## Torres, RobertoJ

**From:** Tebo, David <David.Tebo@TeamInc.com>
**Sent:** Wednesday, September 05, 2018 2:57 PM
**To:** Torres, RobertoJ
**Cc:** Banfield, Earl
**Subject:** [External_Sender] RE: NRC request for additional information - Response required
**Attachments:** Team-NRC -Response to Request for Addt'l Info 090518.pdf; NRC EGM-18-001 Tech Req Addendum_V4db&mbapproved.pdf

Mr. Torres,

Team Industrial Services, Inc. submits the attached response to your letter dated August 6, 2018 regarding the use of the Instadose Dosimeter.

Please contact me should you have any questions or require any additional information.

Sincerely,

*David P. Tebo*
**Corporate Radiation Safety Officer**
TEAM
Office: 219-310-8560
Mobile: 219-229-2909
Fax: 708-367-9949
David.Tebo@TeamInc.com

***"Safety First In Everything We Do"***
zero today

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**From:** Torres, RobertoJ [mailto:RobertoJ.Torres@nrc.gov]
**Sent:** Monday, August 06, 2018 4:57 PM
**To:** Tebo, David
**Subject:** NRC request for additional information - Response required

Mr. Tebo:

The NRC has issued enforcement guidance memorandum for the use of Instadose (see attached ML18068A623). A follow up action to the EGM is that condition 24 of NRC License 42-32219-01 needs to be updated by providing additional information as stated in the attached letter dated August 6, 2018. Please provide a response to the August 6 letter to my attention within 30 days.

Thank you for your cooperation.

Roberto J. Torres, M.S.
Senior Health Physicist

U.S. Nuclear Regulatory Commission, Region IV
1600 East Lamar Boulevard
Arlington, TX 76011-4511
817-200-1189

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578 N. Indiana Ave.
Crown Point, IN 46307
Phone: 219-310-8560

U.S. Nuclear Regulatory Commission
Region IV
1600 E, Lamar Blvd
Arlington, Texas 76011-4511

September 5, 2018

Attn: Roberto J. Torres
Radioactive Materials Licensing

Re: Request for Additional Information
Mail Control No. 588699
USNRC RAM License No. 42-32219-01

Dear Mr. Torres:

Team Industrial Services, Inc., NRC License No. 42-32219-01, submits the following information as requested in your letter dated August 6, 2018 regarding the allowance for radiographers and radiographer's assistants to wear an Instadose dosimeter as their personal dosimeter. The requested information is reiterated for reference followed by our response.

1. *In order to update condition 24 listed in NRC License No. 42-32219-01, please reply to each of the following items of this correspondence.*
    a. *How will you identify those Instadose dosimeters needing replacement, recalibration, or a calibration check over the lifetime of use of each Instadose dosimeter you possess?*
    b. *What specific criteria will you use for requiring replacement of an Instadose dosimeter in your possession?*
    c. *What specific criteria and frequency for calibration checks or recalibrations of dosimeters will you use for Instadose dosimeters in your possession?*

    Response: Instadose dosimeters in possession of Team Industrial Services, Inc. operations requiring replacement, a calibration check or recalibration are identified by Mirion Technologies, Inc. in accordance with their quality assurance program as described in the attached letter provided by Mirion Technologies, Inc. Mirion's Dosimetry Analysis Division routinely communicates to Team Industrial Services personnel (including the affected individual wearer, Location Administrator/Facility RSO, and Corporate RSO) via email/phone when a recall or replacement of Instadose dosimeters has been identified. Upon notification from Mirion, Team personnel are required to 1) collect and un-assign the recalled badge, 2) assign a new badge to the individual, and 3) reply to Mirion that the badge has been un-assigned. Mirion then initiates a formal recall and sends a replacement badge to the affected location with instructions for return of the recalled Instadose dosimeter.

    Team will follow the specific criteria established by Mirion Technologies, Inc. regarding when Instadose dosimeters are recalled and replaced. In addition, any Instadose dosimeter identified by Team personnel that fails to communicate with Mirion's servers (non-communication issues) or is suspected of questionable dose data are immediately reported to Mirion to facilitate a recall and replacement. A request for data extraction from the recalled badge will be included if determined needed to recover any potential missing dose information.

