



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

January 26, 2022

MEMORANDUM TO: Christian Einberg, Chief  
Medical Safety and Events Assessment Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety and Safeguards

FROM: Sarah L. Lopas, Project Manager  
Medical Safety and Events Assessment Branch  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety and Safeguards

SUBJECT: SUMMARY OF JANUARY 5, 2022 CLOSED MEETING WITH  
CHECK-CAP LTD. TO DISCUSS C-SCAN® SYSTEM  
INFORMATION AND RADIATION DOSE ASSESSMENT

On January 5, 2022, the U.S. Nuclear Regulatory Commission (NRC) staff met with representatives from Check-Cap, Ltd. (Check-Cap) during a closed meeting to hear updates from Check-Cap on the C-Scan® system design and results of Check-Cap's radiation dose assessment of disposal of the C-Scan® system to the sanitary sewerage.

Background

Check-Cap is a medical diagnostics company that is developing the C-Scan® system, an ingestible scanning capsule-based system for the prevention of colorectal cancer through the x-ray detection of precancerous polyps. On March 15, 2020, Check-Cap requested interpretation of NRC regulations to confirm that Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2003(b) applied to the disposal of the C-Scan® system in excreta (see Agencywide Documents Access and Management System [ADAMS] Accession No. [ML21007A278](#)). The NRC responded to Check-Cap's request in a letter dated January 27, 2021 (ADAMS Accession No. [ML21011A218](#)), determining that the C-Scan® system is not excreta in the form identified under 10 CFR 20.2003(b) that can be disposed of in the sanitary sewerage.

Meeting Summary

During the January 5, 2022 closed meeting with the NRC, Check-Cap presented commercial proprietary information about the radioactive source in the C-Scan® system and results from a radiation dose assessment of disposal of the C-Scan® system to the sanitary sewerage. The

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dose assessment estimated potential radiation doses that may be encountered by members of the public once C-Scan<sup>®</sup> systems are excreted by patients and released into the sanitary sewerage. Because the NRC staff has determined that the C-Scan<sup>®</sup> system is not excreta that can be disposed of in the sanitary sewerage, Check-Cap<sup>®</sup> conducted the public dose assessment to support potential regulatory actions related to sanitary sewerage disposal, such as exemption requests or a petition for rulemaking. The meeting concluded after Check-Cap provided its updates. Check-Cap may request additional meetings, but these meetings have not been scheduled as of the date of this meeting summary.

The enclosure lists the closed meeting attendees. No written materials were prepared or distributed by the NRC staff for this meeting.

SUBJECT: SUMMARY OF JANUARY 5, 2022, CLOSED MEETING WITH CHECK-CAP LTD. TO DISCUSS C-SCAN® SYSTEM INFORMATION AND RADIATION DOSE ASSESSMENT

DATE: January 26, 2022

ENCLOSURE:  
As stated

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**ADAMS Accession No.: ML22026A164**

**\*via email**

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NAME	SLopas	CValentin-Rodriguez*	CEinberg*	SLopas
DATE	01/24/2022	01/25/2022	01/25/2022	01/26/2022

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**CLOSED MEETING WITH CHECK-CAP LTD. TO DISCUSS C-SCAN® SYSTEM  
INFORMATION AND RADIATION DOSE ASSESSMENT**

**January 5, 2022  
9:00 AM – 10:00 AM EST**

**Meeting Attendees**

<b>Name</b>	<b>Affiliation</b>
Christian Einberg	U.S. NRC, Office of Nuclear Material Safety and Safeguards, Division of Materials Safety, Security, State, and Tribal Programs, Medical Safety and Events Assessment Branch (NRC/NMSS/MSST/MSEB)
Celimar Valentin-Rodriguez	NRC/NMSS/MSST/MSEB
Cindy Flannery	NRC/NMSS/MSST/MSEB
Sarah Lopas	NRC/NMSS/MSST/MSEB
Vincent Holahan	NRC/NMSS/MSST
Chris McKenney	NRC/NMSS, Division of Decommissioning, Uranium Recovery, and Waste Programs, Risk and Technical Analysis Branch
Adam Schwartzman	NRC/NMSS, Division of Decommissioning, Uranium Recovery, and Waste Programs, Risk and Technical Analysis Branch
Ian Irvin	NRC, Office of the General Counsel
Angela Coggins	NRC, Office of the General Counsel
Yevgeny Zigelman	Check-Cap, Ltd.
Israel Hershko	Check-Cap, Ltd.
Yoav Kimchy	Check-Cap, Ltd.
Alex Ovadia	Check-Cap, Ltd.
Amy Roma	Hogan Lovells US, LLP
Stephanie Fishman	Hogan Lovells US, LLP
Jack Buddenbaum	Plexus Scientific Corporation
Dan Brague	Brague Consulting, LLC