NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

NIST X-RAY PRODUCING MACHINE PROGRAM

NIST N 7201.03
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1. PURPOSE

The purpose of this Notice is to establish the general requirements and associated roles and responsibilities for the control of hazards associated with x-ray machines.

2. BACKGROUND

N/A

3. APPLICABILITY

The requirements of this Notice are applicable to all work involving x-ray machines used on the NIST-Boulder and NIST-Gaithersburg campus.

4. REFERENCES

a. 29 CFR 1910.1096, Ionizing Radiation

b. American National Standards Institute, Radiation Safety for X-ray Diffraction and Fluorescence Analysis Equipment, ANSI/HPS N43.2: 2021

5. APPLICABLE NIST DIRECTIVES

a. NIST S 7101.01: *Safety Rights and Responsibilities*

b. NIST S 7101.02: *Employee Reporting of Unsafe or Unhealthful Working Conditions*

c. NIST S 7101.03: *Stop Work*

[1] Please see Appendix A for revision history.

d. NIST S 7101.20: *Work and Worker Authorization Based on Hazard Reviews ("Hazard Review")*

e. NIST O 7201.00: *Ionizing Radiation Safety - Radioactive Material and Ionizing-Radiation-Producing Machines*

f. NIST S 7101.24: *Incident Reporting and Investigation*

6. GENERAL REQUIREMENTS

a. Training, Registration, and Inspection Requirements

(1) All x-ray machine (XRM) users shall receive radiation safety training, refresher training (offered every two years), and be authorized by the NIST Radiation Safety Division (RSD) and line management.

(2) All XRMs are required to be registered with RSD.

(3) All XRMs shall be inspected by RSD while operated by authorized individuals initially at the time of registration, then at prescribed intervals between one and three years and following any repairs or changes to the configuration that affect the hazard assessment.

b. Fail-Safe Interlocks

(1) Purchased systems shall include specifications and certifications that the system includes fail-safe interlocks.

(2) All x-ray machines shall be equipped with fail-safe interlocks (or a vacuum system), such that when triggered the production of x-rays shall be prevented, or the shutter shall close automatically.

(3) All interlocks shall be of a fail-safe design, meaning that upon failure of a safety or warning device, the primary beam is shuttered or powered off.

(a) The x-ray beam cannot be turned on or operated with a failed safety or warning device.

(4) Safety devices (*e.g.*, interlocks, shutters) with fail-safe features shall NEVER be bypassed without approval from the Radiation Safety Officer (RSO). Approval by the IRSC may be necessary for some machines.

(5) All shutters shall be provided with a fail-safe indicator of open/shut status.

(6) Control systems for XRMs shall prevent the unintentional generation of x-rays.

(a) If a key-actuated control is present, it shall be used to ensure that x-ray generation is not possible with the key removed.

(7) The safety interlocks/sensors shall not be used to turn off the XRM except in an emergency. Always use the method (key, software, switch, *etc.*) designed to turn off the specific XRM.

(8) After any interlock is triggered, the user should be able to be reset to full operation from a XRM control panel.

(9) Interlocks shall prevent a ground fault from generating x-rays.

c. Interlock Testing

(1) Safety interlocks shall be tested for operation at a minimum annually, or in accordance with manufacturer instructions.

(a) RSD shall be present while the machine owner or user operates the system to test the interlocks. X-ray machine vendors may also participate in interlock testing.

(b) Records of test results demonstrating that the machine is working properly shall be maintained by RSD for three years.

(c) There shall be a procedure to ensure the interlock safety devices are tested without damaging the devices for which the interlocks are meant to protect.

d. Failure of Interlocks

(1) If the interlocks fail to function normally, the XRM operation shall be subjected to a stop work status until it can be repaired to proper operating conditions.

(2) After an interlock fails and is repaired, the interlock in conjunction with the XRM is required to be retested as discussed in Section 6.c of this Notice "*Interlock Testing*."

(3) The RSO shall be informed immediately.

(4) In some cases, an emergency or administrative procedure shall be implemented per RSO approval.

(a) If unsafe to use administrative protocols, then RSD shall consider the XRM as "Inoperable" and shall tag the XRM with an appropriate notice bearing words such as "Do Not Energize X-ray Unit: This X-ray unit is NOT approved for use (status is INOPERABLE)", or words with similar intent until anomaly is corrected or the XRM is repaired.

