PRIVACY IMPACT ASSESSMENT (PIA)

PRESCRIBING AUTHORITY: DoD Instruction 5400.16, "DoD Privacy Impact Assessment (PIA) Guidance". Complete this form for Department of Defense (DoD) information systems or electronic collections of information (referred to as an "electronic collection" for the purpose of this form) that collect, maintain, use, and/or disseminate personally identifiable information (PII) about members of the public, Federal employees, contractors, or foreign nationals employed at U.S. military facilities internationally. In the case where no PII is collected, the PIA will serve as a conclusive determination that privacy requirements do not apply to the system.

1. DOD INFORMATION SYSTEM/ELECTRONIC COLLECTION NAME:
RaySearch RayStation Radiation Therapy System Version 10.X_AI

2. DOD COMPONENT NAME:
Defense Health Agency

Cyber Logistics COE

3. PIA APPROVAL DATE:
02/28/23

SECTION 1: PII DESCRIPTION SUMMARY (FOR PUBLIC RELEASE)

a. The PII is: (Check one. Note: Federal contractors, military family members, and foreign nationals are included in general public.)
   From members of the general public
   From Federal employees
   x from both members of the general public and Federal employees
   Not Collected (If checked proceed to Section 4)

b. The PII is in a: (Check one.)
   New DoD Information System
   New Electronic Collection
   Existing DoD Information System
   Existing Electronic Collection
   Significantly Modified DoD Information System

   - RayPlanning: Patient contouring and treatment planning software
   - RayPhysics: Treatment machine modeling software
   - RayDoctor: Contouring and evaluation software for physician use
   - RayBiology: Software for research comparison of biological models

   The RaySearch RayStation Radiation Therapy System Version 10.X_AI software is a commercial software suite used by the Radiation Oncology Service to perform treatment planning for patients receiving radiation for a variety of medical conditions. RayStation allows the import and merging of Computed Tomography (CT) scans, Positron Emission Tomography (PET) scans and Magnetic Resonance Imaging (MRI) to provide the Oncologist with the required information for delineating the target volumes as well as avoidance regions; tools for the dosimetrist to plan and calculate the requested radiation plan; and Quality Assurance tools for the physicist to analyze the created therapy plan.

   The major components of RayStation include:
   - RayPlanning: Patient contouring and treatment planning software
   - RayPhysics: Treatment machine modeling software
   - RayDoctor: Contouring and evaluation software for physician use
   - RayBiology: Software for research comparison of biological models

   The categories of individuals with records in this system are Department of Defense (DoD) health care beneficiaries to include Military members of the Armed Forces, Military retirees, and their family members, as well as other categories of individuals eligible to receive medical care at DoD treatment facilities/activities. Personally Identifiable Information (PII) collected includes the patient's demographic information, medical information, and Protected Health Information (PHI). The PII in this system is obtained via a Digital Imaging and Communications in Medicine (DICOM) download from the Picture Archiving and Communication System (PACS), the Radiation Oncology Department CT scanner, or the legacy treatment planning system (Philips Pinnacle). The output documents from Philips Pinnacle and RayStation are stored in the department patient Electronic Medical Record (MHS GENESIS).

Cyberlog is responsible for the RMF process, and gaining an approval from DHA J6 RMED. Local sites are responsible for day to day operations, maintenance, and management of the device. Sites are responsible for ensuring the device is configured to meet CyberLOG and RMED approved configurations.

d. Why is the PII collected and/or what is the intended use of the PII? (e.g., verification, identification, authentication, data matching, mission-related use, administrative use)

   The PII is collected to match an individual with his/her medical images and to ensure accuracy when these images are integrated into the treatment plan for this individual. The PII collected will be used for mission-related purposes to support the delivery of health care services.

e. Do individuals have the opportunity to object to the collection of their PII? Yes x No

   (1) If "Yes," describe the method by which individuals can object to the collection of PII.
(2) If "No," state the reason why individuals cannot object to the collection of PII.

Individuals do not have the opportunity to object to the collection of their PII as RayStation is not the initial point of collection.

f. Do individuals have the opportunity to consent to the specific uses of their PII? Yes ☒ No

(1) If "Yes," describe the method by which individuals can give or withhold their consent.

(2) If "No," state the reason why individuals cannot give or withhold their consent.

Individuals do not have the opportunity to give or withhold consent to specific uses of their PII as RayStation is not the initial point of collection.

g. When an individual is asked to provide PII, a Privacy Act Statement (PAS) and/or a Privacy Advisory must be provided. (Check as appropriate and provide the actual wording.)

| Privacy Act Statement | Privacy Advisory | ☒ Not Applicable |

RayStation does not collect PII directly from individuals; therefore, no Privacy Act Statement or Privacy Advisory is required.

h. With whom will the PII be shared through data/system exchange, both within your DoD Component and outside your Component? (Check all that apply)

☒ Within the DoD Component
☒ Other DoD Components (i.e. Army, Navy, Air Force)
☒ Other Federal Agencies (i.e. Veteran's Affairs, Energy, State)
☒ State and Local Agencies
☒ Contractor (Name of contractor and describe the language in the contract that safeguards PII. Include whether FAR privacy clauses, i.e., 52.224-1, Privacy Act Notification, 52.224-2, Privacy Act, and FAR 39.105 are included in the contract.)
☒ Other (e.g., commercial providers, colleges).

