

From: [Mark Palazzolo](#)
To: [R4Enforcement](#)
Cc: ["Blaine Ikeda"](#); [Katanic, Janine](#); [Bischoff, Kyle](#)
Subject: [External_Sender] Response to Apparent Violations in NRC Inspection Report 030-37399/2021-001; EA-21-120
Date: Wednesday, December 8, 2021 1:46:24 PM
Attachments: [Response to Apparent Violations in NRC Inspection Report 030-37399 2021-....pdf](#)

Dear NRC,

Please find attached, a supplemental letter with Policies and Procedures in response to our 4 apparent violations. The initial letter was sent on 11/25/2021 and the Subject was: Response to Apparent Violations in NRC Inspection Report 030-37399/2021-001; EA-21-120.

Please let me know if you have any questions, or have any trouble opening the document.

Thank you,

Mark Palazzolo
Executive Director
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MARIAN MEDICAL SERVICES

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December 2, 2021

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

Subject: Response to Apparent Violations in
NRC Inspection Report 030-37399/2021-001; EA-21-120

Dear Nuclear Regulatory Commission,

In addition to the response to the four apparent violations identified during the inspection of our facility, Marian Medical Services has created policies and procedures to ensure that these violations never occur again at any of our facilities. We will review these policies and procedures with all staff of Marian Medical Services and RSO, as well as, all owners of both companies, to make sure there is no confusion as to the proper steps to take to correct the situation. These policies and procedures will be reviewed with all of the above mentioned by no later than December 15, 2021.

These policies and procedures will be used to address situations where it is necessary to close a particular site, but also circumstances that could potentially result in sources becoming abandoned. Examples of these potential circumstances could include, but are not limited to, Marian Medical Services' Technologist abruptly quitting without a replacement in place, an unforeseen lockout of our office, or any other similar occurrence that could prevent proper oversight of sources.

Please find attached to this letter, the procedures that will be followed if any situation related to the examples above should occur.

Sincerely,

Mark Palazzolo, Executive Director
Marian Medical Services, LLC

cc: Ms. Mary Muessle, Director
Division of Nuclear Materials Safety
Region IV
1600 E. Lamar Blvd.
Arlington, Texas, 76011

Blaine Ikeda, PharmD, RSO

Policy and Procedure for Termination of Activities^{1,2}

Marian Medical Services (MMS) and RSO will communicate an action plan for termination of a radioactive material license, termination of a specific location, or other license amendment.

If termination of a place of use, or termination of the entire license is determined, MMS will do so in accordance with Title 10 of The Code of Federal Regulations (10 CFR) 30.36.

MMS will notify the NRC in writing within 60 days of the occurrence of any of the following:

- Expiration of its license
- A decision to permanently cease activities at a particular site, or termination of the license in its entirety.
- No activities under the license have been conducted for 24 months.

MMS will submit NRC Form 314, "Certificate of Disposition of Materials" and information demonstrating the premises is suitable for release for unrestricted use. Since MMS primarily uses Tc99m, Tl-201, Mo99-Tc99m generators, and sealed sources, Form 314 will include the following:

- Area radiation level surveys, including a description of instruments used, showing that all areas previously used are at background.
- Area contamination wipes, including a description of instruments used, showing that all areas previously used are at background.
- Leak test for all sealed sources transferred or disposed.
- Transfer or disposal documentation for all sealed sources (and unsealed material, if applicable).

1. 10 CFR 30.36

2. NUREG 1556, Volume 9, Rev 3

Policy and Procedures for Suspension of Activities

Marion Medical Services (MMS) and RSO will communicate an action plan for a temporary suspension of primary activities. A temporary suspension of primary activities may include, but not limited to, termination/change of a nuclear medicine technician, termination/change in RSO, termination/change in authorized physician, damage to an existing facility, or other business decision.

If it is determined that a temporary suspension will last greater than 90 days, a plan will be developed to determine if the RSO will continue to perform quarterly radiation safety duties at the existing facility, or if it will transfer all existing radioactive materials (sealed sources, radioactive materials held for decay, etc.) for storage at an authorized facility (another authorized location for MMS, a nuclear pharmacy, source disposal site, etc.). If at any time it is determined that all radioactive materials cannot be fully secured from unauthorized individuals, a transfer will occur to an authorized location.

If it is determined that a transfer of all existing radioactive materials is the appropriate course of action a complete radiation survey and contamination wipes will be performed at this facility after removal of all radioactive materials.

This action plan will be developed within 30 days of the suspension of primary activities. If appropriate, MMS will notify the appropriate Nuclear Regulatory Office.