

QUALITY ASSURANCE EXCHANGE

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QA Quote of the Day

"In the race for quality, there is no finish line."

-- David T. Kearns

IN THE SPOTLIGHT: THE OFFICE OF ENFORCEMENT INTERVIEW WITH ARNOLD GUEVARA, DIRECTOR



The Department of Energy (DOE) Office of Enforcement (formerly the Office of Price-Anderson Enforcement) has been administering DOE's nuclear safety enforcement program since 1995. This has included enforcement of **10 CFR 830 Subpart A, Quality Assurance Requirements**. Recently, the responsibilities of this office have expanded to include enforcement of DOE's occupational safety and classified information security rules (**10 CFR 851** and **10 CFR 824**). Mr. Arnold Guevara, formerly with the Office of Security Evaluations, was appointed the Director for the Office of Enforcement in early 2007. He shared the following thoughts in a recent interview.

The Office of Enforcement has responsibility for enforcing worker safety and health and classified information security requirements, in addition to implementing the nuclear safety enforcement program. Will there be significant differences in the enforcement approach used among the three programs?

Although the topical areas are different, DOE's nuclear safety, worker safety and health, and classified information security enforcement approaches (as described in **10 CFR Part 820**, **10 CFR Part 851**, and **10 CFR Part 824**, respectively) all share a common principle – that it is the DOE contractor

who is best situated to identify and correct deficiencies before they lead to significant events. Consequently, each enforcement approach includes strong incentives for contractors to self-identify and aggressively correct noncompliances in a manner that prevents recurrence. The Office of Enforcement uses a common approach to enforce the three areas. This open approach is based largely upon that which has been used for the past 13 years to implement the nuclear safety enforcement program.

What role does the implementation of Quality Assurance requirements play in the enforcement issues/actions pursued by your office?

Violations of **10 CFR 830 Subpart A** currently constitute the basis for the majority of noncompliances reported by DOE contractors and the majority of violations formally cited by the Office of Enforcement's nuclear safety enforcement program. This is not surprising because the Subpart A requirements are broader-scoped than the other enforceable regulations and pertain directly to the conduct and improvement of nuclear operations. The specific requirements most frequently cited by the Office of Enforcement are the work process provisions contained in **10 CFR § 830.122 (e)**. Within the past few years, there has been a significant increase in citations by the Office of Enforcement against the quality improvement (**830.122(c)**) and management and independent assessment requirements (**830.122(i)** and **(j)**) of **Subpart A**. These requirements relate directly to the contractor's abilities to self-identify and effectively correct quality problems. Contractor performance in these areas has been and will remain the subject of special emphasis of the Office of Enforcement.

(Continued on page 2)

("In the Spotlight" ...continued from page 1)

What are the key issues the Program Secretarial Officers, Field Elements, and the contractor community face in the effective implementation of quality assurance requirements?

The complexity of DOE operations subject to quality assurance requirements has resulted in correspondingly complex quality assurance programs. Consequently, the degree of attention these programs require to be effective has become relatively significant. This is sometimes viewed in terms of competition for available resources and funding, which can be perceived as having a negative impact on mission accomplishment. While this can be a difficult equation to balance, both contractors and DOE programs need to remain supportive of quality assurance, and understand that effective implementation can result in improved schedule and budget performance (with less downtime due to stand-downs, event investigations, etc.).

A second issue worth noting is the high percentage of recurring events and deficiencies within the DOE complex. The majority of enforcement actions issued by the Office of Enforcement over the past five years have included citations based on ineffective corrective actions for some precursor event or issue. Our ongoing review of contractor assessment, causal analysis and corrective action programs show that these programs continue to demonstrate implementation deficiencies that limit their effectiveness.

Can you share with us any enforcement program enhancements or improvements QAEExchange readers should expect in the next few years?

The Office of Enforcement is working on the following initiatives.

- Improving the overall timeliness of the enforcement process, by initiating investigations earlier, issuing reports sooner, and limiting the use of enforcement conferences when mutually agreeable between DOE and the contractor.
- Better leveraging of enforcement actions and initiatives through the use of the DOE lessons learned program and other forums such as this newsletter.
- Improving the communication of the Office of Enforcement perspectives and initiatives through regular meetings with senior DOE line management, contractor senior management, and the DOE and contractor enforcement coordinator community.
- Better integration between DOE's security and contractor assurance and enforcement communities through the sponsoring of routine interaction between three Energy Facility Contractors Group (EFCOG) working groups: Security; Contractor Assurance; and Safety and Security Regulatory.
- Development of an "integrated" Enforcement Program Review methodology which incorporates the topical areas of information security and worker safety and health into the existing Nuclear Safety Program Review approach.



