



**Engineer Professional Advisory Committee  
Career Development Subcommittee  
Professional Certifications and Credentials Project Team**



# **An Analysis of Credentials for Biomedical Engineers**

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*December 2022*

***DISCLOSURE:*** *This document should be used as a mentoring tool for understanding of available credentials for USPHS Biomedical Engineers.*

## **Introduction**

The 2021 Engineering Category Promotion Benchmarks recognize there are credentials/certifications beyond Professional Engineer (PE) licensure that engineer officers may obtain which demonstrate professional development and advancement that are equally or even more valuable and appropriate to the officer's career, the U.S. Public Health Service Commissioned Corps, and the agencies where officers are assigned.<sup>1</sup> Beginning in Promotion Year (PY) 2022, category-specific benchmarks were replaced with standardized benchmarks that apply to all categories. The PY 2022 benchmarks do not specifically reference PE licensure. Rather, the "Credentials" factor for the T-O5/P-O4 rank calls for "Completion of advanced certification or licensure beyond the required, qualifying credential."

There is currently no clear guidance for biomedical engineers regarding specific credentials that have been identified as valuable in advancing their professional development and, similarly, a lack of guidance to promotion board members on specific credentials that they should consider as having met a particular benchmark. This ambiguity makes it difficult for (1) engineer officers to understand which credentials they should pursue based on value to the USPHS Commissioned Corps, their agencies, and prospective future agencies, and (2) promotion boards to evaluate the relevancy of credentials to Agency and USPHS Commissioned Corps engineering activities.

The lack of guidance is especially relevant to biomedical engineers (BMEs) because they have historically not pursued PE licensure due to the National Council of Examiners for Engineering and Surveying (NCEES)--which administers PE examinations-- not offering an exam specific to biomedical engineering. Moreover, the work of biomedical engineers does not require a licensed signatory (*e.g.*, design of medical devices and diagnostics, medical product manufacturing, biomedical research, and medical countermeasures development). In addition, licensure typically requires a prescribed number of hours working on projects that require that licensure, which are not available to practicing BMEs.

The purpose of this whitepaper is to (1) analyze the credentials relevant to BMEs in terms of their value to Agency and USPHS Commissioned Corps engineering activities, and (2) provide a comparison of the effort involved in obtaining and maintaining these various credentials. Next steps are recommended based on the results of the data analysis and information collected a survey that was conducted.

## **Findings**

In December 2020, the Professional Certifications and Credentials Project Team (hereafter "Team") conducted a survey to gather information from engineer officers about credentials they currently hold or aspire to attain in the future. The survey remained open from December 10, 2020 to January 15, 2021 and

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<sup>1</sup> Per the "Professional Credentials and Certifications" factor of the T-O5/P-O4 PY 2021 Engineering Category Benchmarks, the officer should seek PE licensure or "Registration or board certification, as a CHP, CSP, CIH, CPH, CHMM, Medical Instrumentation, Architect, or job-related fields with value-added to the USPHS, Agency, Corps and engineering profession activities; recognized by the CESB, ABIH, AAMI, ACHA, or relevant board; and approved by the Director CCHQ."



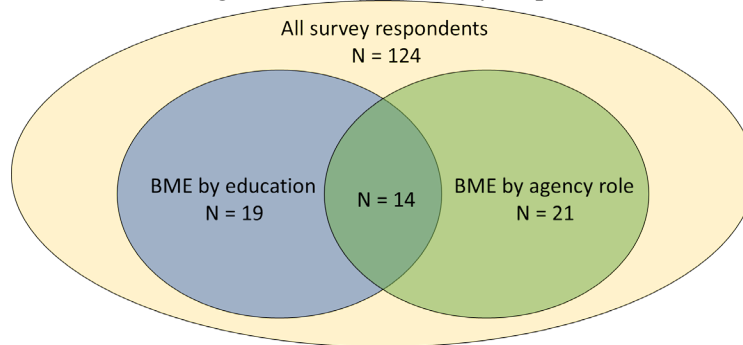
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yielded 124 responses (approximately 35% of the engineer officers in the USPHS Commissioned Corps). The Team analyzed the results to determine how many respondents were BMEs by education or by Agency role. Determining the latter involved reviewing each officer's self-reported Agency job description against the Merriam-Webster definition of biomedical engineering:<sup>2,3</sup>

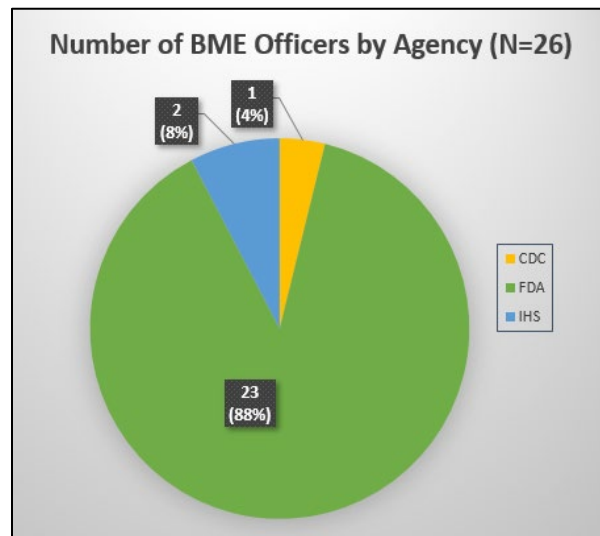
*The application of engineering principles, practices, and technologies to the fields of medicine and biology especially in solving problems and improving care (as in the design of medical devices and diagnostic equipment or the creation of biomaterials and pharmaceuticals)*

As depicted by **Figure 1**, 26 of the 124 survey respondents were BMEs either by education or Agency role. For reference, a breakdown of degrees held by all survey respondents can be seen in **Appendix 1**.



**Figure 1:** Venn diagram showing number of BMEs among survey respondents

23 of the 26 BME respondents work for FDA, while the remaining three (3) work for IHS and CDC (Figure 2). Their job descriptions also vary significantly, which is important to note because it suggests the credentials that are valuable to their Agency roles will likewise vary. Table 1 shows five examples of respondents' job descriptions.



**Figure 2:** Breakdown of BME officers by Agency responding to survey

<sup>2</sup> Source: <https://www.merriam-webster.com/dictionary/bioengineering>

<sup>3</sup> Note that 10 of the 124 responses did not include a job description and thus could not be assessed.



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Agency	Job Description
FDA	“Lead clinical pharmacology reviewer for new oncology and hematology drugs.”
FDA	“Inspecting manufacturers of medical devices to ensure compliance with the Quality System Regulation (design controls, production controls, etc.) and other pertinent regulations.”
FDA	“Provide internal and external stakeholder advice and guidance for drug/biological product development as it relates to FDA statute, regulations, and policy.”
IHS	“Clinical Engineering. Responsible for the repair, maintenance, training, and acquisition of medical equipment for IHS hospitals and clinics. Involved in the research and implementation of new medical equipment.”
CDC	“Regional officer in charge overseeing CDC quarantine stations. Provide regulatory oversight for biological imports including live animals and human remains. Implement syndromic surveillance to detect and prevent the spread of communicable disease.”

