

SUNSI Review Complete
Template=ADM-013
E-RIDS=ADM-03

PUBLIC SUBMISSION

ADD: Harriet
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Comment (20)
Publication Date:
4/21/2023
Citation: 88 FR 24495

As of: 8/22/23, 10:30 AM
Received: August 11, 2023
Status: Pending_Post
Tracking No. ll6-uapk-qgx6
Comments Due: August 20, 2023
Submission Type: API

Docket: NRC-2023-0086

Draft Regulatory Guide: Release of Patients Administered Radioactive Material

Comment On: NRC-2023-0086-0001

Draft Regulatory Guide: Release of Patients Administered Radioactive Material; Extension of Comment Period

Document: NRC-2023-0086-DRAFT-0022

Comment on FR Doc # 2023-08418

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General Comment

As a pediatric intensivist who has cared for patients undergoing MIBG therapy for many years, I wanted to comment on how this new regulation would negatively impact the health of children. Because of their inability to follow simple instructions, small children who are treated with I-131 MIBG require sedation for days. The addition of approximately two more days to their ICU stay to achieve the proposed lower level does not only lengthen stay and increase cost - it seriously increases the risk of withdrawal from sedatives, delirium, and other complications. I understand that there are competing interests here and that lower may seem always better. I am commenting for the purpose of highlighting than an unintended consequence of this change will be harm to children, in addition to cost issues, etc. Please do not make this change!