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If so, please help us maintain the QA Point of Contact database with accurate information by forwarding the following information to:

qaexchange@hq.doe.gov

- name
- phone number
- email address
- Federal or Contractor personnel
- DOE organization or company name
- and site name, if applicable

SQA FAQ

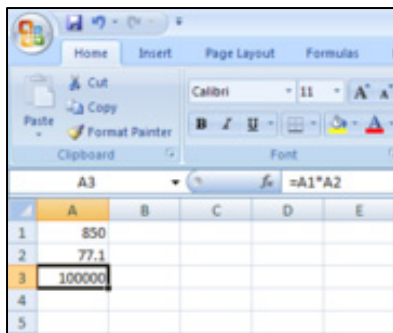
Why does the safety software definition include references to 10 CFR 835, DOE P 450.4, and the DEAR ISMS clause?

The definition for safety software specifies that the software is cited in a Documented Safety Analysis or an approved hazard analysis. 10 CFR 835, DOE P 450.4 and the DEAR ISMS clause were included to link the "below hazard category 3" nuclear facilities to a contractor approved hazard analysis.

EXCEL 2007 DISPLAY ERROR

Background

On September 22, 2007 it was reported that Excel 2007 will show incorrect results in certain situations. Specifically, for some pairs of numbers with a product of 65,535 (such as 850 and 77.1), Excel will report their product as 100,000. This occurs with about 14.5% of such pairs. In addition, if one is added to this result, Excel will give 100,001. However, if one is subtracted from the original product, the correct result of 65,534 is reported. (Also if it is multiplied or divided by 2, the correct answers 131,070 and 32,767.5 are reported, respectively.)



Screen shot of Microsoft Excel 2007 showing the 65,535 display error

The Problem

Microsoft has reported on the Microsoft Excel Blog that the problem exists in the *display* of six specific floating point values between 65534.99999999995 and 65,535, and six values between 65535.99999999995 and 65,536 (not including the integers). Any calculation that results in one of these twelve values will be displayed incorrectly. The actual value stored and passed to other cells is correct, only the displayed value is wrong. However, some instances, such as rounding the value to zero decimal places, will result in an incorrect value in memory. The error was introduced with changes made to the Excel display logic for the 2007 version, and does not exist in previous versions. On October 9, 2007, Microsoft released a fix to the public. This issue is also corrected with Service Pack 1. A detailed explanation of the bug, how it was likely caused by changing 16-bit formatting code to 32-bit code, why it only affects 12 values and then only while formatting, and how the hot fix corrects the bug, is presented in a paper titled "*An Analysis of Excel 2007 '65535' Bug.*"

The Solution

As of today, fixes for this issue in Excel 2007 and Excel Services 2007 are available for download from the following locations.

- Excel 2007: <http://download.microsoft.com/download/6/1/3/61343075-aa12-4152-a761-fccc16d6cef4/office-kb943075-fullfile-x86-glb.exe>
- 64-bit Excel Services 2007: <http://download.microsoft.com/download/c/d/c/cdcccc84-86cd-4199-b01c-1df2dac66534/office-kb943076-fullfile-x64-glb.exe>
- 32-bit Excel Services 2007: <http://download.microsoft.com/download/c/d/c/cdcccc84-86cd-4199-b01c-1df2dac66534/office-kb943076-fullfile-x86-glb.exe>

Other articles have been posted as well.

