Telephone (757) 865-0920
FAX (757) 865-1328

ADVEX CORPORATION
121 FLOYD THOMPSON DRIVE - HAMPTON, VIRGINIA 23666-1307

REPLY TO A NOTICE OF VIOLATION

July 1, 2016

NRC Docket Number 030110069 **NRC License 45-16452-01**

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555

SUBJECT: NRC INSPECTION REPORT NO. 03011069/2016002, ADVEX CORPORATION, HAMPTON, VIRGINIA SITE AND NOTICE OF VIOLATION

TO WHOM IT MAY CONCERN:

We are to submitting our response to the above mentioned Notice of Violation in accordance with the NRC regulations, guidelines, policies and practices detailed in your first letter dated June 3, 2016. Advex Corporation has the following response to the Violation identified as "A" (detailed below):

A. 10 CFR 34.47(a) states in part that the licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.

Contrary to the above, from 2014 to May 31, 2016, the licensee did not use personnel dosimeters processed and evaluated by an accredited NVLAP processor. Specifically, the licensee uses Instadose dosimeters manufactured by Mirion Technologies and the dosimeters are not processed and evaluated by an accredited NVLAP processor and the licensee had not received an exemption from the requirement in accordance with 10 CFR 30.11.

1) **Reason for Violation -** Advex was unaware that Mirion Technologies' Instadose Dosimeters were not being processed and evaluated by an accredited NVLAP processor. This was evidenced by Advex successfully passing previous NRC Audits without any notation of violation in conjunction with Advex's use of Instadose.

2) **Corrective Steps and Results Achieved -** Advex is submitting a "Request for Exemption" to the NRC for acceptance of the use of the Instadose dosimetry. The "Request for Exemption" is enclosed with this letter. Results of this corrective step are dependent upon approval by NRC of the Instadose dosimetry.

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3) **Corrective Steps to Avoid Further Violations -** The "Request for Exemption" response from the NRC will determine Advex's future use of Instadose or any other similar dosimetry manufactured and monitored by other companies. Mirion Technologies is confident that there is sufficient evidence that the NRC will change the regulation, indicating that the meaning of the term "processed" in the regulation is what is left to resolve. If the NRC changes the ruling by allowing Instadose, Advex will continue to use Mirion Technologies dosimetry. If the regulation is sustained, Advex will have dosimetry issued and processed by a NVLAP approved company. Advex will obtain objective evidence that the company issuing and processing the dosimetry has the appropriate NVLAP approval.

4) **Date When Full Compliance Will Be Achieved –** If Advex receives disapproval on the "Request for Exemption", we will initiate procurement of replacement dosimetry form a NVLAP approved company within two (2) business days.

Concerning the Violation "B" detailed below, Advex has the following response:

B. 10 CFR 34.79(b) states, in part that each licensee shall maintain records of semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must include a list showing the items checked and any non-compliance observed by the Radiation Safety Officer (RSO).

Contrary to the above, from May 15, 2015, thru March 3, 2016, the licensee did not maintain records of semi-annual inspections of job performance for each radiographer and each radiographer's assistant. Specifically, on a semi-annual basis, the RSO evaluated the radiographer's job performance during work in NRC jurisdiction, but failed to maintain records of the semi-annual inspections of job performance for each radiographer.

1) **Reason for Violation –** The Advex Radiation Safety Officer was in the position only a few months and was not completely familiar with the process of maintaining document evidence of the semi-annual audits of Radiographers and Assistant Radiographers.

2) **Corrective Steps and Results Achieved -** The RSO has received additional training and guidance regarding the requirement for documentation showing the evidence of the semi-annual audits. The RSO has documented in writing his previous Audit findings and put them in the file. All Radiation Safety Audits of all Radiographers and Assistant Radiographers working in or out of NRC jurisdiction are up to date and filed.

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3) **Corrective Steps to Avoid Further Violations -** A spreadsheet that details all of the regulatory requirements have been developed that includes all of the dates that are needed to accomplish the various regulated activities. The Spreadsheet serves as a timely checklist to assure that all activities are tracked, documented, and performed in the specified time frame that the regulations require. This tracking system will assure that all of the necessary regulations are fully met on time and that all of the documented evidence is maintained.

4) **Date When Full Compliance Will Be Achieved –** The spreadsheet was put into place on May 13, 2016. All documentation will be up to date by July, 12, 2016.

