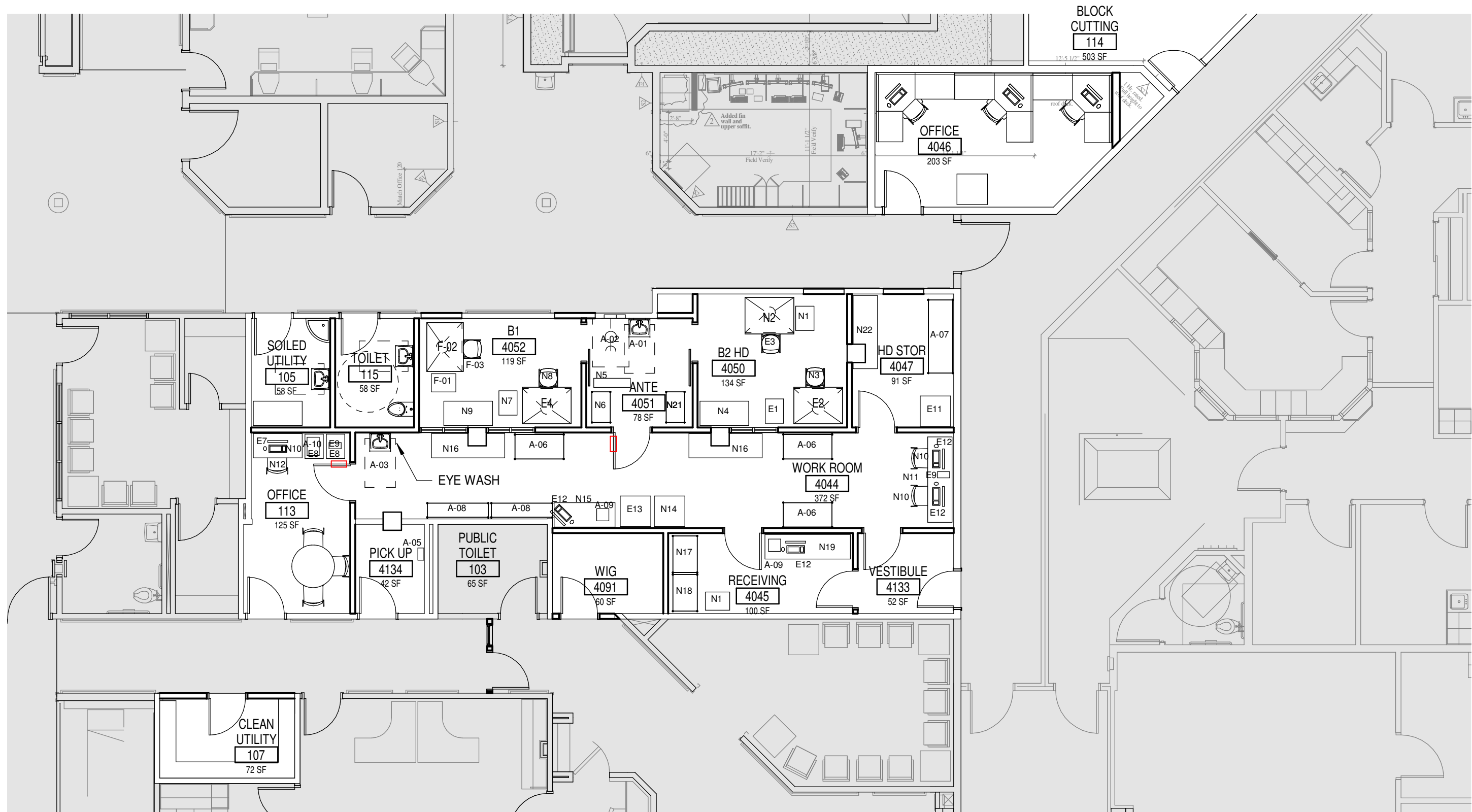




PHARMACY OVERALL
DHMC ST JOHNSBURY PHARMACY
DARTMOUTH HITCHCOCK
 1080 Hospital Drive
 St Johnsbury, VT

4/12/19
 1/16" = 1'-0"