- Excel 2007: <http://support.microsoft.com/default.aspx/kb/943075/>
- Excel Services 2007: <http://support.microsoft.com/default.aspx/kb/943076>

The fix is also available in the first service pack of Office 2007. To download, go to: <http://www.microsoft.com/downloads/details.aspx?FamilyId=9EC51594-992C-4165-A997-25DA01F388F5&displaylang=en>

The Excel Team published this article on 10/09/07 at 5:23 PM by [David Gainer](#)

For more information and footnotes, please visit the website from where this article was obtained: http://en.wikipedia.org/wiki/Microsoft_Excel#Excel_2007_display_issue

News Flash

IMBA User Notification

This is to notify users that while using IMBA (Integrated Modules for Bioassay) Professional Plus (this may apply to IMBA Expert as well) the following user observation was recorded. During verification testing of a Cs-137 inhalation against ICRP*-78 QA values (Appendix. B.7.42.1), the user found that the results obtained using the default $f_1 = 1$ does not produce the results published by ICRP. Subsequently, it was determined that in situations where ICRP reported $f_1 = 1$, the actual value used by ICRP in their calculations was $f_1 = 0.99$. An f_1 of 1.0 mathematically infers an instantaneous uptake into blood. Accordingly, IMBA users should set $f_1 = 0.99$ for situations where ICRP reports state $f_1 = 1$ in order to get the same results.

For additional information, please contact Dr. Anthony C. James at tjames@tricity.wsu.edu.

* ICRP = International Commission on Radiological Protection

SQA WORK ACTIVITY: VERIFICATION AND VALIDATION

(This article is the seventh in the series that will address how the software quality assurance 10 work activities in the DOE O 414.1C relate to ASME NQA-1-2000 and other consensus standards. DOE G 414.1-4 provides details for implementing the 10 work activities to meet the SQA requirements in the DOE O 414.1C.)



The verification and validation of safety software includes many software quality assurance work activities. Software verification includes those activities performed throughout the safety software life cycle to ensure that the software is developed or acquired properly, and quality is built into the safety software at each phase of the life cycle. Software validation activities include those activities performed at the end of the software development or acquisition processes to ensure the software meets the intended requirements for software use, and to ensure that the software performs correctly and does not perform any unintended functions.

Software verification and validation activities include:

- Reviewing and inspecting software deliverables (e.g. requirement specifications, procurement documents, software design, code modules, test plans, results, test cases, training materials, user documentation and process descriptions);¹
- Tracing of software requirements to the software design;^{2,3}
- Ensuring the software design is correct and complete prior to approval for use;⁴
- Observing and testing during the development of safety software;
- Assessing safety software suppliers;
- Factory or site acceptance testing (including functional testing, performance testing, security testing, stress testing, and load testing);⁵
- Installation testing; and
- Operation testing (i.e., in-use testing) to detect any degradation of the software.⁶

Competent staff should perform software verification and validation activities. Individuals who perform verification and validation work should not be the same individuals who developed the safety software being verified or validated.⁷

The rigor of the process and formality of documentation associated with software verification and validation is dependent upon the level (A, B, or C) and type (custom, configurable, acquired, or utility calculations)⁸ of the safety software. Safety software that is classified Level A, except utility calculations, has the highest rigor in process and formality in documentation deliverables. For Level A utility calculations, as well as, Level B and Level C, safety software is graded, applying less rigor in the processes and less formality in the documentation. For example, testing documentation for Level A safety software would include detailed test cases and procedures. Testing documentation for Level A utility calculations, Level B, and Level C safety software could include simple checklists for acceptance test cases and test procedures.

¹ ASME NQA-1-2000, op. cit., Part I, Requirement 4, Section 300, p. 18.

² ASME NQA-1-2000, op. cit., Part II, Subpart 2.7, Section 402.1, p. 106.

³ ASME NQA-1-2000, op. cit., Part I, Requirement 3, Section 801.4, p. 16.

⁴ ASME NQA-1-2000, op. cit., Part II, Subpart 2.7, Section 402.1, p. 106.

⁵ ASME NQA-1-2000, op. cit., Part II, Subpart 2.7, Section 404, p. 106.

⁶ ASME NQA-1-2000, op. cit., Part I, Requirement 11, Section 400, p.29-30

⁷ ASME NQA-1-2000, op. cit., Part I, Requirement 3, Section 801.1, p. 16.

⁸ DOE G 414.1-4, op. cit, Section 2.2

This article was contributed by Toni Austin: taustin@bechtel.com



DOE ESTABLISHING A FEDERAL QUALITY COUNCIL

In recognition of the need for heightened attention to, and consistent and effective implementation of Quality Assurance (QA) within DOE, HSS is establishing a Federal DOE Quality Council comprised of DOE QA professionals. This effort is designed to promote consistent interpretation and implementation of QA requirements, improve communications through shared lessons learned, and build and encourage federal-contractor relationships.