*Table 1: Five examples of job descriptions provided by survey respondents who are BMEs by education and/or job description.*

The benefits of PE licensure for BMEs have been outlined in a 2017 editorial published in IEEE Pulse.<sup>4</sup> Despite the noted benefits, zero (0) of the 26 BME survey respondents stated they hold PE licensure. This low prevalence is consistent with the results of a March 2019 survey of FDA engineer officers conducted by RDML Sean Boyd and CDR Richard “Wes” Ishihara (**Appendix 4**), during which 55 BME respondents raised the following concerns regarding challenges in obtaining a PE:

- NCEES does not offer a PE exam in the biomedical engineering discipline
- There are few PEs available at FDA to fulfill the training requirement (i.e., acceptable, qualified experience under a licensed PE)
- PE licensure is not required for FDA-related work
- The focus should be on obtaining additional education, training, credentials and/or certifications useful to Agency duties or skillsets important to the USPHS Commissioned Corps (e.g., for deployment purposes)

As part of the more recent 2020-2021 survey, respondents were asked to identify certifications/credentials they currently hold or wish to obtain in the future. BME respondents cited 46 unique certifications/credentials a total of 89 times as either being currently held or desired in the future (see **Appendix 2** for details). Respondents were also asked to assign a score from 1 (lowest) to 5 (highest) of how valuable they felt each identified certification/credential is to (1) their Agency work and (2) USPHS Commissioned Corps work.

For the purposes of this whitepaper, three (3) of the 46 certifications/credentials are highlighted based on prevalence and perceived value:

- American Society for Quality (ASQ) Certified Quality Engineer (CQE)
- Association for the Advancement of Medical Instrumentation (AAMI) Certified Biomedical Equipment Technician (CBET)
- Regulatory Affairs Professional Society (RAPS) Regulatory Affairs Certification (RAC)

A matrix of these credentials in terms of prerequisites, level of effort to obtain/maintain, and other factors can be seen in **Appendix 3**. **Table 2** below summarizes how BME respondents perceive the value of PE licensure, the prerequisite Engineer-in-Training (EIT), and the three credentials above to Agency work and USPHS Corps activities. The standard deviation (SD) is included to indicate the level of agreement

<sup>4</sup> “Professional Licensure of Biomedical Engineers”: <https://www.embs.org/pulse/articles/professional-licensure-biomedical-engineers/>



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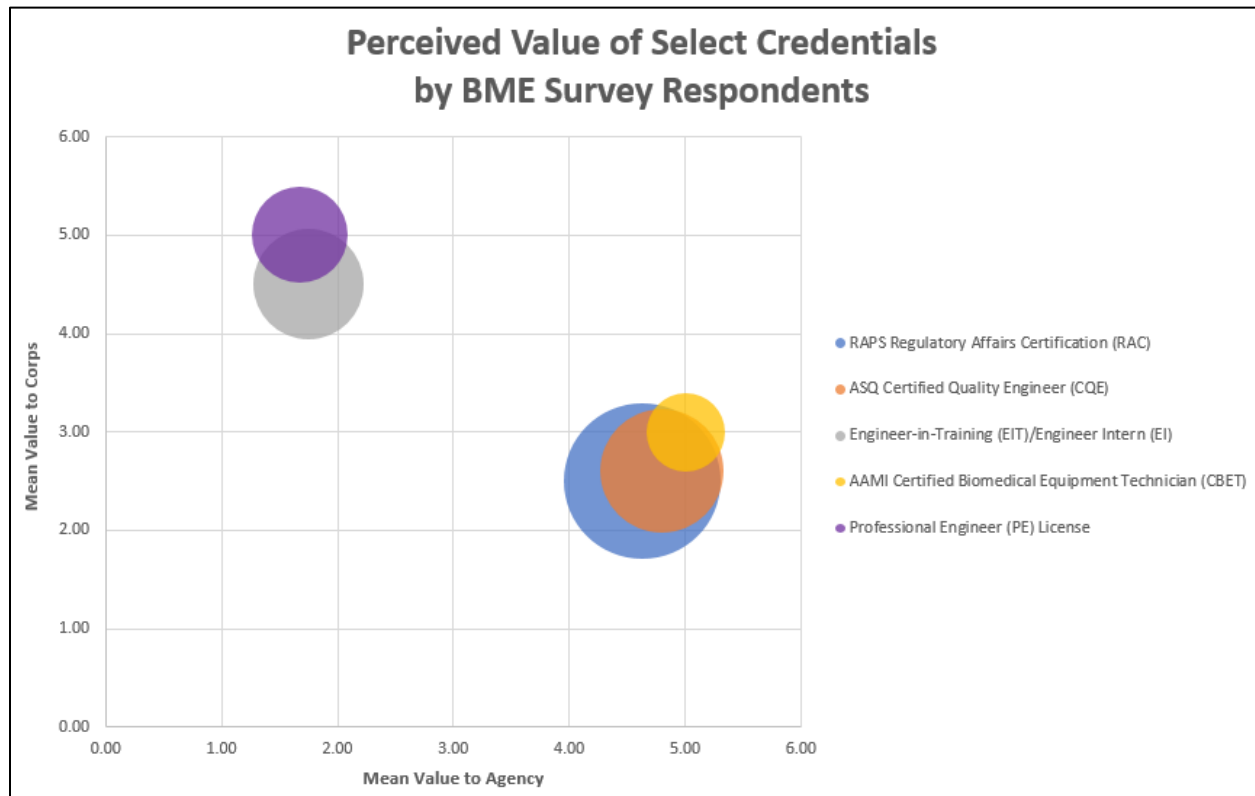


among respondents. For example, the table shows that eight (8) of the 26 BME respondents included the RAPS Regulatory Affairs Certification (RAC) as a credential they either currently hold or with to obtain in the future.

Credential	# BME Respondents	Perceived Value to Agency		Perceived Value to USPHS CC	
		Mean	SD	Mean	SD
Professional Engineer (PE) License	3	1.67	0.58	5.00	0.00
Engineer-in-Training (EIT)/Engineer Intern (EI)	4	1.75	0.96	4.50	0.58
RAPS Regulatory Affairs Certification (RAC)	8	4.63	0.74	2.5	1.41
ASQ Certified Quality Engineer (CQE)	5	4.80	0.45	2.6	1.52
AAMI Certified Biomedical Equipment Technician (CBET)	2	5.00	0.00	3.00	0.00

*Table 2: Value to of EIT/PE and select credentials as reported by BME respondents*

The bubble chart in **Figure 3** provides a visual display of the data presented in **Table 2**. The mean value to Agency and mean value to USPHS Commissioned Corps activities correspond to the X- and Y-axes, respectively, while the size of each bubble indicates the number of BMEs who identified the respective credential in their survey response (both as currently held or desired in the future).



