



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

February 1, 2021

ALL AGREEMENT STATES AND CONNECTICUT

NOTIFICATION OF ISSUANCE OF LETTER TO CHECK-CAP, LTD. REGARDING THEIR
REQUEST FOR APPLICABILITY OF 10 CFR 20.2003(B) FOR DISPOSAL OF C-SCAN®
SYSTEM TO SANITARY SEWER (STC-21-004)

Purpose: To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) issued a letter to Check-Cap Ltd. (Check-Cap) regarding their request for confirmation that Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2003(b) applies to the disposal of the Check-Cap C-Scan® (C-Scan) system in excreta.

Background: Check-Cap's C-Scan system is a preparation-free ingestible scanning capsule-based system for the prevention of colorectal cancer through the detection of precancerous polyps. By letter dated March 15, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21007A278), Check-Cap submitted a request to the NRC to seek an interpretation of NRC's regulations to confirm that 10 CFR 20.2003(b) applies to the disposal of the Check-Cap C-Scan system in excreta. 10 CFR 20.2003(b) allows for the excreta from individuals undergoing medical diagnosis or therapy with radioactive material to be discharged into the sanitary sewerage. 10 CFR 20.2003(b) is designated as Compatibility Category D.

Discussion: The enclosure provides the NRC staff's response letter to Check-Cap dated January 27, 2021 (ADAMS Accession No. ML21011A218). The NRC staff has reviewed the information provided by Check-Cap and has determined that the colon-imaging capsule that is part of the C-Scan system is not excreta of the form identified under 10 CFR 20.2003(b) that can be disposed of to the sanitary sewerage. Additionally, staff has concerns about the ultimate disposal responsibility, and therefore, does not consider the capsule suitable for sanitary sewerage disposal.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below:

POINT OF CONTACT: Lisa Dimmick
TELEPHONE: (301) 415-0694

E-MAIL: Lisa.Dimmick@nrc.gov



Signed by Anderson, Brian
on 02/01/21

Brian C. Anderson, Chief
State Agreement Liaison Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure: Letter to Check-Cap dated January 27, 2021



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

January 27, 2021

Yoav Kimchy, Ph.D.
Founder and Chief Technology Officer
Check-Cap Ltd.
29 Abba Hushi Ave.
PO Box 1271
Isfiya 3009000, Israel

SUBJECT: APPLICABILITY OF TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS*
20.2003(B) TO SANITARY SEWERAGE DISPOSAL FOR C-SCAN SYSTEM

Dear Dr. Kimchy:

By letter dated March 15, 2020 (Agencywide Documents Access and Management System [ADAMS] Accession No. [ML21007A278](#)), Check-Cap Ltd. (Check-Cap) submitted a request to the U.S. Nuclear Regulatory Commission (NRC) seeking an interpretation of NRC's regulations. Check-Cap's request asked whether Title 10 of the *Code of Federal Regulations* (10 CFR) [20.2003\(b\)](#) applies to the disposal of the colon-imaging capsule from the C-Scan® (C-Scan) system in excreta. The provision in 10 CFR 20.2003(b) allows for the excreta from individuals undergoing medical diagnosis or therapy with radioactive material to be discharged into the sanitary sewerage. The NRC staff has reviewed the information provided by Check-Cap and has determined that the capsule is not excreta of the form identified under 10 CFR 20.2003(b) that can be disposed of in the sanitary sewerage.

When 10 CFR 20.2003(b) was promulgated, ingested sealed sources were not envisioned as potential excreta. While the NRC does not define excreta in its regulations, the NRC staff referenced several medical dictionaries, including the Stedman's Medical Dictionary. Based on the definitions of excreta, excrement, excretion, and feces in these medical dictionaries, the NRC staff does not consider the C-Scan capsule to be excreta because it is neither undigested residue of food, a waste product of metabolism, nor the product of a tissue or organ that is waste material to be eliminated from the body.

In addition to evaluating the question posed by Check-Cap, the NRC staff researched the statements of consideration related to the promulgation and revision of 10 CFR Part 20 and evaluated the prospects associated with disposing of the capsule in the sanitary sewer system. The statements of consideration for the final rule revising 10 CFR Part 20 discussed the disposal of insoluble material in sanitary sewerage. In the final rule ([56 FR 23360](#); May 21, 1991), the Commission modified the conditions for disposal of radioactive wastes into sanitary sewer systems so that "dispersible biological materials" may continue to be disposed of by release to sanitary sewers. However, the revised rule no longer permitted the disposal of nonbiological insoluble materials, such as flakes of metallic foil containing americium-241, because of the potential for re-concentration and accumulation of these materials in the sanitary sewer system, sewage treatment plants, and sewage sludge. Because the capsule would be nonbiological insoluble material, the NRC does not consider the capsule suitable for sanitary sewerage disposal.

Additionally, the NRC staff has additional concerns about the disposal of the capsule in a sanitary sewerage. Given the size of the capsule, it is anticipated that these sealed sources

would be collected on screens and filters as part of the pretreatment process at a wastewater treatment plant.¹ These screens and filters are then cleaned and the materials that do not pass through are removed and typically sent to a municipal landfill. The capsules may then be flagged by radiation detectors at the wastewater treatment plant and/or landfill, possibly creating orphan sources that would need to be collected and disposed of consistent with 10 CFR Part 20, Subpart K, "Waste Disposal." If this occurs, the NRC staff is concerned that the ultimate disposal responsibility would then be passed from a licensee (e.g., a physician or clinic) to a non-licensee (e.g., municipal sanitary sewerage facility or landfill). Finally, these capsules may raise concern if found in the public, such as at a wastewater treatment plant or a landfill, because these capsules would have to be labeled pursuant to 10 CFR 20.1904, "Labeling containers".

If you have any questions regarding this letter, please contact me at 301-415-5422, or via e-mail at Christian.Einberg@nrc.gov.

Sincerely,



Signed by Einberg, Christian
on 01/27/21

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

Cc: Amy Roma, Hogan Lovells
Sachin Desai, Hogan Lovells

¹ U.S. Environmental Protection Agency, "Wastewater Technology Fact Sheet: Screening and Grit Removal," June 2003, https://www3.epa.gov/npdes/pubs/final_sgrit_removal.pdf.