If you have any questions or require additional information please do not hesitate to contact me.

Regards,

Charles M. Jackson, III
President / CEO
Advex Corporation
(757) 865-0920 (main)

Email: cjackson@advex.net

Enclosure:
Request for Exemption

Copy to:
Mr. Daniel Dorman
Regional Administrator
U.S. NRC Region 1
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

Telephone (757) 865-0920
FAX (757) 865-1328

ADVEX CORPORATION
121 FLOYD THOMPSON DRIVE - HAMPTON, VIRGINIA 23666-1307

July 1, 2016

Mr. Daniel Dorman
Regional Administrator
U.S. NRC Region 1
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

NRC License 45-16452-01

SUBJECT: REQUEST FOR EXEMPTION TO USE MIRION TECHNOLOGIES INSTADOSE FOR TO ALLOW FOR USE OF THE INSTADOSE PERSONNEL MONITORING

Dear Mr. Dorman:

Advex Corporation of Hampton, VA; NRC License 45-16452-01, hereby requests exemption from the USNRC regulations in accordance with 10 CFR 30.11, Specific Exemptions, to allow for use of the **Instadose** personnel monitoring dosimeter processed by Mirion Technologies.

We request exemption from the following specific regulations noted below:

1) Provide a description of the proposed exemption and provide the reason the exemption is needed.

10 CFR 34.47(a) The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm rate meter, and a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming rate meter is not required.

10 CFR 34.47(a)(3) Film badges must be replaced at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed three months.

10 CFR 34.47(a)(4) After replacement, each personnel dosimeter must be processed as soon as possible.

Additional detailed information regarding the specific exemption requirements and our request is addressed in Section 2 below, "Provide a justification demonstrating that the proposed dosimetry will provide, at least, a level of personnel monitoring equivalent to the devices specified in 10 CFR 34.47."

The basis for the exemption request is to allow Advex Corporation to utilize the Instadose monitoring badge as the personnel dosimeter of choice for monitoring the radiation exposure to employees during industrial radiographic operations.

The Instadose monitoring badge and process already conforms to the provisions of and the intent of the regulation as a personnel monitoring dosimeter processed by a NVLAP accredited processor. The Instadose monitoring badge is supplied by Mirion Technologies who maintains the role and function of the processor. Mirion is a NVLAP accredited processor holding current NVLAP accreditation (Lab Code 100555-0). The Instadose badge has been approved under this NVLAP accreditation for whole body dosimetry since 2nd Quarter 2009, and has been routinely worn in the medical community, homeland

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security, power reactor both in the USA as well as internationally. Instadose is not only accredited by NVLAP in the USA, but is also accredited and an approved dosimeter by the HSE (UK), FANR (UAE), ARPANSA (Australia), New Zealand, Sweden, NNRA (Nigeria), Netherlands and many other countries. The badge satisfies all required personnel monitoring performance criteria and offers many additional safety related benefits, thereby providing accurate measurement of occupational radiation exposure, reporting those exposures and incorporating additional enhancements allowing improved management of those occupational radiation exposures.

The Instadose dosimeter is based on proprietary direct ion storage technology. This breakthrough technology, a combination of an Ion Chamber and a MOSFETT dosimeter, provides radiation workers with a precise measurement of radiation dose and includes accurate long-term exposure tracking. A built-in memory chip stores each user's identity via an embedded unique serial code that is assigned to the user.

Before use, each Instadose dosimeter must be registered online. During the registration process, the driver and client are installed on the user's computer and the device is initialized for use. Unlike other types of personnel monitoring badges, the Instadose badge itself (hardware) is not physically exchanged with the processor. Each time the badge is read, the user logs into the system using a unique user name and password and plugs the USB enabled device into the USB port on the computer and hits (clicks on) "Read Device". The data contained on the badge (radiation exposure data) is then transmitted to (exchanged with) the processor without alteration, modification or other processing by the user for evaluation. Mirion has implemented processes to determine that the device has communicated with the server where the data is received.

The accumulated dose stored on the device processes through a proprietary algorithm. This fully automated transfer of data minimizes the chance of human error and misidentification. The processor, Mirion Technologies, evaluates each reading performed by all of their customers each day by the technical staff. This review includes evaluation of the "raw data" transmitted, the dose determined by the proprietary algorithm and a comparison of the current device parameters with the initial parameters that were established at the time of the registration and initialization of the device.

