DEPARTMENT OF HEALTH

Report of Assembly of an X-ray System

MDH Received Date

1. X-ray System Location

a. Name of Hospital, Doctor, or location of installation	
b. Minnesota X-ray Unit Registration Number	
c. Street Address	
d. City	e. State
f. Zip Code	g. Telephone number

2. Assembler Information

a. Company Name	
b. Street Address	
c. City	d. State
e. Zip Code	f. Telephone number

3. General Information

a. This report is for assembly of certified components which are (*Select appropriate components)*

- ☐ New Assembly - Fully Certified System
- ☐ Reassembly - Fully Certified System
- ☐ Reassembly - Mixed System (Both certified and non-certified components)
- ☐ Change Components in an Existing System
- ☐ Change Tube in an Existing System
- ☐ An Addition to an Existing System

b. Intended use(s) (*Select appropriate uses*)

☐ Accelerator w/OBI	☐ CT-Spect	☐ Industrial Ionizer	☐ Radiographic
☐ Accelerator w/o OBI	☐ Electron Beam Litho	☐ Industrial Irradiator	☐ Rad/Fluoroscopic
☐ Bone Densitometer	☐ Electron Beam Processing	☐ Industrial Package	☐ Security Screening – Humans
☐ Breast Specimen	☐ Electron Beam Weld	☐ Industrial Radiography	☐ Stereotactic
☐ C-arm	☐ Electronic Brachytherapy	☐ Intraoral	☐ Suspected Hazards
☐ C-arm Mini	☐ Extraoral	☐ Intraoral/Ceph	☐ Therapy Superficial System
☐ CBCT	☐ Fluoroscopic	☐ Mammographic	☐ X-ray Diffraction
☐ CBCT-Research	☐ Gamma Knife w/OBI	☐ Medical Irradiator	☐ X-ray Gauge
☐ Cephalometric	☐ Hand-held Fluoroscopic	☐ O-arm	☐ X-ray Photoelectron Spectrometer
☐ CT	☐ Hand-held Intraoral	☐ Panoramic	☐ XRF
☐ CT-Pet	☐ Industrial Cabinet	☐ Pan/Ceph	
☐ CT-Research	☐ Industrial Fluoroscopy	☐ Particle Accelerator	
☐ CT-Simulator	☐ Industrial Ion-Implant	☐ Particle Size Analyzer	

c. The X-ray system is ☐ Stationary ☐ Mobile ☐ Portable	d. The master control is in room _____	e. Date of assembly _____

4. Component Information

a. The master control is ☐ A new installation ☐ Existing (*Certified*) ☐ Existing (*Non-certified*)	b. Control Manufacturer _____	d. Control Serial Number _____	e. Date Manufactured _____
	c. Control Model Number _____	f. System Model Name (*CT Systems Only*) _____	

Complete the following information for the certified components listed below which you installed. For beam limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicated spaces. For other certified components, enter number of each you installed in this system.

g. Selected Components

	Manufacturer	Model Number	Date Manufactured
Beam Limiting Device			
Tables			
Gantry			

h. Other Certified Components (*Enter number of each installed*)

[ ] X-Ray Control	[ ] Cradle
[ ] High Voltage Generator	[ ] Film Changer
[ ] Vertical Cassette Holder	[ ] Image Intensifier
[ ] Tube Housing Assembly	[ ] Spot Film Device
[ ] Dental Tube Head	[ ] Fluoroscopic Imaging Assembly
[ ] Cephalometric Device	[ ] Image Receptor
[ ] Image Receptor Support Device	[ ] Fluoroscopic Air Kerma display device
[ ] Other	

5. Assembler Certification

I affirm that all certified components assembled or installed by me, for which this-report is being made, were adjusted and tested by me according to the instructions provided by the manufacture(s), were of the type required by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21-CFR Part 1020 for this assembly have been furnished to the purchaser and, within 15 days following completion of assembly, a copy of this form will be submitted to the purchaser and, where applicable, to the State agency responsible for radiation protection.

a. Printed Name _____ b. Signature _____ c. Date _____

d. Minnesota Service Provider Number _____ e. Expiration Date _____

6. Comments