

substances without a DEA registration); *John V. Scalera*, 78 FR 12092, 12098 (2013) (same); *Belinda R. Mori, N.P.*, 78 FR 36582, 36588 (2013) (same); *Leo A. Farmer, M.D.*, 78 FR 27997, 27999 (2013) (same); *Glenn D. Krieger, M.D.*, 76 FR 20020, 20024 (2011) (same).

Accordingly, the Agency finds that after considering the factors of 21 U.S.C. 823(g)(1), the Government satisfied its *prima facie* burden showing that Applicant's registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4); *see also* 21 U.S.C. 823(g)(1). The Agency further finds that there is insufficient mitigating evidence to rebut the Government's *prima facie* case. Thus, the only remaining issue is whether, in light of the Agency's finding that Applicant violated the law, Applicant can be trusted with a registration.

V. Sanction

Where, as here, the Government has met the burden of showing that Applicant's proposed registration is inconsistent with the public interest, the burden shifts to Applicant to show why she can be entrusted with a registration. *Morall*, 412 F.3d at 174; *Jones Total Health Care Pharmacy*, 881 F.3d at 830; *Garrett Howard Smith, M.D.*, 83 FR 18882, 18904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual. *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, the Agency requires that a registrant or an applicant who has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that they will not engage in future misconduct. *See Jones Total Health Care Pharmacy*, 881 F.3d at 833; *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995). The Agency requires an applicant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.*, 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.*, 83 FR 29569, 29573 (2018); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 830–31. The Agency also considers the need to deter similar acts by an applicant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR at 46972–73.

Here, Applicant failed to answer the allegations contained in the OSC and did not otherwise avail herself of the opportunity to refute the Government's case. *See supra* Section I. Thus, there is no record evidence that Applicant takes responsibility, let alone unequivocal

responsibility, for the misconduct. Accordingly, she has not convinced the Agency that her future controlled-substance-related actions will comply with the CSA such that she can be entrusted with the responsibilities of a registration.

Further, the interests of specific and general deterrence weigh in favor of denial. Applicant's conduct in this matter concerns the CSA's "strict requirements regarding registration" and, therefore, goes to the heart of the CSA's "closed regulatory system" specifically designed "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Raich*, 545 U.S. at 12–14. If the Agency were to issue a registration to Applicant under these circumstances, it would send a dangerous message that compliance with the law is not essential to obtaining a registration.

In sum, Applicant has not offered any credible evidence on the record that rebuts the Government's case for denial of her application, and Applicant has not demonstrated that she can be entrusted with the responsibility of registration. Accordingly, the Agency will order the denial of Applicant's application for registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny the application for a DEA Certificate of Registration, Control No. W23121768C, submitted by Immacula Michel, M.D., as well as any other pending application of Immacula Michel, M.D., for registration in Florida. This Order is effective October 23, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 17, 2025, by Administrator Terrance Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0009]

Presence Sensing Device Initiation (PSDI) Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Presence Sensing Device Initiation (PSDI) Standard.

DATES: Comments must be submitted (postmarked, sent, or received) by November 24, 2025.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at <https://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov>. Documents in the docket are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the websites. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2010–0009) for the Information Collection Request (ICR). OSHA will place all comments, including any personal information, in the public docket, which may be made available online. Therefore, OSHA cautions interested parties about submitting personal information such as social security numbers and birthdates.

For further information on submitting comments, see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Belinda Cannon, Directorate of

Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693-2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.*, employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The following sections describe who uses the information collected under each requirement, as well as how they use it. Paragraph 1910.217(h) regulates the use of presence sensing devices ("PSDs") used to initiate the operation of mechanical power presses; a PSD (*e.g.*, a photoelectric field or curtain) automatically stops the stroke of a mechanical power press when the device detects an operator entering a danger zone near the press. A mechanical power press using presence sensing device initiation (PSDI) automatically starts (initiates) the stroke when the device detects no operator within the danger zone near the press. The certification/validation of safety systems for PSDI shall consider the press, controls, safeguards, operator, and environment as an integrated system which shall comply with 29 CFR 1910.217(a) through (h). Accordingly, the Standard protects employees from serious crush injuries, amputations, and death.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;

- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;

- The quality, utility, and clarity of the information collected; and

- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information, and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the information collection requirements contained in the Presence Sensing Device Initiation (PSDI) Standard (29 CFR 1910.217(h)). The agency is requesting that the burden of one (1) hour remains the same.

OSHA will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Extension of a currently approved collection.

Title: Presence Sensing Device Initiation (PSDI) Standard.

OMB Control Number: 1218-0143.

Affected Public: Business or other for-profits.

Number of Respondents: 10.

Number of Responses: 10.

Frequency of Responses: On occasion.

Average Time per Response: 6 minutes.

Estimated Total Burden Hours: 1: 1.

Estimated Cost (Operation and Maintenance): \$0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at <https://www.regulations.gov>, which is the Federal eRulemaking Portal; or (2) by facsimile (fax), if your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693-1648. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA-2010-0009). You may supplement electronic submission by uploading document files electronically.

Comments and submissions are posted without change at <https://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the <https://www.regulations.gov> index, some information (*e.g.*, copyrighted material) is not publicly available to read or download from this website. All submission, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <https://www.regulations.gov> website to submit comments and access the docket is available at the website's "User Tips" link.

Contact the OSHA Docket Office at (202) 693-2350, (TTY) (877) 889-5627 for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Amanda Laihow, Acting Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 8-2020 (85 FR 58393).

Signed at Washington, DC, on September 18, 2025.

Amanda Laihow,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[NASA Document Number: 25-040; NASA Docket Number: NASA-2025-0135]

Name of Information Collection: NASA Software Release System

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of a renewal of information collection.

SUMMARY: NASA, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (PRA).

DATES: Comments are due November 24, 2025.