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Via email to Natalie Bennett: Natalie.Bennett@bsigroup.com

January 15, 2014

FORMAL COMPLAINT SUBMITTAL

PREAMBLE

Oxebridge Quality Resources International LLC (“OQRI”) a provider of management system consulting services and a well-known industry stakeholder within the ISO 9001 sphere, alleges that BSI has violated multiple clauses within ISO 17021:2011, specifically those pertaining to the separation of consulting services and ISO 9001/ISO 13485 conformity assessment. OQRI alleges that the violations of ISO 17021 are systemic, widespread and gravely serious. OQRI provides as evidence the provision of BSI “Entropy” TM software as a tool for developing, implementing and maintaining a quality management, which is later audited by BSI auditors as part of quality management system conformity assessment. In addition, OQRI alleges that BSI has breached ISO 17021’s rules against co-marketing consulting and conformity assessment services.

OQRI hereby requests formal corrective action in accordance with clauses 4.7 and 9.8 of ISO 17021:2011, to include a documented acknowledgement of receipt of this complaint, a thorough and systemic investigation, corrective and preventive corrective action, and notification of actions taken when complete.

ISO 17021 clause 4.7 indicates that complaints may be issued to certification bodies by “parties that rely on certification,” and not only direct clients of the certification body. It furthermore references ISO 10002 in its section on complaints, and ISO 10002 allows for the submission of complaints to certification bodies by "interested parties," and not just direct customers. Based on this information, OQRI asserts it right to submit this complaint not only on behalf of its clients, but on behalf of itself as an interested party, directly concerned with the validity of the certificates issued by accredited certification bodies.

APPLICABLE ISO 17021 CLAUSES

The herein complaint relies on the knowledge that BSI is accredited by UKAS to ISO 17021:2011, and that the following rules and definitions of that standard apply to it:
4.2.3 To obtain and maintain confidence, it is essential that a certification body's decisions be based on objective evidence of conformity (or nonconformity) obtained by the certification body, and that its decisions are not influenced by other interests or by other parties.

4.2.4 Threats to impartiality include the following:

a) Self-interest threats: threats that arise from a person or body acting in their own interest. A concern related to certification, as a threat to impartiality, is financial self-interest.

b) Self-review threats: threats that arise from a person or body reviewing the work done by themselves. Auditing the management systems of a client to whom the certification body provided management systems consultancy would be a self-review threat.

5.2.5 The certification body and any part of the same legal entity shall not offer or provide management system consultancy.

Where, per the definition in 3.3, “management consultancy” is defined as: “participation in designing, implementing or maintaining a management system.”

**EXAMPLES**

a) preparing or producing manuals or procedures, and
b) giving specific advice, instructions or solutions towards the development and implementation of a management system.

5.2.7 The certification body shall not certify a management system on which a client has received management system consultancy or internal audits, where the relationship between the consultancy organization and the certification body poses an unacceptable threat to the impartiality of the certification body.

5.2.9 The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides management system consultancy. The certification body shall take action to correct inappropriate claims by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if the certification body were used. A certification body shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

5.2.11 The certification body shall take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations.

5.3.2 The certification body shall evaluate its finances and sources of income and demonstrate to the committee specified in 6.2 that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.
EVIDENCE

Note: copies of evidence are on file with Oxebridge, and available for review, in the event that links have changed since the filing of this complaint.

Currently, the BSI websites for both the UK and USA offices market a software product called Entropy™ which is sold as a software solution for the implementation, management and improvement of a quality management system (QMS).

A video created by BSI and posted on YouTube\(^1\) describing the Entropy™ software includes the caption “Organizations are using Entropy® Software globally to help manage and measure quality and compliance processes, improve reporting, better manage and mitigate their risks, reduce costs, and streamline business processes.”

Screenshots from the video show that the software is used for management of specific requirements (by clause) for such standards as ISO 14001 and ISO 9001, both of which BSI then provides third-party conformity assessment services for, subject to the rules of ISO 17021:2011. A few examples are provided herein:

\[\text{Screenshot showing application's controls for documents under ISO 14001}\]

\(^1\) [http://www.youtube.com/watch?v=bu5Wo4cixN8](http://www.youtube.com/watch?v=bu5Wo4cixN8)
Screenshot showing application’s role in reporting data for ISO 14001, OHSAS 18001 and ISO 9001

Screenshot showing the application’s role in managing CAPA for ISO 9001 and ISO 14001

A second BSI produced video appears on a separate YouTube page\textsuperscript{2}, specifically detailing how Entropy™ is used for management of an internal audit program. The content – and title (“Easy Does It: Entropy Software Audit Module”) – literally violate the ISO 17021 prohibition against a CB saying any consulting service would result in certification being “easier.”