The primary goals of the Council will be to promote communication, consistency, and collaboration across the DOE-complex to improve the Department's QA posture. All DOE organizations are welcome to participate. So far, the organizations expected to be represented on the Council include HSS, ID, RW, NE, CTA Energy, Brookhaven, SRS, EM, RL, NNSA, SC, MA, EE, FE, LANL, LLNL, and the Albuquerque Service Center.

The Council will provide an infrastructure for the analysis and dissemination of QA information to the DOE Complex. Council members, who will be DOE Federal QA professionals, will coordinate with DOE organizations, contractors, regulating entities, and other stakeholders in an effort to ensure that there is a broader collaboration of DOE-wide information, initiatives and QA values. Some potential tasks of the Council include:

- Identifying cross-cutting QA issues and developing recommendations for improvement;
- Making recommendations to HSS for alerts and bulletins concerning QA related operational events;
- Assisting the line with developing, disseminating, and tracking effectiveness of QA lessons learned; and
- Interfacing with the EFCOG QA Subgroup and providing input on the EFCOG QA subgroup initiatives.

The first Council face-to-face meeting to develop the Council Charter is expected to be held in June 2008. If your Federal DOE organization feels it should be represented on the Council, please contact Colette Broussard at (301)-903-5452 or Colette.Broussard@hq.doe.gov.

To further strengthen QA within DOE, effective April 27, 2008 HSS has officially established the Office of Quality Assurance Policy and Assistance (HS-23) within its Office of Nuclear Safety, Quality Assurance and Environment (HS-20). This office will provide a focal point for QA policy, assistance, and guidance.

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SQA FAQ

DOE G 414.1-4 Section 5.2.7 Software Safety identifies guidance in the area of Risk Management, specifically that during the initial concept and requirement analysis phase for the software, potential failures should be identified and evaluated for their consequences of failure and probability of occurrence. Guidance is provided for the evaluation for the consequences of failure, however, no guidance is provided for the probability of occurrence. What is the expectation for performing a probability of occurrence evaluation? If a probability of occurrence is to be determined, does DOE have any information (i.e. data on the mean time to failure, of various software applications and the environments in which the application failed)

Typically, software probability of occurrence is performed using a relative scale that is qualitative (frequent, probable, occasional, remote, improbable) rather than quantitative scales as done with hardware. This is one of the areas that make software failures difficult to predict. DoD comes to mind as a good source for the approach to probability of occurrence. Mean time to failure is one of the best choices to use. It usually can only be calculated on the system as it is in operation. Thus an organization collects the data themselves and then looks at the trends.

HSS QA ACTIVITY CORNER

DNFSB Interactions

On October 4, 2007 representatives from the Office of Health, Safety and Security (HSS), the Office of Environmental Management (EM), and the National Nuclear Security Administration (NNSA) briefed the Defense Nuclear Facilities Safety Board (DNFSB) on the status of several QA and SQA activities. This briefing addressed key accomplishments since the last briefing as well as ongoing and planned activities. One topic of interest to the DNFSB was the remaining activities to complete the Department's implementation plan for DNFSB recommendation 2002-1 on safety software.

HSS, EM and NNSA developed a plan and on February 7, 2008, the DNFSB was presented with the path forward to address the six Central Registry toolbox code gap analysis report recommendations. Working through EM and NNSA, an expert working group is being formed to assist with this effort. The working group is expected to be formed by the end of April.

On March 17, 2008, DOE HSS received a letter from the DNFSB requesting a plan of actions regarding the increasing contribution of manufacturing defects to the high efficiency particulate air (HEPA) filter rejection rates as reported in the past two semi-annual reports issued by the HSS Office of Corporate Safety Programs (HS-31). These semi-annual reports provided the results of the HEPA filter testing performed at the Filter Test Facility (FTF) near Baltimore, MD. The increased manufacturing defects indicate potential problems in quality control programs and manufacturing processes at the filter manufacturer level. A Working Team convened by HSS and made up of Federal and contractor employees, experienced in the use, testing, and qualification of HEPA filters, has been formed and met on April 15 and 16, 2008 to develop a plan of action in response to the DNFSB letter. The Working Team members also visited the FTF on April 17, 2008 and witnessed actual inspection and testing of HEPA filters and samples of rejected filters. The response for DNFSB letter is due in mid May.