    Team will follow the specific criteria and frequency established by Mirion Technologies, Inc. regarding calibration checks or recalibration of Instadose dosimeters in our possession.

2. *Additionally, please commit to the following additional requirements.*

   a. *That you will only use software provided by Mirion Technologies, Inc. to obtain personnel doses from Instadose dosimeters.*

   Response: Team Industrial Services, Inc. commits to only using software provided by Mirion Technologies, Inc. to obtain doses from Instadose dosimeters. Downloading of Mirion Technologies, Inc. proprietary software is required in order to transmit the data from the Instadose dosimeter to Mirion's servers for read analysis.

   b. *That in the use of the Instadose dosimeter as a personnel dosimeter you will follow all recommendations by Mirion Technologies, Inc. concerning replacement, recalibration, or a calibration check over the lifetime of use of each Instadose dosimeter in your possession.*

   Response: Team Industrial Services, Inc. commits to following all recommendations and requirements of Mirion Technologies, Inc. concerning the replacement, recalibration, or a calibration check over the lifetime of the use of each Instadose dosimeter in our possession.

   c. *That your personnel dosimeter issue periods will be no longer than three months and that measurements are obtained as soon as practical after the issue period ends (i.e., minimize collection to read time).*

   Response: Instadose dosimeters are typically issued to an assigned wearer until the dosimeter is recalled or replaced in accordance with the criteria established by Mirion Technologies, Inc. or until the badge is no longer needed by the wearer (i.e., termination of employment, etc.). As provided in our current Operating and Emergency Procedure (30.J.2 rev.14) Team Industrial Services, Inc. commits to obtaining dose measurements (reading the Instadose dosimeters) at a minimum of monthly intervals. However more frequent reads (i.e., weekly or bi-monthly) are acceptable and encouraged to take advantage of the technology offered by the use of the Instadose dosimeter.

If you should require any additional information or should you have any questions regarding the information provided, please contact me at 219/310-8560 or 219/229-2909.

Sincerely,

David P. Tebo
Corporate Radiation Safety Officer
TEAM Industrial Services

Cc: Earl Banfield – Corporate RSM
File

DPT/: Team-NRC Response to Request for Addt'l Info. 090518

MIRION TECHNOLOGIES Dosimetry Services Division

**MEETING NRC "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"**

# NRC EGM-18-001 Technical Requirements for Dosimetry Licensees/Clients

The enforcement guidance memorandum (EGM), dated May 11, 2018, provides guidance for dispositioning potential violations of U.S. Nuclear Regulatory Commission (NRC) requirements for personnel dosimetry during NRC-licensed activities under Title 10 of the Code of Federal Regulations (10 CFR) Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations"; 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"; and 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging."

For licensees subject to these requirements who use direct ion storage (DIS) dosimetry for personnel monitoring (i.e., dosimetry used for the dose of record), the NRC will not pursue enforcement action for some potential violations of NRC requirements associated with the use of these dosimeters, provided the licensee and processor conditions (detailed in the Action Section of the NRC EGM-18-001) are met. This document provides the technical requirements to meet the processor conditions set forth.

Mirion's Instadose™ dosimeter products (Instadose™ and Instadose+™) are based on patented direct ion storage (DIS) technology. All activities related to providing occupational dose assessments to clients are managed under the Mirion Technologies Dosimetry Services Division (DSD) Quality Assurance Manual. This Quality Manual is structured to meet the requirements of the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP accreditation is an assessment of the laboratory against the requirements of ISO/IEC 17025, General Requirements for the Competence of Calibration and Test Laboratories (through NIST Handbook 150 and 150-4).

## ACCREDITATION

Mirion Dosimetry Services Division (DSD), NVLAP Lab Code: 100555-0, is accredited for Ionizing Radiation Dosimetry (to ISO/IEC 17025:2005) under the National Voluntary Laboratory Accreditation Program (NVLAP). The most recent NVLAP certificate and scope of accreditation can be found at: https://www.nist.gov/nvlap

## REMOTE DATA EVALUATION & PROCESSING

Instadose™ dosimeters are designed to remotely transmit raw dose data utilizing readily available communication tools—such as: internet access, smart devices with Bluetooth Low Energy (BLE) Technology, Instadose™ SmartPhone App, instaLink™ USB, and the instaLink™ Hot Spot Station—to Mirion DSD's proprietary servers and data analysis sotware.

