



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

April 22, 2022

VIA E-MAIL

Stephanie Fishman
Hogan Lovells US LLP
Stephanie.Fishman@hoganlovells.com

SUBJECT: NRC APPROVAL OF CHECK-CAP LTD. REQUESTS FOR WITHHOLDING
INFORMATION FROM PUBLIC DISCLOSURE RELATED TO THE C-SCAN®
SYSTEM

Dear Ms. Fishman:

By emails dated January 4, 2022, and January 7, 2022, Hogan Lovells US LLP, on behalf of Check-Cap Ltd., submitted two affidavits dated December 29, 2021, and January 7, 2022, executed by Yoav Kimchy, Founder and Chief Technical Officer of Check-Cap Ltd., requesting that the information contained in the following two documents be withheld from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR), Part 2, Section 2.390:

- Closed meeting slides dated January 5, 2022, titled "Meeting with NRC"
- Report dated December 19, 2021, titled "Radiation Dose Assessment Report"

Both affidavits stated that the submitted information should be considered exempt from mandatory public disclosure for the following reasons:

- a. The information is and has been held in confidence by Check-Cap Ltd.
- b. The information is of a type that is customarily held in confidence by Check-Cap Ltd.
- c. There is a rational basis for withholding because the information contains sensitive trade secret and commercial information concerning the product, technology, and commercial strategy of Check-Cap Ltd.
- d. The information is being transmitted to the NRC voluntarily and in confidence.
- e. The information is not available in public sources or available information has not been previously employed in the same original manner or method to the best of my knowledge.
- f. Public disclosure of this information is likely to cause substantial harm to the competitive position of Check-Cap Ltd. by disclosing its unique product, technology, and commercial strategy to other parties whose commercial interests may be adverse to those of Check-Cap Ltd.

We have reviewed your request and the information in accordance with the requirements of 10 CFR 2.390 and, on the basis of Check Cap Ltd.'s statements, have determined that the submitted information sought to be withheld contains proprietary commercial information and

should be withheld from public disclosure. Therefore, "Meeting with NRC" and "Radiation Dose Assessment Report," both marked as proprietary, will be withheld from public disclosure pursuant to 10 CFR 2.390(b)(5).

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the NRC. The NRC may have cause to review this determination in the future, for example, if the information has been requested in a Freedom of Information Act (FOIA) request. If the NRC determines that the information should be disclosed in response to a FOIA request, you will be notified of this determination and given the opportunity to object, in accordance with 10 CFR 9.28.

If you have any questions regarding this matter, I may be reached at 301-415-5422.

Sincerely,

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

Cc:
Amy Roma, Hogan Lovells

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