*Figure 3: Bubble chart showing value to of EIT/PE and select credentials as reported by BME respondents*



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## Discussion

The survey asked respondents to indicate the perceived value for each credential they identified. It is important to note that perceived value to an organization does not always equal the real value to an organization. Although outside the scope of our analysis, real value of credentials could be determined in other ways, such as by the number of officers who require those credentials to perform their duties at their Agency or during deployments. We expect that officers will have significant insight into the value of certifications for their Agency as they perform those duties daily and are often supported by supervisors and Agency leadership. We also expect that value to the USPHS Commissioned Corps will be influenced heavily by statements from CCHQ leadership and promotion benchmarks; however, there may not be a direct correlation to the activities performed during deployments or during public health emergencies since those duties are not undertaken daily and they may change frequently. Additional studies to determine the correlation between real value and perceived value to USPHS Commissioned Corps, Agency, and officer could be useful in determining which certifications officers should pursue.

With respect to *perceived* value, **Figure 3** shows that each of the five highlighted credentials falls into one of two clusters:

1. A cluster of credentials which are perceived by respondents as low value to BMEs' agencies but high value to USPHS Commissioned Corps activities (PE and EIT).
2. A cluster of credentials which are perceived by respondents as high value to BMEs' agencies but a lower value to USPHS Commissioned Corps activities (all credentials other than PE and EIT).

The low standard deviation numbers shown in **Table 2** also indicate high agreement among respondents on perceived value.

## Conclusion and Recommendations

Officers either with a BME degree or acting in a BME Agency role have reported that obtaining a PE license does not add value to their Agency. Additionally, BMEs have historically faced significant barriers to obtaining a PE as discussed in this whitepaper. Furthermore, it is unclear that obtaining PE licensure in a field unrelated to a BME's assigned duties would add any value to their Agency or the USPHS Commissioned Corps, especially given the additional time and effort required to obtain such a license. Other credentials are available to BMEs that may provide greater value to their Agency and higher impacts to their individual career tracks. The survey results showed that obtaining and maintaining alternative credentials such as the ASQ Certified Quality Engineer (CQE), RAPS Regulatory Affairs Certification (RAC), and AAMI Certified Biomedical Equipment Technician (CBET) benefits officers' knowledge, expertise, and practice beyond the required, qualifying credentials.

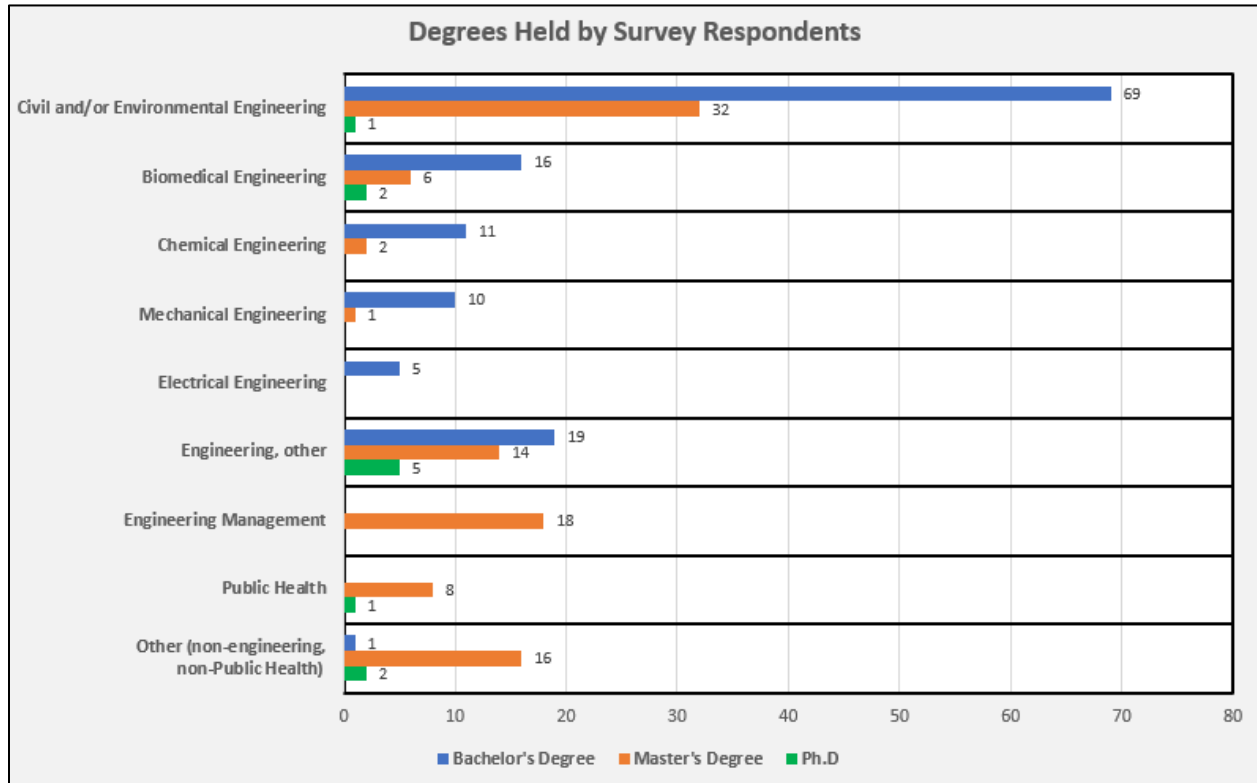
The three credentials of focus were among 46 identified by BMEs who responded to the 2020-2021 survey. The Team collected information on various factors to help BMEs determine the level of effort needed to obtain and maintain the three highlighted credentials but, as a next step, this information for all 46 credentials could be evaluated along with the value each adds to Agency and USPHS Commissioned Corps activities and how they benefit the officer's knowledge, expertise, and practice beyond the required, qualifying credentials. This information could help BMEs identify credentials that are relevant to their career goals and interests and add value to Agency and USPHS Commissioned Corps activities.



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Appendix 1: Academic Degrees Held by Survey Respondents



**Note:** The sum of degrees held exceeds the number of survey responses (n = 124) because many officers hold multiple degrees, which may or may not be in the same discipline. Some officers even hold more than one degree of a given type (e.g., more than one bachelor's degree).