A BSI-developed presence on LinkedIn\textsuperscript{3} includes marketing for the Entropy™ software, and includes the following statements:

\begin{quote}
It’s one thing achieving a standard, but it’s another to stay at that standard. Without constant improvement and attention, standards can easily slip. Entropy can help ensure you stay at compliance level – but it can do far more than that. Put simply, it gives you an organization-wide system for driving performance improvements.
\end{quote}

\begin{footnotes}
\item[2] \url{http://www.youtube.com/watch?v=JXYXXE8WjgY}
\item[3] \url{http://www.linkedin.com/company/bsi/bsi-entropy-software-1637089/product?trk=biz_product}
\end{footnotes}
Oxebridge alleges this provides specific solutions related to QMS development.

Quote: *Entropy eliminates the need for paper forms, spreadsheets or inconsistent data from conflicting sites.*

Oxebridge alleges this provides specific solutions related to document control methods.

Quote: *The features built within Entropy allow users to set objectives and targets, allocate responsibilities, share best practice across the organization, and deal with incidents.*

Oxebridge alleges this provides specific solutions related to quality objectives development, reporting, and responsibilities management.

Quote: *Automatic document control and instant access to all management reports means users can concentrate on analysis and decision-making rather than system maintenance, while the sharing of corporate-wide information increases the efficiency and quality of internal and external communication. All of this contributes to driving down costs and increasing efficiencies.*

Oxebridge alleges this provides specific solutions related to document control methods.

Through a paid press release service, BSI presumably authored a press release appearing on at least one internet outlet where *Entropy™* was discussed. In this article, the role of Entropy in management systems such as ISO 14001, is clearly defined (emphasis added):

*Entropy™ Software helps companies automate the implementation and ongoing operation and maintenance of an environmental management system.* Entropy™ Software's ready-made ISO-focused framework is designed to reduce time and labor costs associated with implementing and running a management system. Entropy Software's™ modular workflows support:

- Audit Management
- Document Management
- Incident Management
- Training Management
- Supply Chain Compliance
- Risk Management
- Performance Management

Oxebridge alleges this is evidence that BSI provides specific solutions related to Management System development.

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TRATEK CASE STUDY

The BSI website includes a “Case Study” for the US company TraTek (Noblesville IN), which had purchased and implemented the Entropy™ software. BSI has also provided TraTek with management system certification services.

In the case study document, it is stated that TraTek used the Entropy™ product for:

- Monitoring and maintenance of ISO 13485 Certification
- Centralized ISO 13485-compliant storage and access to records
- Records of actionable data and information
- Task-driven system with accountability of defined roles and responsibilities
- Streamlined reporting and auditing for reporting

The case study provides a wealth of further damning evidence:

Quote: TraTek made the decision to pursue a software-based quality management system (QMS) in order to reduce, and eventually eliminate, the use of paper records in its plants.

Quote: … the implementation and ongoing maintenance of its ISO 13485 certification.

Oxebridge alleges this is evidence of a violation of ISO 17021 clause 5.2.9 in that it clearly defines the linkage between the BSI software and certification, and violates the clause’s prohibition against saying any consulting service would result in certification being “simpler, easier, faster or less expensive.”

Quote: Since Entropy Software was installed, it serves as the company’s main repository for documents and records associated with ISO 13485 at facilities in both Costa Rica and the U.S. Also, as a web-based system, users at each plant can gain access to records for which they have been assigned the proper authorization.

Quote: The software enables TraTek to use electronic signatures, and also ensures a clear definition of business process where the system recognizes each role is different. The entire application of Entropy Software revolves around the organizational structure so that policy and procedures are limited to the appropriate person(s). Entropy Software’s reporting feature makes it easy for Bulino and his managers to quickly provide auditors with reports on-demand, such as control procedures, audit schedules, management reviews, or internal audit score cards.

Oxebridge alleges this is evidence of a violation of ISO 17021 clause 5.2.5 in that it provides specific solutions related to document approval, distribution methods, as well as audit reporting and internal audit program management.

Quote: “Entropy’s reporting capabilities really streamline the auditing process. If an auditor wants a particular document or specific report, we can retrieve it from our Entropy system as quickly as it takes to pull up a search box and enter a couple of key words,” said Bulino. “It definitely improves my ability to access data, systems, documents, and records.”

Oxebridge alleges this is evidence of a violation of ISO 17021 clause 5.2.5 in that it provides specific solutions related to record retrieval methods and document control.

Quote: “Entropy has definitely improved our audit experiences and made us a more efficient organization,” exudes Bulino.

