



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

March 31, 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 FEBRUARY 22, 2022 CLOSED MEETING WITH
CHECK-CAP LTD. TO DISCUSS THE U.S. NUCLEAR
REGULATORY COMMISSION'S PETITION FOR RULEMAKING
PROCESS

Background

Check-Cap Ltd. (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 U.S. Nuclear Regulatory Commission (NRC) regulations to determine whether Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2003(b) applied to the disposal of the C-Scan[®] system in excreta (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. Subsequently, during a 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 Check-Cap's radiation dose assessment of disposal of the C-Scan[®] system to the sanitary sewerage (ADAMS Accession No. [ML22026A164](#)). Following the January 5, 2022 meeting, Check-Cap had additional questions for NRC staff regarding potential regulatory actions related to sanitary sewerage disposal of the C-Scan[®] system.

Meeting Summary

On February 22, 2022, NRC staff met with representatives from Check-Cap during a closed meeting to discuss the NRC's petition for rulemaking process. The NRC staff informed Check-Cap that NRC regulations related to petitions for rulemaking can be found in Subpart H, "Rulemaking," of 10 CFR Part 2, "Agency Rules of Practice and Procedure." The NRC staff

described the process for filing, docketing, tracking, closing, amending, withdrawing, and resolving a petition for rulemaking; discussed the regulatory basis for 10 CFR 20.2003(b), which is documented in the statements of consideration in the 1991 final rule amending 10 CFR Part 20, "Standards for Protection Against Radiation" (May 21, 1991; 56 FR 23381); and discussed compatibility of Agreement State regulations with certain NRC regulations.

The staff provided Check-Cap with the following links for additional information:

- The NRC's petition for rulemaking process at <https://www.nrc.gov/about-nrc/regulatory/rulemaking/petition-rule.html>
- State Agreements Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements" (ADAMS Accession No. ML20183A325) at <https://www.nrc.gov/docs/ML2018/ML20183A325.pdf>
- Review summary sheets for regulation adoption for new Agreement States/programs at https://scp.nrc.gov/regsumsheets_newregs.html

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

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DATE: March 31, 2022

ENCLOSURE:
As stated

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***via email**

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**CLOSED MEETING WITH CHECK-CAP LTD. TO DISCUSS
THE PETITION FOR RULEMAKING PROCESS**

**February 22, 2022
9:00 AM – 10:00 AM EST**

Meeting Attendees

Name	Affiliation
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
Cindy Bladey	NRC, Division of Rulemaking, Environmental, and Financial Support, Regulatory Analysis and Rulemaking Support 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

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