

between medical devices and systems enabled, new models for monitoring, device interaction, and control—including the development of closed loop, autonomous and semiautonomous systems—can be realized. These new models will provide greater support for patient safety, decrease medical errors, reduce provider burden, reduce practice variability across healthcare facilities/geographic areas and, ultimately, will enhance medical care quality and outcomes.

Future Vision: When people with serious injuries or illness are hospitalized medical device additions and changes are automatically recorded with no deficit in patient safety, loss in data fidelity, or data security as the patient transitions across the continuum of care. Additional medical devices can be added or removed as the patient's status changes and details of these changes, calibration of the instruments, and each equipment's unique device identifier [UDI] and configuration settings are recorded and synchronized. If a piece of equipment breaks, it can be switched seamlessly with a device from another vendor. Data and settings from patient medical devices, such as insulin pumps, are identified, integrated, and time synchronized, and select data are included in the electronic health record. As autonomous capabilities are added, real-time care is logged, and supervisory control established to ensure the provision of real-time patient monitoring and support. When providers are not available, or have competing demands, medical devices will function in a closed loop, autonomous manner with appropriate safety and control measures to stabilize the patient. Data will flow through changes in equipment that occur in moves from the emergency room, to the operating room, to the intensive care unit, to a rehabilitation facility, and finally to the home. This will allow for data and metadata to flow even as changes in equipment are mapped to individual patient needs and environment. Each change in equipment configuration will be noted in the supervisory system/medical record and in the metadata (e.g., the UDI) generated by the device. The resulting patient record from these systems will include device data, metadata, and care documentation. These patient records can be stored and analyzed using medical black box recorder-equivalents to assess adverse events or examine unexpected positive outcomes. This will also improve the consistency and quality of care; create real-time

automated care systems; create a learning health system.

These types of records and the real-time systems interactions they enable are widely used or are being actively developed in other industries, such as the industrial controls and autonomous systems in the automotive, aviation, and energy sectors. That is not the case for healthcare. While there are many factors that may inhibit real-time interaction in a medical setting, interoperability solutions that are relevant for healthcare and patient safety need to be developed. Seamlessly flowing, interoperable data from medical devices and systems, when utilized effectively, could significantly enhance patient outcomes, identify and reduce errors, enhance the efficiency of care delivery, reduce development times and costs, improve standardization/consistency of care delivery, and decrease healthcare provider burnout.

Next Steps: The Government anticipates hosting a conference in June/July 2019 to allow for additional engagement. The results of the conference discussion, in addition to the written responses to this RFI, will be used to determine next steps in addressing federal efforts in interoperability of data, platforms, and medical devices. This RFI is solely issued to engage with interested parties to inform the Government on developing a strategy for medical device, data, and platform interoperability. The Government will not reimburse costs associated with participating in the conference. The Government may contact respondents regarding their submissions, such as to ask questions, to learn more, or to notify them of further developments related to the effort.

Submitted by the National Science Foundation in support of the Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) on February 11, 2019.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

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NUCLEAR REGULATORY COMMISSION

[NRC-2018-0119]

Information Collection: NRC Form 398, "Personal Qualification Statement—Licensee"

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, "NRC Form 398, "Personal Qualification Statement—Licensee."

DATES: Submit comments by March 18, 2019.

ADDRESSES: Submit comments directly to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0090), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: oir_submission@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: INFOCOLLECTS.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID: NRC-2018-0119 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2018-0119. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC-2018-0119 on this website.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-

415-4737, or by email to pdr.resource@nrc.gov. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Package Accession No. ML18166A095. The supporting statement and NRC Form 398 are available in ADAMS under ML18166A123 and ML18166A129.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- **NRC's Clearance Officer:** A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: INFOCOLLECTS.Resource@NRC.GOV.

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <http://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, "NRC Form 398, "Personal Qualification Statement—Licensee." The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on October 10, 2018, 83 FR 50970.

1. *The title of the information collection:* NRC Form 398, "Personal Qualification Statement—Licensee."

2. *OMB approval number:* 3150-0090.

3. *Type of submission:* Extension.

4. *The form number if applicable:* NRC Form 398.

5. *How often the collection is required or requested:* Upon application for an initial or upgrade operator license and every six years for the renewal of operator or senior operator licenses.

6. *Who will be required or asked to respond:* Facility licensees who are tasked with certifying that the applicants and renewal operators are qualified to be licensed as reactor operators and senior reactor operators.

7. *The estimated number of annual responses:* 1,074.

8. *The estimated number of annual respondents:* 1,074.

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 5,711.

10. *Abstract:* NRC Form 398 is used to transmit detailed information required to be submitted to the NRC by a facility licensee on each applicant applying for new and upgraded licenses or license renewals to operate the controls at a nuclear reactor facility. This information is used to determine that each applicant or renewal operator seeking a license or renewal of a license is qualified to be issued a license and that the licensed operator would not be expected to cause operational errors and endanger public health and safety.

Dated at Rockville, Maryland, this 11th day of February 2019.

For the Nuclear Regulatory Commission.

Kristen E. Benney,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

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NUCLEAR REGULATORY COMMISSION

[NRC-2019-0021]

Information Collection: Invoice Submissions by Contractors for NRC Contracts/Invoices

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of

information. The information collection is entitled, "Invoice Submissions by Contractors for NRC Contracts/Invoices."

DATES: Submit comments by April 16, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Website:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2019-0021. Address questions about docket IDs in [Regulations.gov](http://www.regulations.gov) to Krupskaya Castellon; telephone: 301-287-9221; email: Krupskaya.Castellon@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Mail comments to:** David Cullison, Office of the Chief Information Officer, Mail Stop: O-1 F21, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2019-0021 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2019-0021. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC-2019-0021 on this website.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For