AMENDMENT QUESTIONS #5

Responses should be sent to DoN staff at DPH.DON@State.MA.US

While you may submit each answer as available, please

- List question number and question for each answer you provide
- Submit responses as a separate word document, using the above application title and number as a running header and page numbers in the footer
- When providing the answer to the final question, submit all questions and answers in one final document
- Submit responses in WORD or EXCEL; only use PDF's if absolutely necessary. If "cutting and pasting" charts, provide them in a PDF so they can be clearly seen
- Whenever possible, include a table with the response
- For HIPAA compliance Do not include numbers <11.
- 1. Responses to DoN Questions #4 states, "In 2006, a DoN amendment was approved to acknowledge the licensure of the sites as separately licensed clinics and remove Shields Imaging of Massachusetts, LLC as the DoN holder. Accordingly, the three original sites were licensed to the following entities: Baystate MRI and Imaging Center, LLC (BMIC); Shields Imaging of Eastern Massachusetts, LLC (SIEM); and UMass Memorial MRI and Imaging Center, LLC ("UMMIC"). In converting the license to three separate clinics, the clinics each, in effect, acquired the right to operate DoN approved PET/CT service days, which they accomplished by leasing a second PET/CT unit."
 - a. When did the Holder acquire the second, leased PET-CT unit? The Holder began leasing the second PET/CT unit in 2021, after obtaining DoN approval for additional PET/CT service days via amendment UMMIC 20120208-AM and transfer of site approval BMIC-21031112-TS. The table below illustrates the cumulative change in DoN approved PET/CT service days from 2020 to 2021 and where those changes occurred. In total, there were 9 approved PET/CT service days following the approved changes in 2021, necessitating the use/lease of a second PET/CT unit to serve the newly approved days.

	2020	Unit	2021	Unit
UMMIC	2	Original Mobile	4	Original Mobile
SIEM	2	Original Mobile	2	Original Mobile
BMIC	2	Original Mobile	3	Leased Mobile
Total Days	6		9	

- b. Did the Holder receive DoN approval to acquire the second PET-CT unit? As indicated in the table above, the Holder received DoN approval to increase PET/CT service days in 2021 via amendment UMMIC 20120208-AM and transfer of site approval BMIC-21031112-TS. In total, there were 9 approved PET/CT service days following the approved amendment/tranfer in 2021, necessitating the need to lease a second PET/CT unit to serve the newly approved days.
- c. Provide the Holder's rationale for the addition of a second PET-CT unit. The rationale for leasing the second PET/CT unit was to service the aggregate number of DoN approved PET/CT service days for the Project. In total, there were 9 approved PET/CT service days following the DON approvals in 2021, necessitating the lease of a second PET/CT unit to serve the newly approved days.
 - i. Were additional days of PET-CT service added after acquiring the second PET-CT unit?

Yes. In 2023, the Holder received DoN approval for 3 additional PET/CT days of service via UMMIC 22122814-AM. This resulted in a total of 12 approved PET/CT service days. At present, UMMIC has operationalized a total of 5 days of service. The table below illustrates the cumulative number of DoN approved PET/CT service days for the Project in 2020, 2021, and 2023, respectively, and the allocation of those days by site. UMMIC and SIEM continue to be served by the original mobile unit; and BMIC continues to be served by the leased mobile unit.

	2020	2021	2023
UMMIC	2	4	7*
SIEM	2	2	2
BMIC	2	3	3
Total Days	6	9	12

^{*}UMMIC currently provides 5 days of PET/CT service per week, but will Increase to 7 days of per week in Q3 of 2025 as described in response to question 1.d.i., below.

ii. If so, did the Holder receive DoN approval to add the additional days of service? Yes. In 2023, the Holder received DoN approval for 3 additional PET/CT days of service via UMMIC 22122814-AM. In total, there were 12 approved PET/CT service days following the approval in 2023.

- d. The decision letter for the 2006 Amendment states, "The minor change requested in your letter of July 12 involves the deletion of Shields Imaging of Massachusetts, LLC as the provider of service for this project in order to correctly specify the individual consortium members currently licensed to provide the mobile PET services. The reason given for the minor change is that the deletion of Shields Imaging will correctly reflect the three clinics, Baystate MRI and Imaging Center, LLC, UMass Memorial MRI and Imaging Center, LLC and Shields Imaging of Eastern Mass, LLC., as the providers of services under the DoN and all subsequent amendments."
 - i. Explain why the 2006 Amendment, which acknowledged the three clinics as the separate providers of PET services, represents an approval for the acquisition of a second PET-CT unit?

As stated in the response to DoN Amendment Questions #4, the 2006 amendment, in effect, acknowledged the right of each of the three clinics to operate DoN approved PET/CT service days. The Holder received DoN approval to increase PET/CT service days in 2021 via amendment UMMIC 20120208-AM and transfer of site approval BMIC-21031112-TS. In total, there were 9 approved PET/CT service days following the approvals in 2021, necessitating the use/lease a second PET/CT unit to serve the approved days.

In 2023, the Holder received DoN approval for 3 additional PET/CT days of service via UMMIC 22122814-AM. In total, there were 12 approved PETCT service days following the approval in 2023.

The table below represents the cumulative change in PET/CT service days since 2020 inclusive of days reflected in pending DoN amendments SIEM 25020312-AM and BMIC-25012212-AM. It is further noted, that in Q3 of 2025, the original mobile unit approved for the Project will be converted to a fixed PET/CT unit to be located at UMMIC, that PET/CT service days will (if all are approved) be allocated among UMMIC, SIEM and BMIC in 2025 as set forth in the table below), and that the sites will be served by one fixed and two leased mobile PET/CT units as set forth in the table below.

	2020	2021	2023	2025	Unit
UMMIC	2	4	7	7	Fixed Unit
SIEM	2	2	2	7*	Leased Mobile
BMIC	2	3	3	7*	Leased Mobile
Total Days	6	9	12	21	

^{*}Pending DoN Amendment Approvals of all requested days

Health Alliance is a licensed and operational satellite clinic of UMass Memorial MRI and Imaging Center (UMMIC) (see attached clinic license).

After receiving DoN approval in 2023, the UMMIC license was amended to add two additional DoN approved satellite PET/CT clinics, one at Marlborough Hospital and one at Harrington Hospital (see pg 2 of the clinic license).

The Marlborough Hospital approval (UMMIC-22062409-RE), allows for one (1) day of PET/CT service at Marlborough Hospital at 157 Union Street, Marlborough, MA 01752.

The Harrington Hospital approval (UMMIC-22103111-RE) allows for one (1) day of PET/CT service at 100 South Street, Southbridge, MA 01550.

The table below reflects the changes in DoN approved PET/CT days of service allocated to UMMIC over time. The changes in DON approved PET/CT days of service at BMIC and SIEM are reflected in the Applicant's response to the Department's amended question 5.

2001	2005	2021	2023
3 days UMMIC @ Shrewsbury St	2 days UMMIC @ Shrewsbury Street	4 days UMMIC @ Shrewsbury Street per DoN Amendment	7 days UMMIC @Shrewsbury Street per DoN Amendment
	1 day UMMIC @ Health Alliance per DoN Amendment	1 day UMMIC @ Health Alliance	1 day UMMIC @ Health Alliance 1 day UMMIC @ Marlborough Hospital per DoN Amendment

	1 day UMMIC @ Harrington per DoN Amendment