DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	3/3/2026-3/4/2026
	FEI NUMBER 2182762

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Howard D. Larson, President

FIRM NAME	STREET ADDRESS
Radiation Products Design,Inc	5218 Barthel Industrial Dr Ne
CITY, STATE, ZIP CODE, COUNTRY Albertville, MN 55301-9766	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

One or more processes for risk management in product realization have not been adequately documented.

Specifically,

Your firm has not established, implemented or maintained a process for risk management in product realization. For example, I reviewed records pertaining to your tungsten eye shields (PN 936-583 through 936-627. You do not have a risk assessment or other record to formally document risks and risk management during product realization. Additionally, none of your finalized procedures establish how to assess risk.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Christina L Bigham, Investigator

X Christina L Bigham
Investigator
Signed By: Christina L. Bigham -S
Date Signed: 03-04-2026
14:48:50

DATE ISSUED
3/4/2026

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christina L Bigham, Investigator X Christina L Bigham Investigator Signed By: Christina L. Bigham -S Date Signed: 03-04-2026 14:48:50	3/4/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."