(5) All NIST employees and covered associates shall refer to NIST S 7101.01, NIST S 7101.02, and NIST S 7101.03 for their rights and responsibilities for addressing work-related issues (including XRM operations) that presents an imminent danger to the health or safety of NIST employees, associates, visitors, or the public.

e. Radiological Incident and Emergency Reporting or RSD Notifications

(1) Life threating exposures or emergencies shall immediately be reported to

(a) The NIST Emergency Center (Gaithersburg x2222 and Boulder x7777) or call 911 for medical attention; and

(b) The RSO for potential radiation dose assessment and further investigation.

(2) Exposure to accelerating charged particles (*e.g.*, electron or proton beam), or x-rays (primary, scattered, or diffracted), resulting in an unnecessary radiation exposure shall be reported to the RSO immediately for further investigation as well as any other procedural reporting requirement.

(a) For after normal business hours, on weekends, and on holidays, call the NIST Emergency Number for Gaithersburg at x2222 or in Boulder x7777 and inform them to contact the RSO/RSD staff using the RSD call down list.

(3) As the RSO is responsible for the assessment of any radiological incident or emergency, either actual or potential incident/accidental radiation exposures, actual, potential, near miss, minor, or non-life threating exposures shall be reported to the RSO immediately for potential radiation dose assessment. Further investigation and personnel retraining may be required per the RSO's recommendations.

7. DEFINITIONS

a. Fail-Safe – A design in which all realistically anticipated failures of indicators or safety components result in a condition in which personnel are safe from exposure to radiation.

b. Interlock – A device or engineered system that prevents access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

c. Ionizing Radiation Producing Machine (IRPM) – A machine that generates ionizing radiation when energized, including, but not limited to, x-ray units, particle accelerators, neutron generators, and electron microscopes.

d. X-ray Machine – An assembly of components for the controlled production of x-rays using an electron tube designed for the conversion of electrical energy into x-ray energy.

8. ACRONYMS

a. ALARA – As Low As Reasonably Achievable

b. IRPM – Ionizing Radiation Producing Machine

c. RSD – Radiation Safety Division

d. RSO – Radiation Safety Officer

e. XRM – X-ray Machine

9. RESPONSIBILITIES

a. The Radiation Safety Officer (RSO) is responsible for:

(1) Developing, maintaining, reviewing, and enforcing a written radiation safety program for the safe and compliant use/operation of Ionizing Radiation Producing Machines (IRPMs) at NIST;

(2) Offering, as needed, advice and assistance on radiological safety matters to personnel whose assigned duties involve the use of, or exposure to, radiation from IRPMs; and

(3) Ensuring this Notice and other IRPM specific requirements regarding new technologies and NIST invented IRPMs are enforced.

b. OU Line Management (OU Directors, Division Chiefs, and Group Leaders) is responsible for:

(1) Ensuring IRPM users/operator have sufficient training experience commensurate with the proposed IRPM installations, or operations;

(2) Ensuring radiological hazard analysis of each IRPM is performed prior to operation;

(3) Ensuring radiological incidents related to IRPMs are reported and investigated in accordance with the requirements in Section 6.e, "Radiological Incident and Emergency Reporting or RSD Notifications."; and

(4) Ensuring the requirements of this Notice are integrated into the division procedures for authorizing IRPM work and workers in accordance with the requirements of NIST S 7101.20.

c. IRPM Users/Operators are responsible for:

(1) Meeting all applicable initial and refresher training requirements;

(2) Operating the IRPM in compliance with the standard operating procedure(s) (based on manufacturer's operating manual if applicable); and

(3) Immediately stopping work that is potentially unsafe or may result in radiation exposures that are not As Low As Reasonably Achievable (ALARA).

d. All Individuals Having Responsibilities in the IRPM Program are responsible for identifying to the RSO, and when appropriate, their own management, any issues that have, or may have, ALARA, radiation-safety, or regulatory-compliance implications, and providing assistance in the resolution of such issues.

10. AUTHORITIES

None

11. DIRECTIVE OWNER

Chief Safety Officer

12. APPENDICES

A. Revision History

Appendix A: Revision History

Version #	Approval Date	Effective Date	Brief Description of Change
1	05/21/2024	07/01/2024	• Initial document