Dosimeter reads are performed offsite and can be done manually (by pressing a button on the Instadose+™ dosimeter, or connecting the Instadose™ dosimeter into a USB port on a computer with the Instadose™ application installed) or automatically according to a calendar schedule set by the user. Instadose™ dosimeters can only be accessed and dose can only be extracted and transferred using Mirion DSD's proprietary software applications, websites and servers.

Mirion DSD servers capture the raw data responses from the Instadose™ dosimeters and process it through proprietary dose analysis software for assessment of $H_p(10)$ "deep dose" and $H_p(0.07)$ "shallow dose" quantities. This software, which performs the initial data analysis and data management functions, uses an algorithm to calculate reported dose and ensure the proper conversion of dosimeter

response to effective dose equivalent at specific tissue depths, and then records the doses in the Instadose™ system.

A secondary data analysis is then performed by Mirion DSD technicians at their Irvine, California manufacturing facility to verify dose accuracy.

The only way to obtain a personnel dose measurement from an Instadose™ dosimeter is to use Mirion DSD's proprietary software and algorithm. This is the same software and algorithm version used for the latest NVLAP proficiency testing.

## RECALLS & REPLACEMENTS

Instadose™ dosimeters requiring **replacement, a calibration check or recalibration** are identified by Mirion DSD in three ways:

1. Mirion DSD's systems, software, and algorithms automatically identify and flag anomalous reads that arise from detector failure/malfunction or a communication issue.
2. When routine testing for quality control purposes and calibration checks identifies an issue.
3. When the following upper or lower acceptance limits of verification measurements are reached:
    - Battery life
    - Cumulative dose capacity
    - Cumulative signal behavior
    - Detector voltage
    - Detector sensitivities
    - Detector temperature gradients
    - Detector temperature coefficients
    - Signal loss

Dosimeters that fail to communicate **(non-communication issues)** with Mirion DSD servers are identified by the client when scheduled or manual dose reads are not completed. Clients are able to self-identify dosimeters requiring replacement for non-communication issues by reviewing their dose record activity and/or report for missing reads. For non-communicating dosimeters, the client should immediately contact Mirion Client Services to facilitate a replacement.

Once identified, Mirion DSD dose analysis technicians will initiate an order to recall the affected dosimeter, notify the client/account manager via email/phone to provide instructions on returning the affected dosimeter, and send a replacement within 24 hours.

When the recalled device is returned to Mirion DSD, a data extraction procedure may be performed to recover any missing dose information (if possible) for the client dose report and history records.

All data is stored on Mirion DSD servers, which includes data backup at secure, offsite storage facilities, and are maintained according to Mirion DSD's Quality Assurance Manual for records maintenance.

## CALIBRATION

Routine sampling of dosimeters in the field is performed by Mirion DSD to verify the validity of Instadose™ calibrations. There is no need for routine calibration/re-calibration of Instadose™

dosimeters as the technology is a sealed detector system that utilizes the cumulative nature of the device to verify that natural background radiation is always increasing the dosimeter total dose.

Mirion DSD's algorithm and daily dose analysis reviews validate that the dosimeter is accumulating dose at an appropriate background rate. A dosimeter is recalled if this response does not occur.

All returned dosimeters are quarantined and tested according to Mirion DSD's rigorous acceptance testing procedures to identify the root cause of any failures and malfunctions. Dosimeters that can be repaired and/or refurbished must meet Mirion DSD's stringent manufacturing release procedures and initial acceptance test requirements before re-activation. Dosimeters that fail any of these tests/requirements are decommissioned and disposed of.

Mirion Technologies Dosimetry Services Division
**ACKNOWLEDGEMENTS & APPROVALS:**

Quality Assurance Manager

Senior Vice President, Operations

President