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**Appendix 2: Credentials Identified by BME Survey Respondents**

<b>Credential</b>	<b># BMEs who currently hold</b>	<b># BMEs who desire to hold</b>	<b>Total</b>	<b>Mean Agency Value</b>	<b>Mean USPHS CC Value</b>
RAPS Regulatory Affairs Certification (RAC)	3	5	8	4.625	2.5
ASQ Certified Quality Auditor (CQA)	4	2	6	3.833	2.67
ASQ Certified Quality Engineer (CQE)	2	3	5	4.8	2.6
ASQ Certified Quality Improvement Associate (CQIA)	4	1	5	4	2.2
ASQ Certified Medical Device Auditor (CMDA)	3	1	4	4.75	2.25
Engineer-in-Training (EIT)/Engineer Intern (EI)	3	1	4	1.75	4.5
FDA/ORA Level 1 Investigator Certification	3		3	4.67	2.33
FDA/ORA Medical Device Investigator Certification	3		3	5	2
NBPHE Certified in Public Health (CPH)	1	2	3	3	3.67
PMI Project Management Professional (PMP)	1	2	3	3.33	2.67
Professional Engineer (PE) License		3	3	1.67	5
AAMI Certified Biomedical Equipment Technician (CBET)		2	2	5	3
AAMI Certified Radiology Equipment Specialist (CRES)		2	2	5	3
ASPR Forklift Operator	1	1	2	1	4
ASQ Certified Pharmaceutical GMP Professional (CPGP)		2	2	5	3
ASQ Certified Reliability Engineer (CRE)		2	2	5	2.5
ASQ Certified Six Sigma Black Belt (CSSBB)		2	2	4	2
FAI Federal Acquisition Certification for Program and Project Managers (FAC-P/PM) Level I		2	2	5	4.5
AAEES Board Certified Environmental Engineer (BCEE)	1		1	4	3
AAMI Certified Healthcare Technology Manager (CHTM)		1	1	5	5
AAMI Certified Industrial Sterilization Specialist (CISS)		1	1	5	2
ACCE Certified Clinical Engineer (CCE)		1	1	5	5
AEE Certified Energy Auditor (CEA)	1		1	1	3



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<b>Credential</b>	<b># BMEs who currently hold</b>	<b># BMEs who desire to hold</b>	<b>Total</b>	<b>Mean Agency Value</b>	<b>Mean USPHS CC Value</b>
AEE Certified Energy Manager (CEM)	1		1	1	3
ASQ Certified Calibration Technician (CCT)	1		1	4	2
ASQ Certified Manager of Quality/Operational Excellence (CMQ/OE)		1	1	5	3
ASQ Certified Quality Inspector (CQI)		1	1	4	3
ASQ Certified Quality Technician (CQT)	1		1	4	1
ASQ Certified Software Quality Engineer (CSQE)	1		1	5	1
ASQ Certified Supplier Quality Professional (CSQP)		1	1	5	1
BCPE Certified Human Factors Professional (CHFP)		1	1	4	4
BCSP Associate Safety Professional (ASP)	1		1	2	4
BCSP Certified Safety Professional (CSP)		1	1	2	5
CMAA Certified Construction Manager (CCM)		1	1	4	4
CompTIA A+ Certification		1	1	4	3
CompTIA Network+ Certification		1	1	5	4
CompTIA Security+ Certification		1	1	4	4
FAI Contracting Officer Representative (COR) Level I	1		1	5	5
FDA/ORA Imports Investigator Certification	1		1	5	5
FDA/ORA Level 3 Drug Investigator Certification	1		1	5	5
FEMA Type 3 HHS Liaison Officer (LNO)		1	1	1	5
IEEE Computer Society Professional Software Engineering Master (PSEM) Certification		1	1	5	1
OPM Senior Executive Service Candidate Development Program		1	1	5	5
SEI Software Architecture Professional Certificate		1	1	5	1
SME Certified Manufacturing Engineer (CMfgE)		1	1	5	1
UCSF American Course on Drug Development and Regulatory Sciences (ACDRS)		1	1	5	3
<b>Totals</b>	<b>38</b>	<b>51</b>	<b>89</b>		





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### Appendix 3: Analysis of Level of Effort to Obtain & Maintain Select Credentials

	<b>ASQ Certified Quality Engineer (CQE)</b>	<b>AAMI Certified Biomedical Equipment Technician (CBET)</b>	<b>RAPS Regulatory Affairs Certification (RAC)</b>
<b>Granting Authority</b>	American Society for Quality (ASQ)	Association for the Advancement of Medical Instrumentation (AAMI)	Regulatory Affairs Professionals Society (RAPS)
<b>Description</b>	A CQE is a professional who understands the principles of product and service quality evaluation and control. This body of knowledge and applied technologies include, but are not limited to, development and operation of quality control systems, application and analysis of testing and inspection procedures, the ability to use metrology and statistical methods to diagnose and correct improper quality control practices, an understanding of human factors and motivation, facility with quality cost concepts and techniques, and the knowledge and ability to develop and administer management information systems and to audit quality	Healthcare technology management professionals that desire a CBET certification are expected to have experience in a wide-range of electromechanical devices, computers, networks, and software used in the delivery of healthcare. Generally, candidates desiring for this certification may work for medical device manufacturers, hospitals, clinics, home healthcare providers, medical device repair companies, regulatory bodies/agencies, and software manufacturers – such as EMR or device integration providers.	Regulatory Affairs Certification (RAC) is the leading post-academic professional credential for regulatory professionals in the healthcare product sector. It is intended for individuals employed in regulatory agencies, industry, consultancies, and other settings involved with the regulation of healthcare products. Regulatory Affairs Certification tests expertise in two sectors, pharmaceuticals and medical devices, and candidates may choose whether to take the RAC Drugs exam or the RAC Devices exam.



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	<b>ASQ Certified Quality Engineer (CQE)</b>	<b>AAMI Certified Biomedical Equipment Technician (CBET)</b>	<b>RAPS Regulatory Affairs Certification (RAC)</b>
	systems for deficiency identification and correction.		
<b>Pre-requisites</b>	<ul style="list-style-type: none"> <li>• 8 years' work experience (4 years waived with bachelor's degree)</li> <li>• 3 years working in a decision-making role</li> </ul>	Applicants must meet ONE of the following minimum eligibility requirements as of the application deadline: <ul style="list-style-type: none"> <li>• Associate degree or higher in biomedical equipment technology program and two years' full-time BMET work experience</li> <li>• Completion of a U.S. military biomedical equipment technology program and two years' full-time BMET work experience</li> <li>• Associate degree or higher in electronics technology and three years' full-time BMET work experience</li> <li>• Four years' full-time BMET work experience.</li> </ul>	To be eligible for the RAC examination, you need to meet one of the following educational and professional experience requirement combinations: <ul style="list-style-type: none"> <li>• Baccalaureate or equivalent first university degree and a minimum of three years of regulatory or regulatory-related work experience.</li> <li>• Master's degree and a minimum of two years of regulatory or regulatory-related work experience.</li> <li>• Doctorate degree and a minimum of one year of regulatory or regulatory-related work experience.</li> </ul>
<b>Costs</b>	Test: \$498 (ASQ non-member) \$398 (ASQ member)  Handbook (not-required): \$145 (non-member)	Test: \$350 (AAMI member) \$400 (AAMI non-member)  CBET Smart Practice (not required): \$117 (member) \$195 (non-member)	2020-21 Examination Fees <ul style="list-style-type: none"> <li>• RAPS Member \$485 (US)</li> <li>• List \$605 (US)</li> </ul>