Advex Corporation considers the Instadose monitoring badge as meeting the requirements of 10 CFR Part 20 and 10 CFR Part 34 as follows:

1) 10 CFR 20.1003 - Mirion Technologies is a NVLAP accredited organization that, through their proprietary system, processes and evaluates each individual Instadose badge to determine the radiation dose delivered to the badge. As such, Mirion Technologies meets the definition of a dosimetry processor, and, per conversations with USNRC staff, this requirement is not disputed.

2) 10 CFR 20.1501(d)(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or

2) Provide a justification demonstrating that the proposed dosimetry will provide, at least, a level of personnel monitoring equivalent to the devices specified in 10 CFR 34.47.

The USNRC Adam's Database includes many examples where individuals performing radiography who were wearing an Instadose dosimeter were able to identify an adverse radiation environment situation where the individual's radiation dose was determined immediately, where if the individual was wearing a conventional passive dosimeter such as film, TLD or OSL, all work would have ceased until the dosimeters were returned to the NVLAP accredited processor for processing. Instadose enabled the events to be reported to either the USNRC or the Agreement State. Several examples include the following from the USNRC's website Adam's Database:

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- Event Number: 51779, reported to MISSISSIPPI DIV OF RAD HEALTH, March 8, 2016
- Event Number: 50050, reported to KANSAS DEPT OF HEALTH & ENVIRONMENT, April 23, 2014
- Event Number: 48417, reported to TEXAS DEPARTMENT OF HEALTH, October 17, 2012
- Event Number: 48025, reported to CALIFORNIA RADIATION CONTROL PRGM, June 14, 2012

The following section denotes the positive aspects of the Instadose dosimeter as compared to conventional passive dosimeters such as film, and TLD and demonstrates how Instadose is far superior and exceeds the monitoring requirements outlined in § 34.47 Personnel monitoring.

§ 34.47 Personnel monitoring.

(a) The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm rate meter, and a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming rate meter is not required.

(1) Pocket dosimeters must have a range from zero to 2 millisieverts (mSv) (200 millirems) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

Comment: In that Instadose has been NVLAP accredited since 2nd Quarter 2009, the dosimeter is blind proficiency tested every two years, and, the testing has demonstrated that Instadose in most of the NVLAP tested Categories per ANSI N13.11-2009 have outperformed conventional passive dosimeters.

NVLAP blind tests dosimeters between 20 millirem (mR) and 500 Rem (R); however, Mirion Technologies has tested the Instadose from 1 mR up to 1,000 Rem.

(2) Each personnel dosimeter must be assigned to and worn only by one individual.

Comment: Instadose can be assigned to multiple individuals but can only be worn by one individual at a single point in time, and, the entire dose that is determined for each individual is maintained separately in the database, with all readings date and time stamped.

(3) Film badges must be replaced at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed three months.

Comment: The exemption requests that Instadose be considered as meeting this requirement in that the individual reads the Instadose on a more frequent basis as well as all readings are evaluated by Mirion Technologies technical staff each day an Instadose is read. The Instadose dosimeter can be read on-demand, even every minute if the individual is so inclined. The typical process is that the Instadose will be read immediately prior to and at the end of the operation.

This requirement does not take into account the advancement in dosimetry technology of utilization of the Internet for immediate dose determination, reporting and documentation. The Instadose dosimeter far exceeds the requirement for monthly or quarterly dose determination since it can be read on-demand, with immediate dose determination. With the evaluation of each and every dose by a Mirion technical staff

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FAX (757) 865-1328

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after a reading is uploaded, preventative actions can be immediately taken, not having to wait for the dosimeter to be returned and processed.

(4) After replacement, each personnel dosimeter must be processed as soon as possible.

Comment: Per the comment in item 3, the Instadose is processed through the proprietary dose algorithm developed and maintained by Mirion Technologies, and the dose is therefore processed immediately as each individual reads the dosimeter. This eliminates potential loss or inadvertent irradiation during transit to and from Mirion Technologies. An additional benefit is that in the event that the Instadose is lost or damaged, all doses documented since the last reading are still maintained which cannot be done with a conventional passive dosimeter. In that event, the entire dose is lost. Instadose is far superior.

(b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with § 34.83.

Comment: Instadose can be read on-demand before and after each operation with each reading date and time stamped and maintained in the individual's proprietary dose history.