Oxebridge alleges this is evidence of a violation of ISO 17021 clause 5.2.9 in that it clearly defines the linkage between the BSI software and certification, indicating that it “improved the audit experience” and thus violates the clause’s prohibition against saying any consulting service would result in certification being “simpler, easier, faster or less expensive.”

BSI later conducted an ISO 13485 conformity assessment of TraTek, and issued BSI certificate number FM 574904 to the organization; the certificate is current as of this date. OQRI alleges this is irrefutable evidence that BSI auditors assessed a quality management system that was designed and implemented with the help of BSI-provided tools, and that the BSI auditors directly assessed BSI-developed facets of the QMS, such as:

- Document control methods
- Record control methods
- Internal audit program
- CAPA program
- Management review reporting

Oxebridge estimates that the Entropy™ software was used to design nearly 90% of TraTek’s ISO 9001 QMS, by counting the number of “shall clauses” falling under the Entropy™ umbrella, all of which were then assessed and certified by BSI auditors.

**WEB INDUSTRIES CASE STUDY**

A second case study for Entropy™ appears on the BSI website, for Web Industries⁶, an organization for which BSI also provided conformity assessment certification.

In this case study, it is reported that the software was used by Web Industries for document control, management review, CAPA and more.

Quote: For instance, one of the first applications of Entropy Software at Web Industries’ other locations was Management Review. This capability enables managers to discover

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non-conformances and drill down into the database to determine the best course of action for corrective and preventive action (CAPA). Managers can implement and follow an effective and comprehensive CAPA procedure by creating action plans, appointing responsibility, assigning tasks, and tracking completion.

Oxebridge alleges this provides specific solutions related to multiple QMS requirements.

The case study furthermore directly ties the usage of Entropy™ with the certifications obtained by Web Industries, which (As we will see) were granted by BSI:

Quote: To help get each and every job done right, the company’s 350 employees adhere to best practices, as demonstrated by Web Industries’ multiple certifications including two corporate certifications: ISO 9001 and ISO 14001, three plants with ISO 13485 certifications, and one plant with an AS9100C certification. Pulling everything together requires a feature-rich core quality management system (QMS) that offers the consistency and flexibility needed to meet such a wide range of demands.

Oxebridge alleges this provides evidence that BSI was active in developing and implementing the QMS for Web Industries, for which it later provided certification services.

The case study boldly admits that BSI consulted for Web Industries’ QMS development:

Quote: When Waggoner and his team made the decision to implement its medical device certification (ISO 13485), BSI sent several developers out to talk to users and non-users at each of the company’s plants. “The four days they spent on the road enabled the developers to get a much better idea of what they could do to make Entropy more effective for our [Web Industries] certification.”

Oxebridge alleges this provides evidence that BSI was active in developing and implementing the QMS for Web Industries, for which it later provided certification services.

According to BSI records7, BSI has issued multiple ISO 9001, AS9100, ISO 14001 and ISO 13485 certificates to Web Industries, including for their sites in Boston MA, Fort Wayne IN, Dayton CT and Atlanta GA. In particular, the sites in Connecticut, Massachusetts and Indiana were certified by BSI to ISO 13485, for which the BSI case study reveals Entropy™ software was used to develop the Web Industries QMS.

A sampling of BSI certificate numbers issued to Web Industries includes:

- FS 36838
- FS 530766
- FM 531147
- FS 38310
- FM 554223

OTHER CONCERNS WITH ENTROPY™

Other cases studies appear on the BSI website for other companies around the world, who have used the BSI Entropy™ software. Nowhere on the BSI website is there a clear disclaimer that the software cannot be used by BSI certification clients; in fact, the opposite notion appears to be true. On one page (cited below), Entropy™ is advertised along the statement that it may be used when a client is “ready to work towards certification with us.” (Emphasis added.)

BSI aggressively markets the Entropy™ software for its certification clients, going so far as to include a graphic which literally violates three of the four specific prohibitions called out in ISO 17021:2011 clause 5.2.9:

![Entropy Software Graphic]

The BSI Entropy™ page\(^8\) includes a number of claims tying certification with the Entropy™ implementation tool.

Quote: Entropy Software is also helping organizations get the most from their management system investment. Whether you are new to certification and starting your journey, currently implementing management systems or have obtained certification already, Entropy Software can help you maximize its success.

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The page includes language that directly claims the BSI software can “accelerate implementation time.”

The page includes the statement, “whether you are improving an established system or embarking on a new investment for your business, our professional services will be tailored to your needs.” (Emphasis added.)