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	<b>ASQ Certified Quality Engineer (CQE)</b>	<b>AAMI Certified Biomedical Equipment Technician (CBET)</b>	<b>RAPS Regulatory Affairs Certification (RAC)</b>
	\$101.50 (member)  Class (not required): \$2239 (non-member) \$1889 (member)	CBET Study Course (not required): \$200 (member) \$250 (non-member)	
<b>Effort of Studying</b>	~130 hours <sup>5</sup>  ASQ offers <i>The Certified Quality Engineer Handbook</i> as a study guide (684 pages)  2020 Pass Rate: 68% <sup>6</sup>	Prior test takers recommend studying 1-2 hours/day for 8 to 12 weeks before taking the exam. <sup>7</sup>  2006 pass rate 62% <sup>8</sup>	RAPS offers textbooks and online courses to prepare for the exam: <ul style="list-style-type: none"> <li>• <i>Fundamentals of Medical Device Regulations</i> (844 pages)</li> <li>• <i>Fundamentals of Pharmaceutical and Biologics Regulations</i> (1,524 pages)</li> </ul> Pass Rate: Between 40% and 50% <sup>9</sup>
<b>Exam Length</b>	175 multiple choice questions (160 multiple choice questions are scored and 15 are unscored). Total appointment time is five-and-a-half-hours, exam time is 5 hours and 18 minutes.	Three-hour closed book exam consisting of 165 multiple-choice questions.	Two-hour exam consisting of 100 multiple-choice questions.

<sup>5</sup> Source: <https://elsmar.com/elsmarqualityforum/threads/how-much-preparation-time-for-cqe-certified-quality-engineer-exam.21268/>

<sup>6</sup> Source: <https://asq.org/cert/faq/exam-grading-process>

<sup>7</sup> Source: <https://www.indeed.com/certifications/view/cbet-DNFO5FZY/what-advice-would-you-give-to-someone-interested-in-earning>

<sup>8</sup> Source: <https://24x7mag.com/standards/regulations/certification-can-we-ensure-competence/>

<sup>9</sup> Source: <https://www.raps.org/regulatory-focus/news-articles/2018/8/how-to-prepare-for-the-rac-exam>



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	<b>ASQ Certified Quality Engineer (CQE)</b>	<b>AAMI Certified Biomedical Equipment Technician (CBET)</b>	<b>RAPS Regulatory Affairs Certification (RAC)</b>
<b>Re-certification Requirements</b>	Earn 18 recertification units (RUs) or re-take exam every 3 years	30 continuing education units every 3 years	36 credit hours every 3 years
<b>Website</b>	<a href="https://asq.org/cert/quality-engineer">https://asq.org/cert/quality-engineer</a>	<a href="https://www.aami.org/training/about-aci#CBET">https://www.aami.org/training/about-aci#CBET</a>	<a href="https://www.raps.org/rac-credential/home">https://www.raps.org/rac-credential/home</a>



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**Appendix 4: Results of FDA Engineer Survey Conducted in March 2019 by  
RDML Sean Boyd and CDR Richard (Wes) Ishihara**

# FDA CORPS ENGINEER SURVEY

Credentials and Certifications

CAPT Sean Boyd  
CDR Richard (Wes) Ishihara

1

FDA Commissioned Corps Engineer Officers have been asked to provide feedback on the "Professional Credentials and Certifications" portion of Precept 2, Engineer Category Promotion Benchmarks. In particular, we are looking for input specifically as it relates to you as an engineer officer assigned to FDA. Based on your input, feedback and recommended revisions to the Engineer Category Promotion Benchmarks will be provided to the Chief Engineer Officer (RADM Dieser).

## BACKGROUND

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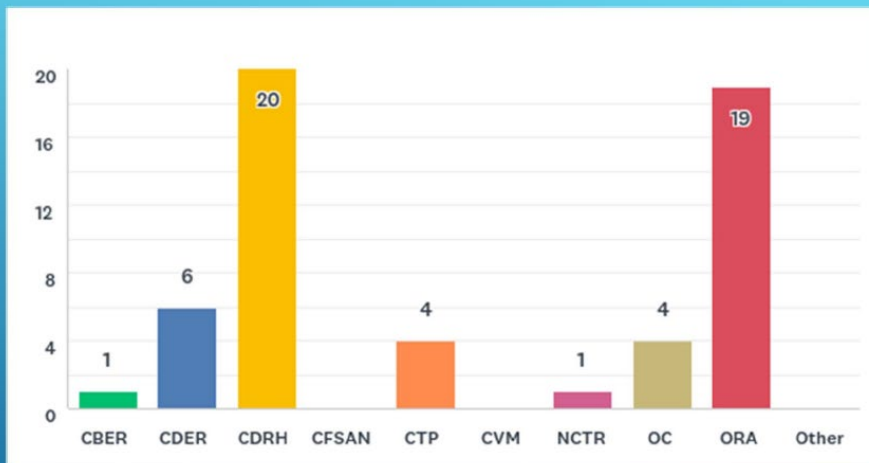


How many FDA engineers responded?

- ▶ 55 Responses
- ▶ ~64% Response Rate (55/86)

RESPONSE RATE

3



Q1: WHAT FDA CENTER ARE YOU  
ASSIGNED TO?

4



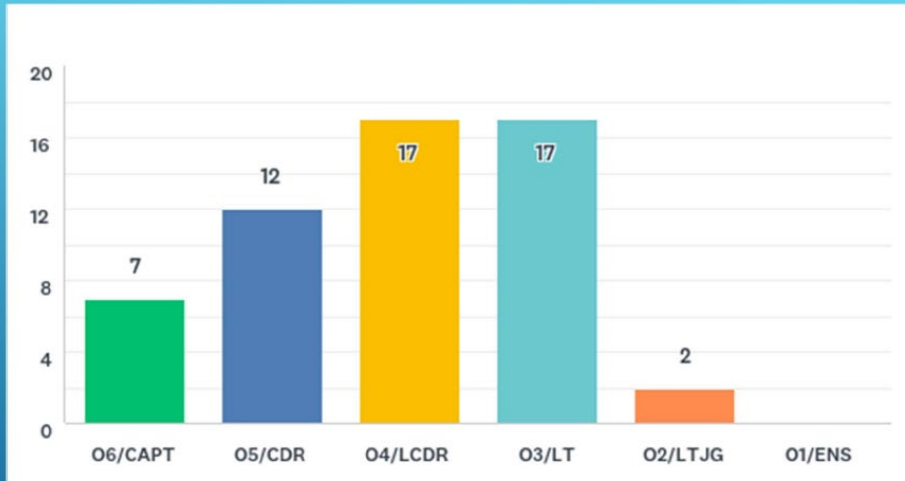
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Deputy Regulatory Operations Officer Investigator Medical Device  
**Director** Lead **Engineer** Specialist  
**Consumer Safety Officer** Office  
**Senior** Branch Chief **Regulatory Officer** Lead Reviewer  
Program Management Officer Regulatory Reviewer

Q2: WHAT IS YOUR POSITION/TITLE/ROLE  
WITHIN YOUR CENTER?