For further information on the Central Registry and Toolbox codes or HEPA filters, please contact Subir Sen at (301) 903-6571 or subir.sen@hq.doe.gov.

The next DNFSB QA Briefing is planned to occur in May '08.

DOE-STD-1172-2003 Revision

DOE-STD-1172-2003, *Safety Software Quality Assurance Functional Area Qualification Standard*, has been revised by a working group of subject matter experts from Headquarters and the Field. The Standard was revised to make it consistent with DOE O 414.1C, *Quality Assurance* and DOE G 414.1-4, *Safety Software Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirement*. The working group is currently responding to comments as a result of the RevCom process. The current schedule has the revised Standard completed by June 2008. For further information, please contact Subir Sen at (301) 903-6571 or subir.sen@hq.doe.gov.

2007 Survey on QA Implementation

The original Working Group that developed the updated 2007 Survey, including representatives from EM, NE, NNSA, SC and several Site Offices has provided input to the Survey report. The report is being finalized and will be submitted to the Deputy Secretary in April. The next Survey will be requested in 2009. For further information, please contact Colette Broussard at (301)-903-5452 or Colette.Broussard@hq.doe.gov.

DOE G 413.3-2 QA Guide for the Acquisition of Capital Assets

DOE G 413.3-2 is now in RevCom and the committed schedule anticipates comment resolution and issuance of the Guide by May 2008. For more information contact Colette Broussard at (301)-903-5452 or Colette.Broussard@hq.doe.gov.

HEPA Filter Test Facility Audit

The plan for a joint triennial ASME NQA-1, *Quality Assurance for Nuclear Facility Applications* audit of the HEPA FTF is being discussed with EFCOG. An audit team of DOE, EFCOG, and other subject matter experts is planning to conduct the audit during the third quarter of FY 2008. The previous audit was performed in mid 2005. The FTF, located outside Baltimore, MD, is owned and operated by Air Techniques International and provides HEPA filter testing services for DOE. For further information, please contact Subir Sen at (301) 903-6571 or subir.sen@hq.doe.gov.

Digital Instrumentation and Control Systems

Digital Instrumentation and Control (DI&C) systems are being used in DOE's nuclear facilities for various safety controls, such as for ventilation and process systems. DI&C systems can share code, data transmission, data, and process equipment to a greater degree than analog systems. Although the sharing is the basis for many of the advantages of digital systems, it also raises a key concern. A design using shared hardware, software, data, and code has the potential to propagate a common-cause or common-mode failure via either software errors, failures of hardware, or any combinations of those, thus defeating the concept of layer of protection (i.e., defense in depth) achieved by the design strategy. At present, DOE does not provide any specific guidance for the use of DI&C systems in the nuclear safety applications.

The Office of Nuclear Safety Policy and Assistance (HS-21) is taking the lead in an effort to address the above mentioned issues and develop a new standard for DI&C systems in nuclear facility safety applications. HS-21 has formed a working group with expertise from DOE sites and held the first working group meeting in December 2007. The working group is challenged with researching and developing a consensus within the DOE complex that would meet the needs of DOE facilities to ensure adequate protection of workers, the public, and the environment. The goal for conducting industry research and developing a standard is December 2008. For further information, please contact Pranab Guha at (301)-903-7089 or pranab.guha@hq.doe.gov.

QA Laughs

Where was the QA?

These men have just finished placing solid steel pillars in concrete to stop vehicles from parking on the pavement outside a sports bar downtown. They are cleaning up at the end of the day.



How long do you think it will be before they realize where their vehicle is parked?

U.S. Department of Energy

Office of Nuclear Safety, Quality Assurance and Environment (HS-20)

Office of Quality Assurance Policy and Assistance (HS-23)

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QA RELATED MEETINGS & CONFERENCES

NQA-1 Meeting

When: April 14-16

Where: New Orleans, Louisiana

For more info: <http://calendar.asme.org/EventDetail.cfm?EventID=5972>

World Conference on Quality and Improvement

When: May 5-7

Where: Houston, Texas

For more info: <http://wcqi.asq.org/index.html>

2008 ASME Annual Meeting

When: June 7-11

Where: Walt Disney World Swan and Dolphin Resort Lake Buena Vista, Florida

For more info: <http://www.asmeconferences.org/annualmeeting08/>

Newsletter Articles Needed

The *Quality Assurance Exchange* is intended to be a forum for the exchange of ideas and the sharing of experience among DOE field offices, contractors, and DOE headquarters to foster continuous improvement in QA implementation.