PHARMACY CONFERENCE RM OPTION 2

DHMC ST JOHNSBURY PHARMACY

DARTMOUTH HITCHCOCK

1080 Hospital Drive

St Johnsbury, VT

4/12/19

1/8" = 1'-0"

EQUIPMENT SCHEDULE					
vv	Room: Name	Count	Description	DHMC Eq Num	Comments
4051	ANTE	1	SINK	A-01	NEW
4051	ANTE	1	EMERGENCY SHOWER	A-02	
4051	ANTE	1	BENCH	N5	NEW
4051	ANTE	1	PPE 18" X 30"	N6	
4051	ANTE	1	METRO RACK 18" X 30"	N21	
4052	B1	1	HOOD 4'-0"	E4	EXISTING
4052	B1	1	CART, 18X24	F-01	FUTURE
4052	B1	1	HOOD 4'-0"	F-02	FUTURE
4052	B1	1	STOOL, AMIA, VINYL	F-03	FUTURE
4052	B1	1	CART, 18X24	N7	NEW
4052	B1	1	STOOL, AMIA, VINYL	N8	NEW
4052	B1	1	TABLE, 24X48	N9	NEW
4050	B2 HD	1	CART, 18X24	E1	EXISTING
4050	B2 HD	1	HOOD 4'-0"	E2	EXISTING
4050	B2 HD	1	STOOL, AMIA, VINYL	E3	EXISTING
4050	B2 HD	1	CART, 18X24	N1	NEW
4050	B2 HD	1	HOOD 4'-0"	N2	NEW
4050	B2 HD	1	STOOL, AMIA, VINYL	N3	NEW
4050	B2 HD	1	TABLE, 24X48	N4	NEW
4135	CONFERENCE	1	TV, WALL MOUNTED	A-04	NEW
4047	HD STOR	1	METRO RACK 24" X 72"	A-07	
4047	HD STOR	1	REFRIGERATOR	E11	EXISTING
4047	HD STOR	1	TABLE, 24X72	N22	NEW
113	OFFICE	1	PRINTER	A-10	EXISTING
113	OFFICE	1	COMPUTER, PC	E7	EXISTING
113	OFFICE	2	FILE CABINET	E8	EXISTING
113	OFFICE	1	PRINTER - ZEBRA	E9	EXISTING
4046	OFFICE	3	COMPUTER, PC	E10	CONFIRM QTY/LOCATION

EQUIPMENT SCHEDULE					
vv	Room: Name	Count	Description	DHMC Eq Num	Comments
4046	OFFICE	1	REFRIGERATOR	E11	EXISTING
113	OFFICE	1	CHAIR	N10	NEW
113	OFFICE	1	DESK, 24X48	N12	NEW
4046	OFFICE	3	CHAIR, AMIA	N13	NEW
4134	PICK UP	1	WALL PHONE	A-05	EXISTING
4045	RECEIVING	1	SCANNER	A-09	EXISTING
4045	RECEIVING	1	COMPUTER, PC	E12	
4045	RECEIVING	1	CART, 18X24	N1	NEW
4045	RECEIVING	1	METRO RACK, 24X36	N17	A-06
4045	RECEIVING	1	METRO RACK, 24X36 2 SHELF	N18	A-06
4045	RECEIVING	1	TABLE, 24X84	N19	NEW
105	SOILED UTILITY	1	TABLE, 24X48	N9	NEW
4044	WORK ROOM	1	SINK	A-03	NEW
4044	WORK ROOM	3	METRO RACK 24" X 48"	A-06	
4044	WORK ROOM	2	METRO RACK 14" X 60"	A-08	
4044	WORK ROOM	1	SCANNER	A-09	EXISTING
4044	WORK ROOM	1	PRINTER - ZEBRA	E9	EXISTING
4044	WORK ROOM	3	COMPUTER, PC	E12	EXISTING
4044	WORK ROOM	1	REFRIGERATOR	E13	EXISTING
4044	WORK ROOM	2	CHAIR	N10	NEW
4044	WORK ROOM	1	DESK, 24X84	N11	NEW
4044	WORK ROOM	1	REFRIGERATOR	N14	NEW
4044	WORK ROOM	1	TABLE, 24X60	N15	NEW
4044	WORK ROOM	2	TABLE, 24X72	N16	NEW