5

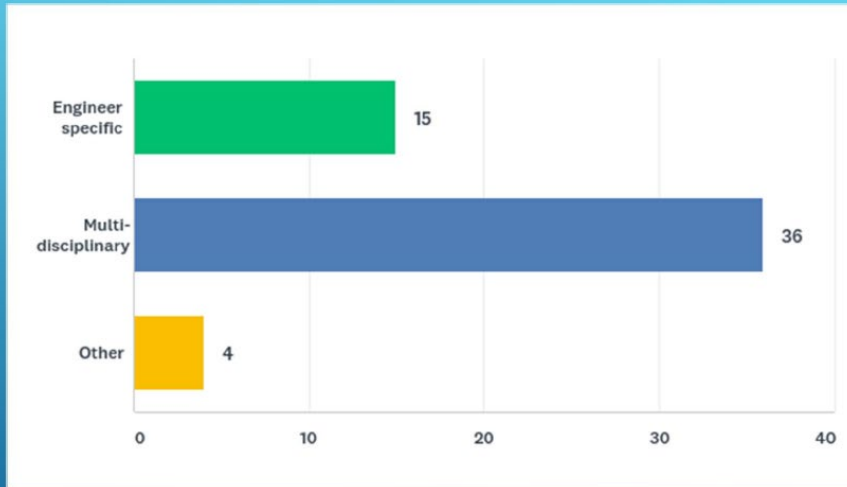


Q3: WHAT IS YOUR RANK?

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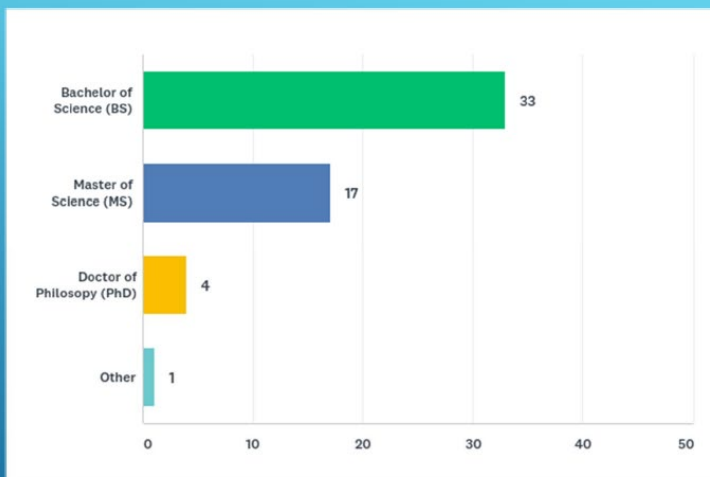


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Q4: IS YOUR CURRENT BILLET?

7



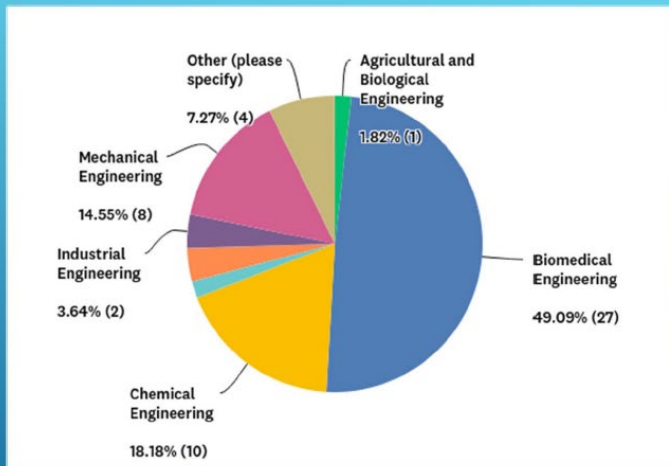
Q5: WHAT IS YOUR QUALIFYING ENGINEERING DEGREE?

8



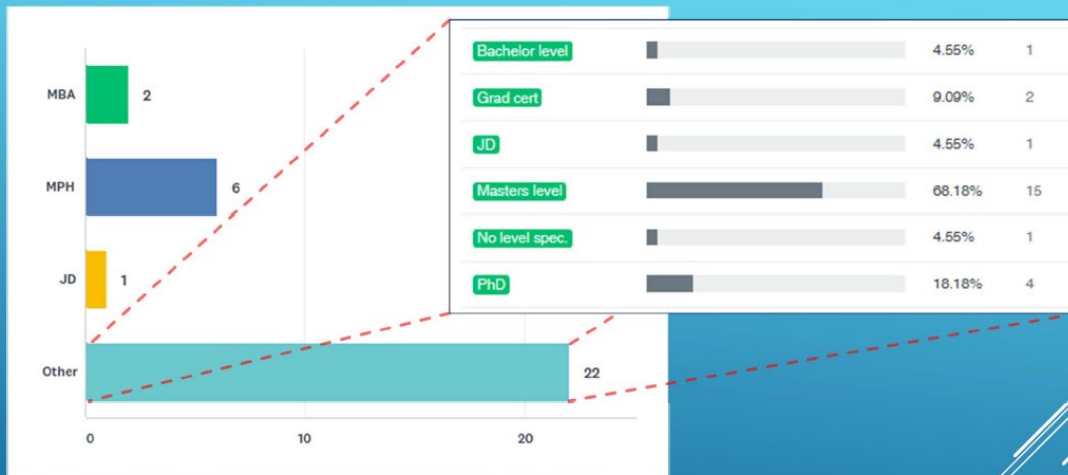


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Q6: WHAT IS THE PROGRAM OR AREA OF STUDY FOR YOUR QUALIFYING DEGREE?

