



November 22, 2016

United States Nuclear Regulatory Commission
Region III
2443 Warrenville Rd. Suite 210
Lisle, IL 60532-4352
Attention: Aaron T. McCraw

Re: "Reply to a Notice of Violation"

Violation 1.

"Title 10 of the Federal Code of Regulations (10 CFR) Section 34.47(a) requires, in part, that the licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all time during radiographic operations, each individual wears, at the trunk of the body, a direct reading dosimeter, an operating alarm ratemeter and a personnel dosimeter. The licensee's use of a single device, the RAD-60, is an apparent violation of 10 CFR 34.47(a)."

Response:

The regulations are not clear on the application of section 10 CFR 34.47(a). The wording implies the NRC is expecting three actions/response to take place. In the past, these three actions required different, individual types of equipment, specific to a required and dedicated response. However, technology has existed for many years that captures all the required responses and notifications to the user in a single unit with the exception of person dosimeter. The NRC is aware of this technology and to date has implied acceptance with the new technology through routine inspections. The inspector would measure compliance by ensuring the detection and notification tools used were compliant with the three requirements as stated in 10 CFR 34.47(a). Until recently the standard was a TLD – Personal Dosimeter and an electronic/digital device that performed rate alarm and direct reading dosimeter readings. It is IRISNDT's position the regulations do not specifically state the devices shall not be used for multiple functions. Only, that each device is to be worn at the trunk of the body. The RAD-60 and other electronic devices performs all functions that are required.

IRISNDT asked for clarity from the NRC on their position on this rule as it is vague as it currently reads. The issue was raised by a Member state that was having difficulty understanding the application of the wording. Once IRISNDT received some clarity on the subject from the NRC, measures were taken to immediately comply with the NRC's regulatory expectations.

IRISNDT is requesting the NRC to reconsider their position and judgement on the application of the regulation. We feel strongly the current technology provides compliance with the wording and application of the existing regulation. At one point in history, three distinct devices were required as the technology did not exist to find them in a single unit. However, with technological advancement, there now exists devices that are compact and meet the requirements of the regulatory wording found in 10 CFR 34.47(a). We are content that we are providing our staff with safer and more reliable devices. The electronic/digital devices provide the same notification and information requirements and in all cases are more reliable than an older style rate alarm and/or direct reading dosimeter. The issue of additional notification devices on a person will enhance safety and reliability is mute; It does not

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1115 W 41st Street
Tulsa, OK 74107
Ph.: (918) 446-8773
Fax: (918) 446-8777

Houston, TX (713) 722-7177
Beaumont, TX (409) 727-2400
Deer Park, TX (281) 476-4444
Corpus Christi, TX (361) 888-4700
El Dorado, KS (316) 452-5440

Tulsa, OK (918) 446-8773
Stanton, CA (714) 861-4058
Denver, CO (303) 289-5253
West Berlin, NJ (856) 809-0270
Canada (780) 437-2022

Claremore, OK (918) 343-1420
Griffith IN (219) 923-8501
Mobile, AL (251) 660-0024
New Orleans, LA (504) 328-0070
United Kingdom +44 1469 575728

Website: www.irisndt.com



matter if you have three or one device on a person, once one of these devices fails or indicates a questionable condition, staff will be required to stop work.

IRISNDT invites the NRC to properly access the use of new technology and associated devices and how this technology supports the wording and intent of 10 CFR 34.47(a). It is IRISNDT's position the most recent NRC interpretation of the application of 10 CFR 34.47(a) is a step backward and does not support the use of sound, reliable technology. The use of a distinct, electronic dosimeter does not jeopardize a worker's safety nor is it out of line with the intent of the wording and regulatory expectations found in 10 CFR 34.47(a).

Violation 2.

"Title 10 CFR Section 34.47(a) states that film badges must be replaced at periods not to exceed one month and that other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed 3 months. The use of Instadose devices relative to compliance with 10 CFR 34.47(a)(3) is an unresolved item, which remains under NRC review."

Response:

The Instadose device is not a film badge. It is a different technology. It works similar to the technology used for computer radiography. The device is NVLAP approved. IRISNDT does not send it out to be processed by the vender. Instead, it is plugged into a computer and is read by the vender's software. The devices are cleared of dose and is able to be reused. IRISNDT cannot manipulate the data that is provided to us by the vender. This is a relatively new technology that has the ability to provide companies and their staff with good, reliable and instantaneous information related to a person's radiation exposure. It eliminates wait time, but also maintains security of the information/data.

There are several positive advantages to using this technology, one being, the ability to read the device at any time, as long as internet connection is available and durability of the USP holder. However, after careful assessment of its current application in our business practices, we have decided to stop using the Instadose device and return to a traditional OSL/TLD system. We had already started the process to switch back to conventional TLD badges by the time the inspection of our facility happened.

IRISNDT is a strong supporter of new technology. The Instadose technology supplies IRISNDT and its staff with good reliable data, immediately and long term. IRISNDT is hoping to return to using the Instadose technology once there is a better maintenance program offered by the Third Party vendors supplying this tool. It also provides the NRC a chance to properly vet this technology so in the future it is an option for use by the radiography industry.

IRISNDT contents we used this device in good faith. It is NVLAP approved and contact was made with regulators to ensure compliance with regulatory programs.

If I can be of further assistance, please do not hesitate to call me at (219) 228-0890.

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Tulsa, OK 74107
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Houston, TX (713) 722-7177
Beaumont, TX (409) 727-2400
Deer Park, TX (281) 476-4444
Corpus Christi, TX (361) 888-4700
El Dorado, KS (316) 452-5440

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Stanton, CA (714) 861-4058
Denver, CO (303) 289-5253
West Berlin, NJ (856) 809-0270
Canada (780) 437-2022

Claremore, OK (918) 343-1420
Griffith IN (219) 923-6501
Mobile, AL (251) 660-0024
New Orleans, LA (504) 328-0070
United Kingdom +44 1469 575728

Website: www.irisndt.com



A handwritten signature in black ink, appearing to read 'Nathan Cox'.

Nathan Cox
Corporate Radiation Safety Officer
IRISNDT, Inc. Griffith, IN.

1115 W 41st Street
Tulsa, OK 74107
Ph.: (918) 446-8773
Fax: (918) 446-8777

Houston, TX (713) 722-7177
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Deer Park, TX (281) 476-4444
Corpus Christi, TX (361) 888-4700
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Griffith IN (219) 923-6501
Mobile, AL (251) 660-0024
New Orleans, LA (504) 328-0070
United Kingdom +44 1469 575728

Website: www.irisndt.com

IRIS NDT
7915 Maryland Ave
Hammond, IN 46323

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