Specify. DHA Military Treatment Facilities (MTFs)
Specify. US Army MTFs
Specify.
Specify.
Specify. The military treatment facilities (MTF) may utilize contractor services to support this product. DoD policy requires such contracts include language to safeguard PII including FAR clauses: 52.224-1, Privacy Act Notification; 52.224-2, Privacy Act; and FAR 39.105, Privacy. When the contractor has access to PHI, a HIPAA Business Associate Agreement is also required.

i. Source of the PII collected is: (Check all that apply and list all information systems if applicable)

Industries Databases
☒ Existing DoD Information Systems Commercial Systems
Other Federal Information Systems

Picture Archiving and Communication System (PACS)
Radiation Oncology Department CT Scanner
Philips Pinnacle

j. How will the information be collected? (Check all that apply and list all Official Form Numbers if applicable)

E-mail Official Form (Enter Form Number(s) in the box below)
In-Person Contact Paper
Fax Telephone Interview
☒ Information Sharing - System to System Website/E-Form
Other (If Other, enter the information in the box below)

k. Does this DoD Information system or electronic collection require a Privacy Act System of Records Notice (SORN)?

A Privacy Act SORN is required if the information system or electronic collection contains information about U.S. citizens or lawful permanent U.S. residents that is retrieved by name or other unique identifier. PIA and Privacy Act SORN information must be consistent.

☒ Yes ☐ No
I. What is the National Archives and Records Administration (NARA) approved, pending or general records schedule (GRS) disposition authority for the system or for the records maintained in the system?

1. NARA Job Number or General Records Schedule Authority.  GRS 5.2, item 020 (DAA-GRS-2017-0003-0002)

2. If pending, provide the date the SF-115 was submitted to NARA.

3. Retention Instructions.

FILE NUMBER: 103-14

DISPOSITION: Temporary. Delete no more than 7 years from the date last modified. (See DoD DTM 22-001 on default disposition policies and OSD Records Manager guidance which file number to associate).

m. What is the authority to collect information? A Federal law or Executive Order must authorize the collection and maintenance of a system of records. For PII not collected or maintained in a system of records, the collection or maintenance of the PII must be necessary to discharge the requirements of a statute or Executive Order.

1. If this system has a Privacy Act SORN, the authorities in this PIA and the existing Privacy Act SORN should be similar.
2. If a SORN does not apply, cite the authority for this DoD information system or electronic collection to collect, use, maintain and/or disseminate PII. (If multiple authorities are cited, provide all that apply).
   a. Cite the specific provisions of the statute and/or EO that authorizes the operation of the system and the collection of PII.
   b. If direct statutory authority or an Executive Order does not exist, indirect statutory authority may be cited if the authority requires the operation or administration of a program, the execution of which will require the collection and maintenance of a system of records.
   c. If direct or indirect authority does not exist, DoD Components can use their general statutory grants of authority ("internal housekeeping") as the primary authority. The requirement, directive, or instruction implementing the statute within the DoD Component must be identified.

5 U.S.C 301, Department Regulations; 10 U.S.C. Chapter 55, Sections 1071-1097b, Medical and Dental Care; 42 U.S.C. Chapter 117, Sections 11131-11152, Reporting of Information; DoD 6025.18-R, DoD Health Information Privacy Regulation; DoD 6010.8-R, CHAMPUS; DoD Instruction 6015.23, Delivery of Healthcare at Military Treatment Facilities: Foreign Service Care; Third-Party Collection; Beneficiary Counseling and Assistance Coordinators (BCACs); Pub.L. 104-91, Health Insurance Portability and Accountability Act of 1996; and E.O. 9397 (SSN), as amended.

n. Does this DoD information system or electronic collection have an active and approved Office of Management and Budget (OMB) Control Number?

Contact the Component Information Management Control Officer or DoD Clearance Officer for this information. This number indicates OMB approval to collect data from 10 or more members of the public in a 12-month period regardless of form or format.

Yes  x  No  Pending

1. If "Yes," list all applicable OMB Control Numbers, collection titles, and expiration dates.
2. If "No," explain why OMB approval is not required in accordance with DoD Manual 8910.01, Volume 2, "DoD Information Collections Manual: Procedures for DoD Public Information Collections."
3. If "Pending," provide the date for the 60 and/or 30 day notice and the Federal Register citation.

The information collected in this system is for the diagnosis and treatment of medical disorders and is not considered a public information collection in accordance with DoDM 8910.01, V2, Encl 3, paragraph 8b(5).