9

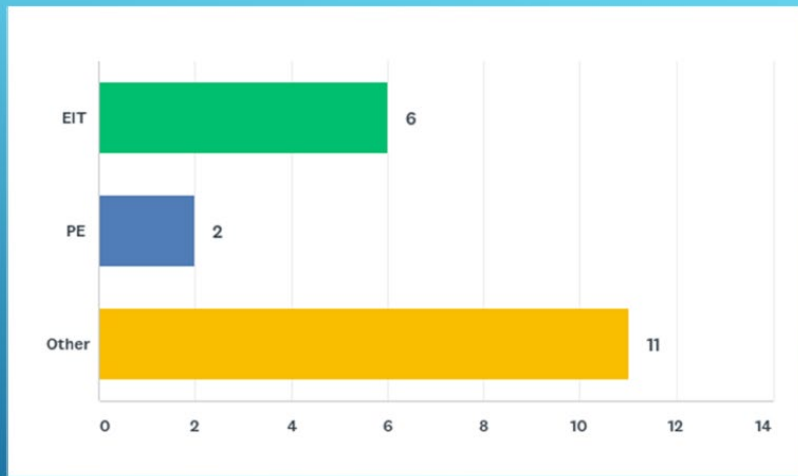


Q7: DO YOU HAVE ANY ADDITIONAL DEGREES OR EDUCATION?

10



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Q8: ENGINEERING FOCUSED CREDENTIALS AND/OR CERTIFICATIONS?

11

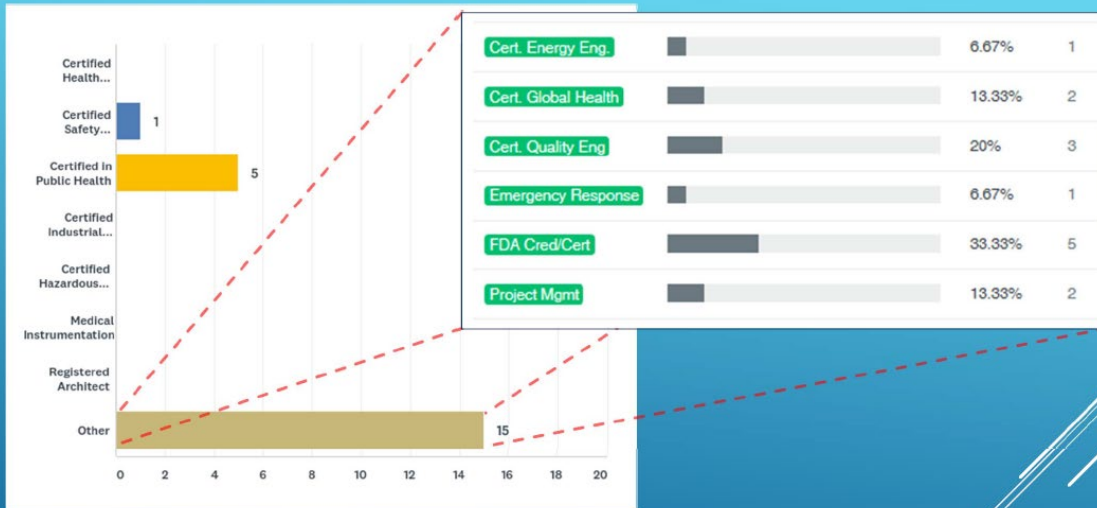
- ▶ “None of these credentials are in line with my future career goals; requiring me to complete any of these would not help in my career development. Furthermore, even if I were to acquire an EIT, I would not be able to earn a PE because no one I work with has a PE”

Q8: ENGINEERING FOCUSED CREDENTIALS AND/OR CERTIFICATIONS? (CONT)

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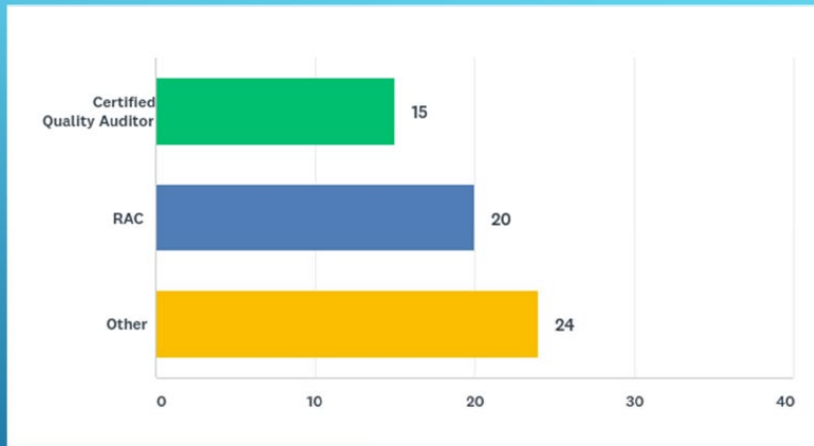


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**Q9: PROFESSIONAL CREDENTIALS AND/OR CERTIFICATIONS**

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**Q10: RECOMMENDED FDA-SPECIFIC AND/OR WORK-RELATED CREDENTIALS AND CERTIFICATIONS**

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Recommendations:

- ▶ Regulatory Affairs Certification (RAC)
- ▶ Certifications offered by American Society for Quality (e.g., CQA, CQE, CRE, CQIA, etc.)
- ▶ Certifications offered by Association for the Advancement of Medical Instrumentation (currently captured on 2019 Benchmarks)
- ▶ ISO 9001 Lead Auditor Certification
- ▶ Lean/Six Sigma Training and Certification
- ▶ Project Management Professional Certification
- ▶ Agency specific/provided certification important to performance of duties

**Q10: RECOMMENDED FDA-SPECIFIC AND/OR WORK-RELATED CREDENTIALS AND CERTIFICATIONS (CON'T)** 15

Sentiment Shared:

- ▶ General shared concern over challenges with obtaining a PE
  - ▶ No program in the area of biomedical
  - ▶ Few PEs available to fulfill the training requirement (acceptable/qualified experience)
  - ▶ Not required for FDA related work
  - ▶ These challenges should be broadly understood (not just by FDA Engineers)
- ▶ ORA Engineers require unique set of skills and certification
- ▶ Encouragement should focus on obtaining certifications/credentials useful to Agency work/PHS

**Q11: ADDITIONAL COMMENTS AND RECOMMENDATIONS**

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### Recommendations

- ▶ Establish a complete list of recognized certifications
- ▶ Provide common ways similar engineers have met these precepts
- ▶ Identify FDA PE's (as a resource) to support a program e.g., "Pathway to PE"

## Q11: ADDITIONAL COMMENTS AND RECOMMENDATIONS

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Do the survey results capture your concerns? Recommendations?

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- ▶ Share results with the EPAC Subcommittee for Mentoring and Career Development
- ▶ Convey recommendations and other general feedback to RADM Dieser
- ▶ Resource development?

NEXT STEPS

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Questions? Comments? Feedback?



