NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
InnerVision Advanced Medical Imaging 3801 Amelia Avenue Lafayette, IN 47905 REPORT NUMBER(S) 13-01	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-35552	13-32273-01	August 15, 2013

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☑ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Claire E. Wellinghoff	Claire Wellinghoff	8/22/13
BRANCH CHIEF	Aaron McCraw		8/22/13

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131	3.01-3.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02200	3	Kent Lancaster, M.D., RSO	(765) 447-7447

☑ Main Office Inspection Next Inspection Date: August 15, 2016

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was a diagnostic clinic authorized for materials in Section 35.100, 35.200, and 35.300. The nuclear medicine department was staffed with two full-time nuclear medicine technologists (NMT) who performed approximately 45 diagnostic nuclear medicine procedures per week. These studies included a full spectrum of diagnostic imaging studies (primarily PET), and the clinic received unit doses from a local radiopharmacy. The licensee rarely performed therapies utilizing I-131 authorized under Section 35.300; on average, only one I-131 treatment was performed per year at the clinic. Additionally, the license employed an outside health physics consultant to audit the radiation safety program on a quarterly basis.

Performance Observations

During the time of the inspection, the inspector observed three patient administrations. The inspector observed an NMT assay a unit dose and use a syringe shield while administering the dose to the patient. The licensee had recently purchased a PET infusion machine; the inspector observed the NMTs use this machine to deliver doses to patients as well. The NMTs demonstrated: (1) package receipt procedures; (2) daily calibrator checks; (3) daily surveys; (4) security of byproduct material; (5) spill response procedures; and (6) an inventory check with not identified issues. The inspection also consisted of a review of select licensee records including: (1) linearity test records; (2) weekly wipe test results; (3) quarterly audit reports; (4) disposal logs; (5) Radiation Safety Committee (RSC) meeting minutes; (6) ALARA notification reports; (7) dosimetry reports; and (8) written directives. The inspector reviewed all of the written directives since the time of the last inspection (last treatments on 3/27/13 and 11/02/12); the directives contained appropriate information including the patient name, prescribed dose, administered dose, and had been signed and dated by an appropriate Authorized User. Of the written directives reviewed, the inspector observed administered doses that ranged from approximately 15-70 mCi of I-131.