(c) Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with § 34.83. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

Comment: Prior to an Instadose being provided to an individual the device is initialized and all original parameters are documented. During each reading specific parameters are validated against the original system initialization to determine if there have been any changes or anomalies in the system that would require replacement of the Instadose. This far exceeds the capabilities of the conventional passive dosimeters that are only processed after being returned by the individual. If there is an issue there is no capability to accurately assess the dose received for the time period where that device has been worn. This is not an issue with Instadose.

(d) If an individual's pocket chamber is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 2 mSv (200 mR), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained in accordance with § 34.83.

Comment: The Instadose dosimeter provides state of the art technology to identify a dose anomaly immediately once read. With an immediate reading, the situation can be immediately assessed whereby the current situation, root cause determination and appropriate countermeasures implemented to bring the adverse situation to a successful termination with a minimal amount of dose received by the individuals involved.

(e) If the personnel dosimeter that is required by paragraph (a) of this section is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements in paragraph (a) is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with § 34.83.

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Comment: An additional benefit is that in the event that the Instadose is lost or damaged, all doses documented since the last reading are still maintained which cannot be done with a conventional passive dosimeter. In that event, the entire dose is lost. Instadose is far superior. This minimizes the amount of work that is required by the RSO to determine all dose received up to that moment in time, therefore, not requiring an estimate, since the entire previous dose has already been documented and is maintained in the system. With spare dosimeters in inventory, a new Instadose device can quickly be assigned to the individual and work commenced again.

(f) Dosimetry reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with § 34.83.

Comment: All dose history, date and time stamped for each reading is maintained in the Mirion server and is accessible by accessing the information with a User ID and Password.

(g) Each alarm rate meter must--

(1) Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of 5 mSv/hr. (500 mR/hr.) with an accuracy of ±20% of the true radiation dose rate;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm rate meter calibrations in accordance with § 34.83.

Comment: During each read all initialization parameters are validated to determine if the Instadose calibration has been affected.

[62 FR 28963, May 28, 1997, as amended at 65 FR 63751, Oct. 24, 2000]

3) Describe a basis to demonstrate any benefits to public health and safety.

Comment: In that each individual is monitored with a direct reading dosimeter as well as an Instadose dosimeter, a radiation environment anomaly is readily identified and the dose immediately determined allowing for the site to be cordoned off, boundaries established and steps taken to appropriately mitigate the situation, protecting not only the site staff, but the general public as well. This is not possible if a conventional passive dosimeter is worn in that it must be returned to the processor for processing and this will take days, if not weeks to have the official dose determined.

4) Provide a basis to show how the exemption from the regulatory requirement will not endanger life, property, or the common defense and security.

Comment: Mirion Technologies is committed to protecting the privacy of the personal Information of their customers and information that they provide to other entities, including governmental agencies, without the expressed consent of the client, or, after a subpoena for information is issued. Mirion security and privacy practices for safeguarding personal information, including personal health information, are described below.
One of Mirion's core business values is Integrity, meaning that Mirion, its employees and representatives are expected to uphold the letter and spirit of all relevant laws, regulations, and policies. This includes all applicable federal and state laws and regulations, including the applicable privacy provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), a federal law designed to ensure the privacy of personal and health information. Mirion has an information security program under which Mirion maintains appropriate measures to safeguard data from loss, misuse, unauthorized access, disclosure, alteration, or destruction. Mirion's information security program consists of an array of proprietary policies and procedures intended to safeguard data and ensure privacy.

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FAX (757) 865-1328

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Mirion's information security program is designed to ensure data integrity, notice, choice, and compliance.

• DATA INTEGRITY: Mirion does not process personal information in a way that is incompatible with the purposes for which it has been collected or subsequently authorized by the individual. To the extent necessary for those purposes, Mirion takes steps to ensure that data is reliable for its intended use, accurate, complete, and current.

• NOTICE: Mirion informs individuals about the purposes for which they collect and use information about them, how to contact the organization with any inquiries or complaints, the types of third parties to whom we disclose the information, and the choices and means they offer individuals for limiting its use and disclosure.

