DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	2/10/2026-2/12/2026
	FEI NUMBER 3006073271

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Thomas M. Kraus, Vice President/Engineer

FIRM NAME	STREET ADDRESS
CNMC Company, Inc.	865 Easthagen Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Nashville, TN 37217-1137	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

Records of risk management activities in product realization were not adequately maintained.

Specifically,

Your firm manufactures a radiation dosimeter which is used in the calibration and quality control of medical equipment that produces ionizing radiation. Section 4.2 of your firm's QMS Risk Management (Doc #: 300021, Revision: A, Date: 08/15/2018), displays a Risk Assessment/Risk Evaluation. This Risk Assessment fails to adequately identify potential hazards and risk control measures associated with the intended use of your firm's medical device. For example,

A. Section 4.2's Risk Assessment/Risk Evaluation does not adequately identify potential hazards associated with the intended use of your medical device, such as those to patients undergoing ionization radiation treatment from medical equipment.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nikki S Bryant, Investigator	X Nikki S Bryant Investigator Signed By: NIKKI S. BRYANT -S Date Signed: 02-12-2026 14:28:36	2/12/2026

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CITY, STATE, ZIP CODE, COUNTRY Nashville, TN 37217-1137	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Promised to correct

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nikki S Bryant, Investigator	X Nikki S Bryant Investigator Signed By: NIKKI S. BRYANT -S Date Signed: 02-12-2026 14:28:36	DATE ISSUED 2/12/2026

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."