The page includes a graphic specifically marketing its consulting and certification services, linking the BSI Entropy™ software with BSI’s certification services. To start, the page includes a graphic indicating that the Entropy™ software can be used to “support certification.”
The page then specifically promotes BSI “management systems assessment” and “certification software” jointly:

![About Entropy™ Software](image)

Nowhere on the BSI Entropy™ site, nor the BSI Global site -- nor on any BSI marketing material anywhere -- is there any statement indicating that the software can be used by a certification body other than BSI.

**OTHER CO-MARKETING OF CERTIFICATION AND CONSULTING**

Beyond merely marketing its Entropy™ software, BSI aggressively co-markets its ability to both certify and consult, while avoiding using the latter word literally. On one BSI website page⁹, it include the following statement which clearly links “implementation” and “certification”:

![How to get certified](image)

The BSI site also advertises a “Post Certification Services” selection¹⁰ which includes an “Ask the Advisor” service only available for BSI certification clients. For this. BSI claims the certification clients may, “Contact our panel of experts for specialist advice regarding your management system.”

Oxebridge alleges this is evidence of a violation of ISO 17021 clause 5.2.5 which demands “The certification body and any part of the same legal entity shall not offer or provide management system consultancy,” the latter of which is defined as “giving specific advice.”

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The BSI Global site includes a page\textsuperscript{11} for “ISO 9001 Quality Management System Toolkits” which directly reference its certification services while claiming they are “tailored” for each certification client. The back-and-forth references between certification and implementation create a confusing promotional environment that appears to grossly violate the prohibition from co-marketing certification and consulting. For example (emphasis added):

\textit{What are they?}

A way to give you all the quality \textbf{certification help and guidance} you need in one place. We developed the new range of toolkits using key products within the ISO 9001 portfolio to help customers \textbf{considering implementing ISO 9001} into their organisation.

\textit{Making decisions about quality management is a big but important commitment. And that’s why our new range of toolkits lets you select a number of specific products without having to buy each one separately. Plus it’s an easy way to group all the tools you need together and support you \textbf{wherever you are on the journey towards certification}.}

\textit{Our ISO 9001 toolkits bring together assessment services, standards and publications, training and an online tool. \textbf{These are tailored to your organization} to help your quality management systems, knowledge and competency through training and experience increased productivity and performance.}

One of the tools (“BSI ISO 9001 Self-Assessment and Project Planning Tool”) overtly advertises that it can be used for ISO 9001 “implementation”:

\textit{This online system will help you \textbf{set up your QMS}, track progress and define responsibilities. With access to expert guidance, BSI Quality Management Self-assessment will help organizations \textbf{implement ISO 9001} and monitor their compliance with its requirements.}

Under its “Toolkit and Pricing” section, BSI directly markets the toolkits, including the “implementation” tool mentioned above, to its certification clients.

\textbf{BSI has created five different Toolkits} - whether you’re new to ISO 9001, gathering information or \textbf{ready to work towards certification with us}. We have the solution for you.

Furthermore, it offers reduced pricing, clearly violating ISO 17021’s requirement that a CB not indicate any specific consulting service would result in a “cheaper” ISO 9001 certification.

\textsuperscript{11} \url{http://www.bsigroup.com/en-GB/iso-9001-quality-management/toolkits-for-iso-9001/}
**Toolkits and pricing**

BSI has created five different Toolkits - whether you're new to ISO 9001, gathering information or ready to work towards certification with us. We have the solution for you.

A quality management system enables you to:

- Drive quality, performance and speed-to-market
- Assist customers in driving down costs
- Deliver continuous improvement
- Manage risk
- Enhance organizational competency
- Protect your brand by improving access to information

And starting from only £49.99, you can start your journey and save up to £400 on the cost of buying the Toolkit items separately.

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<th>Toolkit elements</th>
<th>Innovation Toolkit</th>
<th>Entropy Toolkit</th>
<th>Entropy™ Toolkit 1</th>
<th>Entropy™ Toolkit 2</th>
<th>Entropy™ Toolkit 3</th>
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- **£100 training discount voucher (valid for 12 months)**
  This is redeemable against any BSI ISO 9001 training course. To learn more about the range of BSI ISO 9001 training courses visit our [training page](#).

On the very same page where it is indicated these tools can be used if a client is “ready to work towards certification with us” [BSI], the page then again offers the Entropy™ software, which we have already ascertained is used to develop the QMS:

**Entropy Software**

Find out how Entropy Software has helped BSI clients reduce their management system implementation time on average by 50%. Entropy Software provides you with the tools needed to drive business excellence and ensure you get the most from your ISO 9001 investment.
POINT OF CLARITY REGARDING BSI ORGANIZATIONS

Oxebridge anticipates that BSI may respond to this complaint by providing evidence that its consulting services, Entropy™ software product and certification services are, in fact, issued by separate organizations within the BSI Global group, and that is a sufficient firewall between its consulting services and its certification services.