• CHOICE: Mirion does not require, nor encourage their customers in the United States to provide them with any personal information as a condition to using their services; their customers are free to provide the client with unique identifiers of their own creation to track the dose information for individuals and their customers can link dose information with personal information via their own internal systems. Where Mirion's customers choose, nonetheless, to provide Mirion with personal information, or where the laws of a jurisdiction outside the United States require Mirion to collect and maintain such personal information, then Mirion offers individuals the opportunity to choose (opt out) whether their personal information is (a) to be disclosed to a third party or (b) to be used for a purpose that is incompatible with the purpose(s) for which it was originally collected or subsequently authorized by the individual. For sensitive personal health information (radiation dose is considered as personal health information per the requirements of 10 CFR Part 20), Mirion requires affirmative or explicit (opt in) choice if the information is to be disclosed to a third party or used for a purpose other than those for which it was originally collected or subsequently authorized by the individual through the exercise of opt in choice. In any case, Mirion treats as sensitive any information received from a third party where the third party treats and identifies it as sensitive.

• COMPLIANCE: Mirion provides mechanisms for ensuring compliance by their employees, representatives and contractors with policies and procedures, as well as with applicable federal or state laws and regulations. Internal policies and procedures provide for rigorous sanctions to ensure compliance, including disciplinary action, suspension of employment, and termination of employment for employees, and for third parties with whom Mirion works measures up to and including termination of their business relationships with them. Mirion's Chief Information Officer is responsible for administering our information security program and the Chief Compliance Officer is responsible for investigating allegations of non-compliance. Mirion provides a worldwide toll-free hotline for their employees to report, anonymously or not, any concerns about noncompliance.

Mirion believes that an information security program that is soundly implemented, coupled with good judgment by our customers and Mirion employees, can greatly reduce the risk of improperly disclosing personal data. Mirion's information security program includes the following elements:

1. Mirion conducts comprehensive risk assessments to identify all reasonably foreseeable internal and external threats to the security, confidentiality, and integrity of personal data that could result in loss, misuse, unauthorized access, disclosure, alteration, or destruction of such personal data. Mirion undertakes these risk assessments using either its information technology employees or third party security consultants.

2. When conducting its risk assessment, Mirion seeks to identify any major vulnerabilities that, if exploited, could result in loss, misuse, unauthorized access, disclosure, alteration, or destruction of personal data and/or Mirion's computer systems, networks, software, or databases on which such personal data resides.

3. For any identified threat, Mirion assesses the likelihood that such threat will materialize and evaluates the potential damage that would result if such threat materialized.

4. For any identified threat, Mirion assesses the sufficiency of Mirion's existing policies, procedures, information systems and safeguards in place to control these risks, including a review of:

Telephone (757) 865-0920
FAX (757) 865-1328

ADVEX CORPORATION
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a. employee training and management;

b. Mirion's information systems, including information processing, storage, transmission, and disposal; and

c. prevention and response measures for attacks, intrusions, or other systems failures.

Mirion's information security program consists of a variety of existing policies, procedures, information systems and safeguards in place to control these risks, including but not limited to an Information Sensitivity Policy to highlight privacy considerations; an Information Systems Access Policy and Physical Access Control Policy to control access to our site and systems; a Systems Monitoring Policy and Security Incident Response Policy to monitor our systems and respond to incidents quickly. As part of Mirion's commitment to privacy, we also have a number of policies and procedures to safeguard any transfers of data between Mirion sites. Finally, Mirion's website privacy policies and legal terms and conditions govern the use of Mirion's web sites, including any information that is gathered from users of their on-line systems.

Mirion's information security program is soundly implemented, coupled with good judgment by their customers and Mirion employees can greatly reduce the risk of improperly disclosing personal data. Information security and privacy must be a partnership between Mirion and their customers and they will continue to work with their customers to enhance their own practices that protect privacy to safeguard the integrity of personal information.

5) Provide justification to demonstrate that the exemption from the regulatory requirement is in the public interest.

Comment: In that each individual is monitored with a direct reading dosimeter as well as an Instadose dosimeter, a radiation environment anomaly is readily identified and the dose immediately determined allowing for the site to be cordoned off, boundaries established and steps taken to appropriately mitigate the situation, protecting not only the site staff, but the general public as well. This is not possible if a conventional passive dosimeter is worn in that it must be returned to the processor for processing and this will take days, if not weeks to have the official dose determined.

If you have any questions or need additional information, please do not hesitate to contact me.

Regards,

Charles M. Jackson, III
President / CEO
Advex Corporation
(757) 865-0920 (main)
Email: cjackson@advex.net

Copy to:

Randolph C. Ragland, Jr., Sr. Health Physicist
Nuclear Regulatory Commission
Region I – Division of Nuclear Materials Safety
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713