

Cassata, James

From: Cassata, James
Sent: Monday, September 10, 2018 5:51 PM
To: 'Gary Winkler'
Cc: Burritt, Arthur; Ragland, Randolph
Subject: FW: RE: Use of Direct Ion Storage Dosimeters
Attachments: Mirion Technologies RFI Instadose.pdf

License Number: 10-35278-01
License Docket Number: 3038879
Licensee Name: Applied Technical Services, Inc.

Gary Winkler, Radiation Safety Officer
Applied Technical Services, Inc.
1049 Triad Court
Marietta, Georgia 30062
770-423-1400 x 3426
678-797-3426 (direct)
678-906-7972 (business mobile)

Mr. Winkler,

Thank you for your reply. We will send you a notification letter stating that you have requested to retract your request for a license exemption and we will be voiding your request without prejudice. Which simply means you may ask for an exemption in the future.

Sincerely,

James R. Cassata, Ph.D., CHP
Health Physicist
Nuclear Regulatory Commission (NRC), Region I
Division of Nuclear Materials Safety (DNMS),
Commercial, Industrial, R&D, and Academic Branch (CIRDA)
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From: Gary Winkler [mailto:gwinkler@atslab.com]
Sent: Monday, September 10, 2018 4:23 PM
To: Cassata, James <James.Cassata@nrc.gov>
Subject: [External_Sender] RE: Use of Direct Ion Storage Dosimeters

We sent a letter (attached) to Mirion requesting a response to the issues identified. Therefore, we are selecting option "B"

Retract your exemption request and wait for your next inspection to be evaluated against EGM-18-001. In the meantime, you can pursue the required documents from Mirion using the attached letter, and ensure you meet all the EGM criteria for the NRC to not pursue an enforcement action

From: Cassata, James [<mailto:James.Cassata@nrc.gov>]

Sent: Friday, September 07, 2018 2:15 PM

To: Gary Winkler <gwinkler@atslab.com>

Cc: Ullrich, Elizabeth <Elizabeth.Ullrich@nrc.gov>; Ragland, Randolph <Randolph.Ragland@nrc.gov>

Subject: RE: Use of Direct Ion Storage Dosimeters

Importance: High

License Number: 10-35278-01

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Mr. Winkler,

Have you decided which of the three options are you going to take (see below)? Please call me at your convenience.

Sincerely,

James R. Cassata, Ph.D., CHP

Health Physicist

Nuclear Regulatory Commission (NRC), Region I

Division of Nuclear Materials Safety (DNMS),

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james.cassata@nrc.gov



From: Cassata, James

Sent: Tuesday, August 14, 2018 4:15 PM

To: 'Gary Winkler' <gwinkler@atslab.com>

Cc: Ullrich, Elizabeth <Elizabeth.Ullrich@nrc.gov>

Subject: FW: Use of Direct Ion Storage Dosimeters

Importance: High

License Number: 10-35278-01

License Docket Number: 3038879

Licensee Name: Applied Technical Services, Inc.

Gary Winkler, Radiation Safety Officer
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Mr. Winkler,

As we discussed in our August 14, 2018, telephone call, in a letter dated 11/23/2016 you requested an exemption from the requirements of 10 CFR 34.47(a) to allow the use of direct ion storage (DIS) dosimetry, such as Instadose, for personnel monitoring.

We would like to tell you about recent developments within the NRC that mean you may not find it necessary to request an exemption to use Instadose or other DIS dosimetry.

In May 2018, the NRC issued an Enforcement Guidance Memorandum, EGM-18-001, "Interim Guidance for Dispositioning Apparent Violations of 10 CFR Parts 34, 36, and 39 Requirements Resulting from the Use of Direct Ion Storage Dosimetry during Licensed Activities." This guidance contains three criteria that, if met, would enable you to use Instadose or other DIS dosimetry without the NRC pursuing enforcement action.

At a high level, the criteria in the EGM are:

- (1) the dosimetry system is designed for remote data extraction and digitally transferring data for evaluation to an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor;
- (2) the dosimeters are provided and the dose of record is determined by a NVLAP-accredited processor; and
- (3) the licensee and NVLAP-accredited processor implement the necessary quality controls to ensure that the DIS dosimeter is calibrated at the appropriate intervals and/or replaced when circumstances warrant it.

We will be issuing a regulatory issue summary (RIS) soon that will notify licensees of the availability of the EGM. If you choose to follow the guidance in the EGM, you will have 90 days from the issuance of the RIS to meet the actions described in the EGM. If there are any outstanding violations now or any identified before that 90 day period, we will look at the performance of your program to see if you are meeting the intent of the EGM and whether any violations should be issued.

In addition to the EGM, the NRC is considering issuing a rule to allow the use of DIS dosimetry under 10 CFR Part 34, 36, and 39. Should the Commission approve rulemaking, we anticipate issuing that rule within 18 months. The EGM would be in effect until the rule is issued or rescinded if the NRC decides not to pursue rulemaking. Assuming the rule is issued, you would then need to comply with the rule if you want to continue to use DIS dosimetry.

Based on this, here are three options for your consideration:

- a. Retract the exemption request and don't use direct ion storage dosimeters for the legal dose of record under 10 CFR 34.47, 36.55, or 39.65; OR
- b. Retract your exemption request and wait for your next inspection to be evaluated against EGM-18-001. In the meantime, you can pursue the required documents from Mirion using the attached letter, and ensure you meet all the EGM criteria for the NRC to not pursue an enforcement action, OR

c. You can choose to continue to pursue an exemption from the regulations.

Because NRC plans to pursue rulemaking and will likely approve the use of direct ion storage dosimeters, I think Option 2 is the best choice. That way, you can immediately start to use the DIS dosimeter, while you get your questions answered from Mirion, AND when we come to inspect you, we will evaluate your use of the dosimeter in accordance with the guidance provided in the EGM, and if you are fully compliant with the EGM, we will not issue enforcement .

Please take a bit of time to review this and let us know which option you would like to choose.

Regards,

James R. Cassata, Ph.D., CHP
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