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<p>• <b>Professional Credentials and Certifications</b> (documented in Officers electronic Official Personnel File)</p>	<p>Evidence of pursuit towards registration or board certification relevant for the officer's career path as a professional</p> <p>Examples include registration as an Engineer in Training (EIT), Health Physicist, Safety Professional, Industrial Hygienist, Medical Instrumentation or Public Health Certified Professional, Architect, or job-related fields with value-added to Corps engineering activities; recognized by the National Council of Examiners for Engineering and Surveying (NCEES), Council of Engineering and Scientific Specialty Board (CESB), American Board of Industrial Hygienist (ABIH), Association for the Advancement of Medical Instrumentation (AAMI), National Board of Public Health Examiners (NMPHE), American College of Healthcare Architects (ACHA), or relevant board; and approved by the Director, Commissioned Corps Headquarters (CCHQ).</p>	<p>Evidence of pursuit towards registration or board certification relevant for the officer's career path as a professional</p> <p>Registration as an EIT from NCEES;</p> <p>or</p> <p>Examples include registration or board certification, by examination, as a Health Physicist (HP), Safety Professional (SP), Certified in Public Health (CPH), Certified Hazardous Material Manager (CHMM), Architect, Industrial Hygienist (IH), Medical Instrumentation or job-related fields with demonstrated value-added to Corps engineering activities recognized by the CESB, ABIH, AAMI, NMPHE, ACHA, or relevant board; and approved by the Director CCHQ.</p> <p>Other job-related certifications or licensure should be considered as value added to the Corps and Agency.</p>	<p>Evidence of licensure, registration, or board certification relevant for the officer's career path as a professional</p> <p>Licensure as a Professional Engineer (PE) by NCEES</p> <p>or</p> <p>Registration or board certification, as a CHP, CSP, CIH, CPH, CHMM, Medical Instrumentation, Architect, or job-related fields with value-added to the USPHS, Agency, Corps and engineering profession activities; recognized by the CESB, ABIH, AAMI, ACHA, or relevant board; and approved by the Director CCHQ.</p>	<p>Evidence of continued licensure, registration, and/or multiple board certifications as a professional</p> <p>Licensure as a PE plus one additional credential or board certification</p> <p>or</p> <p>Multiple registrations or board certification, as a CHP, CSP, CIH, CPH, CHMM, Medical Instrumentation, Architect, or job-related fields with value-added to the USPHS, Agency, Corps and engineering profession activities; recognized by the CESB, ABIH, AAMI, ACHA, or relevant board; and approved by the Director CCHQ.</p>
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A survey was initiated March 27, 2019, to solicit feedback on credentials and certifications (and/or bodies that provide such certifications) considered to be important and relevant to FDA Commissioned Corps Engineers. The survey response rate was 64% (55/86 engineers responded). The survey results were analyzed and then presented to FDA Engineers on July 11, 2019, with the objective to ensure the survey results generally reflected the collective feedback of FDA Engineers as well as provide an additional opportunity for FDA Engineer to provide feedback. The following captures the collective feedback from the March 27, 2019, Survey and the July 11, 2019, discussion.

### Key Credentials and Certifications Recommended for Engineers Assigned to FDA:

- Regulatory Affairs Certification (RAC) – Regulatory Affairs Professional Society
- Certifications offered by American Society for Quality (e.g., Certified Quality Auditor, Certified Quality Engineer, Certified Reliability Engineer, Certified Quality Improvement Associate, etc.)
- Certifications offered by Association for the Advancement of Medical Instrumentation (currently captured on 2019 Benchmarks)
- ISO 9001 Lead Auditor Certification
- Lean/Six Sigma Training and Certification
- Project Management Professional Certification
- Agency specific/provided certification important to performance of duties

To provide context for recommendations that emerged from the FDA Engineers, it is relevant to note that there was a general shared concern over challenges with obtaining engineering



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licensure (PE) for officers assigned to FDA, as well as questions over the relevance of completing the Fundamentals of Engineering exam (FE) because:

- No PE program in the area of biomedical currently exists, and we feel that PHS expectations for licensure of its engineers should align with those of the appropriate engineering professional society. One Officer shared that based on discussions with NSPE, feedback was received that no program will be created unless the need arises based on changes to state licensing requirements.
- There are few PEs available at FDA to fulfill the training requirement (acceptable/qualified experience).
- A PE is not required for FDA related work. Similarly, any requirement to complete the FE exam (such as upon application to the Commissioned Corps) would limit applicants who might otherwise be highly qualified for assignment to FDA.
- There should be a strong correlation between an individual's development plan (whether it be additional education, training, credentials, and/or certifications) and the duties at the assigned Agency and/or skillsets important to the Corps (e.g., for deployment purposes).
- FDA engineers expressed a perception that having a PE is a requirement or factor upon which candidates will be evaluated for the position of Chief Engineer. While we have not identified a publicly available document to affirm this, it creates the impression that FDA engineers are not able to successfully represent the Engineering Category in this role.

FDA Engineers believed that these challenges and opportunities should be broadly shared, understood, and appreciated among all Corps Engineers (not just by those assigned to FDA). It was additionally noted that, FDA Engineers assigned to "field offices" (i.e., Office of Regulatory Affairs) require a unique set of skills and FDA certification to perform the duties assigned (i.e., Level 1 or Level 2 investigators, who perform inspectional and testing activity). There was some concern that there is a lack of clarity around whether Engineering Promotion Precept 2 for professional development is intended apply to the work at the engineer's Agency, deployment role, or both. It was emphasized that career development counseling as it relates to pursuit of certifications/credentials (as well as more broadly toward one's individual development, e.g., pursuit of advance degrees) should focus on those activities that are useful to Agency work and/or the Commissioned Corps (and not be viewed as a "check a box" in a list of things to achieve success).

Additional Recommendations to Assist Engineers in Identifying Relevant Credentials/Certifications:

- Establish a list of recognized credentials and certifications<sup>10,11</sup> – by engineer agency assignment. Also consider defining recognized credentials and certifications applicable for certain deployment roles.

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<sup>10</sup> Importantly, this was viewed as intended to guide engineers and not intended to provide a strict criteria or checklist.

<sup>11</sup> This recommendation could be of interest more broadly to Corps Engineers and may not be limited as a resource for FDA Engineers only.





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- Provide common ways similar engineers have met these credentials and certifications. Establishing expectations and/or recommended development activities relevant to specific Agency assignment would be helpful.
- Despite specific questions raised regarding PE licensure for FDA engineers, we see value in identifying PHS officers and civilians who have PEs across agencies (who may serve as a resource) to support engineers considering or pursuing licensure. Exploring initiation of a program to promote PE licensure, “Pathway to PE,” may be of use for this purpose.

Lastly, it was briefly discussed that a useful resource that could be developed (and that is broader in scope than certifications and credentials) that “profiles” common examples of what a successful engineering career at FDA and other agencies might look like (e.g., a road map). FDA Engineers were generally supportive of this effort, and we see value in developing such a resource for various agencies to which engineers are assigned. The resource could also generally discuss cross-cutting career paths in emergency preparedness and response, regulatory affairs, science and technology, for example, where engineers performing similar functions in multiple agencies could have a productive and rewarding career.