

Shields Imaging of Eastern Massachusetts, LLC (SIEM)
DoN # 25020312-AM

AMENDMENT QUESTIONS #1

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. The Original DoN approval, and subsequent amendments involve the acquisition of a mobile PET unit while the proposed Significant Change Amendment involves a request to expand access to PET-CT services. Please explain the Holder's transition from providing PET services to PET-CT services.

Shortly after the original DoN approval, PET alone became obsolete and the industry quickly shifted to PET/CT in order to improve outcomes and add anatomical data to the physiological imaging provided through molecular imaging. There are few to no providers in the state using PET alone, particularly for tumor imaging.

Additionally, Computerized Tomography (CT) was not included on the DoN Required Equipment and Services Guideline until 2017.

2. The application states demand for PET-CT services at the Holder's site at South Shore Hospital, 55 Foggy Road, South Weymouth, has increased, resulting in the need for additional PET-CT capacity at this location (pg.3)

- a. Explain the reason(s) for increasing need for PET-CT services at this site.

There is a wider use and adoption of PET/CT as an imaging modality given its ability to detect and monitor various diseases, especially cancer, and its growing applications in non-oncologic conditions, leading to improved diagnosis and treatment strategies.

Specifically, PETCT has diversified beyond FDG tumor imaging to include prostate PET with PSMA, neuroendocrine tumor imaging with Dotatate tracer, and brain imaging with amyloid tracers. The continued drive in cancer screening, primarily by CT, leads to a malignancy determination often aided by non-invasive PETCT.

Additionally, cardiac applications have proven to be superior in select patient populations, particularly for sarcoidosis, and evaluating coronary disease in diabetic, bariatric, and female patients.

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3. The application states the current wait time is 15 days from referral to the date of the scan (pg.3)

- a. To better understand delays in accessing PET-CT services, provide average wait time from referral to date of scan, in 2020 through 2024.

2020: 11 days

2021: 11 days

2022: 14 days

2023: 17 days

2024: 15 days

- b. Explain the need to reduce the current wait time of 15 days?
i. What is the optimal wait time to receive a PET-CT scan?

The concept of timeliness to treatment suggests a seven to ten day window is best for cancer related cases, with new diagnosis targeted to a 7 day window.

- c. By how much does the Holder expect wait times to decrease as a result of the Proposed Project, and, in what year of project implementation does the Holder expect to see a decrease?

The goal is to accommodate critical cases between seven and ten days of referral, based on severity. Insurance clearance related delays not considered.

- d. Please provide any industry standard/ national benchmarks for optimal wait times for PET-CT services.

Shields is not aware of any industry standard/national benchmarks related to optimal wait times for PET/CT services, however, our experience in the market suggests that in most hospital settings patients are waiting up to 30 days.

At Shields, we strive to accommodate all patients in a timely manner to improve patient access, enhance medical outcomes and increase patient satisfaction.

4. Given the current PET-CT service operates two days a week, explain the methodology used, including data examined, to determine that 5 additional days of PET-CT service were needed to address increasing need for PET-CT service amongst the Holder's Patient Panel.

Several factors were employed to evaluate the expanded future demand for PET/CT. These include:

- Evaluation of CDC reported tumor registry data,
- Advisory Board national and regional PET/CT trending through Medicare data trends
- Incidence per population for specialty exams
- Alzheimer's Association data for patients seeking anti-amyloid therapy
- Hospital Data and incidence per population for cardiac procedures
- Industry trends in new protocol and tracer development

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5. Provide PET-CT scan volume by clinical specialty for the most recent year available.

2024 data

- Oncology: 2012
- Urology: 534
- Endocrinology: 39
- Neurology: 173
- Cardiology: 12

6. To better understand Patient Panel need for 5 additional days of PET-CT service please provide the following information:

- a. PET-CT unit scan capacity per day

Historically operating from 6:30 am to 10 pm, daily capacity is 30 patients

- b. Historical average daily volume per day for the past three years

2022: 19 cases

2023: 21 cases

2024: 26 cases

- c. Utilization rate for the past three years

2022: 63%

2023: 70%

2024: 86%

7. What will the hours of operation be on the 5 additional days of PET-CT services?

Requested Day(s) and Hours of Operation	Mon - Sun	6:30 am to	6:00 PM
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8. How will operating costs be impacted by the 5 additional days of PET-CT services?

The only operating costs impacted by the additional days of service is the daily equipment fee for the mobile unit and staffing of the unit.

9. How many amyloid brain scans were performed in 2024 out of the total number of PET-CT scans performed in 2024?

173 Amyloid brain scans were performed in 2024. This was the first year amyloid brain was commercially available.

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