Oxebridge pre-empts this argument by stating that nowhere on any of the BSI websites is such a division made clear, and in fact the various BSI websites share content across themselves. For example, the BSI Americas website includes information on Entropy™ and the BSI Entropy™ website includes links to BSI Global. All of the sites include the same copyright attribution, that for “The British Standards Institution.” The sites share common logos, and nearly identical website formatting and graphics. Often, the only difference between pages is the URL, something the casual reader or potential client may not notice.

ISO 17021 clause 5.2.5 clearly states, “The certification body and any part of the same legal entity shall not offer or provide management system consultancy.” (Emphasis added.)

ISO 17021 clause 5.2.7 further states, “The certification body shall not certify a management system on which a client has received management system consultancy or internal audits, where the relationship between the consultancy organization and the certification body poses an unacceptable threat to the impartiality of the certification body.” (Emphasis added.)

Furthermore, since Oxebridge alleges that the Entropy™ software is used for internal auditing purposes, ISO 17021 clause 5.2.6 states, “The certification body and any part of the same legal entity shall not offer or provide internal audits to its certified clients.” (Emphasis added.)

Furthermore, the relationship between any BSI organizations is deemed irrelevant, since ISO 17021 clause 5.2.9 states, “The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides management system consultancy.” This applies to external consulting organizations as well as any internal ones.

ALLEGATIONS

Based on the evidence presented herein, OQRI alleges that BSI is currently in severe breach of ISO 17021:2011 as follows:

1. Oxebridge alleges that BSI has violated ISO 17021 clauses prohibiting the provision, or marketing, of consulting services alongside conformity assessment services, which dramatically reduces the trust and validity of ISO 9001 certificates issued by BSI. We base this on the overwhelming evidence that its Entropy™ software is marketed as a BSI product, that it provides implementation and management system development tools, and then that it is used to create specific methods for such MS requirement as document control, internal audit programs, CAPA programs, record control, management review, objectives development, data reporting, continual improvement and
more. (ISO 17021 Clauses 4.2.4b, 5.2.5, 5.2.7)

2. Oxebridge alleges that these violations were done willingly, and thus BSI failed in its required duties under accreditation rules to identify threats to impartiality, properly investigate, document, research and mitigate any conflicts of interest. (ISO 17021 Clauses 4.2.3, 4.2.4, 5.2.11, 5.3.2)

3. Oxebridge alleges that BSI has created an internal conflict of interest that cannot be resolved while providing both Entropy™ software and certification services, since the sale of both result in profits driven to BSI. This violates ISO 17021’s requirement that the certification body identify and mitigate any financial self-interest threat, as a BSI auditor would be unlikely to write a finding against BSI software, since it could result in a direct loss of revenue for BSI; likewise, the arrangement creates an environment where BSI auditors would be predisposed to “auditing lightly” any system implemented with Entropy™ so that no revenue was impacted. (ISO 17021 Clause 4.2.4)

4. Oxebridge alleges that because Entropy™ includes an internal audit module, this results in BSI conformity assessment auditors assessing a client’s audit program that was originally developed by BSI; this would include the methods of internal audit reporting, scheduling and more. (ISO 17021 Clause 5.2.7)

5. Oxebridge alleges that BSI has willingly created a confusing marketing environment through its various websites, online presences and YouTube videos, failing to create a clear distinction between certification and consulting services and products, and which would clearly lead an average “man on the street” to believe the two are linked, and that such linkage was acceptable. (ISO 17021 Clause 5.2.9)

6. Oxebridge alleges that by marketing its Entropy™ implementation product as being able to reduce implementation time, and improve third party audit results, it is in gross violation of rules preventing certification bodies from indicating that the usage of any one consulting service would result in certification being “simpler, easier, faster or less expensive.” (ISO 17021 Clause 5.2.9)

7. Oxebridge alleges that BSI subsequently performed conformity assessment services to at least two users of its Entropy™ software, in violation of the requirements that certification bodies not audit management systems for which they provided consulting implementation services. (ISO 17021 Clauses 5.2.5, 5.2.7)

Oxebridge Quality Resources International formally requests that BSI perform a proper and thorough investigation into its marketing activities, and take suitable corrective action to resolve these violations, or the matter will be escalated to UKAS and/or ANAB.

Respectfully,

Christopher Paris
VP Operations
Oxebridge Quality Resources International LLC

www.oxebridge.com