Readers are strongly encouraged to contribute articles on the implementation of QA requirements, lessons learned, and other QA related topics. We welcome your feedback and suggestions.

Please forward your input to:
qaexchange@hq.doe.gov

EDITORIAL NOTE:

If you are interested in receiving this newsletter electronically, please email your request to be added to the distribution list to qaexchange@hq.doe.gov

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See us at:

hss.energy.gov/csa/csp/qa/

QA Exchange Word Search

ANSWERS

B	L	H	K	R	N	R	B	J	L	X	O	B	L	O	O	T	C	L	N	R	T	J	D	Z
J	M	E	N	R	A	E	L	S	N	O	S	S	E	D	R	T	Q	Q	K	N	R	K	Z	
A	N	A	L	T	I	C	A	L	S	E	R	V	I	C	E	S	P	R	O	G	R	A	M	
J	X	N	J	W	Z	L	Z	T	N	V	F	M	D	C	N	X	Q	T	R	M	Q	B	N	A
F	Q	U	A	L	I	T	Y	A	S	S	U	R	A	N	C	E	H	C	F	V	T	R	P	
W	N	T	T	J	K	Y	R	Z	Y	M	M	M	Q	W	D	M	R	F	P	T	M	R	J	E
V	H	M	K	K	D	K	R	W	T	H	Y	T	N	Z	M	N	W	T	S	C	K	H	W	P
F	H	F	T	T	T	C	N	T	M	N	K	Q	V	R	T	J	A	R	B	F	P	Q	N	L
Z	C	X	W	P	W	L	X	Q	S	O	N	F	F	H	J	C	K	R	N	N	P	D	K	
B	M	W	F	M	N	Z	M	N	Z	I	N	B	M	N	D	V	G	Z	R	K	M	N	Y	Q
J	M	L	Z	N	K	N	B	N	F	T	G	T	M	A	N	J	M	M	R	D	Y	M	D	Q
B	W	N	V	V	N	B	R	J	Y	A	K	E	R	W	Z	R	Y	R	N	B	Z	N	Y	B
L	K	V	P	T	Q	R	R	V	N	T	L	D	R	Z	T	T	T	H	Z	N	B	G	R	
L	Q	Y	L	P	L	T	P	D	M	N	S	H	X	L	W	X	N	Y	R	L	N	T	H	V
W	M	T	P	Z	G	T	K	M	K	E	K	G	N	M	A	R	W	C	L	B	J	R	T	W
R	Y	Q	P	N	M	J	G	E	T	M	R	X	Y	R	L	R	I	Z	B	M	W	H	K	
H	F	P	H	G	Q	L	G	T	N	E	N	N	V	K	G	N	T	V	N	D	T	L	G	L
K	N	W	L	X	D	D	M	N	L	L	B	M	V	N	E	B	M	N	P	H	M	R	I	B
W	D	K	B	J	I	M	W	Y	J	P	J	N	L	M	D	Z	X	K	E	F	M	X	S	M
R	J	T	N	R	T	D	P	K	C	M	K	X	S	T	V	M	F	K	M	O	D	R	R	Q
L	T	N	K	X	M	M	X	B	V	J	R	S	C	J	V	P	V	N	J	N	J	O	E	T
B	K	A	P	R	Y	F	J	L	X	Y	E	Q	R	X	N	N	M	C	H	R	L	K	V	L
G	O	R	X	K	Z	C	N	N	S	T	X	N	J	T	N	Y	D	X	J	Y	L	O	Y	
N	V	N	D	R	Y	M	G	Z	S	Q	X	L	F	H	C	J	M	J	T	L	C	J	T	B
P	G	N	D	L	T	W	M	A	G	T	L	N	N	M	Y	M	W	H	Q	Y	K	K	W	W

Answers for the QA Exchange Word Search issued in *QAE 3.3*